THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2019
APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2018.

39th EDITION

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The publication, Approved Drug Products With Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The main criterion for the inclusion of any product is that the product is the subject of an application with an approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the FD&C Act.

Background of the Publication. To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of drug products. These state laws generally require either that substitution be limited to drugs on a specific list (the positive formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative formulary approach). Because of the number of requests in the late 1970s for FDA assistance in preparing both positive and negative formularies, it became apparent that FDA could not serve the needs of each state on an individual basis. The Agency also recognized that providing a single list based on common criteria would be preferable to evaluating drug products on the basis of differing definitions and criteria in various state laws. As a result, on May 31, 1978, the Commissioner of the Food and Drug Administration sent a letter to officials of each state announcing FDA's intent to provide a list of all prescription drug products that are approved by FDA for safety and effectiveness, along with therapeutic equivalence determinations for multisource prescription products.

The Orange Book was distributed as a proposal in January 1979. It included only currently marketed prescription drug products approved by FDA through new drug applications (NDAs) and abbreviated new drug applications (ANDAs) under the provisions of Section 505 of the FD&C Act and FDA regulations at that time.

The therapeutic equivalence evaluations in the Orange Book reflect FDA's application of specific criteria to the multisource prescription drug products listed in the Orange Book and approved under Section 505 of the FD&C Act. These evaluations are presented in the form of code letters that indicate the basis for the evaluation made. An explanation of the codes appears in the Introduction.
A complete discussion of the background and basis of FDA’s therapeutic equivalence evaluation policy was published in the Federal Register on January 12, 1979 (44 FR 2932). The final rule, which includes FDA’s responses to the public comments on the proposal, was published in the Federal Register on October 31, 1980 (45 FR 72582). The first publication of the Orange Book in October 1980, concurrent with finalization of the rule, incorporated appropriate corrections and additions. Each subsequent edition has included new approvals and made appropriate changes in data.

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments require that FDA, among other things, make publicly available a list of approved drug products with monthly supplements. The Orange Book and its monthly Cumulative Supplements satisfy this requirement. The Addendum to this publication identifies drugs that qualify under the FD&C Act for periods of exclusivity and provides patent information concerning the approved drug products in the Orange Book. The Addendum also provides additional information that may be helpful to those submitting an NDA or ANDA to the Agency.

The Agency intends to use this publication to further its objective of obtaining input and comment on the publication itself and related Agency procedures. Therefore, if you have comments on how the publication can be improved, please send them to the Director, Division of Legal and Regulatory Support, Office of Generic Drug Policy, Office of Generic Drugs, Center for Drug Evaluation and Research, 7620 Standish Place, Rockville, MD 20855-2773. Comments received are publicly available to the extent allowable under the Freedom of Information Act and FDA regulations.
1.0 INTRODUCTION

1.1 Content and Exclusion

The Orange Book is composed of four parts: (1) approved prescription drug products with therapeutic equivalence evaluations; (2) approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; (3) drug products with approval under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research; and (4) a cumulative list of approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn from sale for safety or effectiveness reasons, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing. This publication also includes indices of prescription and OTC drug products by trade name (proprietary name) or established name (if no trade name exists) and by applicant name (holder of the approved application), which have been abbreviated for this publication. Established names for active ingredients generally conform to official compendial names or United States Adopted Names (USAN) as described in 21 CFR 299.4(e). A list of uniform terms is provided in Appendix C.

The Addendum contains patent and exclusivity information for the Prescription, OTC, Discontinued Drug Product Lists, and for the Drug Products with Approval under Section 505 of the FD&C Act Administered by the Center for Biologics Evaluation and Research. The publication may include additional information that the Agency deems appropriate to disseminate.

Prior to the 6th Edition, the publication had excluded OTC drug products and drug products with approval under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research. The Hatch-Waxman Amendments required the Agency to begin publishing an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required.

Under the FD&C Act, some drug products are given tentative approvals. The Agency will not include drug products with tentative approvals in the Orange Book because a drug product that is granted tentative approval is not an approved drug product. Tentative approval lists by month are available on FDA’s website Drugs@FDA. When the tentative approval becomes a final approval through a subsequent action letter to the applicant, the Agency will list the drug product and the date of approval in the appropriate approved drug product list. In addition, we note that Section 505(x) of the FD&C Act affects the date of approval for certain drug products subject to scheduling under the Controlled Substances Act. The Agency will list the drug product in the Orange Book and the date of approval as determined under Section 505(x).

The Orange Book identifies the application holder of a drug product and does not identify distributors or repackagers.

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1 Generally, newly approved products are added to the Active Section of the Orange Book (i.e., the Prescription Drug Product List or the Over-the-Counter Drug Product List), depending on the dispensing requirements (prescription or OTC) or approval authority, unless the Orange Book staff is otherwise notified before publication. See Section 1.12.
1.2 Therapeutic Equivalence-Related Terms

**Pharmaceutical Equivalents.** Pharmaceutical equivalents are drug products in identical dosage forms and route(s) of administration that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where the residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. They may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time, and, within certain limits, labeling.

**Pharmaceutical Alternatives.** Pharmaceutical alternatives are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form, or the same salt or ester (e.g., tetracycline hydrochloride, 250mg capsules vs. tetracycline phosphate complex, 250mg capsules; quinidine sulfate, 200mg tablets vs. quinidine sulfate, 200mg capsules). Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. Different dosage forms and strengths within a product line by a single manufacturer are pharmaceutical alternatives, as are extended-release products when compared with immediate-release or standard-release formulations of the same active ingredient.

**Therapeutic Equivalents.** Approved drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents for which bioequivalence has been demonstrated, and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

FDA classifies as therapeutically equivalent those drug products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations. The concept of therapeutic equivalence applies only to drug products containing the identical active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition (e.g., meperidine hydrochloride vs. morphine sulfate for the treatment of pain). Any drug product in the Orange Book repackaged and/or distributed by other than the applicant is considered to be therapeutically equivalent.

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2 21 CFR 314.3(b).
3 See 21 CFR 314.3(b).
4 21 CFR 314.3(b).
5 21 CFR 314.3(b).
equivalent to the applicant’s drug product even if the applicant’s drug product is single source or coded as non-equivalent (e.g., BN). Distributors or repackagers of an applicant’s drug product are not identified in the Orange Book.

FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and certain aspects of labeling (e.g., the presence of specific pharmacokinetic information), and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a specific product be dispensed as a medical necessity. With this limitation, however, FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product can be expected to have the same clinical effect and safety profile as the prescribed product when administered to patients under the conditions specified in the labeling.

**Strength.** Strength refers to the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes: (1)(a) the total quantity of drug substance in mass or units of activity in a dosage unit or container closure (e.g., weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure); and/or, as applicable, (b) the concentration of the drug substance in mass or units of activity per unit volume or mass (e.g., weight/weight, weight/volume, or units/volume); or (2) such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from a drug product if the weights and measures described in clause (1)(a) do not apply (e.g., certain drug-device combination products for which the amount of drug substance is emitted per use or unit time). Note that if the criteria the Agency establishes for determining and expressing the amount of drug substance in a product evolves over time, the Agency generally does not intend to revise the expressions of strength for drug products already included in the Orange Book, but rather intends to apply the criteria prospectively to drug products added to the Orange Book.

Although the strength of drug products in the Orange Book is generally expressed in terms of the amount of drug substance (active ingredient) in the drug product, it is sometimes expressed in terms of the amount of the active moiety. For example, certain drug products included in the Orange Book include a designation of “EQ” next to their expression of strength. This “EQ” designation generally is used in connection with salt drug products to indicate that the strength of such drug product is being expressed in terms of the equivalent strength of the active moiety (e.g., “EQ 200MG BASE”), rather than in terms of the strength of the active ingredient.

**Bioavailability.** Bioavailability is the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action.
**Bioequivalence.** Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.\(^8\) Section 505(j)(8)(B) of the FD&C Act describes certain conditions under which a test drug and reference listed drug (see Section 1.4) shall be considered bioequivalent:

(i) the rate and extent of absorption of the [test] drug do not show a significant difference from the rate and extent of absorption of the [reference] listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the [test] drug does not show a significant difference from the extent of absorption of the [reference] listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the [reference] listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

Where these above methods are not applicable (e.g., for drug products that are not intended to be absorbed into the bloodstream), other scientifically valid *in vivo* or *in vitro* test methods to demonstrate bioequivalence may be appropriate.

For example, bioequivalence may sometimes be demonstrated using an *in vitro* bioequivalence standard, especially when such an *in vitro* test has been correlated with human *in vivo* bioavailability data. In other situations, bioequivalence may sometimes be demonstrated through comparative clinical trials or pharmacodynamic studies.\(^9\)

1.3 Further Guidance on Bioequivalence

FDA’s regulations and guidance documents provide additional information regarding bioequivalence and bioavailability, including methodologies and statistical criteria used to establish the bioequivalence of drug products.\(^10\)

1.4 Reference Listed Drug and Reference Standard

A reference listed drug is the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.\(^11\) Generally, a reference listed drug is a drug product approved in a new drug application under Section 505(c) of the FD&C Act based on full reports of

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\(^8\) 21 CFR 314.3(b).

\(^9\) 21 CFR 320.24


\(^11\) 21 CFR 314.3(b).
investigations of safety and effectiveness. For an ANDA based on an approved suitability petition (a petitioned ANDA), the reference listed drug generally is the listed drug referenced in the approved suitability petition.\textsuperscript{12}

A reference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval.\textsuperscript{13} FDA generally selects a single reference standard that ANDA applicants must use in in vivo bioequivalence testing. Ordinarily, FDA will select the reference listed drug as the reference standard. However, in some instances, the reference listed drug and the reference standard may be different. For example, where the reference listed drug has been withdrawn from sale and FDA has determined it was not withdrawn for reasons of safety or effectiveness, FDA may select an ANDA as the reference standard.

FDA identifies reference listed drugs in the Prescription Drug Product, OTC Drug Product, and Discontinued Drug Product Lists. Listed drugs identified as reference listed drugs represent drug products upon which an applicant can rely in seeking approval of an ANDA. FDA intends to update periodically the reference listed drugs identified in the Prescription Drug Product, OTC Drug Product, and Discontinued Drug Product Lists, as appropriate.

In some instances when FDA has not designated a listed drug as a reference listed drug, such listed drug may be shielded from generic competition. If FDA has not designated a reference listed drug for a drug product the applicant intends to duplicate, the potential applicant may submit a controlled correspondence to the Office of Generic Drugs to ask FDA to designate a reference listed drug for that drug product. Section 1.7, Therapeutic Equivalence Evaluations Codes (products meeting necessary bioequivalence requirements) explains the character coding system (e.g., AB, AB\textsubscript{1}, AB\textsubscript{2}, AB\textsubscript{3}...) for multisource drug products listed under the same heading with two or more reference listed drugs.

FDA also identifies reference standards in the Prescription Drug Product and OTC Drug Product Lists. Listed drugs identified as reference standards represent FDA’s best judgment at this time as to the appropriate comparator for purposes of conducting any in vivo bioequivalence studies required for approval.

A potential applicant should consult Agency guidance related to referencing approved drug products in ANDA submissions for information on submitting a request for selection of a reference standard. FDA may, on its own initiative, select a new reference standard when doing so will help to ensure that applications for generic drugs may be submitted and evaluated, e.g., in the event that the listed drug currently selected as the reference standard has been withdrawn from sale for other than safety and efficacy reasons.

If an applicant has a question related to the appropriate reference standard, it is recommended that an applicant planning to conduct an in vivo bioequivalence study submit a controlled correspondence to the Office of Generic Drugs.

\textbf{1.5 General Policies and Legal Status}

\textsuperscript{12} 21 CFR 314.94(a)(3)(i).
\textsuperscript{13} 21 CFR 314.3(b).
The Orange Book contains public information and advice. It does not mandate the drug products that are purchased, prescribed, dispensed, or substituted for one another, nor does it, conversely, mandate the products that should be avoided. To the extent that the Orange Book sets forth FDA's evaluations of the therapeutic equivalence of drug products that have been approved, it contains FDA's advice to the public, to practitioners, and to the states regarding drug product selection. These evaluations do not constitute determinations that any product is in violation of the FD&C Act or that any product is preferable to any other. Therapeutic equivalence evaluations are a scientific judgment based upon evidence, while generic substitution may involve social and economic policy administered by the states, e.g., reducing the cost of drugs to consumers. To the extent that the Orange Book identifies drug products approved under Section 505 of the FD&C Act, it sets forth information that the Agency is required to publish and that the public is entitled to under the Freedom of Information Act. Exclusion of a drug product from the Orange Book does not necessarily mean that the drug product is in violation of Section 505 of the FD&C Act, that such a product is not safe or effective, or that such a product is not therapeutically equivalent to other drug products. Rather, the exclusion may be based on the fact that FDA has not evaluated the safety, effectiveness, and quality of the drug product.

1.6 Practitioner/User Responsibilities

Professional care and judgment should be exercised in using the Orange Book. Evaluations of therapeutic equivalence for prescription drugs are based on scientific and medical evaluations by FDA. Products evaluated as therapeutically equivalent can be expected, in the judgment of FDA, to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. However, these products may differ in other characteristics that are not required by statute or regulation to be the same, such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time, and, in some instances, labeling. If products with such differences are substituted for each other, there is a potential for patient confusion, e.g., due to differences in color or shape of tablets, inability to provide a given dose using a partial tablet if the proper scoring configuration is not available, or decreased patient acceptance of certain products because of flavor. There may also be patient-specific allergic reactions in rare cases due to a coloring or a preservative ingredient.

FDA evaluation of therapeutic equivalence in no way relieves practitioners of their professional responsibilities in prescribing and dispensing such products with due care and with appropriate information to individual patients. In those circumstances where the characteristics of a specific product, other than its active ingredient, are important in the therapy of a particular patient, the practitioner's prescribing of that product may be appropriate. Pharmacists must also be familiar with the different characteristics of therapeutically equivalent products, e.g., expiration dates/times and labeling directions for storage of the different products (particularly for reconstituted products), so they can properly advise patients when one product is substituted for another.

Multisource and single-source drug products. In the Orange Book, FDA has evaluated for therapeutic equivalence only multisource prescription drug products approved under Section 505 of the FD&C Act, which in most instances means those pharmaceutical equivalents available from more than one manufacturer. For such products, a therapeutic equivalence code is included.
and product information is highlighted in bold face and underlined. Those
products with approved applications that are single-source (i.e., there is
only one approved product available for that active ingredient, dosage form,
rout of administration, and strength) are also included in the Orange Book,
but no therapeutic equivalence code is included with such products. Any drug
product in the Orange Book repackaged and/or distributed by the applicant or
some other person authorized by the applicant (e.g., an authorized generic)
is considered to be therapeutically equivalent to the applicant’s drug
product even if the applicant’s drug product is single source or coded as
non-equivalent (e.g., BN). Distributors or repackagers of an applicant’s
drug product are not identified in the Orange Book. The details of
therapeutic equivalence codes and the policies underlying them are discussed
in Section 1.7, Therapeutic Equivalence Evaluations Codes.

Products in the Orange Book are identified by the names of the holders of
approved applications (applicants) who may not necessarily be the
manufacturer of the product. There are numerous entities other than the
applicant that may be involved in the development, manufacturing, and/or
marketing of a product. The applicant may or may not be the manufacturer and
may simply be distributing the product for which it has obtained approval.
In many instances, however, the manufacturer of the product is also the
applicant. The name of the manufacturer is permitted by regulation to appear
on the label, even when the manufacturer is not the applicant or marketer.

Although the products in the Orange Book are identified by the names of
the applicants, circumstances, such as changing corporate ownership, have
sometimes made identification of the applicant difficult. The Agency
believes, based on continuing document review and communication with firms,
that the applicant designations in the Orange Book are, in most cases,
correct.

To relate firm name information on a product label to that in the
Orange Book, the following should be noted: the applicant's name always
appears in the Orange Book. This applies whether the applicant (firm name on
the Form FDA 356h in the application) is the manufacturer or marketer (firm
name in largest letters on the label) or not. However, the applicant's name
may not always appear on the label of the product.

If the applicant is the marketer, its name appears in the Orange Book
and on the label; if the applicant is not the marketer, and the Agency is
aware of a corporate relationship (e.g., parent and subsidiary) between the
applicant and the marketer, the name of the applicant appears in the Orange
Book and both firm names may appear on the label. Firms with known corporate
relationships are displayed in Appendix B. If there is no known corporate
relationship between the applicant and the marketer, the applicant's name
appears in the Orange Book; however, unless the applicant is the
manufacturer, packager, or distributor, the applicant's name may not appear
on the label. In this case, the practitioner, from labeling alone, will not be
able to relate the marketed product to an applicant cited in the Orange
Book, and hence to a specific approved drug product. In such cases, to assure
that the product in question is the subject of an approved application, the
firm named on the label should be contacted.

To relate trade name (proprietary name) information on a product label to
that in the Orange Book, the following should be noted: if the applicant is
the marketer, the applicant’s name appears in the Orange Book and on the
label; if the Agency is aware of a corporate relationship between the
applicant and the marketer, the trade name (proprietary name) of the drug
product (established name of the active ingredient, if no trade name exists)
appears in the Orange Book. If a corporate relationship exists between an
applicant and a marketer and both firms are distributing the drug product,
the FDA reserves the right to select the trade name of either the marketer or the applicant to appear in the Orange Book. If there is no known corporate relationship between the applicant and the marketer, the established drug name (i.e., non-proprietary name) appears in the Orange Book.

_Every product in the Orange Book is subject at all times to regulatory action._ From time to time, approved products may be found in violation of one or more provisions of the FD&C Act. In such circumstances, the Agency may commence appropriate enforcement action to correct the violation, if necessary, by securing removal of the product from the market by voluntary recall, seizure, or other enforcement actions. Such regulatory actions are, however, independent of the inclusion of a product in the Orange Book. The main criterion for inclusion of a product is that it has an application that has been approved and that has not been withdrawn for safety or efficacy reasons. FDA believes that retention of a violative product in the Orange Book will not have any significant adverse health consequences, because other legal mechanisms are available to the Agency to prevent the product's actual marketing. FDA may, however, change a product's therapeutic equivalence rating if the circumstances giving rise to the violation change or otherwise call into question the Agency's assessment of whether a product meets the criteria for therapeutic equivalence.

### 1.7 Therapeutic Equivalence Evaluations Codes

Generally, drug products that the Agency considers multisource have been assigned a therapeutic equivalence code. The coding system for therapeutic equivalence evaluations is designed to allow users to determine quickly whether the Agency has evaluated a particular approved product (e.g., a particular strength of an approved drug) as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter). With some exceptions (e.g., therapeutic equivalence evaluations for certain 505(b)(2) applications), the therapeutic equivalence evaluation date is the same as the approval date.

The two basic categories into which multisource drugs have been placed are indicated by the first letter of the relevant therapeutic equivalence code as follows:

**A** Drug products that FDA considers to be **therapeutically equivalent** to other pharmaceutically equivalent products, i.e., drug products for which:

1. there are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP, or AT, depending on the dosage form; or
2. actual or potential bioequivalence problems have been resolved with adequate _in vivo_ and/or _in vitro_ evidence supporting bioequivalence. These are designated AB.

**B** Drug products that FDA at this time, considers not to be **therapeutically equivalent** to other pharmaceutically equivalent products, i.e.,

drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence. Often the problem is with specific dosage forms rather than with the active ingredients. These are designated BC, BD, BE, BN, BP, BR, BS, BT, BX, or B*.
Individual drug products have been evaluated as therapeutically equivalent to the reference product in accordance with the definitions and policies outlined below:

"A" CODES

Drug products that are considered to be therapeutically equivalent to other pharmaceutically equivalent products.

"A" products are those for which there are no known or suspected bioequivalence problems or for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. Drug products designated with an "A" code fall under one of two main policies:

(1) for those active ingredients or dosage forms for which no in vivo bioequivalence issue is known or suspected, the information necessary to show bioequivalence between pharmaceutically equivalent products is either presumed and considered self-evident (based on other information in the application for some dosage forms (e.g., solutions)), or satisfied by a showing that an acceptable in vitro approach is met. A therapeutically equivalent rating is assigned such products so long as they are manufactured in accordance with Current Good Manufacturing Practice regulations and meet the other requirements of their approved applications (these are designated AA, AN, AO, AP, or AT, depending on the dosage form, as described below); or

(2) for those Drug Efficacy Study Implementation (DESI) drug products containing active ingredients or dosage forms that have been identified by FDA as having actual or potential bioequivalence problems, and for post-1962 drug products presenting a potential bioequivalence problem, an evaluation of therapeutic equivalence is assigned to pharmaceutical equivalents only if the approved application contains adequate scientific evidence establishing through in vivo and/or in vitro studies the bioequivalence of the product to a selected reference product (these products are designated as AB).

There are some general principles that may affect the substitution of pharmaceutically equivalent products in specific cases. Prescribers and dispensers of drugs should be alert to these principles so as to deal appropriately with situations that require professional judgment and discretion.

There may be labeling differences among pharmaceutically equivalent products that require attention on the part of the health professional (e.g., pharmaceutically equivalent powders to be reconstituted for administration as oral or injectable liquids may vary with respect to their expiration time or storage conditions after reconstitution). FDA’s determination that such products are therapeutically equivalent is applicable only when each product is reconstituted, stored, and used under the conditions specified in its labeling.

The Agency may use notes in this publication to point out special situations, such as potential differences between two drug products that have been evaluated as bioequivalent and otherwise therapeutically equivalent, when they should be brought to the attention of health professionals. These notes are contained in Section 1.8, Description of Certain Special Situations.
For example, in certain instances, there may be variations among therapeutically equivalent products in their use or in conditions of administration. Such differences may be due to patent or exclusivity rights associated with such use. When such variations may, in the Agency's opinion, affect prescribing or substitution decisions by health professionals, a note may be added to Section 1.8.

Also, occasionally a situation may arise in which changes in a listed drug product after its approval (for example, a change in dosing interval) may have an impact on the substitutability of already approved generic versions of that product that were rated by the Agency as therapeutically equivalent to the listed product. When such changes in the listed drug product are considered by the Agency to have a significant impact on therapeutic equivalence, the Agency will change the therapeutic equivalence ratings for other versions of the drug product unless the manufacturers of those other versions of the product provide additional information to assure equivalence under the changed conditions. Pending receipt of the additional data, the Agency may add a note to Section 1.8, or, in rare cases, may even change the therapeutic equivalence rating.

In some cases (e.g., Isolyte® S w/ Dextrose 5% in Plastic Container and Plasma-Lyte® 148 and Dextrose 5% in Plastic Container), closely related products are listed as containing the same active ingredients, but in somewhat different amounts. In determining which of these products are pharmaceutically equivalent, generally the Agency has considered products to be pharmaceutically equivalent with labeled strengths of an ingredient that do not vary by more than 1%.

Different salts, esters or other noncovalent derivatives (such as a complex, chelate, or clathrate) of the same active moiety are regarded as different active ingredients. For the purpose of this publication, products containing such different active ingredients are considered pharmaceutical alternatives and, thus, not therapeutically equivalent. Anhydrous and hydrated entities, as well as different polymorphs, are considered to be the same active ingredient and are expected to meet the same standards for identity to be considered pharmaceutical equivalents and therapeutic equivalents.

The codes in this book are not intended to preclude health care professionals from converting pharmaceutically different concentrations into pharmaceutical equivalents using accepted professional practice.

Where package size variations have therapeutic implications, products so packaged have not been considered pharmaceutically equivalent. For example, some oral contraceptives are supplied in 21-tablet and 28-tablet packets; the 28-tablet packets contain 7 placebo or iron tablets. These two packaging configurations are not regarded as pharmaceutically equivalent; thus, they are not designated as therapeutically equivalent.

Preservatives and other inactive ingredients may differ among some therapeutically equivalent drug products. These differences do not affect FDA's evaluation of therapeutic equivalence except in cases where these components may influence bioequivalence or routes of administration.

The specific sub-codes for those drugs evaluated as therapeutically equivalent and the policies underlying these sub-codes follow:

**AA Products in conventional dosage forms not presenting bioequivalence problems**

Multisource drug products coded as AA contain active ingredients and are in dosage forms that are not regarded as presenting either actual or
potential bioequivalence problems or drug quality or standards issues. However, all oral dosage forms must, nonetheless, meet an appropriate in vitro bioequivalence standard that is acceptable to the Agency in order to be approved.

**AB, AB1, AB2, AB3... Products meeting necessary bioequivalence requirements**

Multisource drug products listed under the same heading (i.e., identical active ingredients(s), dosage form, and route(s) of administration) and having the same strength (see Section 1.2, *Therapeutic Equivalence-Related Terms, Strength*) generally will be coded AB if data and information are submitted demonstrating bioequivalence.

In certain instances, a number is added to the end of the AB code to make a three character code (i.e., AB1, AB2, AB3, etc.). Three-character codes generally are assigned only in situations when more than one reference listed drug of the same strength has been designated under the same heading. If a study is submitted that demonstrates bioequivalence to a reference listed drug product, the generic product will be given the same three-character code as the reference listed drug it was compared against. For example, Adalat® CC and Procardia XL®, extended-release tablets, are listed under the active ingredient nifedipine. These drug products, listed under the same heading, are not bioequivalent to each other. Adalat® CC and Procardia XL® have been assigned ratings of AB1 and AB2, respectively. Generic drug products deemed by FDA to be bioequivalent to Adalat® CC and Procardia XL® have been approved. As a result, the generic drug products bioequivalent to Adalat® CC have been assigned a rating of AB1 and those bioequivalent to Procardia XL® have been assigned a rating of AB2. (The assignment of an AB1 or AB2 rating to a specific product does not imply product preference.) Even though drug products of distributors and/or repackagers are not included in the Orange Book, they are considered therapeutically equivalent to the applicant’s drug product if the applicant’s drug product is rated either with an AB or three-character code or is single source in the Orange Book. Drugs coded as AB under a heading are considered therapeutically equivalent only to other drugs coded as AB under that heading. Drugs coded with a three-character code under a heading are considered therapeutically equivalent only to other drugs coded with the same three-character code under that heading.

**AN  Solutions and powders for aerosolization**

Uncertainty regarding the therapeutic equivalence of aerosolized products arises primarily because of differences in the drug delivery system. Solutions and powders intended for aerosolization that are marketed for use in general-use delivery systems are considered to be pharmaceutically and therapeutically equivalent and are coded AN. Those products that are compatible only with a specific delivery system or those products that are packaged in and with a specific delivery system are coded BN, unless they have met an appropriate bioequivalence standard and are otherwise determined to be therapeutically equivalent. Solutions or suspensions in a specific delivery system will be coded AN if the bioequivalence standard is based upon in vitro methodology, if bioequivalence needs to be demonstrated by in vivo methodology then the drug products will be coded AB.

**AO  Injectable oil solutions**

The absorption of drugs in injectable (parenteral) oil solutions may vary substantially with the type of oil employed as a vehicle and the
concentration of the active ingredient. Injectable oil solutions are therefore considered to be pharmaceutically and therapeutically equivalent only when the active ingredient, its concentration, and the type of oil used as a vehicle are all identical.

**AP Injectable aqueous solutions and, in certain instances, intravenous non-aqueous solutions**

It should be noted that even though injectable (parenteral) products under a specific listing may be evaluated as therapeutically equivalent, there may be important differences among the products in the general category, Injectable; Injection. For example, historically some injectable products that are rated therapeutically equivalent are labeled for different routes of administration. In addition, some products evaluated as therapeutically equivalent may have different preservatives or no preservatives at all. Injectable products available as dry powders for reconstitution, concentrated sterile solutions for dilution, or sterile solutions ready for injection are pharmaceutical alternative drug products. They are not rated as therapeutically equivalent (AP) to each other even if these pharmaceutical alternative drug products are designed to produce the same concentration prior to injection and are similarly labeled. Consistent with accepted professional practice, it is the responsibility of the prescriber, dispenser, or individual administering the product to be familiar with a product's labeling to assure that it is given only by the route(s) of administration stated in the labeling.

Certain commonly used large volume intravenous products in glass containers are not included in the Orange Book (e.g., dextrose injection 5%, dextrose injection 10%, sodium chloride injection 0.9%) since these products are on the market without FDA approval and FDA has not published conditions for marketing such parenteral products under approved NDAs. When packaged in plastic containers, however, FDA regulations require approved applications prior to marketing. Approval then depends on, among other things, the extent of the available safety data involving the specific plastic component of the product. All large volume parenteral products are manufactured under similar standards, regardless of whether they are packaged in glass or plastic. Thus, FDA has no reason to believe that the packaging container of large volume parenteral drug products that are pharmaceutically equivalent would have any effect on their therapeutic equivalence.

Consistent with the definition of strength included in Section 1.2, Therapeutic Equivalence-Related Terms, the strength of parenteral drug products generally is identified by both the total drug content and the concentration of drug substance in a container approved by FDA. In the past, the strength of liquid parenteral drug products in the Orange Book has not been fully displayed. Rather, the strength of liquid parenteral drug products in the Orange Book has been displayed in terms of concentration, expressed as xmg/mL. Generally, the amount of dry powder or lyophilized powder in a container is identified as the strength, expressed as xmg/vial.

After the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which amended the FD&C Act, it became evident that the format of the Orange Book with respect to parenteral

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14 The strengths of certain parenteral drug products, including contrast agents, may be expressed as a percentage.
solutions should be changed to reflect that each strength of a drug is considered to be a separate listed drug. The Orange Book now displays the strength of all new approvals of parenteral solutions. Previously, we would have displayed only the concentration of an approved parenteral solution, e.g. 50mg/mL. For example, if this application had a 20 mL and 60 mL container approved, we would now display two product strengths, listing both total drug content and concentration of drug substance in the relevant approved container, e.g. 1gm/20mL (50mg/mL) and 3gm/60mL (50mg/mL).

AT Topical products

There are a variety of topical dosage forms available for dermatologic, ophthalmic, otic, rectal, and vaginal administration, including creams, gels, lotions, oils, ointments, pastes, solutions, sprays, and suppositories. Even though different topical dosage forms may contain the same active ingredient and potency, these dosage forms are not considered pharmaceutically equivalent. Therefore, they are not considered therapeutically equivalent. All solutions and DESI drug products containing the same active ingredient in the same topical dosage form for which a waiver of in vivo bioequivalence has been granted, or the application contains adequate scientific evidence establishing through an in vitro approach the bioequivalence of the product to a selected reference product, and for which chemistry and manufacturing processes are adequate to demonstrate bioequivalence, are considered therapeutically equivalent and coded AT. Pharmaceutically equivalent topical products that raise questions of bioequivalence and for which a waiver of in vivo bioequivalence has not been granted, including all post-1962 non-solution topical drug products, are coded AB when supported by adequate in vivo bioequivalence data, and BT in the absence of such data.

"B" CODES

Drug products that FDA, at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

"B" products, for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence, often have a problem with specific dosage forms rather than with the active ingredients. Drug products designated with a "B" code fall under one of three main policies:

(1) the drug products contain active ingredients or are manufactured in dosage forms that have been identified by the Agency as having documented bioequivalence problems or a significant potential for such problems and for which no adequate studies demonstrating bioequivalence have been submitted to FDA; or

(2) the quality standards are inadequate or FDA has an insufficient basis to determine therapeutic equivalence; or

(3) the drug products are under regulatory review.

The specific coding definitions and policies for the "B" sub-codes are as follows:
B* Drug products requiring further FDA investigation and review to determine therapeutic equivalence

The code \textit{B*} is assigned to products previously assigned an \textit{A} or \textit{B} code when FDA receives new information that raises a significant question regarding therapeutic equivalence that can be resolved only through further Agency investigation and/or review of data and information submitted by the applicant. The \textit{B*} code signifies that the Agency will take no position regarding the therapeutic equivalence of the product until the Agency completes its investigation and review.

BC Extended-release dosage forms (capsules, injectables and tablets)

Extended-release tablets are formulated in such a manner as to make the contained drug substance available over an extended period of time following ingestion.

Although bioavailability studies have been conducted on these dosage forms, they may be subject to bioavailability differences, primarily because applicants developing extended-release products for the same active ingredient rarely employ the same formulation approach. FDA, therefore, does not consider different extended-release dosage forms containing the same active ingredient in equal strength to be therapeutically equivalent unless equivalence between individual products in both rate and extent has been specifically demonstrated through appropriate bioequivalence studies. Extended-release products for which such bioequivalence data have not been submitted are coded \textit{BC}, while those for which such data are available have been coded \textit{AB}.

BD Active ingredients and dosage forms with documented bioequivalence problems

The \textit{BD} code denotes products containing active ingredients with known bioequivalence problems and for which adequate studies have not been submitted to FDA demonstrating bioequivalence. Where studies showing bioequivalence have been submitted, the product has been coded \textit{AB}.

BE Delayed-release oral dosage forms

Where the drug may be destroyed or inactivated by the gastric juice or where it may irritate the gastric mucosa, the use of “enteric” coatings is indicated. Such coatings are intended to delay the release of the medication until the tablet has passed through the stomach. Drug products in delayed-release dosage forms containing the same active ingredients are subject to significant differences in absorption. Unless otherwise specifically noted, the Agency considers different delayed-release products containing the same active ingredients as presenting a potential bioequivalence problem and codes these products \textit{BE} in the absence of \textit{in vivo} studies showing bioequivalence. If adequate \textit{in vivo} studies have demonstrated the bioequivalence of specific delayed-release products, such products are coded \textit{AB}.

BN Products in aerosol-nebulizer drug delivery systems

This code applies to drug solutions or powders that are marketed only as a component of, or as compatible with, a specific drug delivery system. There may, for example, be significant differences in the dose of drug and particle size delivered by different products of this type. Therefore,
the Agency does not consider different metered aerosol dosage forms containing the same active ingredient(s) in equal strengths to be therapeutically equivalent unless the drug products meet an appropriate bioequivalence standard; such products are coded \textbf{AB}.

\textbf{BP Active ingredients and dosage forms with potential bioequivalence problems}

FDA's bioequivalence regulations (21 CFR 320.33) contain criteria and procedures for determining whether a specific active ingredient in a specific dosage form has a potential for causing a bioequivalence problem. It is FDA's policy to consider an ingredient meeting these criteria as having a potential bioequivalence problem even in the absence of positive data demonstrating inequivalence. Pharmaceutically equivalent products containing these ingredients in oral dosage forms are coded \textbf{BP} until adequate bioequivalence data are submitted, after which such products are coded \textbf{AB}. Injectable suspensions containing an active ingredient suspended in an aqueous or oleaginous vehicle have also been coded \textbf{BP}. Injectable suspensions are subject to bioequivalence problems because differences in particle size, polymorphic structure of the suspended active ingredient, or the suspension formulation can significantly affect the rate of release and absorption. FDA does not consider pharmaceutical equivalents of these products bioequivalent without adequate evidence of bioequivalence; such products would be coded \textbf{AB}.

\textbf{BR Suppositories or enemas that deliver drugs for systemic absorption}

The absorption of active ingredients from suppositories or enemas that are intended to have a systemic effect (as distinct from suppositories administered for local effect) can vary significantly from product to product. Therefore, FDA considers pharmaceutically equivalent systemic suppositories or enemas bioequivalent only if \textit{in vivo} evidence of bioequivalence is available. In those cases where \textit{in vivo} evidence is available, the products are coded \textbf{AB}. If such evidence is not available, the products are coded \textbf{BR}.

\textbf{BS Products having drug standard deficiencies}

If the drug standards for an active ingredient in a particular dosage form are found by FDA to be deficient so as to prevent an FDA evaluation of either pharmaceutical or therapeutic equivalence, all drug products containing that active ingredient in that dosage form are coded \textbf{BS}. For example, if the standards permit a wide variation in pharmacologically active components of the active ingredient such that pharmaceutical equivalence is in question, all products containing that active ingredient in that dosage form are coded \textbf{BS}.

\textbf{BT Topical products with bioequivalence issues}

This code applies mainly to post-1962 dermatologic, ophthalmic, otic, rectal, and vaginal products for topical administration, including creams, gels, lotions, oils, ointments, pastes, solutions, and sprays, as well as suppositories not intended for systemic drug absorption. Topical products evaluated as having acceptable clinical performance, but that are not bioequivalent to other pharmaceutically equivalent products or that lack sufficient evidence of bioequivalence, will be coded \textbf{BT}.

\textbf{XX}
BX  Drug products for which the data are insufficient to determine therapeutic equivalence

The code BX is assigned to specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence under the policies stated in this document. In these situations, the drug products are presumed to be therapeutically inequivalent until the Agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence.

1.8 Description of Certain Special Situations

Certain drugs listed in the Orange Book present special situations that merit further discussion. The following are descriptions of certain examples of those special situations:

Amino Acid and Protein Hydrolysate Injections. These products differ in the amount and kinds of amino acids they contain and, therefore, are not considered pharmaceutical equivalents. For this reason, these products are not considered therapeutically equivalent. At the same time, the Agency believes that it is appropriate to point out that where nitrogen balance is the sole therapeutic objective and individual amino acid content is not a consideration, pharmaceutical alternatives with the same total amount of nitrogen content may be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

Gaviscon®. Gaviscon® is an OTC product that has been marketed since September 1970. The active ingredients in this product, aluminum hydroxide and magnesium trisilicate, were reviewed by the Agency's OTC Antacid Panel and were considered to be safe and effective ingredients (Category I) by that Panel. However, the tablet failed to pass the antacid test that is required of all antacid products. The Agency, therefore, placed the tablet in Category III for lack of effectiveness. A full NDA with clinical studies was submitted by Marion Laboratories, Inc., and approved by FDA on December 9, 1983. Gaviscon®’s activity in treating reflux acidity is made possible by the physical-chemical properties of the inactive ingredients, sodium bicarbonate and alginic acid. Therefore, all ANDAs that cite Gaviscon® tablets as the reference listed drug must contain the inactive ingredients sodium bicarbonate and alginic acid. A full NDA will be required to support the effectiveness of the drug product if different inactive ingredients are to be substituted for sodium bicarbonate or alginic acid or if different proportions of these ingredients are to be used.

Levothyroxine Sodium. Because there are multiple reference listed drugs for levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium tablet drug products.

Levothyroxine Sodium (Mylan ANDA 076187), Levoxyl (King Pharm NDA 021301), Synthroid (Abbvie NDA 021402), and Levo-T (Cediprof Inc NDA 021342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (Cediprof Inc NDA 021342), Euthyrox (Provell Pharma LLC NDA 021292), Levothyroxine Sodium (Mylan ANDA 076187), and Unithroid (Jerome Stevens NDA 021210) tablets have been determined to be therapeutically equivalent to
corresponding strengths of Synthroid (Abbvie NDA 021402) tablets.

Levo-T (Cediprof Inc NDA 021342), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Thyro-Tabs (Lloyd NDA 021116) tablets.15

The chart outlines TE codes for all 0.025 mg products in the active section of the Orange Book. Other product strengths may be similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One common TE code indicates therapeutic equivalence between products.

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Applicant</th>
<th>Strength</th>
<th>TE Code</th>
<th>Appl No</th>
<th>Product No</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNITHROID</td>
<td>STEVENS J</td>
<td>0.025MG</td>
<td>AB1</td>
<td>021210</td>
<td>001</td>
</tr>
<tr>
<td>LEVO Thyroxine Sod</td>
<td>MYLAN</td>
<td>0.025MG</td>
<td>AB1</td>
<td>076187</td>
<td>001</td>
</tr>
<tr>
<td>LEVOXYL</td>
<td>KING PHARMS</td>
<td>0.025MG</td>
<td>AB1</td>
<td>021301</td>
<td>001</td>
</tr>
<tr>
<td>SYNTHROID</td>
<td>ABBVIE</td>
<td>0.025MG</td>
<td>AB1</td>
<td>021402</td>
<td>001</td>
</tr>
<tr>
<td>LEVO-T</td>
<td>CEDIPROF INC</td>
<td>0.025MG</td>
<td>AB1</td>
<td>021342</td>
<td>001</td>
</tr>
<tr>
<td>SYNTHROID</td>
<td>ABBVIE</td>
<td>0.025MG</td>
<td>AB2</td>
<td>021402</td>
<td>001</td>
</tr>
<tr>
<td>LEVO Thyroxine Sod</td>
<td>MYLAN</td>
<td>0.025MG</td>
<td>AB2</td>
<td>076187</td>
<td>001</td>
</tr>
<tr>
<td>LEVO-T</td>
<td>CEDIPROF INC</td>
<td>0.025MG</td>
<td>AB2</td>
<td>021342</td>
<td>001</td>
</tr>
<tr>
<td>UNITHROID</td>
<td>STEVENS J</td>
<td>0.025MG</td>
<td>AB2</td>
<td>021210</td>
<td>001</td>
</tr>
<tr>
<td>EUTHYROX</td>
<td>PROVELL PHARM</td>
<td>0.025MG</td>
<td>AB2</td>
<td>021292</td>
<td>001</td>
</tr>
<tr>
<td>LEVOXYL</td>
<td>KING PHARMS</td>
<td>0.025MG</td>
<td>AB3</td>
<td>021301</td>
<td>001</td>
</tr>
<tr>
<td>LEVO-T</td>
<td>CEDIPROF INC</td>
<td>0.025MG</td>
<td>AB3</td>
<td>021342</td>
<td>001</td>
</tr>
<tr>
<td>UNITHROID</td>
<td>STEVENS J</td>
<td>0.025MG</td>
<td>AB3</td>
<td>021210</td>
<td>001</td>
</tr>
<tr>
<td>LEVO Thyroxine Sod</td>
<td>MYLAN</td>
<td>0.025MG</td>
<td>AB3</td>
<td>076187</td>
<td>001</td>
</tr>
<tr>
<td>THYRO-TABS</td>
<td>LLOYD</td>
<td>0.025MG</td>
<td>N/A16</td>
<td>021116</td>
<td>001</td>
</tr>
<tr>
<td>LEVO Thyroxine Sod</td>
<td>MYLAN</td>
<td>0.025MG</td>
<td>AB4</td>
<td>076187</td>
<td>001</td>
</tr>
</tbody>
</table>

15 Lloyd's Thyro-Tabs tablets (NDA 021116) (previously known as Levothroid) is currently listed in the Discontinued Drug Product List section of the Orange Book. It is the RLD for the AB4 category. Mylan's levothyroxine product (ANDA 076187) has been selected as the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. If an ANDA that uses Mylan's levothyroxine product as its reference standard is approved, the ANDA will receive an AB4 rating. The ANDA applicant also may obtain an AB rating for its product to the other reference listed drugs (i.e., Unithroid, Synthroid, and Levoxyl) by submitting supplements that demonstrate that the generic product is bioequivalent to these other reference listed drugs and satisfies all other therapeutic equivalence criteria with respect to these reference listed drugs. See Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA to Teri Natalie, Principal Consultant, Lachman Consultant Services, Inc., Docket No. FDA-2015-P-0403 (May 27, 2016).

16 Id. Thyro-Tabs is in the Discontinued Drug Product List and therefore no longer is assigned a TE code.
Patent Certification(s) and Reference Standard for ANDAs Duplicating a Drug Product Approved in a Petitioned ANDA. To submit an ANDA for a generic drug that is not the same as its reference listed drug because it has one different active ingredient in a fixed-combination drug product, or has a different route of administration, dosage form, or strength than that of the reference listed drug, an applicant first must obtain permission from FDA through what is known as a suitability petition pursuant to Section 505(j)(2)(C) of the FD&C Act. A petitioned ANDA relies on the reference listed drug described in the suitability petition. An ANDA seeking approval of a drug that is the same as a drug product approved in a petitioned ANDA should use as its reference listed drug, the reference listed drug that served as the basis for the approved suitability petition, and use the drug product approved in the petitioned ANDA as its reference standard for conducting an in vivo bioequivalence study required for approval. However, the reference listed drug for any such ANDA is generally the listed drug referenced in the approved suitability petition. The ANDA must include appropriate patent certification(s) and an exclusivity statement with respect to the reference listed drug that served as the basis for the approved suitability petition.17 (This concept also generally applies to an ANDA applicant that utilizes a reference standard that is not a reference listed drug, as such an application must include appropriate patent certification(s) and an exclusivity statement with respect to the reference listed drug.)

Waived exclusivity. If an NDA submitted under Section 505(b) of the FD&C Act qualifies for exclusivity under the FD&C Act, the exclusivity is generally listed in the Patent and Exclusivity Section of the Orange Book. If a drug product has received this exclusivity, FDA will not accept for review and/or will not approve a 505(b)(2) application or an ANDA under Section 505(j) of the FD&C Act, as applicable, in accordance with the relevant exclusivity.18 If the listed drug is also protected by one or more patents, the approval date for the ANDA or 505(b)(2) application will be determined based on an analysis of the applicant’s patent certification(s) or statement(s) for each relevant patent and the effect of relevant exclusivity listed in the Orange Book. However, the holder of the NDA may waive its exclusivity as to any or all ANDAs and 505(b)(2) applications that might otherwise be blocked by such exclusivity. If an NDA sponsor waives its exclusivity, qualified ANDAs or 505(b)(2) applications may be accepted for review and/or approved, as applicable. An NDA for which the holder has waived its exclusivity as to all ANDAs and 505(b)(2) applications will be coded with a “W” in the Patent and Exclusivity Section of the Orange Book. The applicant whose product might otherwise be blocked by this exclusivity should indicate in the exclusivity statement in its application that the holder of the listed drug has waived its exclusivity.

1.9 Therapeutic Equivalence Code Change for a Category of Multisource Drug Products

The Agency will use the following procedures when, in response to a petition or on its own initiative, it is considering a change in the therapeutic equivalence code for approved multisource drug products. Such changes will generally occur when the Agency becomes aware of new scientific information affecting the therapeutic equivalence of an entire category of

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17 If after approval of a suitability petition and before approval of an ANDA submitted pursuant to the approved petition, a drug product is approved in an NDA for the change described in the petition, the suitability petition and the listed drug identified in the petition can no longer be the basis of submission for such ANDA. Under these circumstances, an applicant seeking approval for a drug product with the change approved in the suitability petition must submit a new ANDA that identifies the drug product approved under such NDA as the RLD and comply with applicable regulatory requirements. See 21 CFR 314.93(f)(2).

18 See Patent and Exclusivity Information Addendum in the Orange Book.
multisource drug products in the Orange Book (e.g., information concerning the active ingredient or the dosage form), rather than information concerning a single drug product within the category. These procedures will be used when a change in therapeutic equivalence code is under consideration for all drug products found in the Prescription Drug Product List under a specific active ingredient and dosage form. The change may be from the code signifying that the drug does not present a bioequivalence problem (e.g., AA) to a code signifying an actual or potential bioequivalence problem (e.g., BP), or vice versa. This procedure does not apply to a change of a particular product code (e.g., a change from BP to AB or from AB to BX).

Before making a change in a therapeutic equivalence code for an entire category of multisource drug products as described above, the Agency will announce in the Introduction to the Cumulative Supplement that it is considering the change and will invite comments. Comments, along with scientific data, may be sent to the Director, Office of Bioequivalence, Food and Drug Administration, Office of Generic Drugs, Central Document Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266.

The comment period will generally be 60 days in length, and the closing date for comments will be listed in the description of the proposed change for each drug entity.

The most useful type of scientific data submitted to support comments is an in vivo bioavailability/bioequivalence study conducted on batches of the subject drug products. Comments including scientific data from an in vivo bioavailability/bioequivalence study should present a full description of the analytical procedures and equipment used, a validation of the analytical methodology, including the standard curve, a description of the method of calculating results, and a description of the pharmacokinetic and statistical models used in analyzing the data. Anecdotal or testimonial information is the least useful to the Agency, and submission of comments based on such information is discouraged. However, when there is supporting published or unpublished scientific literature, copies should be submitted with comments.

1.10 Change of the Therapeutic Equivalence Evaluation for a Single Product

The procedure described in Section 1.9 does not apply to a change in a single drug product code. For example, a change in a single drug product's code from BP to AB as a result of the submission of an acceptable bioequivalence study ordinarily will not be the subject of notice and comment in the Cumulative Supplement. Likewise, a change in a single drug product's code from AB to BX (e.g., as a result of new information raising a significant question as to bioequivalence) does not require notice and comment. The Agency's responsibility to provide the public with the Agency's most current information related to therapeutic equivalence may require a change in a drug product's code prior to any formal notice and opportunity for the applicant to be heard. The publication in the Federal Register of a proposal to withdraw approval of a drug product will ordinarily result in a change in a product's code from AB to BX if this action has not already been taken.

We recognize that certain drug products approved in 505(b)(2) applications may not have therapeutic equivalence codes, and that FDA may undertake therapeutic equivalence evaluations with respect to such drug products. A person seeking to have a therapeutic equivalence rating for a drug product approved in a 505(b)(2) application may petition the Agency through the citizen petition procedure (see 21 CFR 10.25(a) and 21 CFR 10.30).
1.11 Discontinued Section

Those drug products in the discontinued section of the Orange Book (Discontinued Drug Product List) for which a determination has been made that the products were not withdrawn for safety or effectiveness reasons have been annotated with a footnote following the product strength: “**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**”. The determinations listed in the Orange Book are only reflective of determinations made since 1995 and published in the Federal Register. The identification of these drug products in the Discontinued Drug Product List should avoid the submission of multiple citizen petitions requesting a determination for the same drug product.

Generally, approved products are added to the Discontinued Drug Product List when the applicant notifies the Orange Book staff of the products’ not-marketed status. Products may also be added to the Discontinued Drug Product List if annual reports or other submissions to the Agency indicate the product is not being marketed or as a result of other Agency administrative actions. Changes to the Orange Book are not affected by the drug registration and listing requirements of Section 510 of the FD&C Act.

1.12 Changes to the Orange Book

Every effort is made to ensure the Annual Edition is current and accurate. Applicants are requested to inform the FDA Orange Book Staff of any changes or corrections, including any change in ownership or a product’s marketing status that would result in the product being moved to the Discontinued Drug Product List. FDA notes that under Section 506I(a) of the FD&C Act, applicants must notify the Agency in writing 180 days prior to withdrawing a drug product from sale, or if 180 days is not practicable, not later than the date of withdrawal from sale. Furthermore, Section 506I(b) of the FD&C Act requires that applicants notify the Agency in writing within 180 days of approval of a drug product if such drug product will not be available for sale within 180 days of approval. A request to include a newly approved product in the Discontinued Drug Product List, rather than parts 1, 2 or 3 of the Orange Book (as discussed in Section 1.1), must be submitted to the Orange Book staff by the end of the month in which the product is approved to ensure that the product is not included in the “active” portions of the next published Orange Book update.

In addition, the FDA Orange Book Staff generally will act on requests to change a proprietary name for a listed drug only after approval of a supplement for the relevant change in proprietary name. To the extent that conventions for describing product identification information (i.e., active ingredients, dosage forms, routes of administration, product names, applicants, strengths) evolve over time, the Agency generally does not intend to revise such information for drug products already included in the Orange Book, but rather intends to apply the change prospectively to drug products added to the Orange Book.

You can contact the Orange Book Staff by email at orangebook@fda.hhs.gov.

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19 See, e.g., Section 506I(d) of the FD&C Act.
1.13 Availability of the Edition

Commencing with the 25th edition, the Annual Edition and current monthly Cumulative Supplement are available in a Portable Document Format (PDF) at the Orange Book home page by clicking on Publications. The PDF annual format duplicates previous paper versions except for the Orphan Products Designations and Approvals List. An annual subscription of the PDF format may be obtained from the U.S. Government Publishing Office, https://www.gpo.gov/.
2.0 HOW TO USE THE DRUG PRODUCT LISTS

2.1 Key Sections for Using the Drug Product Lists

This publication contains illustrations, along with Drug Product Lists, indices, and lists of abbreviations and terms which facilitate their use.

**Illustrations.** The annotated Drug Product Illustration, see Section 2.2, and the Therapeutic Equivalence Evaluations Illustration, see Section 2.3, are offered to provide further clarification. These depict the format found in the Prescription Drug Product List (the only list in which therapeutic equivalence evaluation codes are displayed).

**Drug Product Lists.** The Prescription and OTC Drug Product Lists, arranged alphabetically by active ingredient(s), contain product identification information (active ingredients, dosage forms, routes of administration, product names, applicants, strengths) for single and multiple ingredient drug products. Also shown are the application number and drug product number (FDA internal computer data use only) and approval dates for those drug products approved on or after January 1, 1982. The application number preceded by “N” is a New Drug Application (NDA or commonly the innovator). The application number preceded by an “A” is an Abbreviated New Drug Application (ANDA or commonly the generic).

The Discontinued Drug Product List, arranged alphabetically by active ingredient(s), contains product identification information (dosage form, product name, strength, and application number).

If a prescription drug product is available from more than one source (multisource), a therapeutic equivalence code will appear in front of the applicant's name. If a product is therapeutically equivalent to one or more products or to an appropriate reference, it will be designated with a code beginning with "A" and the entry will be underlined and printed in bold font for emphasis.

Active ingredient headings for multiple ingredient (combination) drug products are arranged alphabetically. For purposes of this publication, this alphabetical sort takes precedence over United States Pharmacopeia official monograph order (i.e., Reserpine, Hydralazine Hydrochloride, Hydrochlorothiazide). For example, product information labeled as Reserpine, Hydrochlorothiazide and Hydralazine Hydrochloride appears under the active ingredient heading Hydralazine Hydrochloride; Hydrochlorothiazide; Reserpine. A cross-reference to the product information (for prescription and OTC products) appears for each additional active ingredient in the product. For combination drug products, the ingredient strengths are separated by semicolons and appear in the same relative sequence as the ingredients in the heading. Available strengths of the dosage form from an applicant appear on separate lines.

To use the Drug Product Lists, determine by alphabetical order the ingredient under which the product information is listed, using the Product Name Index, if necessary. Then, find the ingredient in the applicable Drug Product List. Proceed to the dosage form and route of administration and compare products within that ingredient heading only. Therapeutic equivalence or inequivalence for prescription products is determined on the basis of the therapeutic equivalence codes provided within that specific dosage form and route heading. The OTC Drug Product List, Discontinued Drug Product List, and
Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List have their data arranged similarly.

The Discontinued Drug Product List contains approved products that have never been marketed, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, are for military use, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing. All products having a "@" in the December Cumulative Supplement of the previous Edition List have been added to the Discontinued Drug Product List appearing in this Edition. In addition, approved drug products that are not in the commercial distribution channel e.g., approved drug products in applications for export only are also listed in the Discontinued Drug Product List.

**Product Name Index** (Prescription and OTC Drug Product Lists). This is an index of drug products by trade name or established name of the active ingredient, if no trade name exists. The second term of each entry indicates the active ingredient name under which product information can be found in the appropriate Drug Product List. For those drug products with multiple active ingredients, only the first active ingredient (in alphabetical order) will appear. OTC products are so designated.

**Product Name Index Listed by Applicant** (Prescription and OTC Drug Product Lists). This is an index that cross-references applicants to drug products. The bolded and underlined entry represents the applicant name abbreviation used in this publication. Each complete applicant name that is represented by the abbreviated name is marked with an asterisk (*). Listed under each complete applicant name is the first alphabetically arranged ingredient under which product information can be found in the appropriate Drug Product List. OTC products are so designated. To use the Drug Product Lists, determine by alphabetical order the ingredient under which the product information is listed, using the Product Name Index, if appropriate.

**Uniform Terms.** To improve readability, uniform terms are used to designate dosage forms, routes of administration, and abbreviations used to express strengths. These terms are listed in Appendix C. In some cases, the terms used may differ from those used in product labels and other labeling.
2.2 DRUG PRODUCT ILLUSTRATION

SINGLE INGREDIENT

ACTIVE INGREDIENT MEPERIDINE HYDROCHLORIDE

DOSAGE FORM; ROUTE OF ADMINISTRATION INJECTABLE; INJECTION

TRADE OR GENERIC NAMES

HEXANON

REFERENCE LISTED DRUG* (+)
AP +! PAGE PHARMA 25MG/ML N013111 001 AUG 22, 1983
AP +! 50MG/ML N013111 002 AUG 22, 1983
AP +! 75MG/ML N013111 003 AUG 22, 1983
AP +! 100MG/ML N013111 004 JAN 04, 1989

REFERENCE STANDARD * (!)
MEPERIDINE HCL
AP GREENBERG PHARM 25MG/ML A064890 001 FEB 29, 1987
AP 50MG/ML A064890 002 FEB 29, 1987
AP 75MG/ML A064890 003 FEB 29, 1987
AP 100MG/ML A064890 004 MAR 08, 1992

THERAPEUTIC EQUIVALENCE (TE)
AP 50MG/ML A064890 002 FEB 29, 1987
AP 75MG/ML A064890 003 FEB 29, 1987

CODE FOR MULTISOURCE PRODUCT

SINGLE SOURCE PRODUCT (NO TE CODE)
! TIMOKIM LLC 10MG/ML A099225 001 DEC 12, 1995
AP JOHNSON MED 25MG/ML A099226 001 NOV 27, 1993
! KENDRA PHARM 150MG/ML A079444 001 OCT 31, 1999

APPLICANT

AVAILABLE STRENGTH(S) OF A PRODUCT

APPLICATION NUMBER AND PRODUCT NUMBER

PRODUCT NUMBER IS FOR FDA INTERNAL COMPUTER DATA USE ONLY

APPROVAL DATE

*NOTE: REFERENCE LISTED DRUG AND REFERENCE STANDARD ARE DISCUSSED IN THE PREFACE SECTION 1.4

MULTIPLE INGREDIENTS WITH PRODUCT INFORMATION

ALPHABETICALLY SORTED BY
ACTIVE INGREDIENT HYDRAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

PRODUCT INFORMATION

HYDRAZINE HYDROCHLORIDE, HYDROCHLOROTHIAZIDE, RESERPINE
TABLET; ORAL
REINWALD LABS 25MG; 15MG; 0.1MG A069808 001 JAN 18, 1982

THIS EXAMPLE IS FOR PURPOSE OF ILLUSTRATION ONLY. IT DOES NOT REPRESENT ACTUAL PRODUCTS FROM THE PRESCRIPTION DRUG PRODUCT LIST.
2.3 THERAPEUTIC EQUIVALENCE EVALUATIONS ILLUSTRATION

Drug products coded **AB** (or any code beginning with an "A") under an ingredient and dosage form heading are considered therapeutically equivalent only to other products coded **AB** (or any code beginning with an "A") and **NOT** to those coded **BP** (or any code beginning with a "B") and any products not listed. Drug products coded **BP** (or any code beginning with a "B") are **not** considered therapeutically equivalent to any other product. For a complete explanation of the TE codes refer to Section 1.7 of the Introduction.

**Products considered therapeutically equivalent to each other**

- **SULFASALAZINE**
  - **FAZINE**
    - **AB** PARKLAND 500MG A042999 001
  - **SULFASALAZINE**
    - **AB** URSA 500MG A042222 001

**Products considered **NOT** therapeutically equivalent to any other products listed**

- **SULFASALAZINE**
  - **FAZINE**
    - **AB** PARKLAND 500MG A042999 001
  - **SULFASALAZINE**
    - **BP** BROWN 500MG A041297 001
    - **BP** BROWN 500MG A041297 001
    - **SOUTH** 500MG A067627 001

Note: Bold font and underlining denotes multisource products which are considered therapeutically equivalent.

This example is for purposes of illustration only. It does not represent actual products from the prescription drug product list.
<p>| ABACAVIR SULFATE  | SOLUTION; ORAL  | ABOVINDO PHARMA LTD  | EQ 20MG BASE/ML  | A077950 001 Mar 14, 2018  |
| ABACAVIR SULFATE  | SOLUTION; ORAL  | HETERO LABS LTD III  | EQ 20MG BASE/ML  | A201107 001 Sep 26, 2016  |
| ABACAVIR SULFATE  | SOLUTION; ORAL  | VIIV HLTHCARE  | EQ 20MG BASE/ML  | N020978 001 Dec 17, 1998  |
| ABACAVIR SULFATE  | TABLET; ORAL   | ABOVINDO PHARMA LTD  | EQ 20MG BASE/ML  | A077844 001 Dec 17, 2012  |
| ABACAVIR SULFATE  | TABLET; ORAL   | Cipla  | EQ 20MG BASE/ML  | A091560 001 Sep 13, 2013  |
| ABACAVIR SULFATE  | TABLET; ORAL   | STRIDES PHARMA  | EQ 30MG BASE  | A091050 001 Oct 28, 2016  |
| ABACAVIR SULFATE  | TABLET; ORAL   | VIIV HLTHCARE  | EQ 30MG BASE  | N020977 001 Aug 22, 2014  |
| ABACAVIR SULFATE, LAMIVUDINE  | TABLET; ORAL | ABOVINDO PHARMA LTD  | EQ 600MG BASE; 300MG  | A090159 001 Nov 15, 2018  |
| ABACAVIR SULFATE, LAMIVUDINE  | TABLET; ORAL | CIPLA  | EQ 600MG BASE; 300MG  | A091144 001 Mar 28, 2017  |
| ABACAVIR SULFATE, LAMIVUDINE  | TABLET; ORAL | TEVA PHARMA USA  | EQ 600MG BASE; 300MG  | A079246 001 Sep 29, 2016  |
| ABACAVIR SULFATE, LAMIVUDINE  | TABLET; ORAL | Zydus pharma USA INC  | EQ 600MG BASE; 300MG  | A208990 001 Nov 15, 2018  |
| ABACAVIR SULFATE, LAMIVUDINE  | TABLET; ORAL | VIIV HLTHCARE  | 300MG BASE  | N021652 001 Aug 02, 2004  |
| ABACAVIR SULFATE, LAMIVUDINE, ZIDOVUDINE  | TABLET; ORAL | LUPIN LTD  | EQ 300MG BASE; 150MG; 300MG  | A202912 001 Dec 05, 2013  |
| ABACAVIR SULFATE, LAMIVUDINE, ZIDOVUDINE  | TABLET; ORAL | VIIV HLTHCARE  | EQ 300MG BASE; 150MG; 300MG  | N021205 001 Nov 14, 2000  |
| ABALOPARATIDE  | SOLUTION; SUBCUTANEOUS  | RADIUS HEALTH INC  | 3.12MG/1.56ML (2MG/ML)  | N208743 001 Apr 28, 2017  |
| ABEMACICLIB  | TABLET; ORAL  | ELI LILLY AND CO  | 50MG  | N208716 001 Sep 28, 2017  |
| ABEMACICLIB  | TABLET; ORAL  | 100MG  | N208716 002 Sep 28, 2017  |
| ABEMACICLIB  | TABLET; ORAL  | 150MG  | N208716 003 Sep 28, 2017  |
| ABEMACICLIB  | TABLET; ORAL  | 200MG  | N208716 004 Sep 28, 2017  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | AMNEAL PHARMS  | 250MG  | A208327 001 Jan 07, 2019  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | APOTEX INC  | 250MG  | A208439 001 Oct 31, 2018  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | HIKMA PHARMS  | 250MG  | A208439 001 Oct 31, 2018  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | MYLAN PHARMS INC  | 250MG  | A208446 001 Oct 31, 2018  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | TEVA PHARMA USA  | 250MG  | A208432 001 Oct 31, 2018  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | JANSSEN BIOTECH  | 250MG  | N202379 001 Apr 28, 2011  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | SUN PHARMA GLOBAL  | 125MG  | N210308 001 May 22, 2018  |
| ABIRATERONE ACETATE  | TABLET; ORAL  | JANSSEN BIOTECH  | 500MG  | N202379 002 Apr 14, 2017  |</p>
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<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Company</th>
<th>Strength</th>
<th>NDC</th>
<th>Date</th>
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<tbody>
<tr>
<td><strong>Acalabrutinib</strong></td>
<td>Capsule; Oral</td>
<td>Calquence</td>
<td>100mg</td>
<td>N210259</td>
<td>Oct 31, 2017</td>
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<td><strong>Acamprosate Calcium</strong></td>
<td>Tablet, Delayed Release; Oral</td>
<td>ACAMPROSATE CALCIUM</td>
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<td></td>
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<tr>
<td>AB BARR LABS DIV TEVA</td>
<td>333mg</td>
<td>A200143</td>
<td>001</td>
<td>Nov 18, 2013</td>
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</tr>
<tr>
<td>AB GLENMARK GENERICS</td>
<td>333mg</td>
<td>A202229</td>
<td>001</td>
<td>Jul 16, 2013</td>
<td></td>
</tr>
<tr>
<td>AB MYLAN PHARMS INC</td>
<td>333mg</td>
<td>A200142</td>
<td>002</td>
<td>Mar 11, 2014</td>
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</tr>
<tr>
<td>AB ZYDUS PHARMS USA INC</td>
<td>333mg</td>
<td>A205998</td>
<td>001</td>
<td>May 26, 2017</td>
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<tr>
<td><strong>Acarbose</strong></td>
<td>Tablet; Oral</td>
<td>ACARBOSE</td>
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<td>AB EMCURE PHARMS LTD</td>
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<td>AB MYLAN</td>
<td>50mg</td>
<td>A078470</td>
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<td>May 07, 2008</td>
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<td>AB WEST-WARD PHARMS INT</td>
<td>100mg</td>
<td>A078470</td>
<td>003</td>
<td>May 07, 2008</td>
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<td><strong>Precose</strong></td>
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<td>PRECOSE</td>
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<td>AB BAYER HLTHCARE</td>
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<td>May 29, 1997</td>
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<td>AB +</td>
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<td>Sep 06, 1995</td>
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<td><strong>Acetaminophen</strong></td>
<td>Capsule; Oral</td>
<td>ACETAMINOPHEN</td>
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<td><strong>Acetaminophen</strong></td>
<td>Solution; Intravenous</td>
<td>ACETAMINOPHEN</td>
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<td></td>
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<tr>
<td>AP CUSTOPHARM INC</td>
<td>1GM/100ML (10MG/ML)</td>
<td>A202605</td>
<td>001</td>
<td>Jun 13, 2016</td>
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</tr>
<tr>
<td>AP SANDOZ INC</td>
<td>1GM/100ML (10MG/ML)</td>
<td>A204052</td>
<td>002</td>
<td>Mar 22, 2016</td>
<td></td>
</tr>
<tr>
<td>AP MALLINCKRODT HOSP. ACETAMINOPHEN FRESENIUS KABI USA</td>
<td>1GM/100ML (10MG/ML)</td>
<td>N022450</td>
<td>001</td>
<td>Nov 02, 2010</td>
<td></td>
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<tr>
<td><strong>Acetaminophen; Benzyldihydroxyone Hydrochloride</strong></td>
<td>Tablet; Oral</td>
<td>ACETAMINOPHEN; BUTALBITAL</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acetaminophen; Butalbital</strong></td>
<td>Capsule; Oral</td>
<td>BUTALBITAL AND ACETAMINOPHEN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AA CNTY LINE PHARMS</td>
<td>300MG;50MG</td>
<td>A207635</td>
<td>001</td>
<td>Jun 05, 2017</td>
<td></td>
</tr>
<tr>
<td>AA LARKEN LABS INC</td>
<td>325MG;50MG</td>
<td>A203484</td>
<td>002</td>
<td>Dec 04, 2015</td>
<td></td>
</tr>
</tbody>
</table>


### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST
### PRESCRIPTION DRUG PRODUCT LIST

#### 3-3 (of 452)

<table>
<thead>
<tr>
<th>Description</th>
<th>Company</th>
<th>Strength</th>
<th>ID</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACETAMINOPHEN; BUTALBITAL</strong></td>
<td>MIKART</td>
<td>300MG;50MG</td>
<td>A207386</td>
<td>Nov 15, 2016</td>
</tr>
<tr>
<td><strong>BUTALBITAL AND ACETAMINOPHEN</strong></td>
<td>NEXGEN PHARMA</td>
<td>300MG;50MG</td>
<td>A090956</td>
<td>Aug 23, 2011</td>
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<tr>
<td><strong>BUTAPAP</strong></td>
<td>MIKART</td>
<td>325MG;50MG</td>
<td>A089987</td>
<td>Oct 26, 1992</td>
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<tr>
<td><strong>ACETAMINOPHEN; BUTALBITAL; CAFFEINE</strong></td>
<td>AUROLIFE PHARMA LLC</td>
<td>325MG;50MG;40MG</td>
<td>A204733</td>
<td>Sep 26, 2018</td>
</tr>
<tr>
<td><strong>ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE</strong></td>
<td>MAYNE PHARMA INC</td>
<td>325MG;50MG;40MG</td>
<td>A089007</td>
<td>Mar 17, 1986</td>
</tr>
<tr>
<td><strong>ACETAMINOPHEN; BUTALBITAL; CAFFEINE</strong></td>
<td>NEXGEN PHARMA</td>
<td>300MG;50MG;40MG</td>
<td>A040885</td>
<td>Nov 16, 2009</td>
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<tr>
<td><strong>ACETAMINOPHEN; BUTALBITAL; CAFFEINE</strong></td>
<td>NUVO PHARM INC</td>
<td>300MG;50MG;40MG</td>
<td>A207118</td>
<td>Dec 04, 2015</td>
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<tr>
<td><strong>ACETAMINOPHEN; BUTALBITAL; CAFFEINE</strong></td>
<td>ABHAI LLC</td>
<td>325MG;50MG;40MG</td>
<td>A211106</td>
<td>Jan 31, 2003</td>
</tr>
<tr>
<td><strong>ACETAMINOPHEN, BUTALBITAL, CAFFEINE AND CODINE PHOSPHATE</strong></td>
<td>ACTAVIS LABS UT INC</td>
<td>325MG;50MG;40MG;30MG</td>
<td>A088616</td>
<td>Jun 09, 1984</td>
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<td><strong>ACETAMINOPHEN, BUTALBITAL, CAFFEINE AND CODINE PHOSPHATE</strong></td>
<td>CNTY LINE PHARMS</td>
<td>325MG;50MG;40MG;30MG</td>
<td>A204984</td>
<td>Jan 10, 2017</td>
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<td><strong>ACETAMINOPHEN, BUTALBITAL, CAFFEINE AND CODINE PHOSPHATE</strong></td>
<td>HIKMA PHARMs</td>
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<td>A089718</td>
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<td><strong>ACETAMINOPHEN, BUTALBITAL, CAFFEINE AND CODINE PHOSPHATE</strong></td>
<td>LANNETT CO INC</td>
<td>325MG;50MG;40MG;30MG</td>
<td>A200243</td>
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<td><strong>ACETAMINOPHEN, BUTALBITAL, CAFFEINE AND CODINE PHOSPHATE</strong></td>
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<td>NEXGEN PHARMA INC</td>
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<td>A205857</td>
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<td><strong>ACETAMINOPHEN, BUTALBITAL, CAFFEINE AND CODINE PHOSPHATE</strong></td>
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<td><strong>ACETAMINOPHEN, BUTALBITAL, CAFFEINE AND CODINE PHOSPHATE</strong></td>
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<td>NEXGEN PHARMA INC</td>
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<td><strong>ACETAMINOPHEN; CODEINE PHOSPHATE</strong></td>
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**Note:** The table above lists approved drug products as of the 39th edition in 2019.
### Acetaminophen; Codeine Phosphate

**Table: Oral**

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**OXYCODONE AND ACETAMINOPHEN**

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<td>Tablet; Oral</td>
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<td>ACCORD HLTHCARE</td>
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<td>AT</td>
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<td>AB BOSCOGEN</td>
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<td>AB CARLSBAD TECHNOLOGY</td>
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ACYCLOVIR SODIUM
INJECTABLE; INJECTION

ACYCLOVIR SODIUM

AP
AUROBINDO PHARMA LTD
EQ 50MG BASE/ML
A203701 001 Oct 11, 2013

AP
! FRESENIUS KABI USA
! ZYDUS PHARMS USA INC
EQ 50MG BASE/ML
A074930 001 May 13, 1998
EQ 500MG BASE/VIAL
A206535 001 Aug 31, 2018
EQ 1GM BASE/VIAL
A206535 002 Aug 31, 2018

ACYCLOVIR; HYDROCORTISONE
CREAM; TOPICAL

KERESE
+! VALEANT BERMUDA
5%; 1%
N022436 001 Jul 31, 2009

ADAPALENE
CREAM; TOPICAL

ADAPALENE

AP
FOUGERA PHARMS
0.1%
A090824 001 Jun 30, 2010

ADAPALENE

AP
GALDERMA LABS LP
0.1%
N020748 001 May 26, 2000

ADAPALENE

AP
ACTAVIS MID ATLANTIC
0.3%
A201000 001 Oct 27, 2014

ADAPALENE

AP
GLENMARK GENERICS
0.1%
A091314 001 Jul 01, 2010

ADAPALENE

AP
PLIVA HRVATSKA DOO T&V
0.1%
A090962 001 Jun 02, 2010

ADAPALENE

AP
TARO
0.3%
A208322 001 Jun 23, 2016

ADAPALENE

AP
TOLMAR
0.3%
A200299 001 Jun 14, 2012

ADAPALENE

AP
GALDERMA LABS LP
0.3%
N021753 001 Jun 19, 2007

ADAPALENE

AP
CALL INC
0.1%
A203981 001 Sep 23, 2016

ADAPALENE, BENZOYL PEROXIDE
GEL; TOPICAL

ADAPALENE AND BENZOYL PEROXIDE

AP
ACTAVIS MID ATLANTIC
0.1%; 2.5%
A203790 001 Sep 30, 2015

AP
PERRIGO ISRAEL
0.1%; 2.5%
A205033 001 Jan 23, 2018

AP
TARO
0.1%; 2.5%
A206959 001 Jan 24, 2018

AP
TOLMAR
0.1%; 2.5%
A209148 001 Oct 17, 2018

AP
GALDERMA LABS LP
0.1%; 2.5%
A206164 001 May 23, 2018

EPIDUO

AP
GALDERMA LABS LP
0.1%; 2.5%
N022320 001 Dec 08, 2008

EPIDUO FORTE

AP
GALDERMA LABS
0.3%; 2.5%
N207917 001 Jul 15, 2015

ADEFOVIR DIPIVOXIL
TABLET; ORAL

ADEFOVIR DIPIVOXIL

AP
APOTEX INC
10MG
A205459 001 Jul 06, 2018

AP
SIGMAPHARM LABS LLC
10MG
A202051 001 Aug 29, 2013

HEPSERA

AP
GILEAD
10MG
N021449 001 Sep 20, 2002

ADENOSINE
INJECTABLE; INJECTION

ADENOSINE

AP
AKORN
3MG/ML
A078076 001 Oct 31, 2008

AP
FRESENIUS KABI USA
3MG/ML
A077133 001 Apr 27, 2005

AP
GLAND PHARMA LTD
3MG/ML
A205568 001 Apr 16, 2018

AP
LUITPOLD
3MG/ML
A077283 001 Jun 14, 2007

AP
MYLAN LABS LTD
3MG/ML
A078640 001 Mar 21, 2014

AP
WEST-WARD PHARMS INT
3MG/ML
A076886 001 May 13, 2009

AP
3MG/ML
A076500 001 Jun 16, 2004
## Adenosine

**Solution; Intravenous**

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<th>Approval Number</th>
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<td>60mg/20ml (3mg/ml)</td>
<td>Nov 02, 2017</td>
<td>A205531 001</td>
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<td>Adenosine Solution; Intravenous</td>
<td>Emcure Pharma Ltd</td>
<td>90mg/30ml (3mg/ml)</td>
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<td>Adenosine Solution; Intravenous</td>
<td>Fresenius Kabi USA</td>
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<td>Sep 15, 2014</td>
<td>A202313 001</td>
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<td>Adenosine Solution; Intravenous</td>
<td>Hospira Inc USA</td>
<td>90mg/30ml (3mg/ml)</td>
<td>Nov 27, 2017</td>
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<td>Mylan Asi</td>
<td>60mg/20ml (3mg/ml)</td>
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<td>A203883 001</td>
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<tr>
<td>Adenosine Solution; Intravenous</td>
<td>Teva Pharma USA</td>
<td>90mg/30ml (3mg/ml)</td>
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<td>A077425 002</td>
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## Afatinib Dimaleate

**Tablet; Oral**

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<th>Approval Date</th>
<th>Approval Number</th>
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<tbody>
<tr>
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<td>Gilotrif</td>
<td>EQ 20mg Base</td>
<td>Jul 12, 2013</td>
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<td>Gilotrif</td>
<td>EQ 30mg Base</td>
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## Albendazole

**Tablet; Oral**

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<td>Albendazole 200mg</td>
<td>Cipla Ltd</td>
<td>200mg</td>
<td>Sep 21, 2018</td>
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<td>Albendazole 200mg</td>
<td>Strides Vivimed</td>
<td>200mg</td>
<td>Dec 07, 2018</td>
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<td>Albendazole 200mg</td>
<td>Zyus Pharma Usa Inc</td>
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## Albendazole

**Injection**

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<tr>
<td>Albendazole 10mg/ml</td>
<td>GE Healthcare</td>
<td>10mg/ml</td>
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## Albumin Human

**Injectable; Injection**

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<td>ISO TEX 100uCi/10ML (100uCi/10ML)</td>
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<td>ISO TEX 500uCi/0.5ML (500uCi/0.5ML)</td>
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<td>Albumin Iodinated I-131 Serum</td>
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## Albuterol Sulfate

**Aerosol, Metered; Inhalation**

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<tr>
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<td>PROVENTIL-HFA</td>
<td>Oct 29, 2004</td>
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<tr>
<td>Albuterol Sulfate 0.09mg/base/inh</td>
<td>3M Drug Delivery</td>
<td>VENTOLIN HFA</td>
<td>Aug 15, 1996</td>
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<td>GlaxoSmithKline</td>
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<td>Apr 19, 2001</td>
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<td>Mylan Specialty LP</td>
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## Albuterol Sulfate

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<td>Albuterol Sulfate 0.5% Base</td>
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<td>EQ 0.5% Base</td>
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<td>Albuterol Sulfate 0.5% Base</td>
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<td>EQ 0.5% Base</td>
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<td>Albuterol Sulfate 0.021% Base</td>
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<td><strong>SUN PHARMA GLOBAL</strong></td>
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<td><strong>AN</strong></td>
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<td>EQ 2MG BASE A072637 002 Dec 05, 1989</td>
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<td><strong>AN</strong></td>
<td><strong>VIRTUS PHARM</strong></td>
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<td><strong>AN</strong></td>
<td><strong>MYLAN</strong></td>
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<tr>
<td><strong>SOLUTION; INHALATION</strong></td>
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<tr>
<td><strong>AN</strong></td>
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<td><strong>EQ 0.083% BASE; 0.017%</strong> A077559 001 Dec 31, 2007</td>
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<td><strong>AN</strong></td>
<td><strong>Nephron</strong></td>
<td><strong>EQ 0.083% BASE; 0.017%</strong> A076749 001 Dec 31, 2007</td>
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<td><strong>AN</strong></td>
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<tr>
<td><strong>+! BOEHRINGER</strong></td>
<td><strong>EQ 0.1MG BASE/INH; 0.02MG/INH</strong> N021747 001 Oct 07, 2011</td>
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### Alcohol

- **Sodium Solution; Intra-Arterial**
  - **Ablynol**
    - + Belcher Pharms LLC: 99% (1mL) N207987 001 Jun 21, 2018
    - +! 99% (5mL) N207987 002 Jun 21, 2018

### Alectinib Hydrochloride

- **Capsule; Oral**
  - **Alecensa**
    - + Hoffmann-La Roche: EQ 150mg Base N208434 001 Dec 11, 2015

### Alendronate Sodium

- **Solution; Oral**
  - **Arendavon**
    - + West-Ward Pharms: EQ 70mg Base/75mL A090520 001 Feb 25, 2013

#### Alendronate Sodium

| Brand | Strength | Lot Code | Date
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<tr>
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<tbody>
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<td>AB</td>
<td>EQ 10mg Base</td>
<td>A077982 002</td>
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<td>AB</td>
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### Fosamax

- **Tablet, Effervescent; Oral**
  - **Binosto**
    - +! Mission Pharma: EQ 70mg Base N202344 001 Mar 12, 2012

### Alendronate Sodium; Cholecalciferol

| Brand | Strength | Lot Code | Date
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### Alphentanil Hydrochloride

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    - +! Akorn: EQ 0.5mg Base/ml N019353 001 Dec 29, 1986
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**Legend:**
- **AP**: Approved
- **NDC**: National Drug Code
- **EQ**: Equivalent
- **INT**: INT
- **May 17, 1996**: May 17, 1996
- **Mar 03, 2016**: March 03, 2016
- **Nov 09, 2015**: November 09, 2015
- **Jul 07, 2015**: July 07, 2015
- **Jan 25, 2013**: January 25, 2013
- **Dec 22, 2016**: December 22, 2016
- **Dec 23, 2003**: December 23, 2003
- **Dec 22, 2016**: December 22, 2016
- **Feb 23, 2018**: February 23, 2018
- **Feb 09, 2000**: February 09, 2000
- **May 18, 2000**: May 18, 2000
- **Jun 16, 2003**: June 16, 2003
### ALPRAZOLAM

**CONCENTRATE; ORAL**

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**ALPRAZOLAM**

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*Note: The above list is not exhaustive and only includes products that were approved in the specified years.*
### ALPRAZOLAM

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### XANAX XR

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### ARIKAYCE KIT

**Suspension, Liposomal; Inhalation**

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<tbody>
<tr>
<td>INSMED INC</td>
<td>EQ 590MG BASE/8.4ML</td>
<td>N207356 001</td>
<td>Sep 28, 2018</td>
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</table>

### AMILORIDE HYDROCHLORIDE

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Provider</th>
<th>Strength</th>
<th>NDC</th>
<th>Expire</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAR PHARM</td>
<td>5MG</td>
<td>A070346 001</td>
<td>Jan 22, 1986</td>
</tr>
<tr>
<td>SIGMAPHARM LABS LLC</td>
<td>5MG</td>
<td>A079133 001</td>
<td>Jan 30, 2009</td>
</tr>
<tr>
<td>USPHARMA WINDLAS</td>
<td>5MG</td>
<td>A204180 001</td>
<td>Aug 07, 2015</td>
</tr>
<tr>
<td>Paddock LLC</td>
<td>5MG</td>
<td>N018200 001</td>
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</table>

### AMILORIDE HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

**Tablet; Oral**

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<thead>
<tr>
<th>Provider</th>
<th>Strength</th>
<th>NDC</th>
<th>Expire</th>
</tr>
</thead>
<tbody>
<tr>
<td>BARR</td>
<td>EQ 5MG ANHYDROUS:50MG</td>
<td>A071111 001</td>
<td>May 10, 1988</td>
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<tr>
<td>MYLAN</td>
<td>EQ 5MG ANHYDROUS:50MG</td>
<td>A073209 001</td>
<td>Oct 31, 1991</td>
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### AMINO ACIDS

**Injectable; Injection**

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<th>Strength</th>
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<th>Expire</th>
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</thead>
<tbody>
<tr>
<td>B BRAUN</td>
<td>15% (150GM/1000ML)</td>
<td>A091112 001</td>
<td>Apr 13, 2012</td>
</tr>
<tr>
<td>B BRAUN</td>
<td>15% (300GM/2000ML)</td>
<td>A091112 002</td>
<td>Apr 13, 2012</td>
</tr>
<tr>
<td>ICU MEDICAL INC</td>
<td>10% (10GM/100ML)</td>
<td>N017673 003</td>
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</tr>
<tr>
<td>ICU MEDICAL INC</td>
<td>8.5% (8.5GM/100ML)</td>
<td>N017673 004</td>
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</tr>
<tr>
<td>ICU MEDICAL INC</td>
<td>10% (100MG/1000ML)</td>
<td>N020015 001</td>
<td>Dec 19, 1991</td>
</tr>
<tr>
<td>ICU MEDICAL INC</td>
<td>15% (150MG/100ML)</td>
<td>N020041 001</td>
<td>Dec 19, 1991</td>
</tr>
<tr>
<td>ICU MEDICAL INC</td>
<td>10% (10GM/100ML)</td>
<td>N019492 002</td>
<td>Oct 17, 1986</td>
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<tr>
<td>ICU MEDICAL INC</td>
<td>7% (70MG/1000ML)</td>
<td>N019398 001</td>
<td>Sep 06, 1985</td>
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<tr>
<td>BAXTER HLTHCARE</td>
<td>15% (150GM/1000ML)</td>
<td>A020512 001</td>
<td>Aug 30, 1996</td>
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<tr>
<td>FREAMINE HBC 6.9%</td>
<td>6.9% (6.9GM/100ML)</td>
<td>N016822 006</td>
<td>May 17, 1983</td>
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<td>FREAMINE III 10%</td>
<td>10% (10GM/100ML)</td>
<td>N016822 005</td>
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<tr>
<td>FREAMINE III 8.5%</td>
<td>8.5% (8.5GM/100ML)</td>
<td>N016822 004</td>
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<tr>
<td>HEPATAMINE 8%</td>
<td>8% (8GM/100ML)</td>
<td>N018676 001</td>
<td>Aug 03, 1982</td>
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<tr>
<td>NPHRAMINE 5.4%</td>
<td>5.4% (5.4GM/100ML)</td>
<td>N017766 001</td>
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<tr>
<td>BAXTER HLTHCARE</td>
<td>10% (10GM/1000ML)</td>
<td>A075880 002</td>
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<td>BAXTER HLTHCARE</td>
<td>6% (60MG/100ML)</td>
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<td>AMINO ACIDS</td>
<td>INJECTABLE; INJECTION</td>
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<td>-------------</td>
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<tr>
<td>TRAVASOL 10% IN PLASTIC CONTAINER</td>
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<tr>
<td>BAXTER HLTHCARE 10% (10MG/100ML)</td>
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<td></td>
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<tr>
<td>N018931 003 Aug 23, 1984</td>
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<tr>
<td>TRAVASOL 5.5% IN PLASTIC CONTAINER</td>
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<tr>
<td>BAXTER HLTHCARE 5.5% (5.5GM/100ML)</td>
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<tr>
<td>N018931 001 Aug 23, 1984</td>
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<tr>
<td>TRAVASOL 8.5% IN PLASTIC CONTAINER</td>
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<td>BAXTER HLTHCARE 8.5% (8.5GM/100ML)</td>
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<tr>
<td>N018931 002 Aug 23, 1984</td>
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<tr>
<td>TROPHAMINE 10%</td>
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</tr>
<tr>
<td>B BRAUN 6% (6GM/100ML)</td>
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<tr>
<td>N019018 001 Jul 20, 1984</td>
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<td>TROPHAMINE 10%</td>
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<tr>
<td>B BRAUN 10% (10GM/100ML)</td>
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<tr>
<td>N019018 003 Sep 07, 1988</td>
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</table>

| AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE |
| INJECTABLE; INJECTION |
| PROCALAMINE |
| B BRAUN 3%;26MG/100ML;3GM/100ML;54MG/100ML;41MG/100ML;150MG/100ML;200MG/100ML;120MG/100ML |
| N018582 001 May 08, 1982 |

| AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE |
| INJECTABLE; INJECTION |
| CLINIMIX E 2.75/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 2.75%;33MG/100ML;10GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;59MG/100ML |
| N020678 002 Mar 26, 1997 |
| CLINIMIX E 2.75/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 2.75%;33MG/100ML;25GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 005 Mar 26, 1997 |
| CLINIMIX E 2.75/5 SULFITE FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 2.75%;33MG/100ML;5GM/100ML;51MG/100ML;112MG/100ML;217MG/100ML;77MG/100ML |
| N020678 008 Mar 26, 1997 |
| CLINIMIX E 4.25/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 4.25%;33MG/100ML;10GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 009 Mar 26, 1997 |
| CLINIMIX E 4.25/20 SULFITE FREE W/ ELECT IN DEXTROSE 20% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 4.25%;33MG/100ML;20GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 011 Mar 26, 1997 |
| CLINIMIX E 4.25/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 4.25%;33MG/100ML;25GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 012 Mar 26, 1997 |
| CLINIMIX E 4.25/5 SULFITE FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 4.25%;33MG/100ML;5GM/100ML;51MG/100ML;112MG/100ML;217MG/100ML;77MG/100ML |
| N020678 008 Mar 26, 1997 |
| CLINIMIX E 5/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 5%;33MG/100ML;10GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 016 Mar 26, 1997 |
| CLINIMIX E 5/15 SULFITE FREE W/ ELECT IN DEXTROSE 15% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 5%;33MG/100ML;15GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 017 Mar 26, 1997 |
| CLINIMIX E 5/20 SULFITE FREE W/ ELECT IN DEXTROSE 20% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 5%;33MG/100ML;20GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 018 Mar 26, 1997 |
| CLINIMIX E 5/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 5%;33MG/100ML;25GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 019 Mar 26, 1997 |
| CLINIMIX E 5/35 SULFITE FREE W/ ELECT IN DEXTROSE 35% W/ CALCIUM IN PLASTIC CONTAINER |
| BAXTER HLTHCARE 5%;33MG/100ML;35GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;77MG/100ML |
| N020678 021 Mar 26, 1997 |

| AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL |
| EMULSION; INTRAVENOUS |
| KABIVEN IN PLASTIC CONTAINER |
| FRESENIUS KABI USA 3.3%;29MG/100ML;9.8GM/100ML;96MG/100ML;174MG/100ML;239MG/100ML;147MG/100ML;3.9GM/100ML;100ML |
| N200656 004 Aug 25, 2014 |
| KABIVEN IN PLASTIC CONTAINER |
| FRESENIUS KABI USA 3.3%;29MG/100ML;9.8GM/100ML;96MG/100ML;174MG/100ML;239MG/100ML;147MG/100ML;3.9GM/100ML;150ML |
| N200656 005 Aug 25, 2014 |
| KABIVEN IN PLASTIC CONTAINER |
| FRESENIUS KABI USA 3.3%;29MG/100ML;9.8GM/100ML;96MG/100ML;174MG/100ML;239MG/100ML;147MG/100ML;3.9GM/100ML;205ML |
| N200656 006 Aug 25, 2014 |
| KABIVEN IN PLASTIC CONTAINER |
| FRESENIUS KABI USA 3.3%;29MG/100ML;9.8GM/100ML;96MG/100ML;174MG/100ML;239MG/100ML;147MG/100ML;3.9GM/100ML;256ML |
| N200656 007 Aug 25, 2014 |
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL EMULSION; INTRAVENOUS

PERIKABIVEN IN PLASTIC CONTAINER
  + FRESENIUS RABI USA 2.4%;20MG/100ML;6.8GM/100ML;68MG/100ML;124MG/100ML;170MG/100ML;105MG/100ML;3.5 GM/100ML (1440ML)
  + FRESENIUS RABI USA 2.4%;20MG/100ML;6.8GM/100ML;68MG/100ML;124MG/100ML;170MG/100ML;105MG/100ML;3.5 GM/100ML (1920ML)
  + FRESENIUS RABI USA 2.4%;20MG/100ML;6.8GM/100ML;68MG/100ML;124MG/100ML;170MG/100ML;105MG/100ML;3.5 GM/100ML (2400ML)

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION
  CLINIMIX 2.75/10 SULFITE FREE IN DEXTROSE 10% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 2.75%;10GM/100ML
  CLINIMIX 2.75/25 SULFITE FREE IN DEXTROSE 25% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 2.75%;25GM/100ML
  CLINIMIX 4.25/10 SULFITE FREE IN DEXTROSE 10% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 4.25%;10GM/100ML
  CLINIMIX 4.25/20 SULFITE FREE IN DEXTROSE 20% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 4.25%;20GM/100ML
  CLINIMIX 4.25/25 SULFITE FREE IN DEXTROSE 25% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 4.25%;25GM/100ML
  CLINIMIX 4.25/5 SULFITE FREE IN DEXTROSE 5% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 4.25%;5GM/100ML
  CLINIMIX 5/10 SULFITE FREE IN DEXTROSE 10% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 5%;10GM/100ML
  CLINIMIX 5/15 SULFITE FREE IN DEXTROSE 15% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 5%;15GM/100ML
  CLINIMIX 5/20 SULFITE FREE IN DEXTROSE 20% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 5%;20GM/100ML
  CLINIMIX 5/25 SULFITE FREE IN DEXTROSE 25% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 5%;25GM/100ML
  CLINIMIX 5/35 SULFITE FREE IN DEXTROSE 35% IN PLASTIC CONTAINER
    BAXTER HLTHCARE 5%;35GM/100ML

AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE

INJECTABLE; INJECTION
  FREAMINE III 8.5% W/ ELECTROLYTES
    B BRAUN 8.5%;110MG/100ML;230MG/100ML;10MG/100ML N016822 007 Jul 01, 1988
    440MG/100ML;690MG/100ML
  FREAMINE III 3% W/ ELECTROLYTES
    ICU MEDICAL INC 3.5%;23MG/100ML;40MG/100ML;128MG/100ML;234MG/100ML

AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION
  AMINOSYN 3.5% M
    ICU MEDICAL INC 3.5%;23MG/100ML;40MG/100ML;128MG/100ML;234MG/100ML

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC

INJECTABLE; INJECTION
  AMINOSYN 8.5% W/ELECTROLYTES
    ICU MEDICAL INC 8.5%;102MG/100ML;487MG/100ML;28MG/100ML;425MG/100ML

AMINOCAPROIC ACID

INJECTABLE; INJECTION
  AMINOCAPROIC ACID

AP
  LUITPOLD 250MG/ML A071192 001 Dec 01, 1987
  AMINOCAPROIC ACID IN PLASTIC CONTAINER
  AP ! HOSPIRA 250MG/ML A070010 001 Mar 09, 1987
  SYRUP; ORAL
  AMICAR
    +! CLOVER PHARMS 1.25GM/5ML N015230 002
### Aminocaproic Acid

**Tablet; Oral**

<table>
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<tr>
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<th>Strength</th>
<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMICAR</td>
<td>500 mg</td>
<td>N015197 001</td>
<td>CLOVER PHARMS</td>
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<tr>
<td>AMICAR</td>
<td>1000 mg</td>
<td>N015197 002</td>
<td>CLOVER PHARMS</td>
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### Aminolevulinic Acid Hydrochloride

**For Solution; Oral**

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<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLEOLAN</td>
<td>1.5 mg/mL</td>
<td>N208630 001</td>
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**Gel; Topical**

<table>
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<th>Strength</th>
<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMELUZ</td>
<td>10%</td>
<td>N208081 001</td>
<td>BIOFRONTERA</td>
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**Solution; Topical**

<table>
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<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEVULAN</td>
<td>20%</td>
<td>N020965 001</td>
<td>DUSA</td>
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### Aminophylline

**Injectable; Injection**

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<th>Strength</th>
<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPIRA</td>
<td>25 mg/mL</td>
<td>A087242 001</td>
<td>HOSPIRA INC</td>
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### Aminosalicylic Acid

**Granule, Delayed Release; Oral**

<table>
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<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>JACOBUS</td>
<td>4 g/packet</td>
<td>A074346 001</td>
<td>MYLAN INSTITUTIONAL</td>
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### Amiodarone Hydrochloride

**Injectable; Injection**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUROBINDO PHARMA LTD</td>
<td>50 mg/mL</td>
<td>A204550 001</td>
<td>AUROBINDO PHARMA LTD</td>
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**Tablet; Oral**

<table>
<thead>
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<th>Brand</th>
<th>Strength</th>
<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACERONE</td>
<td>200 mg</td>
<td>A078578 001</td>
<td>UPSHER SMITH LABS</td>
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### Amiodarone Hydrochloride

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taro Pharm</td>
<td>100 mg</td>
<td>A075424 001</td>
<td>Taro Pharm</td>
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</table>

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>NDC</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zydus Pharma USA Inc</td>
<td>200 mg</td>
<td>A075929 001</td>
<td>ZYDUS PHARMS USA Inc</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Strength</td>
<td>Reference Number</td>
<td>Date</td>
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<tr>
<td>-----------------------------------------------</td>
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</tr>
<tr>
<td>AMITRIPTYLINE HYDROCHLORIDE</td>
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<tr>
<td><strong>TABLET; ORAL</strong></td>
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<tr>
<td>AMITRIPTYLINE HYDROCHLORIDE</td>
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<tr>
<td>AB ACCORD HLTHCARE</td>
<td>10MG</td>
<td>A202446</td>
<td>Jun 04, 2014</td>
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<tr>
<td>AB 25MG</td>
<td>A202446</td>
<td>002</td>
<td>Jun 04, 2014</td>
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<tr>
<td>AB 50MG</td>
<td>A202446</td>
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<tr>
<td>AB MYLAN</td>
<td>10MG</td>
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<tr>
<td>AB 25MG</td>
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<tr>
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**AMLODIPINE BESYLATE; BENZAPEPRIL HYDROCHLORIDE**

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**AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE**

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**AMLODIPINE BESYLATE; CELECOXIB**

**TABLET; ORAL**

**CONSENSI**

| + KITOV PHARMS LTD             | EQ 2.5MG BASE;10MG | N210045 001 | May 31, 2018  |
| + EQ 5MG BASE;200MG            | N210045 002 | May 31, 2018  |
| +! EQ 10MG BASE;200MG          | N210045 003 | May 31, 2018  |

**AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL**

**TABLET; ORAL**

**OLMESARTAN MEDOXOMIL, AMLODIPINE AND HYDROCHLOROTHIAZIDE**

| PAR PHARM INC                  | EQ 5MG BASE;12.5MG;20MG | A206137 001 | Oct 26, 2016  |
| AB                             | EQ 5MG BASE;12.5MG;40MG | A206137 002 | Oct 26, 2016  |
| AB                             | EQ 5MG BASE;25MG;40MG | A206137 003 | Oct 26, 2016  |
| AB TEVA PHARMS USA             | EQ 5MG BASE;12.5MG;20MG | A202491 001 | Nov 03, 2016  |
| AB                             | EQ 5MG BASE;12.5MG;40MG | A202491 002 | Nov 03, 2016  |
| AB                             | EQ 5MG BASE;25MG;40MG | A202491 003 | Nov 03, 2016  |
| AB                             | EQ 10MG BASE;12.5MG;20MG | A20491 004 | Nov 03, 2016  |
| AB                             | EQ 10MG BASE;25MG;40MG | A20491 005 | Nov 03, 2016  |
| AB TORRENT PHARMS LTD          | EQ 5MG BASE;12.5MG;20MG | A203580 001 | Oct 26, 2016  |
| AB                             | EQ 5MG BASE;12.5MG;40MG | A203580 002 | Oct 26, 2016  |
| AB                             | EQ 5MG BASE;25MG;40MG | A203580 003 | Oct 26, 2016  |
### AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL

#### TABLET; ORAL

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### AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN

#### TABLET; ORAL

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### AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL

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### EXFORGE HCT

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### AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL

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### Approved Drug Product List

#### Prescription Drug Product List

**AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL**

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<td>EQ 5MG BASE; 40MG</td>
<td>A205234</td>
<td>Nov 17, 2016</td>
</tr>
<tr>
<td>LUPIN LTD</td>
<td>EQ 5MG BASE; 40MG</td>
<td>A025156</td>
<td>Aug 26, 2014</td>
</tr>
<tr>
<td>MYLAN PHARMS INC</td>
<td>EQ 5MG BASE; 40MG</td>
<td>A202516</td>
<td>Aug 26, 2014</td>
</tr>
<tr>
<td>TRUESTA</td>
<td>EQ 5MG BASE; 40MG</td>
<td>N022401</td>
<td>Oct 16, 2009</td>
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</tbody>
</table>

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**AMLODIPINE BESYLATE; PERINDOPRIL ARGinine**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>ADRN</th>
<th>Date Approved</th>
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<tr>
<td>PRESTALIA</td>
<td>EQ 5MG BASE; 7MG</td>
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<td>A091154</td>
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<tr>
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<td>N022401</td>
<td>Oct 16, 2009</td>
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**TELIMSARTAN AND AMLODIPINE**

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<tbody>
<tr>
<td>ALEMBIC PHARMS LTD</td>
<td>EQ 5MG BASE; 40MG</td>
<td>A205234</td>
<td>Nov 17, 2016</td>
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<tr>
<td>LUPIN LTD</td>
<td>EQ 5MG BASE; 40MG</td>
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<td>EQ 5MG BASE; 40MG</td>
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<tr>
<td>BOEHRINGER INGELHEIM</td>
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<tr>
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<td>Mar 30, 2015</td>
</tr>
<tr>
<td>ALEMBIC PHARM LTD</td>
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<td>30mCi-300mCi/8ML (3.75-37.5mCi/ML)</td>
<td>Mar 30, 2015</td>
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<tr>
<td>ALEMBIC PHARM LTD</td>
<td>EQ 10MG BASE;160MG</td>
<td>30mCi-300mCi/8ML (3.75-37.5mCi/ML)</td>
<td>Mar 30, 2015</td>
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<tr>
<td>TEVA PHARMA USA</td>
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<tr>
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<tr>
<td>TEVA PHARMA USA</td>
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<tr>
<td>TEVA PHARMA USA</td>
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<td>30mCi-300mCi/8ML (3.75-37.5mCi/ML)</td>
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<tr>
<td>+! NOVARTIS</td>
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<td>30mCi-300mCi/8ML (3.75-37.5mCi/ML)</td>
<td>Jun 20, 2007</td>
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<tr>
<td>+! NOVARTIS</td>
<td>EQ 10MG BASE;320MG</td>
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<td>Jun 20, 2007</td>
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</table>
### Ammonia N-13

**Injectable; Intravenous**

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<th>Strength</th>
<th>Company</th>
<th>Date</th>
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<tbody>
<tr>
<td>Ammonia N 13</td>
<td>3.75-260mCi/ML</td>
<td>SherTech Labs LLC</td>
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<tr>
<td>WI Medcl Cyclotron</td>
<td>3.75-260mCi/ML</td>
<td>A204366</td>
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### Ammonium Chloride

**Injectable; Injection**

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<th>Strength</th>
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<th>Date</th>
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<tr>
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<td>5.0 Meq/ML</td>
<td>Hospira</td>
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### Ammonium Lactate

**Cream; Topical**

<table>
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<tr>
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<th>Company</th>
<th>Date</th>
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<tbody>
<tr>
<td>Ammonium Lactate</td>
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<td>Perrigo New York</td>
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<tr>
<td>Ammonium Lactate</td>
<td>EQ 12% Base</td>
<td>Taro</td>
<td>Apr 10, 2003</td>
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<tr>
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<td>Watson Labs Inc</td>
<td>Feb 07, 2006</td>
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### Amoxapine

**Tablet; Oral**

<table>
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<th>Company</th>
<th>Date</th>
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<tbody>
<tr>
<td>Amoxapine</td>
<td>25mg</td>
<td>Watson Labs</td>
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<tr>
<td>Amoxapine</td>
<td>50mg</td>
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<td>Aug 28, 1992</td>
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<tr>
<td>Amoxapine</td>
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### Amoxicillin

**Capsule; Oral**

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<th>Strength</th>
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<tr>
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<td>Dec 28, 2006</td>
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<tr>
<td>Amoxicillin</td>
<td>500mg</td>
<td>Am Antibiotics</td>
<td>Dec 28, 2006</td>
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<tr>
<td>Amoxicillin</td>
<td>250mg</td>
<td>Aurobindo</td>
<td>Sep 15, 2014</td>
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<tr>
<td>Amoxicillin</td>
<td>500mg</td>
<td>AmoXil</td>
<td>Dec 28, 2006</td>
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<tr>
<td>Amoxicillin</td>
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**Suspension; Oral**

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<th>Date</th>
</tr>
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<tbody>
<tr>
<td>Amoxicillin</td>
<td>200mg/5ml</td>
<td>Aurobindo</td>
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<tr>
<td>Amoxicillin</td>
<td>400mg/5ml</td>
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<td>Dec 28, 2006</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>125mg/5ml</td>
<td>Aurobindo Pharma Ltd</td>
<td>Sep 15, 2014</td>
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<tr>
<td>Amoxicillin</td>
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<td>Amoxicillin</td>
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<tr>
<td>AB NEOPHARMA 50MG/ML</td>
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<td>AB 125MG/5ML</td>
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<td>AB 250MG/5ML</td>
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<tr>
<td>AB NEOPHARMA 125MG/5ML</td>
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<td>AB 250MG/5ML</td>
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<tr>
<td>AB AUROBINDO 500MG</td>
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<tr>
<td>AB 875MG</td>
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<tr>
<td>AB HIKMA 500MG</td>
</tr>
<tr>
<td>AB SANDOZ 875MG</td>
</tr>
<tr>
<td>AB TEVA 500MG</td>
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<td>AB 875MG</td>
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<tr>
<th>TABLET, CHEWABLE; ORAL AMOXICILLIN</th>
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<td>AB TEVA 125MG</td>
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<td>AB 250MG</td>
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<tr>
<th>AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE</th>
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<tbody>
<tr>
<td>CAPSULE, CAPSULE, DELAYED REL PELLETS, TABLET; ORAL</td>
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<tr>
<td>LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN</td>
</tr>
<tr>
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</tr>
<tr>
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<th>AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE</th>
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<td>OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN</td>
</tr>
<tr>
<td>AB +! CUMBERLAND PHARMS 500MG N/A, N/A; N/A, 500MG N/A, N/A, 20M G</td>
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| AMOXICILLIN; CLAVULANATE POTASSIUM FOR SUSPENSION; ORAL |
| AMOXICILLIN AND CLAVULANATE POTASSIUM |
| AB AUROBINDO PHARMA LTD 2000MG/5ML; EQ 28.5MG BASE/5ML | A201090 001 |
| AB 4000MG/5ML; EQ 57MG BASE/5ML | A201090 002 |
| AB 6000MG/5ML; EQ 42.9MG BASE/5ML | A201091 001 |
| AB HIKMA PHARMS 2000MG/5ML; EQ 28.5MG BASE/5ML | A065191 001 |
| AB 4000MG/5ML; EQ 57MG BASE/5ML | A065191 002 |
| AB SANDOZ 6000MG/5ML; EQ 42.9MG BASE/5ML | A065373 001 |
| AB 2000MG/5ML; EQ 28.5MG BASE/5ML | A065066 001 |
| AB 4000MG/5ML; EQ 57MG BASE/5ML | A065066 002 |
| AB SANDOZ INC 6000MG/5ML; EQ 42.9MG BASE/5ML | A065098 001 |
| AB 2000MG/5ML; EQ 28.5MG BASE/5ML | A065098 002 |
| AB TEVA 6000MG/5ML; EQ 42.9MG BASE/5ML | A065358 001 |
| AB 2000MG/5ML; EQ 28.5MG BASE/5ML | A065089 001 |
| AB 4000MG/5ML; EQ 57MG BASE/5ML | A065089 002 |
| AB + WOCKHARDT BIO AG 6000MG/5ML; EQ 42.9MG BASE/5ML | A065431 001 |
| AB 2000MG/5ML; EQ 28.5MG BASE/5ML | A065420 001 |
| AB +! NEOPHARMA 2500MG/5ML; EQ 62.5MG BASE/5ML | N050575 002 |
| AB +! AUGMENTIN '125' + NEOPHARMA 125MG/5ML; EQ 31.25MG BASE/5ML | N050575 001 |

<table>
<thead>
<tr>
<th>TABLET; ORAL AMOXICILLIN AND CLAVULANATE POTASSIUM</th>
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<tbody>
<tr>
<td>AB AUROBINDO PHARMA LTD 2500MG EQ 125MG BASE</td>
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<tr>
<td>AB 5000MG EQ 125MG BASE</td>
</tr>
<tr>
<td>AB 875MG EQ 125MG BASE</td>
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<tr>
<td>AB HIKMA PHARMS 875MG EQ 125MG BASE</td>
</tr>
<tr>
<td>AB MICRO LABS LTD INDIA 2500MG EQ 125MG BASE</td>
</tr>
<tr>
<td>AB 5000MG EQ 125MG BASE</td>
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<tr>
<td>AB SANDOZ 875MG EQ 125MG BASE</td>
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<tr>
<td>AB 5000MG EQ 125MG BASE</td>
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<tr>
<td>AB 875MG EQ 125MG BASE</td>
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## AMOXICILLIN; CLAVULANATE POTASSIUM

**TABLET; ORAL**

<table>
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<th>Strength</th>
<th>Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
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<td>500MG; EQ 125MG BASE</td>
<td>A065117</td>
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<tr>
<td><em>TEVA</em></td>
<td>875MG; EQ 125MG BASE</td>
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<tr>
<td><em>TEVA PHARMAS USA</em></td>
<td>500MG; EQ 125MG BASE</td>
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<td>875MG; EQ 125MG BASE</td>
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<td>N050720</td>
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<td><em>DR REDDYS LABS INC</em></td>
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## AMOXICILLIN AND CLAVULANATE POTASSIUM

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## AMPHETAMINE

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## AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROMPHETAMINE SACCHARATE; DEXTROMPHETAMINE SULFATE

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### Approved Drug Product List

#### Prescriptions

**AMPHEMATE ASPARTATE; AMPHEMATE SULFATE; DEXTROMPHAMATE SACCHARATE; DEXTROMPHAMATE SULFATE**

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### AMPICILLIN SODIUM

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## AMPHETAMINE ASPARATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

#### TABLET; ORAL

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## AMPHETAMINE SULFATE

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## AMPHETAMINE SULFATE

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## AMPHETAMINE SULFATE

### INJECTABLE; INJECTION

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### AMPICILLIN SODIUM

**Injectable; Injection**

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**Powder; Intravenous**

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### AMPICILLIN SODIUM; Sulbacatam Sodium

**Injectable; Injection**

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<td>EQ 1GM BASE/VIAL; EQ 5MG BASE/VIAL</td>
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### AMPICILLIN SODIUM; SULBACTAM SODIUM
**Injectable; Injection**

**UNASYN**

**AP** +!

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### AMPICILLIN/AMPICILLIN TRIHYDRATE
**Capsule; Oral**

**AMPICILLIN TRIHYDRATE**

**AB**

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<th>DAVA PHARMS INC</th>
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| FOR SUSPENSION; ORAL **AMPICILLIN TRIHYDRATE**
| DAVA PHARMS INC |
| EQ 125MG BASE/5ML |
| A062982 001 | Feb 10, 1989 |
| ! EQ 250MG BASE/5ML |
| A062982 002 | Feb 10, 1989 |

### ANAGRELIDE HYDROCHLORIDE
**Capsule; Oral**

**AGRYLIN**

**AB**

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### ANASTROZOLE
**Tablet; Oral**

**ANASTROZOLE**

**AB**

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<td>BEIJING YILING</td>
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<td>BOSCOCEN</td>
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**ARTIMIDEX**

**AB** +!

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### ANGIOTENSIN II ACETATE
**Solution; Intravenous**

**GIAPREZA**

| EQ 2.5MG BASE/ML (EQ 2.5MG BASE/ML) |
| N209360 001 | Dec 21, 2017 |

### ANIDULAFUNGIN
**Powder; Intravenous**

**ERAXIS**

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### APALUTAMIDE
**Tablet; Oral**

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### APIXABAN
**Tablet; Oral**

**ELIQUIS**

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<td>Arsenic trioxide</td>
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<td>Articaine hydrochloride; epinephrine bitartrate</td>
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ASCORBIC ACID
SOLUTION; INTRAVENOUS
ASCOR +! MCGUFF
25,000MG/50ML (500MG/ML) N209112 001 Oct 02, 2017

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K
INJECTABLE; INTRAVENOUS
INFUVITE PEDIATRIC +! SANDOX INC
80MG/VIAL; 0.02MG/VIAL; 0.01MG/VIAL; 0.14MG/VIAL; 0.2MG/VIAL; EQ 1.2MG BASE/VIAL; 0.7MG/VIAL; 7 IU/VIAL; 2,300 IU/VIAL; 0.2MG/VIAL
N021265 001 Feb 21, 2001

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)
+! SANDOX INC
80MG/VIAL; 0.02MG/VIAL; 0.01MG/VIAL; 0.14MG/VIAL; 0.2MG/VIAL; EQ 1.2MG BASE/VIAL; 0.7MG/VIAL; 7 IU/VIAL; 2,300 IU/VIAL; 0.2MG/VIAL
N021646 001 Jan 29, 2004

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)
+! SANDOX INC
80MG/VIAL; 0.02MG/VIAL; 0.01MG/VIAL; 0.14MG/VIAL; 0.2MG/VIAL; EQ 1.2MG BASE/VIAL; 0.7MG/VIAL; 7 IU/VIAL; 2,300 IU/VIAL; 0.2MG/VIAL
N021646 001 Jan 29, 2004

ASPCRIBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E
INJECTABLE; INTRAVENOUS
M.V.I. PEDIATRIC
80MG/VIAL; 0.02MG/VIAL; 0.001MG/VIAL; 5MG/VIAL; 0.01MG/VIAL; 0.001MG/VIAL; 0.14MG/VIAL; 17MG/VIAL; 0.2MG/VIAL; 1MG/VIAL; 1.4MG/VIAL; 1.2MG/VIAL; 7 IU/VIAL; 2,300 IU/VIAL; 0.2MG/VIAL
N018920 001 Sep 21, 2000

M.V.I. ADULT PHARMACY BULK PACKAGE
80MG/VIAL; 0.02MG/VIAL; 0.001MG/VIAL; 5MG/VIAL; 0.01MG/VIAL; 0.001MG/VIAL; 0.14MG/VIAL; 17MG/VIAL; 0.2MG/VIAL; 1MG/VIAL; 1.4MG/VIAL; 1.2MG/VIAL; 7 IU/VIAL; 2,300 IU/VIAL; 0.2MG/VIAL
N021625 001 Jan 30, 2004

M.V.I. ADULT (PHARMACY BULK PACKAGE)
80MG/5ML; 0.02MG/5ML; 0.001MG/5ML; 5MG/5ML; 0.01MG/5ML; 0.001MG/5ML; 0.14MG/5ML; 17MG/5ML; 0.2MG/5ML; 1MG/5ML; 1.4MG/5ML; EQ 1.2MG BASE/5ML; 0.7MG/5ML; 7 IU/VIAL; 2,300 IU/VIAL; 0.2MG/VIAL
N021643 001 Feb 18, 2004

ASPCRIBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE
FOR SOLUTION; ORAL
MOVIPREP
+! SALIX PHARMS
4.7GM; 100GM; 1.015GM; 5.9GM; 2.691GM; 7.5GM N021881 001 Aug 02, 2006
PLENVU
+! SALIX PHARMS INC
7.5GM; 140GM; 2.2GM; 48.11GM; 5.2GM; 9GM N209381 001 May 04, 2018

ASENAPINE MALEATE
TABLET; SUBLINGUAL
ASENAPINE MALEATE
TABLET; SUBLINGUAL
AB SIGMAPHARM LABS LLC EQ 5MG BASE A206107 001 Jul 17, 2018
AB SIGMAPHARM LABS LLC EQ 10MG BASE A206107 002 Jul 17, 2018
AB SAPPHIS +! FOREST LABS LLC EQ 5MG BASE N022117 001 Aug 13, 2009
AB SAPPHIS +! FOREST LABS LLC EQ 10MG BASE N022117 002 Aug 13, 2009
AB SAPPHIS +! FOREST LABS LLC EQ 2.5 BASE N022117 003 Mar 12, 2015

ASPIRIN
CAPSULE, EXTENDED RELEASE; ORAL
DURLAZA +! ESPERO
162.5MG N200671 001 Sep 04, 2015

ASPIRIN; BUTALBITAL; CAFFEINE
CAPSULE; ORAL
FIORINAL +! ALLERGAN SALES LLC 325MG; 50MG; 40MG N017534 005 Apr 16, 1986
LANORINAL +! LANNETT 325MG; 50MG; 40MG A086996 002 Oct 11, 1985
PII TABLET; ORAL
BUTALBITAL; ASPIRIN AND CAFFEINE +! HIRMA INTL PHARMS 325MG; 50MG; 40MG A086162 002 Feb 16, 1984
PII 325MG; 50MG; 40MG A204195 001 Sep 22, 2016
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<th>Strength/Other Details</th>
<th>NDC Code</th>
<th>Date Approved</th>
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<td>Aspirin; Butalbital; Caffeine; codeine phosphate capsule; oral</td>
<td>BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE</td>
<td>AB MAYNE PHARMA INC 325MG;50MG;40MG;30MG</td>
<td>A203335 001</td>
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<td>AB NEXGEN PHARMA INC 325MG;50MG;40MG;30MG</td>
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<td>AB STEVENS J 325MG;50MG;40MG;30MG</td>
<td>A074551 001</td>
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<td>FIORINAL W/CODEINE</td>
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<td>N019429 003</td>
<td>Oct 26, 1990</td>
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<td>Aspirin; Caffeine; Orphenadrine citrate tablet; oral</td>
<td>Orphenadrine citrate, aspirin, and caffeine</td>
<td>AB SANOZ 385MG;30MG;25MG</td>
<td>A074654 001</td>
<td>Dec 31, 1996</td>
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<td>AB 770MG;60MG;50MG</td>
<td>A074654 002</td>
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<td>Aspirin; Carisoprodol</td>
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<td>AB INGENUS PHARMS NJ 325MG;200MG;16MG</td>
<td>A040860 001</td>
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<td>AB SANOZ 325MG;200MG</td>
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<td>Aspirin; Dipryridamole</td>
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<td>AB BOEHRINGER 25MG;200MG</td>
<td>N020884 001</td>
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<td>A206392 001</td>
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<td>AB BARR 25MG;200MG</td>
<td>A078804 001</td>
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<td>AB DR REDDYS LABS LTD 25MG;200MG</td>
<td>A209048 001</td>
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<td>AB PAR PHARM INC 25MG;200MG</td>
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<td>AB SUN PHARMA GLOBAL 25MG;200MG</td>
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<td>AB SYDUS PHARMS USA INC 25MG;200MG</td>
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<td>Aspirin; Omeprazole</td>
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<td>AB STEVENS J 325MG;400MG</td>
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<td>Aspirin; Oxycodone Hydrochloride</td>
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<td>AB ACTAVIS LABS FL INC 325MG;4.8355MG</td>
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<td>AB MAYNE PHARMA INC 325MG;4.8355MG</td>
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<td>AB ENDO PHARMS 325MG;4.8355MG</td>
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<td>A204806 001</td>
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<td>AB EQ 150MG BASE</td>
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<td>AB MYLAN PHARMS INC EQ 150MG BASE</td>
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<td>AB EQ 200MG BASE</td>
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### ATAZANAVIR SULFATE

**Capsule; Oral**

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<td>AB</td>
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### REYATAZ

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<td>AB + BRISTOL MYERS SQUIBB</td>
<td>EQ 150MG BASE</td>
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<td>EQ 200MG BASE</td>
<td>N021567 003</td>
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<td>AB + BRISTOL MYERS SQUIBB</td>
<td>EQ 300MG BASE</td>
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### ATAZANAVIR SULFATE; CORICISTAT

**Tablet; Oral**

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### ATENOLOL

**Tablet; Oral**

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### TENORMIN

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### ATENOLOL; CHLORTALIDONE

**Tablet; Oral**

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### ATENOLOL; CHLORTHALIDONE
**Tablet; Oral**

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| **ATENOLOL AND CHLORTHALIDONE**

#### TENORETIC 100
- **Watson Labs**
  - 50MG;25MG
  - NDC: A073665 001
  - Approval Date: Jul 02, 1992

#### TENORETIC 50
- **Alvogen Malta**
  - 100MG;25MG
  - NDC: N018760 001
  - Approval Date: Jun 08, 1984

### ATOMOXETINE HYDROCHLORIDE
**Capsule; Oral**

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| **ATOMOXETINE HYDROCHLORIDE**

#### APOTEX INC
- 10MG
  - NDC: A078983 001
  - Approval Date: May 30, 2017

#### Aurobindo Pharma Ltd
- 10MG
  - NDC: A077016 001
  - Approval Date: May 30, 2017

#### Dr Reddys Labs Ltd
- 10MG
  - NDC: A079016 001
  - Approval Date: May 30, 2017

#### Glenmark Pharms Ltd
- 10MG
  - NDC: A078983 001
  - Approval Date: May 30, 2017

#### Teva Pharms USA
- 10MG
  - NDC: A078983 001
  - Approval Date: May 30, 2017

### STRATTERA
**Capsule; Oral**

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| **Lilly**

#### Atorvastatin Calcium
**Tablet; Oral**

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| **ATORVASTATIN CALCIUM**

#### Accord Hlthcare
- EQ 10MG BASE
  - NDC: A207687 001
  - Approval Date: Mar 30, 2018

#### Apotex Inc
- EQ 20MG BASE
  - NDC: A207687 002
  - Approval Date: Mar 30, 2018

#### Dr Reddys Labs Ltd
- EQ 10MG BASE
  - NDC: A091650 001
  - Approval Date: Jul 17, 2012

#### Graviti Pharms
- EQ 10MG BASE
  - NDC: A209918 001
  - Approval Date: Jun 18, 2018
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**ATORVASTATIN CALCIUM: EZETIMIBE**

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**ATOVAQUONE**

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<td>GLENMARK GENERICS</td>
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<td>0.025MG;1MG</td>
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<td>0.025MG;2.5MG</td>
<td>ANI PHARMS INC</td>
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<td>0.025MG;2.5MG</td>
<td>BAYSHORE PHARMS LLC</td>
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<td>+! 200MG</td>
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<th>AZATHIOPRINE</th>
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<td><strong>AZATHIOPRINE SODIUM</strong></td>
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<td>AZELASTINE HYDROCHLORIDE</td>
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<td>Aztreonam for Solution; Inhalation</td>
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<td>Aztreonam Injectable; Injection</td>
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<td>Aztreonam Injectable in Plastic Container</td>
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AZTREONAM
INJECTABLE; INJECTION
AZACTAM IN PLASTIC CONTAINER
+!
AZTREONAM
FRESENIUS KABI USA 500MG/VIAL A065439 001 Jun 18, 2010

BACITRACIN
INJECTABLE; INJECTION
BACIIM
AP X GEN PHARMS 50,000 UNITS/VIAL A064153 001 May 09, 1997
AP BACITRACIN
AP AKORN 50,000 UNITS/VIAL A206719 001 Oct 20, 2017
AP FRESENIUS KABI USA 50,000 UNITS/VIAL A065116 001 Dec 03, 2002
AP PHARMACIA AND UPJOHN 50,000 UNITS/VIAL A060733 002
AP XELLI A PHARMS APS 50,000 UNITS/VIAL A203177 001 Aug 25, 2014

OINTMENT; TOPICAL
BACITRACIN
AP PERRIGO CO 500 UNITS/GM A061212 001

BACITRACIN ZINC; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
OINTMENT; OPHTHALMIC
BACITRACIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE
AP PERRIGO CO 400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 10,000 UNITS/GM A062166 002
TENNESSEE

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
OINTMENT; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES; BACITRACIN ZINC AND HYDROCORTISONE
AT AKORN 400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 10,000 UNITS/GM
AT Bausch and Lomb 400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 10,000 UNITS/GM A064068 001 Oct 30, 1995
OINTMENT; TOPICAL
CORTISPORIN
AT MONARCH PHARMS 400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 5,000 UNITS/GM B050168 002 May 04, 1984

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
OINTMENT; TOPICAL
NEOMYCIN AND POLYMYXIN B SULFATES; BACITRACIN ZINC
AT AKORN 400 UNITS/GM; EQ 3.5MG BASE/GM; 10,000 UNITS/GM
AT Bausch and Lomb 400 UNITS/GM; EQ 3.5MG BASE/GM; 10,000 UNITS/GM
AT PERRIGO CO 400 UNITS/GM; EQ 3.5MG BASE/GM; 10,000 UNITS/GM A060764 002
TENNESSEE

BACLOFEN
INJECTABLE; INTRatheCAL
BACLOFEN
AP EMERALD INTL LTD 0.05MG/ML A091193 001 May 03, 2016
AP 0.5MG/ML A091193 002 May 03, 2016
AP 2MG/ML A091193 003 May 03, 2016
AP MYLAN LABS LTD 0.5MG/ML A209592 001 Mar 21, 2018
AP 2MG/ML A209592 002 Mar 21, 2018
AP PIRAMAL CRITICAL 0.05MG/ML N022462 001 Nov 19, 2010
AP 0.5MG/ML N022462 002 Nov 19, 2010
AP 1MG/ML N022462 004 Jun 22, 2012
AP 2MG/ML N022462 003 Nov 19, 2010
AP LIORESAL
AP SAOL THERAPS RES LTD 0.05MG/ML N020075 003 Nov 07, 1996
### BACLOFEN

**injectable; intrathecal**

**LIoresal**

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<th>Strength</th>
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<tbody>
<tr>
<td>+!</td>
<td>0.5 mg/ml</td>
<td>N020075 001</td>
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<tr>
<td>+!</td>
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**tablet; oral**

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<td>IMX LABS</td>
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<td>20 mg</td>
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<td>IVX SUB TEVA</td>
<td>IVAX SUB TEVA</td>
<td>10 mg</td>
<td>A077223 003</td>
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<tr>
<td>LANNETT CO INC</td>
<td>LANNETT CO INC</td>
<td>10 mg</td>
<td>A090334 001</td>
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<td>MYLAN</td>
<td>MYLAN PHARMS INC</td>
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<td>NORTHSTAR HLTHCARE</td>
<td>NORTHSTAR HLTHCARE</td>
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<td>NORTHSTAR HLTHCARE</td>
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<td>OXFORD PHARMS</td>
<td>OXFORD PHARMS</td>
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<td>RUBICON RES PVT LTD</td>
<td>RUBICON RES PVT LTD</td>
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<td>SUN PHARM IND S INC</td>
<td>SUN PHARM IND S INC</td>
<td>10 mg</td>
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<td>USL PHARMA</td>
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<td>ZYDUS WORLDWIDE</td>
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### BALOXAVIR MARBOXIL

**tablet; oral**

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<tr>
<td>APOTEX INC</td>
<td>APOTEX INC</td>
<td>20 mg</td>
<td>N210854 001</td>
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<td>APOTEX INC</td>
<td>APOTEX INC</td>
<td>40 mg</td>
<td>N210854 002</td>
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### BALSALAZIDE DISODIUM

**capsule; oral**

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<tr>
<td>APOTEX INC</td>
<td>APOTEX INC</td>
<td>750 mg</td>
<td>A077883 001</td>
<td>Dec 28, 2007</td>
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<td>MYLAN</td>
<td>MYLAN</td>
<td>750 mg</td>
<td>A077807 001</td>
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<td>WEST-WARD PHARMS INT</td>
<td>WEST-WARD PHARMS INT</td>
<td>750 mg</td>
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### COLAPAL

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<tr>
<td>VALEANT PHARMS INTL</td>
<td>VALEANT PHARMS INTL</td>
<td>750 mg</td>
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### GIAZO

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<tr>
<td>PAR PHARM INC</td>
<td>PAR PHARM INC</td>
<td>1.1 gm</td>
<td>A206336 001</td>
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### BARICITINIB

**tablet; oral**

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<td>ELI LILLY AND CO</td>
<td>ELI LILLY AND CO</td>
<td>2 mg</td>
<td>N207924 001</td>
<td>May 31, 2018</td>
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### BARIUM SULFATE

**for suspension; oral**

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<tr>
<td>+! BRACCO</td>
<td>BRACCO</td>
<td>98% (334GM/BOT)</td>
<td>N208036 001</td>
<td>Jan 11, 2016</td>
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<td>+! BRACCO</td>
<td>BRACCO</td>
<td>96% (169GM/BOT)</td>
<td>N208036 002</td>
<td>Apr 07, 2017</td>
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<td>VARIBAR PUDDING</td>
<td>BRACCO</td>
<td>40%</td>
<td>N208844 001</td>
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**suspension; oral**

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<tr>
<td>+! BRACCO</td>
<td>BRACCO</td>
<td>60% (213GM/BOT)</td>
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<td>Mar 01, 2017</td>
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<td>+! BRACCO</td>
<td>BRACCO</td>
<td>2% (9GM/BOT)</td>
<td>N208143 001</td>
<td>Jan 15, 2016</td>
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<td>Product Name</td>
<td>Manufacturer</td>
<td>Strength/Unit</td>
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<td>SUSPENSION; ORAL</td>
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<tr>
<td>+! BRACCO 2% (9GM/BOT)</td>
<td>N208143 002</td>
<td>Jan 15, 2016</td>
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<td>TAGITOL V 40% (8GM/BOT)</td>
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<td>VARIABAR HONEY 40% (100GM/250ML)</td>
<td>N208143 007</td>
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<td>VARIABAR NECTAR 40% (96GM/240ML)</td>
<td>N208143 004</td>
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<td>VARIABAR THIN HONEY 40% (100GM/250ML)</td>
<td>N208143 006</td>
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<td><strong>BAZEDOXIFENE ACETATE; ESTROGENS, CONJUGATED</strong></td>
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<td>DUAVEE +! WYETH PHARMS 20MG BASE;0.45MG</td>
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<td><strong>BECLOMETHASONE DIPROPIONATE</strong></td>
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<td>AEROSOL, METERED; INHALATION</td>
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<td>QVAR REDIHALER 0.04MG/INH</td>
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<td>+ 0.08MG/INH</td>
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<td>QNASL +! TEVA BRAND PHARM 0.04MG/ACTUATION</td>
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<td>+! 0.08MG/ACTUATION</td>
<td>N202813 001</td>
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<td><strong>BECLOMETHASONE DIPROPIONATE MONOHYDRATE</strong></td>
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<td>SPRAY, METERED; NASAL</td>
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<td>BECONASE AQ +! GLAXOSMITHKLINE 0.042MG DIPROP/SPRAY</td>
<td>N019389 001</td>
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<td><strong>BEDAQUILINE FUMARATE</strong></td>
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<td>SIRTUGO +! JANSSEN THERAP 100MG BASE</td>
<td>N204384 001</td>
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<td><strong>BELINOSTAT</strong></td>
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BENOXINATE HYDROCHLORIDE; FLUORESCEIN SODIUM
SOLUTION/DROPS; OPHTHALMIC
ALTAFLUOR BENOX
+! ALTAIRE PHARMS INC 0.4%; 0.25% N208582 001 Dec 14, 2017

BENZNIDAZOLE
TABLET; ORAL
BENZNIDAZOLE
+ CHEMO RESEARCH SL 12.5MG N209570 001 Aug 29, 2017
+! 100MG N209570 002 Aug 29, 2017

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CAPSULE; ORAL
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AA AIPING PHARM INC 100MG A210562 001 Nov 09, 2018
AA 150MG A210562 002 Nov 09, 2018
AA 200MG A210562 003 Nov 09, 2018
AA APOTEX INC 100MG A091310 001 Jan 16, 2015
AA 200MG A091310 002 Jan 16, 2015
AA BIONPHARMA INC 100MG A081297 001 Jan 29, 1993
AA 200MG A081297 002 Oct 30, 2007
AA CSPC NBP PHARM CO 100MG A202765 001 Jul 31, 2015
AA 200MG A202765 002 Jul 31, 2015
AA MIKART 100MG A040851 001 Nov 09, 2009
AA 150MG A040851 002 Nov 09, 2009
AA 200MG A040851 003 Nov 09, 2009
AA ORIT LABS LLC 100MG A040682 001 Jul 30, 2007
AA 200MG A040682 002 Jul 30, 2007
AA PURACAP PHARM LLC 100MG A206948 001 Dec 19, 2018
AA 200MG A206948 002 Dec 19, 2018
AA STRIDES PHARMA 100MG A091133 001 Jul 30, 2007
AA 200MG A091133 002 Jul 30, 2007
AA SUN PHARM INDUS INC 100MG A040587 001 Jun 26, 2012
AA 200MG A040587 002 Jun 26, 2012
AA THEPHARMANETWORK LLC 100MG A040627 001 Mar 30, 2007
AA 150MG A201209 001 Sep 24, 2014
AA 200MG A040749 001 Jul 25, 2007
AA ZYDUS PHARMS USA 100MG A040597 001 Jun 08, 2007
AA 200MG A040597 002 Jun 08, 2007

TESSALON
AB +! PFIZER 100MG N011210 001

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE
GEL; TOPICAL

ACANYA
AB +! DOW PHARM 2.5%; EQ 1.2% BASE N050819 001 Oct 23, 2008
BENZACIN
AB +! VALEANT BERMUDA 5%; EQ 1% BASE N050756 001 Dec 21, 2000
CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE
AB ACTAVIS LABS UT INC 2.5%; EQ 1.2% BASE A205128 001 Jun 19, 2015
AB MYLAN PHARMS INC 5%; EQ 1% BASE A065443 001 Aug 11, 2009
AB PERRIGO ISRAEL 5%; EQ 1% BASE A208440 001 Sep 21, 2015
AB TARGAMON 5%; 1.2% A090979 001 Jun 26, 2012
AB TARO 3.75%; EQ 1.2% BASE A208688 001 Jun 05, 2018
AB TARGAMON 5%; EQ 1% BASE A206241 001 May 25, 2018
AB TARGAMON 5%; 1.2% A206241 002 May 25, 2018
AB TARGAMON 5%; EQ 1% BASE A203488 001 Dec 15, 2017
AB TARGAMON 5%; 1.2% A203488 002 Dec 15, 2017
AB ZYDUS PHARMS USA INC 5%; 1.2% A210794 001 Aug 26, 2002

DUAC
AB +! STIEFEL 5%; 1.2% N050741 001 Nov 24, 2014
ONEKTON
AB +! DOW PHARM 3.75%; EQ 1.2% BASE N050819 001 Nov 24, 2014

BENZOYL PEROXIDE; ERYTHROMYCIN
GEL; TOPICAL

BENZAMICIN
AB +! VALEANT INTL 5%; 3% N050557 001 Oct 26, 1984
ERYTHROMYCIN AND BENZOYL PEROXIDE
AB LYNE 5%; 3% A065385 001 Sep 18, 2015
AB TOLMAR 5%; 3% A065312 001 Mar 29, 2004
BENZOYL PEROXIDE; ERYTHROMYCIN
GEL; TOPICAL
AKTIPAK
+! CUTANEA 5%; 3%
N050769 001 Nov 27, 2000

BENZPHETAMINE HYDROCHLORIDE
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<td>EPIC PHARMA LLC</td>
<td>50MG</td>
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<td>KVR TECH</td>
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<td>AA</td>
<td>MIKART</td>
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BENZTROPINE MESYLATE
INJECTABLE; INJECTION

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<td>NAVINTA LLC</td>
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<td>OAK PHARMS AKORN</td>
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BENZTROPINE MESYLATE
TABLET; ORAL

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BENZYL ALCOHOL
LOTION; TOPICAL
ULESFIA
+! SHIONOGI INC 5%
N022129 001 Apr 09, 2009

BENZYPENICILLLOYL POLYLYSINE
INJECTABLE; INJECTION
PRE-PEN
+! ALLERQUEST 60UMOLAR
N050114 001

BEPOTASTINE BESILATE
SOLUTION/DROPS; OPHTHALMIC
BEPREVE
+! BAUSCH AND LOMB INC 1.5%
N022288 001 Sep 08, 2009

BERACTANT
SUSPENSION; INTRATRACHEAL
SURVANTA
+! ABBIvie 25MG/ML
N020032 001 Jul 01, 1991
BESIFLOXACIN HYDROCHLORIDE
SUSPENSION/DROPS;OPHTHALMIC
BESIVANCE
+! BAUSCH AND LOMB EQ 0.6% BASE
N022308 001 May 28, 2009

BETAINE
FOR SOLUTION;ORAL
CYSTADANE
+! ORPHAN EUROPE 1GM/SCOOPFUL
N020576 001 Oct 25, 1996

BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE
INJECTABLE;INJECTION
BETAMETHASONE ACETATE AND BETAMETHASONE SODIUM PHOSPHATE
AB LUITPOLD 3MG/ML;EQ 3MG BASE/ML A090747 001 Jul 31, 2009

CELESTONE SOLUSPAN
AB +! MERCK SHARP DOHME 3MG/ML;EQ 3MG BASE/ML N014602 001

BETAMETHASONE DIPROPIONATE
CREAM;TOPICAL
BETAMETHASONE DIPROPIONATE
AB ACTAVIS MID EQ 0.05% BASE A070885 001 Feb 03, 1987
AB +! FOUGERA PHARMS EQ 0.05% BASE N019137 001 Jun 26, 1984
AB TARO EQ 0.05% BASE A210217 001 Oct 12, 2018
AB ZYDUS PHARMS USA INC EQ 0.05% BASE A208885 001 Jan 11, 2019

CREAM, AUGMENTED;TOPICAL
BETAMETHASONE DIPROPIONATE
AB ANDA REPOSITORY EQ 0.05% BASE A076603 001 Jan 23, 2004
AB FOUGERA PHARMS EQ 0.05% BASE A076215 001 Dec 09, 2003
AB GLENMARK GENERICS EQ 0.05% BASE A078930 001 Sep 23, 2008
AB PERRIGO NEW YORK EQ 0.05% BASE A076592 001 Dec 09, 2003
AB TARO EQ 0.05% BASE A076543 001 Dec 09, 2003

DIPROLENE AF
GEL, AUGMENTED;TOPICAL
BETAMETHASONE DIPROPIONATE
AB +! MERCK SHARP DOHME EQ 0.05% BASE N019555 001 Apr 27, 1987

BETAMETHASONE DIPROPIONATE
LOTION;TOPICAL
BETAMETHASONE DIPROPIONATE
AB ACTAVIS MID EQ 0.05% BASE A070281 001 Jul 31, 1985
AB +! FOUGERA PHARMS INC EQ 0.05% BASE A070275 001 Aug 12, 1985
AB G AND W LABS INC EQ 0.05% BASE A071467 001 Aug 10, 1987
AB HI-TECH PHARMACAL EQ 0.05% BASE A209896 001 Feb 06, 2018
AB PERRIGO NEW YORK EQ 0.05% BASE A072538 001 Jan 31, 1990

LOTION, AUGMENTED;TOPICAL
BETAMETHASONE DIPROPIONATE
AB FOUGERA PHARMS EQ 0.05% BASE A077111 001 May 21, 2007
AB TARO EQ 0.05% BASE A077477 001 May 21, 2007
AB TELIGENT PHARMA INC EQ 0.05% BASE A206389 001 Feb 13, 2018

OINTMENT;TOPICAL
BETAMETHASONE DIPROPIONATE
AB ACTAVIS MID EQ 0.05% BASE A071012 001 Feb 03, 1987
AB +! FOUGERA PHARMS INC EQ 0.05% BASE N019141 001 Sep 04, 1984
AB TARO EQ 0.05% BASE A074271 001 Sep 15, 1994

OINTMENT, AUGMENTED;TOPICAL
BETAMETHASONE DIPROPIONATE
AB ACTAVIS MID EQ 0.05% BASE A074304 001 Aug 31, 1995
AB FOUGERA PHARMS EQ 0.05% BASE A075373 001 Jun 22, 1999
AB TARO EQ 0.05% BASE A076753 001 Oct 12, 2004
AB TELIGENT PHARMA INC EQ 0.05% BASE A206118 001 Nov 05, 2017

DIPROLENE
SERNIVO
+! PROMIUS PHARMA LLC EQ 0.05% BASE/SPRAY N208079 001 Feb 05, 2016
BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE
AEROSOL, FOAM;TOPICAL
ENSTILAR
+! LEO PHARMA AS 0.064%;0.005% N207589 001 Oct 16, 2015

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE
OINTMENT;TOPICAL
CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE
PERRIGO ISRAEL 0.064%;0.005% A200174 001 Dec 12, 2014
TOLMAR 0.064%;0.005% A201615 001 Jan 14, 2013

AB +! LEO PHARMA AS 0.064%;0.005% N221858 001 May 09, 2008
AB +! LEO PHARMA AS 0.064%;0.005% N222185 001 May 09, 2008

AB +! MERCK SHARP DOHME 0.05% BASE;1% N018827 001 Dec 08, 2000

BETAMETHASONE VALERATE
AEROSOL, FOAM;TOPICAL
BETAXOLOL HYDROCHLORIDE
SOLUTION/DROPS;OPHTHALMIC
BETAXOLOL HYDROCHLORIDE
SOLUTION/DROPS;OPHTHALMIC
BETOPTIC
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<tr>
<th>Drug Name</th>
<th>Strength</th>
<th>Company</th>
<th>NDC Code</th>
<th>Approval Date</th>
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<td>BETHANECHOL CHLORIDE</td>
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<td>AMNEAL PHARM</td>
<td>A040855 001</td>
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<td>5MG</td>
<td>ECI PHARMS LLC</td>
<td>A040726 001</td>
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<td>5MG</td>
<td>HERITAGE PHARMA</td>
<td>A091256 001</td>
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<td>5MG</td>
<td>LANNETT CO INC</td>
<td>A040677 001</td>
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<td>DUVOID</td>
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<td>BI-COASTAL PHARMA</td>
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<td>50MG</td>
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<td>TARGRETIN</td>
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<td>80MG</td>
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<td>BICALUTAMIDE</td>
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<td>ACCORD HLTHCARE</td>
<td>A079517 001</td>
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<td>50MG</td>
<td>APOTEX INC</td>
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<td>SUN PHARMA GLOBAL</td>
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### Bicalutamide

**Tablet; Oral**

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<td>TEVA</td>
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<td>WATSON LABS TEVA</td>
<td>50MG</td>
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<td>ZYDUS PHARMS USA INC</td>
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### Bicalutamide AB

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<td>ANI PHARMS INC</td>
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### Bimatoprost

**Solution/Drops; Ophthalmic**

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<td>APOTEX INC</td>
<td>0.03%</td>
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<tr>
<td>HI-TECH PHARMA CO</td>
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<td>SANDOZ INC</td>
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<td>A203991 001</td>
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<tr>
<td>LUMIGAN</td>
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### Bimatoprost AT

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<td>HI-TECH PHARMACAL</td>
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<tr>
<td>SANDOZ INC</td>
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### Bimatoprost LATISSE

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### Binimetinib

**Tablet; Oral**

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<td>MYLAN</td>
<td>5MG</td>
<td>A077910 001</td>
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<td>CASI PHARMS INC</td>
<td>5MG</td>
<td>A075643 001</td>
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<td>MYLAN</td>
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<td>TEVA PHARMS</td>
<td>5MG</td>
<td>A075644 001</td>
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### Bismuth Subcitrate Potassium; Metronidazole; Tetracycline

**Capsule; Oral**

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<td>ALLERGAN SALES LLC</td>
<td>140MG;125MG;125MG</td>
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### Bismuth Subsalicylate; Metronidazole; Tetracycline Hydrochloride

**Tablet, Chewable, Tablet, Capsule; Oral**

### Bismuth Subsalicylate, Metronidazole and Tetracycline Hydrochloride

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<tbody>
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<td>AILEX PHARMS LLC</td>
<td>262.4MG, N/A, N/A; N/A, 250MG, N/A; N/A, 500MG</td>
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### Bisoprolol Fumarate

**Tablet; Oral**

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</tr>
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<tbody>
<tr>
<td>AUROBINDO PHARMA</td>
<td>5MG</td>
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<td>CASI PHARMS INC</td>
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<td>MYLAN</td>
<td>5MG</td>
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<td>MYLAN</td>
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<td>A075644 001</td>
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<td>UNICHEM PHARMS (USA)</td>
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### Bisoprolol Fumarate and Hydrochlorothiazide

**Tablet; Oral**

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<th>Formulation</th>
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<td>SANDOZ</td>
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<td>A075768 003</td>
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<td>SANDOZ</td>
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<td>BISOPROL FUMARATE AND HYDROCHLOROTHIAZIDE</td>
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<td>Bivalirudin</td>
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<td><strong>Angiomax</strong></td>
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<td>BIVALIRUDIN</td>
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<td>AP +! SANDOZ INC 250MG/VIAL</td>
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<td>AP ACCORD HLTCARE 250MG/VIAL</td>
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<td>AP FRESENUS KABI USA 250MG/VIAL</td>
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<td>AP HOSPIRA INC 250MG/VIAL</td>
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<td>+! BAXTER HLTCARE 500MG/100ML (5MG/ML)</td>
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<td>Bleomycin Sulfate</td>
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<td>BLEOMYCIN SULFATE EQ 15 UNITS BASE/VIAL</td>
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<td>Bortezomib</td>
<td>Injectable; Intravenous, Subcutaneous</td>
<td>VELCADE</td>
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<td>BORTEZOMIB</td>
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<td>+! MILLENNIUM PHARMS 3.5MG/VIAL</td>
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<td>Bosentan</td>
<td>Tablet; Oral</td>
<td>TRACLEER</td>
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<td></td>
<td></td>
<td>+ ACTELION PHARMS LTD 62.5MG</td>
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<td>Bosutinib Monohydrate</td>
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<td>+! PF PRISM CV EQ 100MG BASE</td>
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<td>+ EQ 400MG BASE</td>
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<td>Bretyllium Tosylate</td>
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<td>Brimonidine Tartrate</td>
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<td>Suspension; Drops; Ophthalmic</td>
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<td>Solution; Drops; Ophthalmic</td>
<td>0.2%; Eq 0.5% Base</td>
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<td>Brinzolamide</td>
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<td>Brivaracetam</td>
<td>Solution; Intravenous</td>
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### BROMFENAC SODIUM

**SOLUTION/DROPS; OPHTHALMIC**

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<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
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<tbody>
<tr>
<td>Hi-Tech Pharmaca</td>
<td>Acido A203395</td>
<td>0.09%</td>
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<td>Sun Pharma Global</td>
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<td>0.075%</td>
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<td>Apr 08, 2016</td>
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<td>Bausch and Lomb</td>
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<td>0.07%</td>
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### BROMOCRIPTINE MESYLATE

**CAPSULE; ORAL**

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<tbody>
<tr>
<td>Parlodex</td>
<td>Mylan Ab</td>
<td>5MG Base</td>
<td>A077226</td>
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<td>A074631</td>
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### BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

**SYRUP; ORAL**

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<tr>
<td>Bromfed-DM</td>
<td>Wockhardt Bio AG</td>
<td>0.08MG/2ML; 0.16MG/2ML</td>
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### BUDERONIDE

**AEROSOL, FOAM; RECTAL**

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<tr>
<td>Entocort RC</td>
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<td>2MG/ACTUATION</td>
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### ENTOCORT EC

**POWER; METERED; INHALATION**

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### BUDERONIDE

**CAPSULE; ORAL**

<table>
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<tbody>
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<td>Barr Labs Div Teva</td>
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<td>A090379</td>
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<td>Mayne Pharma</td>
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<td>Mylan</td>
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<td>Rising Pharma</td>
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<td>Sciecure Pharma Inc</td>
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<td>Zydus Pharmas USA Inc</td>
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### BUDESONIDE

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**BUPRENORPHINE**

**FILM, EXTENDED RELEASE; TRANSDERMAL**

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<th>Approval Date</th>
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BUPRENORPHINE
SOLUTION, EXTENDED RELEASE; SUBCUTANEOUS
SUBLOCAD
+ INDIVIOR INC 100MG/0.5ML (100MG/0.5ML) N209819 001 Nov 30, 2017
+ 300MG/1.5ML (200MG/ML) N209819 002 Nov 30, 2017

BUPRENORPHINE HYDROCHLORIDE
FILM, BUCCAL
BELBUCA
+ BDSI EQ 0.075MG BASE N018401 001 Jun 06, 2014
+ EQ 0.15MG BASE N018401 002 Jun 06, 2014
+ EQ 0.3MG BASE N018401 003 Jun 06, 2014
+ EQ 0.45MG BASE N018401 004 Jun 06, 2014
+ EQ 0.6MG BASE N018401 005 Jun 06, 2014
+ EQ 0.75MG BASE N018401 006 Jun 06, 2014
+ EQ 0.9MG BASE N018401 007 Jun 06, 2014

IMPLANT; IMPLANTATION
PROBUPHINE
+ TITAN PHARMS EQ 0.075MG BASE N090819 001 Feb 19, 2015
+ EQ 0.15MG BASE N090819 002 Feb 19, 2015
+ EQ 0.3MG BASE N090819 003 Feb 19, 2015
+ EQ 0.45MG BASE N090819 004 Feb 19, 2015
+ EQ 0.6MG BASE N090819 005 Feb 19, 2015
+ EQ 0.75MG BASE N090819 006 Feb 19, 2015
+ EQ 0.9MG BASE N090819 007 Feb 19, 2015

INJECTABLE; INJECTION
BUPRENEX
+ INDIVIOR INC EQ 0.3MG BASE/ML N018401 001 Oct 23, 2015
+ EQ 0.3MG BASE/ML N018401 002 Oct 23, 2015
+ EQ 0.3MG BASE/ML N018401 003 Oct 23, 2015
+ EQ 0.3MG BASE/ML N018401 004 Oct 23, 2015
+ EQ 0.3MG BASE/ML N018401 005 Oct 23, 2015
+ EQ 0.3MG BASE/ML N018401 006 Oct 23, 2015
+ EQ 0.3MG BASE/ML N018401 007 Oct 23, 2015

TABLET; SUBLINGUAL
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE
FILM; BUCCAL, SUBLINGUAL
BUNAVAIL
+ BDSI EQ 2.1MG BASE; EQ 0.3MG BASE N205637 001 Nov 07, 2018
+ EQ 4.2MG BASE; EQ 0.7MG BASE N205637 002 Nov 07, 2018
+ EQ 6.3MG BASE; EQ 1MG BASE N205637 003 Nov 07, 2018

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE
FILM; BUCCAL, SUBLINGUAL
SUBOXONE
+ INDIVIOR INC EQ 2MG BASE; EQ 0.5MG BASE N022410 001 Aug 30, 2010
+ EQ 4MG BASE; EQ 1MG BASE N022410 002 Aug 30, 2010
+ EQ 8MG BASE; EQ 2MG BASE N022410 003 Aug 30, 2010
+ EQ 12MG BASE; EQ 3MG BASE N022410 004 Aug 30, 2010

CASSIPA
+ TEVA PHARMS USA EQ 16MG BASE; EQ 4MG BASE N208042 001 Sep 07, 2018
### Buprenorphine Hydrochloride; Naloxone Hydrochloride

**Tablet; Sublingual**

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<th>Date Approved</th>
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<td>Feb 22, 2013</td>
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<td>Amneal</td>
<td>EQ 2mg Base; EQ 2mg Base</td>
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<td>ETHEYPHARM USA CORP</td>
<td>EQ 2mg Base; EQ 0.5mg Base</td>
<td>Oct 16, 2015</td>
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<td>Lannett Co Inc</td>
<td>EQ 2mg Base; EQ 2mg Base</td>
<td>Sep 19, 2016</td>
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<tr>
<td>SpecGX LLC</td>
<td>EQ 2mg Base; EQ 0.5mg Base</td>
<td>Dec 13, 2017</td>
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<td>Sun Pharm Inds Ltd</td>
<td>EQ 2mg Base; EQ 0.5mg Base</td>
<td>Aug 05, 2016</td>
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<td>Teva Pharmaceuticals USA</td>
<td>EQ 2mg Base; EQ 0.5mg Base</td>
<td>Sep 08, 2014</td>
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<td>West Ward Pharmaceuticals</td>
<td>EQ 2mg Base; EQ 0.5mg Base</td>
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<td>Zubsolv</td>
<td>EQ 0.7mg Base; EQ 0.18mg Base</td>
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<td>EQ 1.4mg Base; EQ 0.36mg Base</td>
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<td>EQ 2.9mg Base; EQ 0.71mg Base</td>
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<td>EQ 5.7mg Base; EQ 1.4mg Base</td>
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<td>EQ 8.6mg Base; EQ 2.1mg Base</td>
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<td>EQ 11.4mg Base; EQ 2.9mg Base</td>
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### Bupropion Hydrobromide

**Tablet, Extended Release; Oral**

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### Bupropion Hydrochloride

**Tablet; Oral**

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<td><strong>AB3</strong> Jubilant Generics</td>
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<td>A074590 001</td>
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<td><strong>AB3</strong> Sciegen Phams Inc</td>
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<td><strong>AB3</strong> Sinotherapeutics Inc</td>
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<td><strong>AB3</strong> Twi Pharmas</td>
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<td><strong>AB3</strong> Watson labs inc</td>
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<td><strong>AB3</strong> Yichang HumanaWell</td>
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<td><strong>AB3</strong> Zydus Pharma Usa Inc</td>
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<td><strong>WELLEUTRIN SR</strong></td>
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<td><strong>AB3</strong> Valeant Intl</td>
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<td><strong>AB3</strong> Valeant Intl</td>
<td>300MG</td>
<td>N021515 002</td>
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### Bupropion Hydrochloride
- **Tablet, Extended Release; Oral**
  - **Forfivo XL**
    - **450mg**
    - **Alvogen**
    - **N022497 001**
    - **Nov 10, 2011**

### Bupropion Hydrochloride; Naltrexone Hydrochloride
- **Tablet, Extended Release; Oral**
  - **Contrace**
    - **90mg; 8mg**
    - **N200063 001**
    - **Sep 10, 2014**

### Buspirone Hydrochloride
- **Tablet; Oral**
  - **Accord Healthcare**
    - **5mg**
    - **A202557 001**
    - **Dec 30, 2014**
  - **Amneal Pharma LTD**
    - **5mg**
    - **A208829 001**
    - **May 24, 2017**
  - **Heritage Pharma**
    - **5mg**
    - **A204582 001**
    - **Sep 18, 2015**
  - **Impax Labs Inc**
    - **5mg**
    - **A074253 001**
    - **Mar 28, 2001**
  - **Inventia Healthcare**
    - **5mg**
    - **A074253 002**
    - **Mar 28, 2001**
  - **Mylan**
    - **5mg**
    - **A078246 001**
    - **Feb 27, 2009**
  - **Oxford Pharma**
    - **5mg**
    - **A078246 003**
    - **Feb 27, 2009**
  - **Strides Pharma**
    - **5mg**
    - **A078246 002**
    - **Feb 27, 2009**
  - **Teva**
    - **5mg**
    - **A075467 002**
    - **Mar 28, 2001**
  - **Yiling Pharm LTD**
    - **5mg**
    - **A076008 001**
    - **Jun 28, 2001**
  - **Zydus Pharms USA INC**
    - **5mg**
    - **A078888 001**
    - **Feb 07, 2014**

### Busulfan
- **Injectable; Injection**
  - **Actavis LLC**
    - **6mg/ml**
    - **A205139 001**
    - **Dec 08, 2017**
  - **Amneal Pharma CO**
    - **6mg/ml**
    - **A209580 001**
    - **Dec 18, 2017**
  - **Hospira Inc**
    - **6mg/ml**
    - **A205672 001**
    - **Jul 31, 2018**
  - **Luitpol D**
    - **6mg/ml**
    - **A202259 001**
    - **Dec 22, 2015**
  - **Mylan Labs LTD**
    - **6mg/ml**
    - **A205184 001**
    - **Jul 31, 2018**
| BUSULFAN | INJECTABLE; INJECTION |  |
|—— | —— | —— |
| AP | NEXUS PHARMS | 6MG/ML | A207794 001 Jan 14, 2019 |
| AP | PHARMA SCIENCE INC | 6MG/ML | A207050 001 Mar 24, 2017 |
| AP | SANDOZ INC | 6MG/ML | A205106 001 Sep 21, 2018 |
| AP | OTSUKA PHARM | 6MG/ML | N020954 001 Feb 04, 1999 |
| AP | ASPEN GLOBAL INC | 6MG/ML | A208536 001 Nov 20, 2017 |
| TABLET; ORAL | MYLERAN | 2MG | N009386 001 |
| TABLET; ORAL | BUTISOL SODIUM | 30MG | N000793 004 |
| CREAM; TOPICAL | MENTAX | 1% | N020524 001 Oct 18, 1996 |
| CREAM; VAGINAL | GYNAZOLE-1 | 2% | A200923 001 May 18, 2012 |

| BUSULFAN | INJECTABLE; INJECTION |  |
|—— | —— | —— |
| AP | HIKMA FARMACEUTICA | 1MG/ML | A078400 001 May 01, 2009 |
| AP | WEST-WARD PHARMS | 2MG/ML | A075045 001 Aug 12, 1998 |
| INT | BUTORPHANOL TARTRATE PRESERVATIVE FREE |  |
| AP | HOSPIRA | 1MG/ML | A074626 001 Jan 23, 1997 |
| AP | WEST-WARD PHARMS | 1MG/ML | A075045 002 Aug 12, 1998 |
| INT | BUTORPHANOL TARTRATE |  |
| AP | APOTEX INC | 1MG/SPRAY | A075499 001 Dec 04, 2002 |
| AP | MYLAN | 1MG/SPRAY | A075759 001 Aug 08, 2001 |
| INT | CABAZITAXEL |  |
| SOLUTION; INTRAVENOUS | JUVITANA KIT | 60MG/1.5ML (40MG/ML) | N201023 001 Jun 17, 2010 |

<p>| CABERGOLINE | TABLET; ORAL |  |
|—— | —— | —— |
| AB | ACTAVIS LABS FL INC | 0.5MG | A078035 001 Apr 21, 2008 |
| AB | INGENUS PHARMS LLC | 0.5MG | A204736 001 Aug 01, 2018 |
| AB | IVAX SUB TEVA PHARMS | 0.5MG | A077750 001 Mar 07, 2007 |
| AB | MYLAN PHARMS INC | 0.5MG | A202947 001 Dec 02, 2013 |
| AB | PAR PHARM | 0.5MG | A076310 001 Dec 29, 2005 |
| CAPSOZANTIN | CAPSOZANTIN B-MALATE |  |
| CAPSULE; ORAL | COMETIQ |  |
| + | EXELIXIS | EQ 20MG BASE | N203756 001 Nov 29, 2012 |
| + | EXELIXIS | EQ 80MG BASE | N203756 002 Nov 29, 2012 |
| TABLET; ORAL | CABOMETYX |  |
| + | EXELIXIS INC | EQ 20MG BASE | N208692 001 Apr 25, 2016 |
| + | EXELIXIS | EQ 40MG BASE | N208692 002 Apr 25, 2016 |
| + | EXELIXIS | EQ 60MG BASE | N208692 003 Apr 25, 2016 |</p>
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<td>SOLUTION; INTRAVENOUS</td>
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<tr>
<td><strong>Cafcit</strong></td>
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<td><strong>AP</strong></td>
<td><strong>WEST-WARD PHARMS</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>N020793 001 Sep 21, 1999</td>
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<td><strong>CAFFEINE CITRATE</strong></td>
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<td><strong>AP</strong></td>
<td><strong>AROBINDO PHARMA LTD</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A205013 001 Sep 22, 2015</td>
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<td><strong>AP</strong></td>
<td><strong>EXELA PHARMA SCIENCE</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A077233 001 Sep 21, 2006</td>
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<tr>
<td><strong>AP</strong></td>
<td><strong>PRESENIUS KABI USA SCIENCE</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A077997 001 Jul 20, 2007</td>
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<td><strong>AP</strong></td>
<td><strong>LUITPOLD</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A077906 001 May 15, 2007</td>
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<td><strong>SAGENT PHARMS</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A090827 001 Aug 29, 2012</td>
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<td><strong>AP</strong></td>
<td><strong>SUN PHARMA GLOBAL</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A090077 001 Sep 30, 2009</td>
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<td><strong>CAFFEINE; ERGOTAMINE TARTRATE</strong></td>
<td><strong>SUPPOSITORY; RECTAL</strong></td>
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<tr>
<td><strong>Migergot</strong></td>
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<td><strong>AA</strong></td>
<td><strong>WEST-WARD PHARMS INT</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>N020793 002 Apr 12, 2000</td>
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<td><strong>EXELA PHARMA SCS LLC</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A077304 001 Sep 21, 2006</td>
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<td><strong>AA</strong></td>
<td><strong>PRESENIUS KABI USA SCIENCE</strong></td>
<td>EQ 30MG BASE/3ML (EQ 10MG BASE/ML)</td>
<td>A078002 001 Jan 31, 2008</td>
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<td><strong>ERGOTAMINE TARTRATE AND CAFFEINE</strong></td>
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<td><strong>Suppository, rectal</strong></td>
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<td><strong>Cafergot</strong></td>
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<tr>
<td><strong>AA</strong></td>
<td><strong>SANDOZ</strong></td>
<td>100MG; 2MG</td>
<td>A086557 001 Oct 04, 1983</td>
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<td><strong>CAPSULE, EXTENDED RELEASE; ORAL</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Rayaldee</strong></td>
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<tr>
<td><strong>+! OPKO IRELAND GLOBAL</strong></td>
<td>0.03MG</td>
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<td><strong>N208010 001</strong></td>
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<td><strong>CALCIOTRIENE</strong></td>
<td><strong>AEROSOL, FOAM; TOPICAL</strong></td>
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<td><strong>Sonilux</strong></td>
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<tr>
<td><strong>+! MAYNE PHARMA</strong></td>
<td>0.005%</td>
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<tr>
<td><strong>CALCIOTRIENE</strong></td>
<td><strong>CREAM; TOPICAL</strong></td>
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<tr>
<td><strong>GLENMARK PHARMS</strong></td>
<td>0.005%</td>
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<td><strong>A205772 001</strong></td>
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<td><strong>DOVONEX</strong></td>
<td><strong>OINTMENT; TOPICAL</strong></td>
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<tr>
<td><strong>+! LEO PHARMA AS</strong></td>
<td>0.005%</td>
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<td><strong>SOLUTION; TOPICAL</strong></td>
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<td><strong>GLENMARK PHARMS INC</strong></td>
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<td><strong>CALCIOTIN SALMON</strong></td>
<td><strong>INJECTABLE; INJECTION</strong></td>
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<td><strong>Micacalcin</strong></td>
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<td>200 IU/ML</td>
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<td><strong>SPRAY, METERED; NASAL</strong></td>
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<tr>
<td><strong>Apotex Inc</strong></td>
<td>200 IU/Spray</td>
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<td><strong>A076396 001</strong></td>
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<td><strong>AP</strong></td>
<td><strong>PAR PHARM</strong></td>
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<td>Capsule; Oral</td>
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<td>Amneal Pharmacies</td>
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<td>0.25 MCG</td>
<td>BioPharma Inc</td>
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<td>0.5 MCG</td>
<td>BioPharma Inc</td>
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<td></td>
<td></td>
<td>0.25 MCG</td>
<td>Strides Pharma</td>
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<td>0.25 MCG</td>
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<td>Validus Pharmacies</td>
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<td>West-Ward Pharmacies</td>
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<td>Invatech Pharma</td>
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<td>Capsule; Oral</td>
<td>667 MG</td>
<td>Amneal Pharmacies</td>
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<td>667 MG</td>
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<td>Lotus Pharma Co Ltd</td>
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<td>Lupin Ltd</td>
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<td>Nostrom Labs Inc</td>
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<td>Tablets; Oral</td>
<td>667 MG</td>
<td>Invagen Pharmas</td>
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<tr>
<td></td>
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<td>667 MG</td>
<td>Paddock LLC</td>
</tr>
<tr>
<td></td>
<td>Injectable; Injection</td>
<td></td>
<td>Heritage Pharma Inc</td>
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<tr>
<td></td>
<td>Capsule; Oral</td>
<td>667 MG</td>
<td>Heritage Pharma Inc</td>
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<tr>
<td></td>
<td></td>
<td>667 MG</td>
<td>Paddock LLC</td>
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<td>Luitpold</td>
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<td>Injectable; Injection</td>
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<td>Hospira</td>
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<td>Injectable; Injection</td>
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CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE INJECTABLE; INJECTION

PRISMASOL B22GK 4/0 IN PLASTIC CONTAINER
+! BAXTER HLTHCARE N/A/1000ML; 20GM/1000ML; 5.4GM/1000ML; 2.2GM/1000ML; 3.0GM/1000ML; 4.64GM/1000ML (5000ML)

PRISMASOL BGK 0/2.5 IN PLASTIC CONTAINER
+! BAXTER HLTHCARE N/A/1000ML; 20GM/1000ML; 5.4GM/1000ML; 3.68GM/1000ML; 2.0GM/1000ML; 3GM/1000ML; 0.314GM/1000ML; 3.09GM/1000ML; 6.46GM/1000ML (5000ML)

PRISMASOL BGK 2/0 IN PLASTIC CONTAINER
+! BAXTER HLTHCARE N/A/1000ML; 20GM/1000ML; 5.4GM/1000ML; 3.05GM/1000ML; 0.157GM/1000ML; 3.09GM/1000ML; 6.46GM/1000ML (5000ML)

PRISMASOL BGK 2/3.5 IN PLASTIC CONTAINER
+! BAXTER HLTHCARE N/A/1000ML; 20GM/1000ML; 5.4GM/1000ML; 3.68GM/1000ML; 2.03GM/1000ML; 0.157GM/1000ML; 3.09GM/1000ML; 6.46GM/1000ML (5000ML)

PRISMASOL BGK 4/0/1.2 IN PLASTIC CONTAINER
+! BAXTER HLTHCARE N/A/1000ML; 20GM/1000ML; 5.4GM/1000ML; 3.05GM/1000ML; 0.314GM/1000ML; 3.09GM/1000ML; 6.46GM/1000ML (5000ML)

PRISMASOL BGK 4/2.5 IN PLASTIC CONTAINER
+! BAXTER HLTHCARE N/A/1000ML; 20GM/1000ML; 5.4GM/1000ML; 3.68GM/1000ML; 2.03GM/1000ML; 0.314GM/1000ML; 3.09GM/1000ML; 6.46GM/1000ML (5000ML)

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE SOLUTION; INTRAPERITONEAL

DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 25.7MG/100ML; 1.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML; 5.4GM/100ML; 2.2GM/100ML; 3.0GM/100ML; 6.46GM/100ML (5000ML)

DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 567MG/100ML; 392MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 18.4MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 567MG/100ML; 392MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 25.7MG/100ML; 2.5GM/100ML; 15.2MG/100ML; 67MG/100ML; 392MG/100ML; 5.4GM/100ML; 2.2GM/100ML; 3.0GM/100ML; 6.46GM/100ML (5000ML)

DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 67MG/100ML; 392MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 18.4MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 67MG/100ML; 392MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 25.7MG/100ML; 4.25GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML; 5.4GM/100ML; 2.2GM/100ML; 3.0GM/100ML; 6.46GM/100ML (5000ML)

DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER
AT FRESENIUS MEDCL 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 567MG/100ML; 392MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

 DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT BAXTER HLTHCARE 18.3MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 536MG/100ML; 448MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

 DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT BAXTER HLTHCARE 18.3MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 536MG/100ML; 448MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

 DIANEAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
AT BAXTER HLTHCARE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 536MG/100ML; 448MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)

 DIANEAL PD-2 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
AT BAXTER HLTHCARE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 536MG/100ML; 448MG/100ML; 3.09GM/100ML; 6.46GM/100ML (5000ML)
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE
SOLUTION; INTRAPERITONEAL
Dianeal PD-2 w/ Dextrose 4.25% in Plastic Container
658MG/100ML; 448MG/100ML

Dianeal Low Calcium w/ Dextrose 2.5% in Plastic Container
Baxter Healthcare 18.3MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 5 N020183 002 Dec 04, 1992
38MG/100ML; 448MG/100ML

Dianeal Low Calcium w/ Dextrose 3.5% in Plastic Container
Baxter Healthcare 18.3MG/100ML; 3.5GM/100ML; 5.08MG/100ML; 5 N020183 003 Dec 04, 1992
38MG/100ML; 448MG/100ML

Dianeal Low Calcium w/ Dextrose 4.25% in Plastic Container
Baxter Healthcare 18.3MG/100ML; 4.25GM/100ML; 5.08MG/100ML; N020183 004 Dec 04, 1992
538MG/100ML; 448MG/100ML

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE
INJECTABLE; INTRATHecal
Elliotte's B Solution
+B! Lukare Medical LLC 0.2MG/ML; 0.8MG/ML; 0.3MG/ML; 0.3MG/ML; 1.9 N020577 001 Sep 27, 1996
MG/ML; 7.3MG/ML; 0.2MG/ML

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER
AP + ICu Medical INC
20MG/100ML; 5GM/100ML; 30MG/100ML; 600MG/1 N017608 001
00ML; 310MG/100ML

DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER
AP
20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/1 N019367 006
00ML; 310MG/100ML

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER
AP
20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/1 N019367 007
00ML; 310MG/100ML

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER
AP
20MG/100ML; 5GM/100ML; 328MG/100ML; 600MG/1 N019367 008
00ML; 310MG/100ML

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER
AP
20MG/100ML; 5GM/100ML; 328MG/100ML; 600MG/1 N019367 007
00ML; 310MG/100ML

BSS
AT ! Alcon 0.4MG/ML; 0.3MG/ML; 0.75MG/ML; 3.9MG/ML; 6 A020742 001 Dec 10, 1997
4MG/ML; 1.7MG/ML
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<th>Patent Information</th>
<th>Dosage Form</th>
<th>Strengths</th>
<th>Company</th>
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<td>Jun 15, 2017</td>
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### CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE

**TABLET; ORAL**

**INVOKAMET**

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**TABLET, EXTENDED RELEASE; ORAL**

**INVOKAMET XR**

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### CANDESARTAN CILEXETIL

**TABLET; ORAL**

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**CANDESARTAN CILEXETIL**

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**CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE**

**TABLET; ORAL**

**ATACAND HCT**

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**CANADIAN CRITICAL PATHWAYS**

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**CANGRELOR**

**POWDER; INTRAVENOUS**

**KENGREAL**

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| XELODA | TABLET;ORAL | HOFFMANN LA ROCHE | 150MG | N020896 001 | Apr 30, 1998 |

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| CAPSAICIN | PATCH;TOPICAL | QUTENZA | AVERITAS | 8% | N022395 001 | Nov 16, 2009 |

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### CAPTOPRIL; HYDROCHLOROTHIAZIDE
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<th>NDC Code</th>
<th>Date Approved</th>
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<tbody>
<tr>
<td>25MG;15MG</td>
<td>Captopril and Hydrochlorothiazide</td>
<td>MYLAN</td>
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<td>Dec 29, 1997</td>
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<td>25MG;25MG</td>
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<td>MYLAN</td>
<td>A074896 002</td>
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### CARBACHOL
**Solution; Intracocular**

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### CARBAMAZEPINE
**Capsule, Extended Release; Oral**

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<td>Sep 30, 1997</td>
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### SUSPENSION; Oral

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### TEGRETOL-XR TABLET, Extended Release; Oral

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### CARBAMAZEPINE TABLET, Extended Release; Oral

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## CARBAMAZEPINE

**TABLET, EXTENDED RELEASE; ORAL**

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<td>TEGRETOL-XR</td>
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## CARBIDOPA

**TABLET; ORAL**

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<tr>
<td>ALVOGEN MALTA</td>
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<td>AMERIGEN PHARMS LTD</td>
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<td>A203263 001</td>
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<td>EDENBRIDGE PHARMS</td>
<td>25MG</td>
<td>A205304 001</td>
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<td>NOVEL LABS INC</td>
<td>25MG</td>
<td>A204763 001</td>
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<td>ZYDUS PHARMS USA</td>
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## LODOSYN

**TABLET; ORAL**

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## CARBIDOPA; ENTACAPONE; LEVODOPA

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<td>WOCKHARDT LTD</td>
<td>12.5MG; 200MG; 50MG</td>
<td>A090786 001</td>
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<td>25MG; 200MG; 100MG</td>
<td>A090833 001</td>
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<td>31.25MG; 200MG; 125MG</td>
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## STALEVO

**CAPSULE, EXTENDED RELEASE; ORAL**

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<td>25MG; 200MG; 100MG</td>
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<td>31.25MG; 200MG; 125MG</td>
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## DUOPA

**SUSPENSION; ENTERAL**

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<td>CARBIDOPA; LEVODOPA</td>
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<td>SINEMET CR</td>
<td>MERCK SHARP DOHME</td>
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<td>MIKART</td>
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<td>EUGIA PHARMA</td>
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<td>A077266</td>
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<td>CARBOPLATIN INJECTABLE; IV (INFUSION)</td>
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### CARBOPLATIN
**Injectable; IV (Infusion)**

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### CARBOPLATIN

**Injectable; IV (Infusion)**

### CARBOPLASTR TROMETHAMINE
**Injectable; Injections Hemabate**

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**Tablet; Oral Carbaglu**

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**Capsule; Oral Vraylar**

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<td>AA HIKMA INTL PHARMS</td>
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**TABLET; ORAL**

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## CARMUSTINE
**IMPLANT; INTRACRANIAL**

### GLIADEL

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### CARMUSTINE

**INJECTABLE; INJECTION**

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## CARTEOLOL HYDROCHLORIDE
**SOLUTION/DROPS; OPHTHALMIC**

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## CARVEDILOL
**TABLET; ORAL**

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### CARVEDILOL

**TABLET; ORAL**

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### CARVEDILOL PHOSPHATE

**CAPSULE; EXTENDED RELEASE; ORAL**

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### CASPOFUNGIN ACETATE

**POWDER; INTRAVENOUS**

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SOLUTION; INTRAVENOUS
CEFAZOLIN IN PLASTIC CONTAINER
BAXTER HLTHCARE EQ 2GM BASE/100ML (EQ 20MG BASE/ML) N207131 001 Aug 07, 2015

CEFDINIR
CAPSULE; ORAL
AB AUROBINDO PHARMA 300MG A065434 001 Jan 07, 2008
AB LUPIN 300MG A065264 001 May 19, 2006
AB ORCHID HLTHCARE 300MG A065418 001 Jul 18, 2007
AB SANDOZ 300MG A065330 001 Apr 06, 2007
AB TEVA PHARMS 300MG A065368 001 May 09, 2007
FOR SUSPENSION; ORAL
AB AUROBINDO PHARMA 125MG/5ML A065473 001 Dec 14, 2007
AB 250MG/5ML A065473 002 Dec 14, 2007
AB LUPIN 125MG/5ML A065259 001 May 31, 2006
AB 250MG/5ML A065259 002 May 07, 2007
AB ORCHID HLTHCARE 125MG/5ML A065429 001 Jul 18, 2007
AB 250MG/5ML A065429 002 Jul 18, 2007
AB SANDOZ 125MG/5ML A065337 001 Apr 06, 2007
AB 250MG/5ML A065337 002 Apr 06, 2007
AB TEVA PHARMS 125MG/5ML A065332 001 May 04, 2007
AB 250MG/5ML A065332 002 May 04, 2007

CEFEPIME HYDROCHLORIDE
INJECTABLE; INJECTION
CEFEPIME HYDROCHLORIDE
AP ACS DOBFAR EQ 1GM BASE/VIAL A065441 001 Mar 20, 2008
AP EQ 2GM BASE/VIAL A065442 002 Mar 20, 2008
AP HOSPIRA INC EQ 500MG BASE/VIAL A065369 001 Jun 18, 2007
AP EQ 1GM BASE/VIAL A065369 002 Jul 30, 2012
AP EQ 2GM BASE/VIAL A065369 003 Jun 18, 2007
AP EQ 2GM BASE/VIAL A202268 001 Jul 30, 2012
AP EQ 500MG BASE/VIAL A203704 001 Feb 01, 2016
AP EQ 1GM BASE/VIAL A203704 002 Feb 01, 2016
AP EQ 2GM BASE/VIAL A203704 003 Feb 01, 2016
AP SAGENT PHARMS EQ 1GM BASE/VIAL A091048 001 Jan 04, 2017
AP EQ 2GM BASE/VIAL A091048 002 Jan 04, 2017
MAXIPIME
AP HOSPIRA INC EQ 500MG BASE/VIAL N050679 001 Jan 18, 1996
AP EQ 1GM BASE/VIAL N050679 002 Jan 18, 1996
AP EQ 2GM BASE/VIAL N050679 003 Jan 18, 1996
CEFEPIME AND DEXTROSE IN DUPLEX CONTAINER
B BRAUN EQ 1GM BASE/VIAL N050821 001 May 06, 2010
B BRAUN EQ 2GM BASE/VIAL N050821 002 May 06, 2010
CEFEPIME IN PLASTIC CONTAINER
+! BAXTER HLTHCARE EQ 1GM BASE/50ML (EQ 20MG BASE/ML) N050817 001 Aug 05, 2008
+! EQ 2GM BASE/100ML (EQ 20MG BASE/ML) N050817 002 Aug 05, 2008
POWDER; INTRAVENOUS
CEFEPIME HYDROCHLORIDE IN PLASTIC CONTAINER
SAMSON MEDCL EQ 100GM BASE A209408 001 Aug 21, 2018
CEFIXIME
CAPSULE; ORAL
AB ALKEM LABS LTD 400MG A210574 001 Oct 09, 2018
SUPRAX
AB LUPIN LTD 400MG A203195 001 Jun 01, 2012
FOR SUSPENSION; ORAL
AB AUROBINDO PHARMA LTD 100MG/5ML A204835 001 Apr 14, 2015
AB BELCHER PHARMS LLC 200MG/5ML A206938 002 Feb 06, 2017
AB SANDOZ INC 500MG/5ML A206939 002 Feb 06, 2017
AB TEVA PHARMS 200MG/5ML A206144 002 Nov 17, 2017
SUPRAX
AB LUPIN LTD 500MG/5ML A202091 001 Feb 20, 2013
CEFIXIME
FOR SUSPENSION; ORAL
SUPRAX
AR
LUPIN PHARMS
100MG/5ML   A065129 001 Feb 23, 2004
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200MG/5ML   A065355 001 Apr 10, 2007
TABLET; ORAL
SUPRAX
AR
LUPIN PHARMS
400MG   A065130 001 Feb 12, 2004
TABLET, CHEWABLE; ORAL
SUPRAX
LUPIN LTD
100MG   A065380 001 Oct 25, 2010
150MG   A065380 002 Oct 25, 2010
200MG   A065380 003 Oct 25, 2010

CEFOTAXIME SODIUM
INJECTABLE; INJECTION
CEFOTAXIME
AP
HIKMA
EQ 500MG BASE/VIAL   A065072 001 Nov 20, 2002
AP
EQ 1GM BASE/VIAL   A065072 002 Nov 20, 2002
AP
EQ 2GM BASE/VIAL   A065072 003 Nov 20, 2002
AP
WOCKHARDT
EQ 1GM BASE/VIAL   A065197 001 Aug 29, 2006
CEFOTAXIME SODIUM
AP
HOSPIRA INC
EQ 500MG BASE/VIAL   A065290 001 Aug 11, 2006
AP
EQ 1GM BASE/VIAL   A065290 002 Aug 11, 2006
AP
EQ 1GM BASE/VIAL   A065293 001 Aug 10, 2006
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EQ 1GM BASE/VIAL   A065293 002 Aug 10, 2006
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EQ 1GM BASE/VIAL   A065293 003 Aug 10, 2006
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WOCKHARDT
EQ 500MG BASE/VIAL   A065197 002 Jun 20, 2008
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EQ 2GM BASE/VIAL   A065197 003 Jun 20, 2008
CEFOTETAN DISODIUM
INJECTABLE; INJECTION
CEFOTAN
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+ TELIGENT
EQ 1GM BASE/VIAL   N050588 001 Dec 27, 1985
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+ EQ 2GM BASE/VIAL   N050588 002 Dec 27, 1985
CEFOTETAN
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FRESENIUS KABI USA
EQ 1GM BASE/VIAL   A065374 001 Aug 09, 2007
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EQ 2GM BASE/VIAL   A065374 002 Aug 09, 2007
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HIKMA FARMACEUTICA
EQ 1GM BASE/VIAL   A091031 001 Oct 26, 2011
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EQ 2GM BASE/VIAL   A091031 002 Oct 26, 2011
AP
WEST-WARD PHARM CORP
CEFOTETAN AND DEXTROSE IN DUPLEX CONTAINER
+ B BRAUN
EQ 1GM BASE/VIAL   N065430 001 Aug 09, 2007
+ EQ 2GM BASE/VIAL   N065430 002 Aug 09, 2007
CEFOPITIN SODIUM
INJECTABLE; INJECTION
CEFOPITIN
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ACS DOBFAR
EQ 1GM BASE/VIAL   A065414 001 Jun 12, 2009
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EQ 2GM BASE/VIAL   A065414 002 Jun 12, 2009
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HIKMA FARMACEUTICA
EQ 1GM BASE/VIAL   A065415 001 May 19, 2010
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EQ 2GM BASE/VIAL   A065415 002 May 19, 2010
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EQ 10GM BASE/VIAL   A065238 001 Mar 12, 2010
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EQ 2GM BASE/VIAL   A065238 002 Mar 12, 2010
AP
HOSPIRA INC
EQ 1GM BASE/VIAL   A065313 001 Jan 23, 2006
AP
EQ 2GM BASE/VIAL   A065313 002 Jan 23, 2006
AP
EQ 10GM BASE/VIAL   A065312 001 Feb 13, 2006
AP
WEST-WARD PHARM INT
CEFOTETAN AND DEXTROSE IN DUPLEX CONTAINER
+ B BRAUN
EQ 1GM BASE/VIAL   N065214 001 Mar 10, 2006
+ EQ 2GM BASE/VIAL   N065214 002 Mar 10, 2006
MEFOXIN IN PLASTIC CONTAINER
MYLAN INSTITUTIONAL
EQ 20MG BASE/ML   A063182 001 Jan 25, 1993
EQ 40MG BASE/ML   A063182 002 Jan 25, 1993
### Cefoxitin Sodium

**Powder; Intravenous**

**Cefoxitin in Plastic Container**

**Samson Medcl EQ** 100GM Base A200938 001 Nov 16, 2015

### Cefpodoxime Proxetil

**For Suspension; Oral**

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### Cefprozil

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<td>AUROBINDO PHARMA</td>
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### Ceftaroline Fosamil

**Powder; Intravenous**

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### Ceftazidime

**Injectable; Injection**

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## 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**PRESCRIPTION DRUG PRODUCT LIST**

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### CEFTAZIDIME

**INJECTABLE; INJECTION**

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### CEFTAZIDIME IN DEXTROSE CONTAINER

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### CEFTOLOZANE SULFATE; TAZOBACTAM SODIUM

**POWDER; INTRAVENOUS**

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<tr>
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<th>Brand Name</th>
<th>Strength</th>
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<td>1GM BASE/VIAL</td>
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### CEFTRIAXONE SODIUM

**INJECTABLE; INJECTION**

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### CEFTRIAXONE AND DEXTROSE IN DUPLEX CONTAINER

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### CEFTRIAXONE IN PLASTIC CONTAINER

**INJECTABLE; INTRAMUSCULAR, INTRAVENOUS**

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CAPSULE; ORAL

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AB 200MG A206827 003 Feb 01, 2016
AB 50MG A206827 004 Feb 01, 2016
AB CIPLA 50MG A207446 001 Sep 23, 2015
AB 100MG A207446 002 Sep 23, 2015
AB 200MG A207446 003 Sep 23, 2015
AB 400MG A207446 004 Sep 23, 2015
AB CSPC OUYI PHARM CO 50MG A210071 001 Jan 23, 2018
AB 100MG A210071 002 Jan 23, 2018
AB 200MG A210071 003 Jan 23, 2018
AB JUBILANT GENERICS 50MG A207061 001 Apr 04, 2017
AB 100MG A207061 002 Apr 04, 2017
AB 200MG A207061 003 Apr 04, 2017
AB 400MG A207061 004 Apr 04, 2017
AB LUPIN LTD 50MG A202240 001 Oct 29, 2014
AB 100MG A202240 002 Jun 09, 2015
AB 200MG A202240 003 Jun 09, 2015
AB 400MG A202240 004 Jun 09, 2015
AB MACLEODS PHARMS LTD 50MG A204590 001 Mar 16, 2016
AB 100MG A204590 002 Mar 16, 2016
AB 200MG A204590 003 Mar 16, 2016
AB 400MG A204590 004 Mar 16, 2016
AB MICRO LABS 50MG A204776 001 Apr 30, 2018
AB 100MG A204776 002 Apr 30, 2018
AB 200MG A204776 003 Apr 30, 2018
AB 400MG A204776 004 Apr 30, 2018
AB MYLAN PHARMS INC 50MG A078857 001 May 30, 2014
AB 100MG A078857 002 May 30, 2014
AB 200MG A078857 003 May 30, 2014
AB 400MG A078857 004 May 30, 2014
AB TEVA 50MG A076898 001 May 30, 2014
AB 100MG A076898 002 May 30, 2014
AB 200MG A076898 003 May 30, 2014
AB 400MG A076898 004 May 30, 2014
AB TORRENT PHARMS LTD 50MG A207677 001 Dec 23, 2015
AB 100MG A207677 002 Dec 23, 2015
AB 200MG A207677 003 Dec 23, 2015
AB 400MG A207677 004 Dec 23, 2015
AB WATSON LABS INC 50MG A200562 001 Feb 11, 2015
AB 100MG A200562 002 Feb 11, 2015
AB 200MG A200562 003 Feb 11, 2015
AB 400MG A200562 004 Feb 11, 2015

CEPHALEXIN
CAPSULE; ORAL

CEPHALEXIN
AB ALKEM LABS LTD EQ 250MG BASE A090836 001 Dec 20, 2010
AB EQ 500MG BASE A090836 002 Dec 20, 2010
AB EQ 750MG BASE A090836 003 Mar 29, 2013
AB AUROBINDO PHARMA LTD EQ 250MG BASE A065253 001 Nov 16, 2005
AB EQ 500MG BASE A065253 002 Nov 16, 2005
AB BELCHER PHARMS EQ 250MG BASE A062713 001 Jul 15, 1988
AB EQ 500MG BASE A062713 002 Jul 15, 1988
AB HIKMA EQ 250MG BASE A065215 001 Jan 24, 2006
AB EQ 500MG BASE A065215 002 Jan 24, 2006
AB LUPIN EQ 250MG BASE A065229 001 Nov 25, 2005
AB EQ 500MG BASE A065229 002 Nov 25, 2005
AB ORCHID HLTHCARE EQ 250MG BASE A065248 001 Jun 28, 2005
AB EQ 500MG BASE A065248 002 Jun 28, 2005
AB SUN PHARM IND (IN) EQ 250MG BASE A062791 001 Jun 11, 1987
AB EQ 500MG BASE A062791 002 Jun 11, 1987
AB TEVA EQ 250MG BASE A062702 001 Feb 13, 1987
AB EQ 500MG BASE A062702 002 Feb 13, 1987
AB YUNG SHIN PHARM EQ 250MG BASE A065152 001 Feb 24, 2005
AB EQ 500MG BASE A065152 002 Feb 24, 2005

KEFLEX
AB + PRAGMA EQ 250MG BASE N050405 002 May 12, 2006
AB + EQ 500MG BASE N050405 003
AB +! EQ 750MG BASE N050405 005
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CAPSULE; ORAL

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10MG A083116 001
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25MG A084769 001
LIBRUM
AB
VALENT PHARM INTL
5MG A085461 001
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10MG A085472 001
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25MG A085475 001

CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE
CAPSULE; ORAL
LIBRAX
+! VALENT PHARMS
5MG;2.5MG N012750 001

CHLORHEXIDINE GLUCONATE
SOLUTION; DENTAL

CHLORHEXIDINE GLUCONATE
AT
HI TECH PHARMA
0.12%
A074356 001 May 07, 1996
AT
LYNE
0.12%
A074291 001 Dec 28, 1995
AT
TEVA
0.12%
A074522 001 Dec 15, 1995
AT
WOCKHARDT BIO AG
0.12%
A075006 001 Mar 03, 2004
AT
XTTRIUM
0.12%
A077789 001 Jun 18, 2009
PAROEX
AT
SUNSTAR AMERICAS
0.12%
A076434 001 Nov 29, 2005
PERIDEX
AT
+! 3M
0.12%
N019028 001 Aug 13, 1986
PERIOGARD
AT
COLGATE PALMOLIVE
CO
0.12%
A073695 001 Jan 14, 1994
AT
COLGATE-PALMOLIVE
CO
0.12%
A203212 001 Jan 28, 2016
TABLET; DENTAL
PERIOCHIP
+! DEXCEL PHARMA
2.5MG N020774 001 May 15, 1998

CHLOROPROCAINE HYDROCHLORIDE
INJECTABLE; INJECTION

CHLOROPROCAINE HYDROCHLORIDE
AP
HOSPIRA
2%
A087447 001 Apr 16, 1982
AP
3%
A087446 001 Apr 16, 1982
AP
WEST-WARD PHARMS
INT
A040273 001 Sep 09, 1998
AP
3%
A040273 002 Sep 09, 1998
NESACAINE
AP
+ FRESENIUS KABI USA
2%
N009435 002
NESACAINE-MPF
AP
+! FRESENIUS KABI USA
2%
N009436 006 May 02, 1996
AP
+! FRESENIUS KABI USA
3%
N009438 007 May 02, 1996
NESACAINE
+! FRESENIUS KABI USA
1%
N009435 001
SOLUTION; INTRATHECAL
CLOROTEKAL
+ B BRAUN MEDICAL INC
50MG/5ML (10MG/ML) N208791 001 Sep 26, 2017

CHLORQUINE PHOSPHATE
TABLET; ORAL

CHLORQUINE PHOSPHATE
AA
HIKMA PHARMS
EQ 150MG BASE A083082 001
AA
EQ 300MG BASE A083082 002 Sep 17, 1999
AA
IPCA LABS LTD
EQ 150MG BASE A090610 001
AA
EQ 300MG BASE A090610 002 Dec 03, 2009
AA
NATCO PHARMA LTD
EQ 150MG BASE A090612 001 Jan 21, 2011
AA
EQ 200MG BASE A090612 002 Jan 21, 2011

CHLOROTHIAZIDE
SUSPENSION; ORAL
DIURIL
+! SALIX PHARMS
250MG/5ML N011870 001

TABLET; ORAL
CHLOROTHIAZIDE
+ MYLAN
250MG A084217 002
500MG A084217 001
### CHLOROTHIAZIDE SODIUM

**Injectable; Injection**

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td>FRESENIUS KABI USA</td>
<td>EQ 500MG BASE/VIAL</td>
<td>A90896 001</td>
<td>Oct 16, 2009</td>
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<tr>
<td>LUITPOLD</td>
<td>EQ 500MG BASE/VIAL</td>
<td>A202561 001</td>
<td>Apr 22, 2013</td>
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<tr>
<td>MYLAN INSTITUTIONAL</td>
<td>EQ 500MG BASE/VIAL</td>
<td>A202493 001</td>
<td>Jun 18, 2014</td>
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<tr>
<td>SAGENT PHARMS GLOBAL</td>
<td>EQ 500MG BASE/VIAL</td>
<td>A202462 001</td>
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<tr>
<td>Sun Pharma Global</td>
<td>EQ 500MG BASE/VIAL</td>
<td>A091546 001</td>
<td>Jul 26, 2011</td>
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<tr>
<td>OAK PHARMS AKORN</td>
<td>EQ 500MG BASE/VIAL</td>
<td>N011145 005</td>
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### CHLORPHENIRAMINE MALEATE; CODEINE PHOSPHATE

**Tablet, Extended Release; Oral**

<table>
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<th>Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date</th>
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<tbody>
<tr>
<td>MAINPOINTE ER</td>
<td>8MG;54.3MG</td>
<td>N206323 001</td>
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### CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE

**Solution; Oral**

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<th>Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCELLA PHARMS LLC</td>
<td>4MG/5ML;5MG/5ML</td>
<td>A206891 001</td>
<td>Jun 09, 2017</td>
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<tr>
<td>VITUS</td>
<td>4MG/5ML;5MG/5ML</td>
<td>N204307 001</td>
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### CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE AND PSEUDOEPHEDRINE HYDROCHLORIDE

**Solution; Oral**

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<th>Name</th>
<th>Strength</th>
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<th>Date</th>
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<tbody>
<tr>
<td>ACCELLA PHARMS LLC</td>
<td>4MG/5ML;5MG/5ML;60MG/5ML</td>
<td>A205657 001</td>
<td>Aug 03, 2015</td>
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<tr>
<td>Paddock LLC</td>
<td>4MG/5ML;5MG/5ML;60MG/5ML</td>
<td>A204627 001</td>
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<tr>
<td>VITUS</td>
<td>4MG/5ML;5MG/5ML;60MG/5ML</td>
<td>N022439 001</td>
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### CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

**Suspension, Extended Release; Oral**

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<th>Date</th>
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<tbody>
<tr>
<td>AYRU</td>
<td>EQ 2.8MG BASE/5ML;EQ 14.7MG BASE/5ML</td>
<td>N207768 001</td>
<td>Apr 30, 2015</td>
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### CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

**Capsule, Extended Release; Oral**

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<th>Name</th>
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<th>Date</th>
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<tbody>
<tr>
<td>ECR PHARMA</td>
<td>EQ 4MG MALEATE;EQ 5MG BITARTRATE</td>
<td>A077273 002</td>
<td>Sep 24, 2007</td>
</tr>
<tr>
<td></td>
<td>EQ 8MG MALEATE;EQ 10MG BITARTRATE</td>
<td>A077273 001</td>
<td>Sep 24, 2007</td>
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### HYDROCODONE BITARTRATE AND CHLORPHENIRAMINE POLISTIREX

**Suspension, Extended Release; Oral**

<table>
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<th>Name</th>
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<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIS PHARMA INC</td>
<td>EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML</td>
<td>A091632 001</td>
<td>Oct 01, 2010</td>
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<tr>
<td>NEOS THERAP INC</td>
<td>EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML</td>
<td>A091671 001</td>
<td>Jun 29, 2012</td>
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### CHLORPROMAMIDE HYDROCHLORIDE

**Injectable; Injection**

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<tbody>
<tr>
<td>WEST-WARD PHARMS INT</td>
<td>25MG/ML</td>
<td>A083329 001</td>
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### CHLORPROPAMIDE

**Tablet; Oral**

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<tr>
<td>MYLAN</td>
<td>100MG</td>
<td>A088549 002</td>
<td>Jun 01, 1984</td>
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<tr>
<td></td>
<td>250MG</td>
<td>A088549 001</td>
<td>Jun 01, 1984</td>
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<tr>
<td>CHLORTHALIDONE</td>
<td>TABLET; ORAL</td>
<td>CHLORTHALIDONE</td>
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<tr>
<td>----------------</td>
<td>-------------</td>
<td>----------------</td>
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</tr>
<tr>
<td>AB</td>
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<tr>
<td>APPCO PHARMA LLC</td>
<td>25MG</td>
<td>A210742 001 Oct 12, 2018</td>
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<tr>
<td>MYLAN</td>
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<td>RICONPHARMA LLC</td>
<td>25MG</td>
<td>A206904 003 Mar 30, 2017</td>
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<td>SUN PHARM INDUSTRIES</td>
<td>25MG</td>
<td>A089286 002 Jul 21, 1986</td>
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<tr>
<td>UMEDICA LABS PVT LTD</td>
<td>50MG</td>
<td>A207222 001 May 24, 2018</td>
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<table>
<thead>
<tr>
<th>CHLORZOXAZONE</th>
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<tbody>
<tr>
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<tr>
<td>MIDDLETON</td>
<td>250MG</td>
<td>A207483 001 Jun 24, 2016</td>
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<tr>
<td>750MG</td>
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<td>A040861 002 Jun 01, 2010</td>
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<td>WATSON LABS</td>
<td>500MG</td>
<td>A089859 001 May 04, 1988</td>
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<thead>
<tr>
<th>CHOLESTYRAMINE</th>
<th>POWDER; ORAL</th>
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<tbody>
<tr>
<td>AB</td>
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<tr>
<td>ANI PHARMS INC</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074554 001 Oct 02, 1996</td>
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<tr>
<td>PAR PHARM</td>
<td>EQ 4GM RESIN/SCOOPFUL</td>
<td>A074554 002 Oct 02, 1996</td>
</tr>
<tr>
<td>AB</td>
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<tr>
<td>SANDOZ</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A077203 001 Aug 26, 2005</td>
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<tr>
<td>ZYDUS PHARMS USA INC</td>
<td>EQ 4GM RESIN/SCOOPFUL</td>
<td>A02902 001 Jul 25, 2018</td>
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<thead>
<tr>
<th>CHOLESTYRAMINE LIGHT</th>
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<th>CHOLESTYRAMINE LIGHT</th>
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<tbody>
<tr>
<td>AB</td>
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<tr>
<td>PAR PHARM</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A077203 001 Aug 26, 2005</td>
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<td>SANDOZ</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074554 002 Aug 15, 1996</td>
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<td>ZYDUS PHARMS USA INC</td>
<td>EQ 4GM RESIN/SCOOPFUL</td>
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<th>PREVALITE</th>
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<tr>
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<tr>
<td>UPSHER SMITH LABS</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A073263 001 Feb 22, 1996</td>
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<table>
<thead>
<tr>
<th>CHOLIC ACID</th>
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<th>CHOLIC ACID</th>
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<tbody>
<tr>
<td>AB</td>
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<tr>
<td>CHOLAM</td>
<td>+ RTRX</td>
<td>50MG</td>
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<tr>
<td>AB</td>
<td>+!</td>
<td>250MG</td>
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<thead>
<tr>
<th>CHOLINE C-11</th>
<th>INJECTABLE; INTRAVENOUS</th>
<th>CHOLINE C-11</th>
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<tr>
<td>AB</td>
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<tr>
<td>GLOBAL ISOTOPES LLC</td>
<td>4-33.1mCi/ML</td>
<td>A206319 001 Nov 13, 2015</td>
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<tr>
<td>MCPPR</td>
<td>4-33.1mCi/ML</td>
<td>A203155 002 Sep 12, 2012</td>
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<td>UCSF RODIOPHARM</td>
<td>4-33.1mCi/ML</td>
<td>A208444 001 Nov 20, 2017</td>
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<td>WA UNIV SCH MED</td>
<td>4-33.1mCi/ML</td>
<td>A208413 001 Jan 10, 2017</td>
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<td>UNIV TX MD ANDERSON</td>
<td>4-100mCi/ML</td>
<td>A205690 001 Oct 29, 2015</td>
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<table>
<thead>
<tr>
<th>CHOLINE FENOFRIBRATE</th>
<th>CAPSULE, DELAYED RELEASE; ORAL</th>
<th>FENOFRIBRACID</th>
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<tbody>
<tr>
<td>AB</td>
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<tr>
<td>ACTAVIS ELIZABETH</td>
<td>EQ 45MG FENOFRIBRIC ACID</td>
<td>A200920 001 Oct 07, 2015</td>
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<td>ALEMBIC PHARMS LTD</td>
<td>EQ 135MG FENOFRIBRIC ACID</td>
<td>A200920 002 Oct 07, 2015</td>
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<tr>
<td>ANCHEN PHARMS</td>
<td>EQ 135MG FENOFRIBRIC ACID</td>
<td>A204705 005 May 12, 2017</td>
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<td>IMPAX LABS INC</td>
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<td>A200264 001 Sep 07, 2016</td>
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<td>LUPIN LTD</td>
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<tr>
<td>MYLAN PHARMS INC</td>
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<td>A200913 001 Mar 25, 2013</td>
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<td>AB</td>
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<tr>
<td>ROYAL PHARMS INC</td>
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### CHOLINE FENOFIBRATE
CAPSULE, DELAYED RELEASE; ORAL

**TRILIPIX**

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<tbody>
<tr>
<td><strong>AB</strong> +</td>
<td>ABBVIE EQ 45MG FENOFIBRIC ACID</td>
<td>N022224 001</td>
<td>Dec 15, 2008</td>
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<tr>
<td><strong>AB</strong> +!</td>
<td>ABBVIE EQ 135MG FENOFIBRIC ACID</td>
<td>N022224 002</td>
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### CHORIOGONADOTROPIN ALFA
INJECTABLE; SUBCUTANEOUS

**OVIDREL**

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<th>Date</th>
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<tbody>
<tr>
<td>+! EMD SERONO</td>
<td>EQ 0.25MG /0.5ML</td>
<td>N021149 002</td>
<td>Oct 06, 2003</td>
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### CHROMIC CHLORIDE
INJECTABLE; INJECTION

**CHROMIC CHLORIDE IN PLASTIC CONTAINER**

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<th>Date</th>
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<tbody>
<tr>
<td>+! HOSPIRA</td>
<td>EQ 0.004MG CHROMIUM/ML</td>
<td>N018961 001</td>
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### CICLESONIDE
AEROSOL, METERED; INHALATION

**ALVESCO**

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<th>Date</th>
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<tbody>
<tr>
<td>+! ASTRazeneca PHARMS</td>
<td>0.08MG/INH</td>
<td>N021658 002</td>
<td>Jan 10, 2008</td>
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<tr>
<td>+!</td>
<td>0.16MG/INH</td>
<td>N021658 003</td>
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**ZETONNA**

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<th>Date</th>
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<tbody>
<tr>
<td>+! ASTRazeneca PHARMS</td>
<td>0.037MG/INH</td>
<td>N022129 001</td>
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**OMNARIS**

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<th>Date</th>
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<tbody>
<tr>
<td>+! ASTRazeneca PHARMS</td>
<td>0.05MG/INH</td>
<td>N022004 001</td>
<td>Oct 20, 2006</td>
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### CICLOPIROX
CREAM; TOPICAL

**CICLOPIROX**

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</thead>
<tbody>
<tr>
<td>AB +!</td>
<td>MEDIMETRIKS PHARMS 0.77%</td>
<td>N018748 001</td>
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**GEL; TOPICAL**

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<tr>
<td>AB +!</td>
<td>MEDIMETRIKS PHARMS 0.77%</td>
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**SOLUTION; TOPICAL**

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<th>NDC</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>AB +!</td>
<td>MEDISIC 1%</td>
<td>N021159 001</td>
<td>Feb 28, 2003</td>
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### LOPROX

<table>
<thead>
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<th>NDC</th>
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<tbody>
<tr>
<td>AB +!</td>
<td>MEDIMETRIKS PHARMS 0.77%</td>
<td>N018748 001</td>
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### PENLAC
SUSPENSION; TOPICAL

<table>
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<tbody>
<tr>
<td>AB +!</td>
<td>VALEANT BERMUDA 8%</td>
<td>N021022 001</td>
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### CICLOPIROX

<table>
<thead>
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</tr>
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<tbody>
<tr>
<td><strong>AB</strong> +</td>
<td>FOUGERA PHARMS 0.77%</td>
<td>A076435 001</td>
<td>Dec 29, 2004</td>
</tr>
<tr>
<td><strong>AB</strong></td>
<td>G AND W LABS INC 0.77%</td>
<td>A076463 001</td>
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<tr>
<td><strong>AB</strong></td>
<td>GLENMARK PHARMS 0.77%</td>
<td>A090273 001</td>
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<tr>
<td><strong>AB</strong></td>
<td>PERRIGO NEW YORK 0.77%</td>
<td>A077364 001</td>
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</tr>
<tr>
<td><strong>AB</strong></td>
<td>TARO 0.77%</td>
<td>A076790 001</td>
<td>Apr 12, 2005</td>
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<table>
<thead>
<tr>
<th>Brand</th>
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<tr>
<td><strong>AB</strong></td>
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</tr>
<tr>
<td><strong>AB</strong></td>
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<td>A091595 001</td>
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<tr>
<td><strong>AB</strong></td>
<td>PADDICK LLC 0.77%</td>
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<tr>
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<td>CNTY LINE PHARMS 0.77%</td>
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<tr>
<td><strong>AT</strong></td>
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<tr>
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<tbody>
<tr>
<td><strong>AT</strong></td>
<td>ACTAVIS MID 1%</td>
<td>A090490 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>PERRIGO PHARMS 1%</td>
<td>A090146 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>TARI 1%</td>
<td>A078524 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>TARI 1%</td>
<td>A090279 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>TELIGENT PHARMA INC 1%</td>
<td>A209975 001</td>
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<table>
<thead>
<tr>
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<tbody>
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<td><strong>AT</strong></td>
<td>ACTAVIS MID 1%</td>
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<tr>
<td><strong>AT</strong></td>
<td>AKORN 1%</td>
<td>A078975 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>APOTEX INC 1%</td>
<td>A078172 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>G AND W LABS 1%</td>
<td>A078233 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>HI TECH PHARMA 1%</td>
<td>A078270 001</td>
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<td><strong>AT</strong></td>
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<td><strong>AT</strong></td>
<td>TARI PHARM INDS 1%</td>
<td>A078144 001</td>
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<tr>
<td><strong>AT</strong></td>
<td>TOLMAR 1%</td>
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<table>
<thead>
<tr>
<th>Brand</th>
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<th>Date</th>
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</thead>
<tbody>
<tr>
<td><strong>AT</strong> +!</td>
<td>VILEAN BERMUDA 8%</td>
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### CICLOPIROX

<table>
<thead>
<tr>
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<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AB</strong> +</td>
<td>FOUGERA PHARMS 0.77%</td>
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<tr>
<td><strong>AB</strong></td>
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<tr>
<td><strong>AB</strong></td>
<td>TARO 0.77%</td>
<td>A077098 001</td>
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<td>Formulation</td>
<td>Manufacturer</td>
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<tr>
<td>CICLOPIROX LOPROX</td>
<td>SUSPENSION;TOPICAL</td>
<td>MEDIMETRIKS PHARMS</td>
<td>0.77%</td>
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<tr>
<td>CIDOFOVIR</td>
<td>INJECTABLE;INJECTION</td>
<td>EMCURE PHARMS LTD</td>
<td>EQ 75MG BASE/ML</td>
</tr>
<tr>
<td>CIDOFOVIR</td>
<td>INJECTABLE;INJECTION</td>
<td>MYLAN INSTITUTIONAL</td>
<td>EQ 75MG BASE/ML</td>
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<tr>
<td>CILASTATIN SODIUM; IMIPENEM</td>
<td>POWDER;INTRAVENOUS</td>
<td>ACS DOBFAR</td>
<td>EQ 500MG BASE/VIAL;500MG/VIAL</td>
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<tr>
<td>IMIPENEM AND CILASTATIN</td>
<td></td>
<td>HQC INC</td>
<td>EQ 500MG BASE/VIAL;500MG/VIAL</td>
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<tr>
<td>CILOSTAZOL</td>
<td>TABLET;ORAL</td>
<td>APOTEX INC</td>
<td>50MG</td>
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<tr>
<td>CILOSTAZOL</td>
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<td>MYLAN</td>
<td>100MG</td>
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<tr>
<td>CIMETIDINE</td>
<td>TABLET;ORAL</td>
<td>APOTEX</td>
<td>200MG</td>
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<tr>
<td>CIMETIDINE</td>
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<td>MYLAN</td>
<td>300MG</td>
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<tr>
<td>CIMETIDINE</td>
<td></td>
<td>400MG</td>
<td>Dec 18, 1998</td>
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<tr>
<td>CIMETIDINE</td>
<td></td>
<td>800MG</td>
<td>Dec 18, 1998</td>
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<tr>
<td>CIMETIDINE HYDROCHLORIDE</td>
<td>INJECTABLE;INJECTION</td>
<td>DAVA PHARMS INC</td>
<td>EQ 300MG BASE/2ML</td>
</tr>
<tr>
<td>CIMETIDINE HYDROCHLORIDE</td>
<td>SOLUTION;ORAL</td>
<td>ANI PHARMAS INC</td>
<td>EQ 300MG BASE/5ML</td>
</tr>
<tr>
<td>CIMETIDINE HYDROCHLORIDE</td>
<td></td>
<td>HI TECH PHARMA</td>
<td>EQ 300MG BASE/5ML</td>
</tr>
<tr>
<td>CIMETIDINE HYDROCHLORIDE</td>
<td></td>
<td>PHARM ASSOC</td>
<td>EQ 300MG BASE/5ML</td>
</tr>
<tr>
<td>CIMETIDINE HYDROCHLORIDE</td>
<td></td>
<td>WOCKHARDT BIO AG</td>
<td>EQ 300MG BASE/5ML</td>
</tr>
<tr>
<td>CINACALCET HYDROCHLORIDE</td>
<td>TABLET;ORAL</td>
<td>AUROBINDO PHARMA LTD</td>
<td>EQ 30MG BASE</td>
</tr>
<tr>
<td>CINACALCET HYDROCHLORIDE</td>
<td></td>
<td>EQ 60MG BASE</td>
<td>Mar 08, 2018</td>
</tr>
<tr>
<td>CINACALCET HYDROCHLORIDE</td>
<td></td>
<td>EQ 90MG BASE</td>
<td>Mar 08, 2018</td>
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### CINACALCET HYDROCHLORIDE

**TABLET; ORAL**

<table>
<thead>
<tr>
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<th>Strength(s)</th>
<th>NDC</th>
<th>Date</th>
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<tbody>
<tr>
<td>Cipla</td>
<td>EQ 30MG BASE</td>
<td>A208915 001</td>
<td>Mar 08, 2018</td>
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<tr>
<td>Mylan Pharms Inc</td>
<td>EQ 30MG BASE</td>
<td>A203422 002</td>
<td>Oct 16, 2018</td>
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<tr>
<td>Piramal Hlthcare UK</td>
<td>EQ 30MG BASE</td>
<td>A210207 001</td>
<td>Aug 01, 2018</td>
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<tr>
<td>Strides Pharma</td>
<td>EQ 30MG BASE</td>
<td>A209226 001</td>
<td>Apr 30, 2018</td>
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<tr>
<td>Sun Pharma Global</td>
<td>EQ 30MG BASE</td>
<td>A207008 001</td>
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<tr>
<td>Watson Labs Teva</td>
<td>EQ 30MG BASE</td>
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#### Sensipar

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<tr>
<td>Amgen</td>
<td>EQ 30MG BASE</td>
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### Ciprofloxacin

**FOR SUSPENSION; ORAL**

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<th>Company</th>
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<th>Date</th>
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<tbody>
<tr>
<td>Bayer Hlthcare</td>
<td>250MG/5ML</td>
<td>N020780 001</td>
<td>Sep 26, 1997</td>
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<tr>
<td>Hikma Farmaceutica</td>
<td>400MG/40ML (10MG/ML)</td>
<td>A078062 001</td>
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<tr>
<td>Hospira</td>
<td>200MG/20ML (10MG/ML)</td>
<td>A076717 001</td>
<td>Dec 22, 2006</td>
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<tr>
<td>InforLife</td>
<td>200MG/100ML</td>
<td>A077753 001</td>
<td>Mar 18, 2008</td>
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**INJECTABLE, INJECTION**

<table>
<thead>
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<th>NDC</th>
<th>Date</th>
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<tbody>
<tr>
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<td>200MG/20ML (10MG/ML)</td>
<td>A078024 001</td>
<td>Mar 18, 2008</td>
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<tr>
<td>Hikma Farmaceutica</td>
<td>400MG/200ML</td>
<td>A078024 002</td>
<td>Mar 18, 2008</td>
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<tr>
<td>Hospira</td>
<td>200MG/100ML</td>
<td>A077753 001</td>
<td>Mar 18, 2008</td>
</tr>
<tr>
<td>Inforlife</td>
<td>200MG/200ML</td>
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**Ciprofloxacin in Dextrose 5% in Plastic Container**

<table>
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<th>NDC</th>
<th>Date</th>
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### Ciprofloxacin Hydrochloride

**OINTMENT; OPHTHALMIC**

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength(s)</th>
<th>NDC</th>
<th>Date</th>
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<tr>
<td>Novartis Pharms Corp</td>
<td>EQ 0.3% BASE</td>
<td>N019992 001</td>
<td>Dec 31, 1990</td>
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**SOLUTION; DROPS; OPHTHALMIC**

<table>
<thead>
<tr>
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<th>Strength(s)</th>
<th>NDC</th>
<th>Date</th>
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<tr>
<td>Novartis Pharms Corp</td>
<td>EQ 0.3% BASE</td>
<td>N020369 001</td>
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**OTIPRIO**

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<tr>
<td>Otonomy Inc</td>
<td>6% (60MG/ML)</td>
<td>N207986 001</td>
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### Ciprofloxacin Hydrochloride

**FOR INTRAVENOUS AND INTRAMUSCULAR INJECTION**

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<th>NDC</th>
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<tbody>
<tr>
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<td>EQ 0.3% BASE</td>
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**FOR SUSPENSION**

<table>
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<tr>
<td>Alza</td>
<td>EQ 0.3% BASE</td>
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**FOR SUSPENSION; ORAL**

<table>
<thead>
<tr>
<th>Company</th>
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<th>Date</th>
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<tbody>
<tr>
<td>Alza</td>
<td>EQ 0.3% BASE</td>
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**FOR SUSPENSION; ORAL**

<table>
<thead>
<tr>
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<th>Strength(s)</th>
<th>NDC</th>
<th>Date</th>
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<tr>
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### CIPROFLOXACIN HYDROCHLORIDE

**SOLUTION/DROPS;OTIC**

<table>
<thead>
<tr>
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<th>Strength</th>
<th>Company Name</th>
<th>NDC Number</th>
<th>Date Approved</th>
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<tbody>
<tr>
<td>CETRAXAL +!</td>
<td>0.2%</td>
<td>WRASER PHARMS</td>
<td>0021918</td>
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<tr>
<td>CETRAXAL +!</td>
<td>0.5%</td>
<td>BAYER HLTHCARE</td>
<td>019537</td>
<td>Oct 22, 1987</td>
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### CIPROFLOXACIN HYDROCHLORIDE

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>Company Name</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIPRO</td>
<td>250MG</td>
<td>AB + BAYER HLTHCARE</td>
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<tr>
<td>CIPRO</td>
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<td>AB + BAYER HLTHCARE</td>
<td>019537</td>
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<td>A076896</td>
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<tr>
<td>CIPRO</td>
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<td>A077859</td>
<td>Apr 26, 2007</td>
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<td>CIPRO</td>
<td>750MG</td>
<td>AB CARLSBAD</td>
<td>A076126</td>
<td>Jun 09, 2004</td>
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<tr>
<td>CIPRO</td>
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<td>AB DR REDDYS LABS LTD</td>
<td>A075593</td>
<td>Jun 09, 2004</td>
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<tr>
<td>CIPRO</td>
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<td>AB HIKMA</td>
<td>A076558</td>
<td>Jun 09, 2004</td>
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<tr>
<td>CIPRO</td>
<td>750MG</td>
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<td>Jun 09, 2004</td>
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<tr>
<td>CIPRO</td>
<td>500MG</td>
<td>AB MYLAN</td>
<td>A076089</td>
<td>Jun 09, 2004</td>
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<tr>
<td>CIPRO</td>
<td>250MG</td>
<td>AB TARO PHARM</td>
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<tr>
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<td>AB UNIQUE PHARM LABS</td>
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<td>Sep 10, 2004</td>
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<tr>
<td>CIPRO</td>
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<td>AB WATSON LABS</td>
<td>A076639</td>
<td>Sep 10, 2004</td>
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<td>AB YILING PHARM LTD</td>
<td>A208921</td>
<td>Jun 22, 2018</td>
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</table>

#### CIPROFLOXACIN HYDROCHLORIDE; FLUCONOLONE ACETONIDE

**SOLUTION/DROPS;OTIC**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>Company Name</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTOVEL</td>
<td>0.3%;0.025%</td>
<td>LABORATORIOS SALVAT</td>
<td>N208251</td>
<td>Apr 29, 2016</td>
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#### CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE

**SUSPENSION/DROPS;OTIC**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>Company Name</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIPRO HC</td>
<td>0.2%;1%</td>
<td>NOVARTIS PHARMS</td>
<td>N208205</td>
<td>Feb 10, 1998</td>
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### CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

**TABLET, EXTENDED RELEASE;ORAL**

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<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
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<th>NDC Number</th>
<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>ANCHEN PHARMS</td>
<td>212.6MG;EQ 287.5MG</td>
<td>A078166</td>
<td>Nov 27, 2007</td>
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<tr>
<td>DR REDDYS LABS LTD</td>
<td>425.2MG;EQ 574.9MG</td>
<td>A078166</td>
<td>Nov 27, 2007</td>
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<tr>
<td>MYLAN PHARMS INC</td>
<td>212.6MG;EQ 287.5MG</td>
<td>A077701</td>
<td>Mar 26, 2007</td>
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<tr>
<td></td>
<td>425.2MG;EQ 574.9MG</td>
<td>A078183</td>
<td>Mar 22, 2007</td>
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### CIPROFLOXACIN; DEXAMETHASONE

**SUSPENSION/DROPS;OTIC**

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<tbody>
<tr>
<td>CIPRODEX</td>
<td>0.3%;0.1%</td>
<td>NOVARTIS PHARMS</td>
<td>N201537</td>
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## CISATRACURIUM BESYLATE

**INJECTABLE; INJECTION**

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<tr>
<th>Company</th>
<th>Strength</th>
<th>Approval Date/Exp Date</th>
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</thead>
<tbody>
<tr>
<td>ACCORD HLCARE</td>
<td>EQ 2MG BASE/ML</td>
<td>0205873D 001</td>
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<tr>
<td>FRESENIUS KABI USA</td>
<td>EQ 2MG BASE/ML</td>
<td>0203183D 001</td>
</tr>
<tr>
<td>JIANGSU HENGRIU MED</td>
<td>EQ 2MG BASE/ML</td>
<td>0209334D 001</td>
</tr>
<tr>
<td>SANDOZ INC</td>
<td>EQ 2MG BASE/ML</td>
<td>0200159D 001</td>
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<tr>
<td>ACCORD HLCARE</td>
<td>EQ 10MG BASE/ML</td>
<td>0205872D 001</td>
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<tr>
<td>FRESENIUS KABI USA</td>
<td>EQ 10MG BASE/ML</td>
<td>0203182D 001</td>
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<tr>
<td>JIANGSU HENGRIU MED</td>
<td>EQ 10MG BASE/ML</td>
<td>0204960D 001</td>
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<td>SANDOZ INC</td>
<td>EQ 10MG BASE/ML</td>
<td>0200154D 001</td>
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<tr>
<td>ABBVIE</td>
<td>EQ 2MG BASE/ML</td>
<td>N020551I 001</td>
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<tr>
<td>NIMBEX PRESERVATIVE FREE</td>
<td>EQ 2MG BASE/ML</td>
<td>N020551I 003</td>
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<tr>
<td>ABBVIE</td>
<td>EQ 10MG BASE/ML</td>
<td>N020551I 002</td>
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## CISPLATIN

**INJECTABLE; INJECTION**

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>Approval Date/Exp Date</th>
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</thead>
<tbody>
<tr>
<td>ACCORD HLCARE</td>
<td>1MG/ML</td>
<td>A206774D 001</td>
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<tr>
<td>FRESENIUS KABI USA</td>
<td>1MG/ML</td>
<td>A074735D 001</td>
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<tr>
<td>GLAND PHARMA LTD</td>
<td>1MG/ML</td>
<td>A207323D 001</td>
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<tr>
<td>HP SPC LTD</td>
<td>1MG/ML</td>
<td>N018057I 004</td>
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<tr>
<td>NYLAN LABS LTD</td>
<td>1MG/ML</td>
<td>A081062D 001</td>
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<tr>
<td>PHARMACHEMIE BV</td>
<td>1MG/ML</td>
<td>A074656D 001</td>
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<tr>
<td>WEST-NARD PHARMS INT</td>
<td>1MG/ML</td>
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## CITALOPRAM HYDROBROMIDE

**SOLUTION; ORAL**

<table>
<thead>
<tr>
<th>Company</th>
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<tbody>
<tr>
<td>AUROBINDO PHARMA LTD</td>
<td>EQ 10MG BASE/5ML</td>
<td>A077812D 001</td>
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<tr>
<td>WETERO LABS LTD III</td>
<td>EQ 10MG BASE/5ML</td>
<td>A201450D 001</td>
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<tr>
<td>LANNETT CO INC</td>
<td>EQ 10MG BASE/5ML</td>
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<tr>
<td>WEST-NARD PHARMS INT</td>
<td>EQ 10MG BASE/5ML</td>
<td>A077043D 001</td>
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## CELEXA

**TABLET; ORAL**

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<th>Company</th>
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<tbody>
<tr>
<td>ALLERGAN SALES LLC</td>
<td>EQ 10MG BASE</td>
<td>N020822G 002</td>
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<tr>
<td>+</td>
<td>EQ 20MG BASE</td>
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<tr>
<td>+</td>
<td>EQ 40MG BASE</td>
<td>N020822G 003</td>
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## CITALOPRAM HYDROBROMIDE

**TABLET; ORAL**

<table>
<thead>
<tr>
<th>Company</th>
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<tbody>
<tr>
<td>AMNEAL PHARMS NY</td>
<td>EQ 10MG BASE</td>
<td>A077289D 001</td>
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<tr>
<td>APOTEX INC</td>
<td>EQ 10MG BASE</td>
<td>A077046D 001</td>
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<tr>
<td>AUROBINDO</td>
<td>EQ 10MG BASE</td>
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<tr>
<td>CHARTWELL MOLECULAR</td>
<td>EQ 10MG BASE</td>
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<tr>
<td>DR REDDYS LABS LTD</td>
<td>EQ 10MG BASE</td>
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<tr>
<td>EPIC PHARMA</td>
<td>EQ 10MG BASE</td>
<td>A077045D 002</td>
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<tr>
<td>G AND W LABS INC</td>
<td>EQ 10MG BASE</td>
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<tr>
<td>GLENMARK GENERICS</td>
<td>EQ 10MG BASE</td>
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<tr>
<td>INVAGEN PHARMS</td>
<td>EQ 10MG BASE</td>
<td>A077534D 002</td>
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<td>Brand Name</td>
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<td>JUBILANT GENERICS</td>
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<tr>
<td><strong>CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE</strong></td>
<td><strong>SOLUTION; IRRIGATION</strong> +! UNITED GUARDIAN</td>
<td>6.602GM/100ML; 198MG/100ML; 3.177GM/100ML</td>
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<td><strong>CITRIC ACID; MAGNESIUM OXIDE; SODIUM PICOSULFATE</strong></td>
<td><strong>FOR SOLUTION; ORAL</strong> +! FERRING PHARMS INC</td>
<td>12GM/PACKET; 3.5GM/PACKET; 10MG/PACKET</td>
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<td><strong>CLADRIBINE</strong></td>
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<tr>
<td>FRESENIUS KABI USA</td>
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<td><strong>CLAIRETHROMYCIN</strong></td>
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<tr>
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<td>APOTEX CORP</td>
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<tr>
<td>Clarithromycin</td>
<td>tablet, extended release; oral</td>
<td>Lupin Ltd</td>
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<td>Mayne Pharma</td>
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<td>Sunshine Lake</td>
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<td>Clemastine Fumarate</td>
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<td>Teva</td>
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<td>tablet; oral</td>
<td>Teva</td>
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<tr>
<td>Clevidipine</td>
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<td>Chiesi USA Inc</td>
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<td>Clindamycin Hydrochloride</td>
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<td>Pharmacia and Upjohn</td>
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<td>Pharmacia and Upjohn</td>
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<td>Perrigo UK Finco</td>
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</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE CREAM; VAGINAL</td>
<td>FOUGERA PHARMS</td>
<td>EQ 2% BASE</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE GEL; TOPICAL</td>
<td>PHARMACIA AND UPJOHN</td>
<td>EQ 1% BASE</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE INJECTABLE; INJECTION</td>
<td>PHARMACIA AND UPJOHN</td>
<td>EQ 150MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER</td>
<td>PHARMACIA AND UPJOHN</td>
<td>EQ 150MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% TOPICAL LOTION</td>
<td>PHARMACIA AND UPJOHN</td>
<td>EQ 900MG BASE/100ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>BAXTER HLTHCARE CORP</td>
<td>EQ 300MG BASE/50ML</td>
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<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>BAXTER HLTHCARE CORP</td>
<td>EQ 600MG BASE/50ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>BAXTER HLTHCARE CORP</td>
<td>EQ 900MG BASE/50ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>G AND W LABS INC</td>
<td>EQ 6MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>GLASSHOUSE PHARMS</td>
<td>EQ 6MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>G AND W LABS INC</td>
<td>EQ 12MG BASE/ML</td>
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<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>PERRIGO NEW YORK</td>
<td>EQ 18MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>ALVOGEN INC</td>
<td>EQ 150MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>AKORN INC</td>
<td>EQ 6MG BASE/ML</td>
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<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>AKORN INC</td>
<td>EQ 12MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>AKORN INC</td>
<td>EQ 18MG BASE/ML</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>SANDOZ INC</td>
<td>EQ 6MG BASE/ML</td>
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<tr>
<td>CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% INTRAVENOUS</td>
<td>SANDOZ INC</td>
<td>EQ 12MG BASE/ML</td>
</tr>
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CLOBETASOL PROPIONATE
- **OINTMENT; TOPICAL**
  - **EMBELINE**
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CLOBETASOL PROPIONATE
- **SHAMPOO; TOPICAL**
  - **AB** ACTAVIS MID 0.05% A078854 001 Jun 07, 2011
  - **AB** HI-TECH PHARMA 0.05% A209871 001 Oct 27, 2017
  - **AB** PERRIGO ISRAEL 0.05% A090974 001 Aug 09, 2012

CLOBEX
- **SOLUTION; TOPICAL**
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CLOBETASOL PROPIONATE
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  - **G AND W LABS INC** 0.05% A074331 001 Dec 15, 1995
  - **GLENMARK PHARMS LTD** 0.05% A209361 001 Oct 27, 2017
  - **MACLEODS PHARMS LTD** 0.05% A210190 001 Apr 18, 2018
  - **NOVEL LABS INC** 0.05% A206075 001 Nov 16, 1998
  - **TARO** 0.05% A075363 001 Dec 29, 2000
  - **WOCKHARDT BIO AG** 0.05% A075205 001 Nov 13, 1998
  - **EMBELINE** 0.05% A074222 001 Dec 06, 1995

CLODOROL
- **CREAM; TOPICAL**
  - **CLODOR**
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CLOFARABINE
- **SOLUTION; INTRAVENOUS**

CLOFARABINE
- **AP**
  - **ABON PHARMS LLC** 20MG/20ML (1MG/ML) A204029 001 May 09, 2017
  - **AMNEAL PHARMS CO** 20MG/20ML (1MG/ML) A208857 001 Nov 06, 2017
  - **DR REDDYS LABS LTD** 20MG/20ML (1MG/ML) A205375 001 Nov 06, 2017
  - **GLAND PHARMA LTD** 20MG/20ML (1MG/ML) A207831 001 Oct 31, 2018
  - **HOSPIRA INC** 20MG/20ML (1MG/ML) A210283 001 Dec 27, 2017
  - **INGENUS PHARMS LLC** 20MG/20ML (1MG/ML) A210270 001 Sep 14, 2018
  - **MSN LABS PVT LTD** 20MG/20ML (1MG/ML) A209775 001 Dec 06, 2017
  - **MYLAN LABS LTD** 20MG/20ML (1MG/ML) A208860 001 Nov 06, 2017

CLOLAR
- **AP** +! GENZYM 20MG/20ML (1MG/ML) N021673 001 Dec 28, 2004

CLOMIPHENE CITRATE
- **TABLET; ORAL**

CLOMIPHENE CITRATE
- **AP**
  - **PAR PHARM** 50MG A075528 001 Aug 30, 1999

CLOMIPRAMINE HYDROCHLORIDE
- **CAPSULE; ORAL**

ANAPRANIL
- **AP** +! SPECGX LLC 25MG N019906 001 Dec 29, 1989
- **AP** 50MG N019906 002 Dec 29, 1989
- **AP** 75MG N019906 003 Dec 29, 1989

CLOMIPRAMINE HYDROCHLORIDE
- **AP**
  - **AMNEAL PHARMS CO** 25MG A208632 001 Oct 31, 2018
  - **LUNOVOT LTD** 25MG A074947 001 Apr 30, 1998
  - **ZYSYS PHARMA LTD** 25MG A074947 001 Apr 30, 1998
### CLOMIPRAMINE HYDROCHLORIDE

**Capsule; Oral**

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### CLONAZEPAM

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### KLONOPIN

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### KLONOPIN

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39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST
PRESCRIPTION DRUG PRODUCT LIST
3-107 (of 452)

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HYDROCHLORIDE

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<td>AB1</td>
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KAPVAY

| AB1 | CONCORDIA PHARMS INC | 0.1MG | N022331 | 003 | Sep 28, 2010 |

CLONIDINE HYDROCHLORIDE

| AB2 | ACTAVIS ELIZABETH | 0.1MG | A202792 | 001 | May 15, 2015 |

CLOPIDOGREL BISULFATE

TABLET; ORAL

CLOPIDOGREL BISULFATE

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PLAVIX

| AB  | SANOFI AVENTUS US | EQ 75MG BASE | N020839 | 001 | Nov 17, 1997 |
| AB  | RECORDI RARE      | EQ 300MG BASE | N020839 | 002 | Sep 20, 2007 |

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

| AB  | MYLAN           | 3.75MG | A071858 | 002 | Jul 17, 1987 |
| AB  | MYLAN           | 7.5MG  | A071858 | 003 | Jul 17, 1987 |
| AB  | TARO PHARM      | 3.75MG | A075343 | 003 | Apr 27, 2000 |
| AB  | 7.5MG           | A075343 | 002 | Apr 27, 2000 |
| AB  | 15MG            | A075343 | 001 | Apr 27, 2000 |

GEN-XENE

| AB  | ALKA            | 3.75MG | A071787 | 001 | Apr 26, 1988 |
| AB  | 7.5MG           | A071788 | 001 | Apr 26, 1988 |
| AB  | 15MG            | A071788 | 002 | Apr 26, 1988 |

TRANXENE

<p>| AB  | RECORATI RARE   | 7.5MG  | N017105 | 007 |             |</p>
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<td>EQ 3MG BASE/ML;10MG/ML;EQ 3.3MG BASE/ML;0.5MG/ML</td>
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*Note: Codes and dates indicate the approval and most recent update dates for each product.*
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<td>20MG/100ML (0.2MG/ML)</td>
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<td>BAYER HEALTHCARE</td>
<td>60MG/VIAL</td>
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<td>PARAGARO T 380A</td>
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<td>CRISABOROLE OINTMENT; TOPICAL</td>
<td>EUCRISA</td>
<td>ANACOR PHARMS INC</td>
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### Crotamiton

**Cream; Topical**

- Sun Pharm Inds Inc, 10%
  - N006927 001

**Lotion; Topical**

- Marlpharm, 10%
  - A087204 001

### Crotan

**Cream; Topical**

- Sun Pharm Inds Inc, 10%
  - N009112 003

### Cupric Chloride

**Injectable; Injection**

- Cupric Chloride in Plastic Container, 10%
  - Hospira Eq 0.4mg Copper/ml
    - N018960 001, Jun 26, 1986

### Cyanocobalamin

**Injectable; Injection**

- Cyanocobalamin, 1mg/ml
  - Luitpold, 1mg/ml
    - A080737 001
  - Mylan Theraps (Int), 1mg/ml
    - A204829 001, Jun 05, 2017
  - Mylan Labs Ltd, 1mg/ml
    - A206503 001, Dec 11, 2015
  - Enzo Pharma, 1mg/ml
    - A209429 002, Dec 18, 2018
  - Mylan Theraps (Int), 1mg/ml
    - A209558 001, Dec 18, 2018
  - Mylan Theraps (Int), 1mg/ml
    - A2080518 002

**Spray, Metered; Nasal**

- Nasconal, 0.5mg/spray
  - Endo Pharma Inc
    - N021642 001, Jan 31, 2005

### Cyclobenzaprine Hydrochloride

**Capsule, Extended Release; Oral**

- Amrix, 7.5mg
  - Teva Pharma Int'l, 15mg
    - N021777 002, Feb 01, 2007
  - Apotex Inc, 30mg
    - N021777 002, Feb 01, 2007

**Tablet; Oral**

- Cyclobenzaprine Hydrochloride
  - Actavis Labs Fl Inc, 5mg
    - A071611 001, Feb 03, 2006
  - Aurobindo Pharma, 7.5mg
    - A071611 002, Feb 03, 2006
  - Aurobindo Pharma, 10mg
    - A071611 003, May 03, 1989
  - Frontida Biopharm, 5mg
    - A078643 001, Sep 26, 2008
  - Invagen Pharma, 5mg
    - A078643 002, Sep 26, 2008
  - Invagen Pharma, 10mg
    - A073541 002, Apr 06, 2006
  - Jubilant Cadista, 5mg
    - A073541 001, May 23, 1995
  - Jubilant Cadista, 7.5mg
    - A077563 001, Aug 25, 2017
  - Jubilant Cadista, 10mg
    - A077563 002, Apr 19, 2006
  - Kvk Tech, 5mg
    - A078048 001, Feb 28, 2011
  - Kvk Tech, 10mg
    - A078048 002, Feb 28, 2011
  - Mylan Pharma Inc, 5mg
    - A073144 001, Feb 03, 2006
  - Mylan Pharma Inc, 7.5mg
    - A073144 002, May 25, 2013
  - Mylan Pharma Inc, 10mg
  - Orit Labs Llc, 5mg
    - A078213 001, Jun 19, 2015
  - Orit Labs Llc, 10mg
    - A078213 002, Apr 18, 2008
  - Oxford Pharma, 5mg
    - A077209 001, Feb 03, 2006
  - Oxford Pharma, 10mg
    - A077209 002, Feb 03, 2006
  - Pliva, 5mg
    - A077209 001, Oct 04, 2005
  - Prinston Inc, 5mg
    - A077209 001, Sep 29, 1995
  - Prinston Inc, 10mg
    - A077209 001, Sep 29, 1995
  - Rubicon Res Pvt Ltd, 5mg
    - A077209 001, Feb 28, 2007
  - Rubicon Res Pvt Ltd, 10mg
    - A077209 001, Feb 28, 2007
  - Sun Pharm Inds Ltd, 5mg
    - A078722 001, May 12, 2008
  - Sun Pharm Inds Ltd, 7.5mg
    - A078722 002, May 12, 2008
  - Sun Pharm Inds Ltd, 10mg
    - A078722 003, May 12, 2008
CYCLOPENTOLATE HYDROCHLORIDE
SOLUTION/DROPS;OPHTHALMIC

AKPENTOLATE

AT
AKORN 1% A040164 001 Jan 13, 1997

AT ! ALCON LABS INC 0.5% A084109 001

AT + 1% A084110 001

CYCLOPENTOLATE HYDROCHLORIDE

AT
AKORN INC 0.5% A205937 001 Dec 09, 2015

PENTOLAIR

AT BAUSCH AND LOMB 1% A040075 001 Apr 29, 1994

CYCLOMYDRIL

AT ALCON LABS INC 0.2%;1% A084300 001

CYCLOSPORINE
CAPSULE;ORAL

AB1 IVAX SUB TEVA PHARMS 25MG A065110 003 Mar 29, 2005

AB1 100MG A065110 002 Mar 29, 2005

AB1 MAYNE PHARMA 25MG A065044 002 Dec 20, 2000

AB1 100MG A065044 001 Dec 20, 2000

AB1 SANDOZ 25MG A065017 002 Jan 13, 2000

AB1 100MG A065017 001 Jan 13, 2000

GENGRAF

AB1 ABBVIE 25MG A065003 001 May 12, 2000

AB1 100MG A065003 003 May 12, 2000

NEORAL

AB1 + NOVARTIS 25MG N050718 001 Jul 14, 1995

AB1 +! 100MG N050718 002 Jul 14, 1995

CYCLOSPORINE

AB2 APOTEX 25MG A065040 001 May 09, 2002

AB2 100MG A065040 002 May 09, 2002

SANDIMMUNE

AB2 + NOVARTIS 25MG N050625 001 Mar 02, 1990

AB2 +! 100MG N050625 002 Mar 02, 1990

BX + 50MG N050625 003 Nov 23, 1992

CYCLOSPORINE

IVAX SUB TEVA PHARMS 50MG A065110 001 Mar 29, 2005
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### Cytarabine

**Injectable; Injection**

#### Cytarabine

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#### Cytarabine; Daunorubicin

**Powder; Intravenous**

**Vyxeos**

- 100mg/44mg | N209401 001 | Aug 03, 2017 |

#### Dabigatran Etxilate Mesylate

**Capsule; Oral**

- Pradaxa
  - Boehringer
    - Ingelheim
      - EQ 75mg base | N022512 001 | Oct 19, 2010 |
  - EQ 110mg base | N022512 003 | Nov 20, 2015 |
  - EQ 150mg base | N022512 002 | Oct 19, 2010 |

- Ingelheim
  - EQ 75mg base | N022806 001 | May 29, 2013 |
  - EQ 75mg base | N022806 002 | May 29, 2013 |

#### Dabrafenib Mesylate

**Capsule; Oral**

- Tafinlar
  - Novartis Pharms Corp
    - EQ 50mg base | N202806 001 | May 29, 2013 |
  - EQ 75mg base | N202806 002 | May 29, 2013 |

#### Dacarbazine

**Injectable; Injection**

#### Dacarbazin

**Tablet; Oral**

- Daklinza
  - Bristol-Myers Squibb
    - EQ 30mg base | N206843 001 | Jul 24, 2015 |
  - EQ 60mg base | N206843 002 | Jul 24, 2015 |
  - EQ 90mg base | N206843 003 | Apr 13, 2016 |

#### Dacomitinib

**Tablet; Oral**

- Vizimpro
  - Pfizer Inc
    - EQ 15mg | N211288 001 | Sep 27, 2018 |
  - EQ 30mg | N211288 002 | Sep 27, 2018 |
  - EQ 45mg | N211288 003 | Sep 27, 2018 |

#### Dactinomycin

**Injectable; Injection**

- Cosmegen
  - Recordati Rare
    - EQ 0.5mg/vial | N050682 001 |

#### Dalbavancin Hydrochloride

**Powder; Intravenous**

- Allergan Sales LLC
  - EQ 500mg base/vial | N021883 001 | May 23, 2014 |
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<td>+ 5 mg; 1 gm</td>
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<td>+ 10 mg; 500 mg</td>
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<td>+! 10 mg; 1 gm</td>
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<td>Oct 20, 2017</td>
</tr>
<tr>
<td>Darifenacin</td>
<td>Darifenacin Hydrobromide</td>
<td>EQ 7.5 mg base</td>
<td>A207302 001</td>
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<tr>
<td>+! Macleods Pharms Ltd</td>
<td>EQ 15 mg base</td>
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<tr>
<td>+! Alembic Pharms Ltd</td>
<td>EQ 7.5 mg base</td>
<td>A207681 001</td>
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<tr>
<td>+! Anchen Pharms</td>
<td>EQ 15 mg base</td>
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<tr>
<td>+! Auropindo Pharma LTD</td>
<td>EQ 7.5 mg base</td>
<td>A206743 001</td>
<td>Sep 19, 2016</td>
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<tr>
<td>+! Cipla</td>
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<td>A207664 001</td>
<td>Sep 01, 2016</td>
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<tr>
<td>+! Jubilant Generics</td>
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<td></td>
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<tr>
<td>+! Torrent Pharms Ltd</td>
<td>EQ 7.5 mg base</td>
<td>A205550 001</td>
<td>Oct 12, 2016</td>
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<tr>
<td>+! Torrent Pharms Ltd</td>
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<td>A205550 002</td>
<td>Oct 12, 2016</td>
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<td>+! Torrent Pharms Ltd</td>
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<td>A205209 001</td>
<td>Nov 17, 2016</td>
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<tr>
<td>+! Torrent Pharms Ltd</td>
<td>EQ 15 mg base</td>
<td>A205209 002</td>
<td>Nov 17, 2016</td>
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</tbody>
</table>
DARIFENACIN HYDROBROMIDE
TABLET, EXTENDED RELEASE; ORAL
ENABLEX
AB + APIL
EQ 7.5MG BASE N021513 001 Dec 22, 2004
AB +! APIL
EQ 15MG BASE N021513 002 Dec 22, 2004

DARUNAVIR ETHANOLATE
SUSPENSION; ORAL
PREZISTA
AB +! JANSSEN PRODS
EQ 100MG BASE/ML N202895 001 Dec 16, 2011
TABLET; ORAL
AB ! TEVA PHARMS USA
EQ 600MG BASE A202118 001 Nov 21, 2017
PREZISTA
AB + JANSSEN PRODS
EQ 150MG BASE N021976 003 Dec 18, 2008
AB +! JANSSEN PRODS
EQ 800MG BASE N021976 004 Nov 09, 2012

DASABUVIR SODIUM; OMBITASVIR; PARITAPREVIR; RITONAVIR
TABLET, TABLET; ORAL
VIEKIRA PAK (COPACKAGED)
AB +! ABBVIE INC
N/A, 12.5MG, 75MG, 50MG; N206619 001 Dec 19, 2014
TABLET, EXTENDED RELEASE; ORAL
VIEKIRA XR
AB +! ABBVIE INC
EQ 250MG BASE, N/A, N/A, N/A; N/A, 12.5MG, 75MG, 50MG N208624 001 Jul 22, 2016

DASATINIB
TABLET; ORAL
SPRYCEL
AB + BRISTOL MYERS SQUIBB
20MG N021986 001 Jun 28, 2006
AB 50MG N021986 002 Jun 28, 2006
AB 70MG N021986 003 Jun 28, 2006
AB 80MG N021986 005 Oct 28, 2010
AB +! 100MG N021986 004 May 30, 2008
AB + 140MG N021986 006 Oct 28, 2010

DAUNORUBICIN HYDROCHLORIDE
INJECTABLE; INJECTION
CERUBIDINE
AB +! WEST-WARD PHARMS INT
EQ 20MG BASE/VIAL A064103 001 Feb 03, 1995
DAUNORUBICIN HYDROCHLORIDE
AB FRESENIUS KABI USA
EQ 20MG BASE/VIAL A065000 001 May 25, 1999
AB TEVA PHARMS USA
EQ 5MG BASE/ML A065036 001 Jan 24, 2000
AB +! WEST-WARD PHARMS INT
EQ 5MG BASE/ML N050731 001 Jan 30, 1998
AB FRESENIUS KABI USA
EQ 5MG BASE/VIAL A065034 001 Nov 20, 2001

DECITABINE
INJECTABLE; INTRAVENOUS
DACOCEN
AB +! OTSUKA PHARM CO LTD
50MG/VIAL N021790 001 May 02, 2006
DECITABINE
AB ACCORD HLTHCARE
50MG/VIAL A203475 001 Feb 27, 2017
AB CHEMI SPA
50MG/VIAL A206033 001 Sep 22, 2017
AB CIPLA
50MG/VIAL A208601 001 Nov 16, 2017
AB DR REDDY'S LABS LTD
50MG/VIAL A203131 001 Jul 11, 2013
AB LUPIN LTD
50MG/VIAL A201075 001 Nov 09, 2018
AB PHARMASCIENCE INC
50MG/VIAL A204607 001 May 31, 2017
AB SAGENT PHARMS
50MG/VIAL A207100 001 Mar 16, 2018
AB SANDOZ INC
50MG/VIAL A202969 001 Aug 28, 2014
POWDER; INTRAVENOUS
DECITABINE
AB +! SUN PHARMA GLOBAL
50MG/VIAL N205582 001 Jan 28, 2014

DEFERRASIOX
GRANULE; ORAL
JADENU SPRINKLE
AB + NOVARTIS PHARMS CORP
90MG N207968 001 May 18, 2017
AB 180MG N207968 002 May 18, 2017
AB +! 360MG N207968 003 May 18, 2017
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Strength(s)</th>
<th>Manufacturer(s)</th>
<th>FDA Approval Date</th>
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</thead>
<tbody>
<tr>
<td>Deferasirox</td>
<td>Tablet; Oral</td>
<td>90mg, 180mg, 360mg</td>
<td>Jadenu Novartis Pharm Corp</td>
<td>Mar 30, 2015</td>
</tr>
<tr>
<td>Deferasirox</td>
<td>Tablet, For Suspension; Oral</td>
<td>125mg, 250mg, 500mg</td>
<td>Actavis Elizabeth, Novartis</td>
<td>Jan 26, 2016, Nov 02, 2005</td>
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<tr>
<td>Deferasirox</td>
<td>Tablet, For Suspension; Oral</td>
<td>80mg/mL, 100mg/mL</td>
<td>Aropharma Inc</td>
<td>Apr 20, 2018, Sep 09, 2015</td>
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<tr>
<td>Deferasirox</td>
<td>2gm/vial</td>
<td></td>
<td>Direct Supply</td>
<td>May 30, 2007</td>
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<tr>
<td>Deferasirox</td>
<td>500mg/vial</td>
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<td>Direct Supply</td>
<td>May 25, 2000</td>
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<td>Deferasirox</td>
<td>2gm/vial</td>
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<td>Direct Supply</td>
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<tr>
<td>Deferasirox</td>
<td>500mg/vial</td>
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<td>Direct Supply</td>
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<tr>
<td>Deferasirox</td>
<td>22.75mg/mL</td>
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<td>Direct Supply</td>
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<td>Deferasirox</td>
<td>30mg</td>
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<td>Deferasirox</td>
<td>80mg base/vial</td>
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<td>Direct Supply</td>
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<td>Deferasirox</td>
<td>120mg base/vial</td>
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<tr>
<td>Deferasirox</td>
<td>450mg base</td>
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<td>Direct Supply</td>
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<td>DRUG NAME</td>
<td>FORMULATION</td>
<td>DOSAGE</td>
<td>SIZE</td>
<td>NDC</td>
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<td>-------------------------------</td>
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<tr>
<td>DELAVIRDINE MESYLATE</td>
<td>TABLET; ORAL</td>
<td>100MG</td>
<td>VIIV HLTHCARE</td>
<td>N020705 001 Apr 04, 1997</td>
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<tr>
<td>DEMECLOCYCLINE HYDROCHLORIDE</td>
<td>TABLET; ORAL</td>
<td>150MG</td>
<td>AKORN</td>
<td>A065389 001 Dec 01, 2008</td>
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<tr>
<td></td>
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<td>150MG</td>
<td>AMNEAL PHARM</td>
<td>A065426 001 Feb 27, 2008</td>
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<td></td>
<td></td>
<td>150MG</td>
<td>BARR</td>
<td>A065171 001 Dec 13, 2004</td>
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<tr>
<td></td>
<td></td>
<td>150MG</td>
<td>EPIC PHARMA LLC</td>
<td>A065447 001 Aug 18, 2015</td>
</tr>
<tr>
<td>DEOXYCHOLIC ACID</td>
<td>SOLUTION; SUBCUTANEOUS</td>
<td>20MG/2ML (10MG/ML)</td>
<td>KYTHERA BIOPHARMS</td>
<td>N206333 001 Apr 29, 2015</td>
</tr>
<tr>
<td>DESFLURANE</td>
<td>LIQUID; INHALATION</td>
<td>100%</td>
<td>SHANGHAI HENGRUI</td>
<td>A208234 001 Feb 26, 2018</td>
</tr>
<tr>
<td>DESIPRAMINE HYDROCHLORIDE</td>
<td>TABLET; ORAL</td>
<td>10MG</td>
<td>ACTAVIS TOTOWA</td>
<td>A074430 001 Feb 09, 1996</td>
</tr>
<tr>
<td></td>
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<td>50MG</td>
<td>ANI PHARMS INC</td>
<td>A071586 001 Oct 05, 1987</td>
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<td>100MG</td>
<td>ANI PHARMS INC</td>
<td>A071766 001 Oct 05, 1987</td>
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<td></td>
<td>25MG</td>
<td>HERITAGE PHARMS INC</td>
<td>A074430 001 Feb 09, 1996</td>
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<td>150MG</td>
<td>HERITAGE PHARMS INC</td>
<td>A071601 001 Jun 05, 1987</td>
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<td></td>
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<td>150MG</td>
<td>INGENUS PHARMS LLC</td>
<td>A071766 001 Oct 05, 1987</td>
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<td></td>
<td>25MG</td>
<td>SANOZ</td>
<td>A072099 001 May 24, 1988</td>
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<td>50MG</td>
<td>SANOZ</td>
<td>A072101 001 May 24, 1988</td>
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<td>100MG</td>
<td>SANOZ</td>
<td>A072103 001 Jun 20, 1988</td>
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<tr>
<td>NORPRAMIN</td>
<td>+</td>
<td>10MG</td>
<td>US PHARM HOLDINGS</td>
<td>N014399 007 Feb 11, 1982</td>
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<td></td>
<td>+</td>
<td>50MG</td>
<td>US PHARM HOLDINGS</td>
<td>N014399 003</td>
</tr>
<tr>
<td></td>
<td>+</td>
<td>75MG</td>
<td>US PHARM HOLDINGS</td>
<td>N014399 004</td>
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### Desipramine Hydrochloride

**Tablet, Oral**

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<thead>
<tr>
<th>Brand Name</th>
<th>Dosage</th>
<th>NDC Code</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORPRAMIN</td>
<td>100mg</td>
<td>0014399</td>
<td>Sep 01, 2004</td>
</tr>
<tr>
<td>NORPRAMIN</td>
<td>150mg</td>
<td>0014399</td>
<td>Jun 30, 2015</td>
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### Desloratadine

**Solution, Oral**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Approval Date</th>
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</thead>
<tbody>
<tr>
<td>MERCK SHARP DOHME</td>
<td>0.5mg/ml</td>
<td>021300</td>
<td>May 26, 2016</td>
</tr>
<tr>
<td>Taro Pharm</td>
<td>0.5mg/ml</td>
<td>0202936</td>
<td>Apr 19, 2012</td>
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**Tablet, Oral**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Dosage</th>
<th>NDC Code</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>MERCK SHARP DOHME</td>
<td>5mg</td>
<td>021312</td>
<td>Jul 14, 2005</td>
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<tr>
<td>REDDYS</td>
<td>2.5mg</td>
<td>021333</td>
<td>Dec 16, 2010</td>
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</table>

**Tablet, Orally Disintegrating, Oral**

<table>
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<th>Brand Name</th>
<th>Dosage</th>
<th>NDC Code</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>MERCK SHARP DOHME</td>
<td>2.5mg</td>
<td>021166</td>
<td>Dec 21, 2001</td>
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**Desloratadine; Pseudoephedrine Sulfate**

**Tablet, Extended Release, Oral**

<table>
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<th>Dosage</th>
<th>NDC Code</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>MERCK SHARP DOHME</td>
<td>5mg; 240mg</td>
<td>021605</td>
<td>Mar 03, 2005</td>
</tr>
<tr>
<td>REDDYS</td>
<td>2.5mg; 120mg</td>
<td>021313</td>
<td>Feb 01, 2006</td>
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**Desmopressin Acetate**

**Injectable, Injection**

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<th>Brand Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>FERRING PHARMS INC</td>
<td>0.004mg/ml</td>
<td>018938</td>
<td>Mar 30, 1984</td>
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**DDAVP**

<table>
<thead>
<tr>
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<th>Strength</th>
<th>NDC Code</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>FERRING PHARMS INC</td>
<td>0.01mg/spay</td>
<td>017922</td>
<td>Apr 07, 1996</td>
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**DDAVP (Needs No Refrigeration)**

<table>
<thead>
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<th>Brand Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>FERRING PHARMS INC</td>
<td>0.01mg/spay</td>
<td>017922</td>
<td>Jan 27, 2005</td>
</tr>
<tr>
<td>DESMOPRESSIN ACETATE</td>
<td>TABLET; ORAL</td>
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<td>-----------------------</td>
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</tr>
<tr>
<td><strong>DDAVP</strong></td>
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<td></td>
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</tr>
<tr>
<td>AB + FERRING PHARMS INC</td>
<td>0.1MG</td>
<td>N019955 001 Sep 06, 1995</td>
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<tr>
<td>AB + FERRING PHARMS INC</td>
<td>0.2MG</td>
<td>N019955 002 Sep 06, 1995</td>
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<tr>
<td>AB ACTAVIS LABS FL INC</td>
<td>0.1MG</td>
<td>A076470 001 Jul 01, 2005</td>
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<tr>
<td>AB ACTAVIS LABS FL INC</td>
<td>0.2MG</td>
<td>A076470 002 Jul 01, 2005</td>
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<tr>
<td>AB APOTEX INC</td>
<td>0.1MG</td>
<td>A077414 001 Mar 07, 2006</td>
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<tr>
<td>AB APOTEX INC</td>
<td>0.2MG</td>
<td>A077414 002 Mar 07, 2006</td>
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<tr>
<td>AB GLENMARK PHARMS LTD</td>
<td>0.1MG</td>
<td>A201831 001 May 28, 2015</td>
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<tr>
<td>AB GLENMARK PHARMS LTD</td>
<td>0.2MG</td>
<td>A201831 002 May 28, 2015</td>
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<td>AB HERITAGE PHARMA LTD</td>
<td>0.1MG</td>
<td>A207880 001 May 26, 2017</td>
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<tr>
<td>AB IMPAX LABS INC</td>
<td>0.1MG</td>
<td>A207880 002 May 26, 2017</td>
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<td>AB IMPAX LABS INC</td>
<td>0.2MG</td>
<td>A077122 001 Jan 25, 2006</td>
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<tr>
<td>AB IMPAX LABS INC</td>
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<tr>
<td>AB APOTEX INC</td>
<td>0.1MG</td>
<td>A200653 001 Jun 27, 2014</td>
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<tr>
<td>AB APOTEX INC</td>
<td>0.2MG</td>
<td>A200653 002 Jun 27, 2014</td>
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<td>TABLET; SUBLINGUAL</td>
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<tr>
<td>NOCDURNA + FERRING PHARMS INC</td>
<td>0.0277MG</td>
<td>N022517 001 Jun 21, 2018</td>
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<tr>
<td>NOCDURNA + FERRING PHARMS INC</td>
<td>0.0553MG</td>
<td>N022517 002 Jun 21, 2018</td>
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<thead>
<tr>
<th>DESOGESTREL; ETHINYL ESTRADIOL</th>
<th>TABLET; ORAL - 28</th>
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<tbody>
<tr>
<td><strong>BRYKEEN</strong></td>
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<tr>
<td>AB LUPIN LTD</td>
<td>0.15MG N/A; 0.02MG 0.01MG</td>
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<td>CYCLEEISA</td>
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<td>AB ASPEN GLOBAL INC</td>
<td>0.1MG 0.125MG, 0.15MG; 0.025MG, 0.025MG 0.025MG</td>
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<tr>
<td>AB ORGANON USA INC</td>
<td>0.15MG 0.03MG</td>
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<td><strong>DESOGESTREL AND ETHINYL ESTRADIOL</strong></td>
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<td>AB ACCORD HLTHCARE</td>
<td>0.15MG N/A; 0.02MG 0.01MG</td>
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<td>AB AUROBINDO PHARMA LTD</td>
<td>0.15MG 0.03MG</td>
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<td>AB DURAMED PHARMS BARR</td>
<td>0.15MG 0.03MG</td>
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<td>AB MAYNE PHARMA</td>
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<td>AB MAYNE PHARMA</td>
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<td>AB NOVAST LABS</td>
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<td>AB WATSON LABS</td>
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<td>AB VINTAGE PHARMS LLC</td>
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<td>AB LUPIN LTD</td>
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<td>AB BARR</td>
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<td>AB KIMIDESR</td>
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<td>AB VINTAGE PHARMS</td>
<td>0.15MG N/A; 0.02MG 0.01MG</td>
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<td>AB PINTREAP</td>
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DEXAMETHASONE INSERT;OPHTHALMIC
DEXTENZA
+! OCULAR THERAPEUTIX 0.4MG N208742 001 Nov 30, 2018

SOLUTION;ORAL
DEXAMETHASONE
+! WEST-WARD PHARMS 0.5MG/5ML INT A088248 001 Sep 01, 1983

SUSPENSION;INTRAOCULAR
DEXYCU KIT
+! EYEPONT PHARMS 9% N208912 001 Feb 09, 2018

SUSPENSION/DROPS;OPHTHALMIC
MAXIDEX
+! NOVARTIS PHARMS 0.1% CORP N013422 001

TABLET;ORAL
DEXAMETHASONE
AB ECR 1.5MG A040700 001 Aug 15, 2008
AB LARKEN LABS INC 1.5MG A201270 001 Jul 17, 2017
AB WEST-WARD PHARMS 1.5MG A084610 001

BP FERA PHARMS LLC 0.5MG A088481 001 Apr 28, 1983
BP 0.75MG A088481 003 Apr 28, 1983
BP 4MG A088481 004 Apr 28, 1983
BP 6MG A088481 001 Nov 28, 1983
BP WEST-WARD PHARMS 0.5MG A084611 001
BP 0.75MG A084613 001
BP 1MG A088306 001 Sep 15, 1983
BP 2MG A087916 001 Aug 26, 1982
BP 4MG A084612 001
BP XSPIRE PHARMA 1.5MG A088237 001 Apr 28, 1983

DEXAMETHASONE SODIUM PHOSPHATE INJECTABLE;INJECTION
DEXAMETHASONE SODIUM PHOSPHATE PRESERVATIVE FREE

AP AMNEAL PHARMS CO EQ 4MG PHOSPHATE/ML A208689 001 Aug 22, 2018
AP AUROBINDO PHARMA LTD EQ 4MG PHOSPHATE/ML A206781 001 Dec 01, 2015
AP FRESENIUS KABI USA EQ 4MG PHOSPHATE/ML A084916 001
AP ! FRESENIUS KABI USA EQ 10MG PHOSPHATE/ML A208690 001
AP LUITPOLD EQ 4MG PHOSPHATE/ML A209192 001
AP MYLAN LABS LTD EQ 4MG PHOSPHATE/ML A040572 001 Apr 22, 2005
AP SOMERSET THERAPS LLC EQ 4MG PHOSPHATE/ML A088237 001
AP WEST-WARD PHARMS INT EQ 4MG PHOSPHATE/ML A084282 001
AP ! WEST-WARD PHARMS INT EQ 10MG PHOSPHATE/ML A087702 001 Sep 07, 1982

SOLUTION/DROPS;OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE

AT BAUSCH AND LOMB EQ 0.1% PHOSPHATE A040659 001 Jul 26, 1996
AT SANDOZ INC EQ 0.1% PHOSPHATE A088771 001 Jan 16, 1985

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMIXIN B SULFATE

MAXITROL
+! NOVARTIS PHARMS CORP 0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM N050065 002

NEOMYCIN AND POLYMIXIN B SULFATES AND DEXAMETHASONE

AT BAUSCH AND LOMB 0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM A064063 001 Jul 25, 1994
AT PERRIGO CO 0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM A062938 001 Jul 31, 1989

SUSPENSION/DROPS;OPHTHALMIC
DEXASPORIN
AT BAUSCH AND LOMB 0.1%;EQ 3.5MG BASE/MIL;10,000 UNITS/MIL A064135 001 Sep 13, 1995
DEXAMETHASONE; NEOMYCIN SULFATE; POLYMIXIN B SULFATE
SUSPENSION/DROPS;OPHTHALMIC
MAXITROL
**AT +! NOVARTIS PHARMS CORP** 0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML N050023 002
SANDOZ INC

DEXAMETHASONE; TOBRAMYCIN
OINTMENT;OPHTHALMIC
TOBRADEX
**AB +! NOVARTIS PHARMS CORP** 0.1%;0.3% N050616 001
**AB +! BAUSCH AND LOMB TOBRADEX ST** 0.1%;0.3% N050592 001

DEXCHLORPHENIRAMINE MALEATE
SYRUP;ORAL
**AA ! WOCKHARDT BIO AG** 2MG/5ML A088251 001
**AA CAPELLON PHARMS LLC** 2MG/5ML A202520 001

DEXLANSOPRAZOLE
CAPSULE, DELAYED RELEASE;ORAL
DEXILANT
**AB TAKEDA PHARMS USA** 60MG N022287 002
**AB PAR PHARM INC** 60MG A202294 001

DEXMEDETOMIDINE HYDROCHLORIDE
INJECTABLE;INJECTION
**AP ACCORD HLTCARE** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A204023 001
**AP ACTAVIS INC** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A204686 001
**AP AKORN INC** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A202585 001
**AP AUROBINDO PHARMA LTD** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A205867 001
**AP BAXTER HLTCARE CORP** EQ 200MCG BASE/50ML (EQ 4MCG BASE/ML) A208532 001
**AP FRESENIUS KABI USA** EQ 400MCG BASE/100ML (EQ 4MCG BASE/ML) A208532 002
**AP FRESENIUS KABI USA** EQ 800MCG BASE/200ML (EQ 4MCG BASE/ML) A208129 001
**AP JIANGSU HENRUI MED LTD** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A208129 002
**AP LUITPOLD** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A209065 001
**AP MYLAN INSTITUTIONAL PRODUCTS** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A203773 001
**AP PAR STERILE** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A205972 001
**AP SANDOZ INC** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A091465 001
**AP SUN PHARM INDS INC** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A202126 001
**AP TEVA PHARMS USA** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A205272 001
**AP WEST-WARD PHARMS INC** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A205046 001
**AP ZYDUS PHARMS USA INC** EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) A206798 001

PRECEDEX
**AP HOSPIRA** EQ 800MCG BASE/20ML (EQ 4MCG BASE/ML) N021038 004

SOLUTION;INTRAVENOUS
DEXMEDETOMIDINE HYDROCHLORIDE
+! **HQ SPCLT PHARMA** EQ 1MG BASE/10ML (EQ 100MCG BASE/ML) N206628 003
+ EQ 200MCG BASE/4ML (EQ 4MCG BASE/ML) N206628 001
+ EQ 400MCG BASE/100ML (EQ 4MCG BASE/ML) N206628 004
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<td><strong>AB</strong> SUN PHARMS INDUSTRIES</td>
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<td>A077107</td>
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### DEXMETHYLPHENIDATE HYDROCHLORIDE

**Tablet; Oral**

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<th>Date</th>
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<td>TRIS PHARMA INC</td>
<td>5MG</td>
<td>A077107</td>
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**FOCALIN**

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<tr>
<td>NOVARTIS</td>
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### DEXRAZOXANE HYDROCHLORIDE

**Injectable; Injection**

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<tr>
<td>Glide Pharma Ltd</td>
<td>EQ 500MG Base/Vial</td>
<td>A207321</td>
<td>Aug 26, 2016</td>
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<tr>
<td>Mylan Institutional</td>
<td>EQ 250MG Base/Vial</td>
<td>A200752</td>
<td>Oct 19, 2011</td>
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<td>West-Ward Pharms Int</td>
<td>EQ 250MG Base/Vial</td>
<td>A200752</td>
<td>Oct 19, 2011</td>
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<tr>
<td>Zinecard</td>
<td>EQ 500MG Base/Vial</td>
<td>A076068</td>
<td>Sep 28, 2004</td>
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<td>Pharmacia And Upjohn</td>
<td>EQ 250MG Base/Vial</td>
<td>N020212</td>
<td>May 26, 1995</td>
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<tr>
<td>Tect</td>
<td>EQ 500MG Base/Vial</td>
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### DEXTROAMPHETAMINE SULFATE

**Capsule, Extended Release; Oral**

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**DEXTROAMPHETAMINE SULFATE**

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<td>Nesser Pharma</td>
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<td>Mylan Pharma Inc</td>
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<td>10MG</td>
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<td>Nesser Pharma</td>
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<td>Specgx LLC</td>
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<td>A076353</td>
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<td>Vintage Pharma</td>
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<td>Tris Pharma Inc</td>
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### DEXTROAMPHETAMINE SULFATE

**Tablet; Oral**

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<th>Strength</th>
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<td>Barr</td>
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<td>SPECGX LLC</td>
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<td>15MG/5ML; 6.25MG/5ML</td>
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<td>HI TECH PHARMA</td>
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<td>WOCKHARDT BIO AG</td>
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<td>ACTAVIS ELIZABETH</td>
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<td>DEXTROSE INJECTABLE; INJECTION</td>
<td>B BRAUN</td>
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<td>BAXTER HLTHCARE</td>
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<td>DEXTROSE 10% IN PLASTIC CONTAINER</td>
<td>B BRAUN</td>
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<td>BAXTER HLTHCARE</td>
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<td>FRESENIUS KABI USA</td>
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<td>ICU MEDICAL INC</td>
<td>5GM/100ML</td>
<td>N016730 001</td>
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<td>DEXTROSE 5% IN PLASTIC CONTAINER</td>
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<td>BAXTER HLTHCARE</td>
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<td>DEXTROSE 20% IN PLASTIC CONTAINER</td>
<td>ICU MEDICAL INC</td>
<td>20GM/100ML</td>
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<td>ICU MEDICAL INC</td>
<td>50GM/100ML</td>
<td>N019445 003</td>
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DEXTROSE; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE
INJECTABLE; INJECTION
NORMOSOL-M AND DEXTROSE 5% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 21MG/100ML; 128MG/100ML; 234MG/100ML N017610 001

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE
INJECTABLE; INJECTION
ISOLYTE P IN DEXTROSE 5% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 31MG/100ML; 130MG/100ML; 26MG/100ML N019873 001 Jun 10, 1993

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE
INJECTABLE; INJECTION
DEXTROSE 5% AND ELECTROLYTE NO. 48 IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 31MG/100ML; 141MG/100ML; 20MG/100ML; 12MG/100ML; 260MG/100ML; 25MG/100ML N017484 001

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC ANHYDROUS
INJECTABLE; INJECTION
IONOSOL MB AND DEXTROSE 5% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 30MG/100ML; 141MG/100ML; 15MG/100ML; 260MG/100ML; 25MG/100ML N019513 001 May 08, 1986

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE
INJECTABLE; INJECTION
NORMOSOL-R AND DEXTROSE 5% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML N017609 001

DEXTROSE; POTASSIUM CHLORIDE
INJECTABLE; INJECTION
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 75MG/100ML; 200MG/100ML N018037 006 Apr 13, 1982

DEXTROSE 5% AND POTASSIUM CHLORIDE 0.224% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 224MG/100ML; 200MG/100ML N018037 003

DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML N018037 002

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 224MG/100ML; 15MG/100ML N018699 004 Sep 29, 1989

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 350MG/100ML N018699 006 Sep 29, 1989

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 224MG/100ML; 200MG/100ML N013871 002

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 298MG/100ML N013871 003

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE
INJECTABLE; INJECTION
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ
BAXTER HLTHCARE 5GM/100ML; 75MG/100ML; 200MG/100ML; 150MG/100ML N018037 006 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 224MG/100ML; 200MG/100ML; 150MG/100ML N018037 007 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML; 150MG/100ML N018037 004

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML; 150MG/100ML N018037 001

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ
BAXTER HLTHCARE 5GM/100ML; 224MG/100ML; 200MG/100ML; 150MG/100ML N018037 005 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 40MEQ
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML; 150MG/100ML N018037 009 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 50MEQ
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML; 150MG/100ML N018037 002

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 75MG/100ML; 200MG/100ML; 150MG/100ML N018037 006 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 224MG/100ML; 200MG/100ML; 150MG/100ML N018037 007 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML; 150MG/100ML N018037 001

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 224MG/100ML; 200MG/100ML; 150MG/100ML N018037 005 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 40MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML; 150MG/100ML N018037 009 Apr 13, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 50MEQ (K)
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 200MG/100ML; 150MG/100ML N018037 002

DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER
AP 5GM/100ML; 75MG/100ML; 330MG/100ML N018629 006 Mar 23, 1982

AP 5GM/100ML; 150MG/100ML; 330MG/100ML N018629 002 Mar 23, 1982
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE
INJECTABLE; INJECTION

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER
AP
BAXTER HLTHCARE
5GM/100ML;244MG/100ML;300MG/100ML
N018629 003 Mar 23, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER
AP
BAXTER HLTHCARE
5GM/100ML;150MG/100ML;300MG/100ML
N018629 004 Mar 23, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER
AP
BAXTER HLTHCARE
5GM/100ML;224MG/100ML;300MG/100ML
N018629 007 Mar 23, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER
AP
BAXTER HLTHCARE
5GM/100ML;300MG/100ML;330MG/100ML
N018629 008 Mar 23, 1982

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER
AP
BAXTER HLTHCARE
5GM/100ML;75MG/100ML;330MG/100ML
N018629 001 Mar 23, 1982

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;298MG/100ML;900MG/100ML
N019630 008 Feb 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;75MG/100ML;900MG/100ML
N019630 012 Feb 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;150MG/100ML;200MG/100ML
N019630 002 Feb 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;150MG/100ML;330MG/100ML
N019630 016 Feb 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;150MG/100ML;450MG/100ML
N019630 022 Feb 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;300MG/100ML;300MG/100ML
N019630 005 Feb 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;300MG/100ML;330MG/100ML
N019630 018 Feb 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;300MG/100ML;450MG/100ML
N019630 024 Feb 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;300MG/100ML;900MG/100ML
N019630 028 Feb 17, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;300MG/100ML;200MG/100ML
N019630 006 Apr 28, 1982

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;300MG/100ML;330MG/100ML
N019630 010 Jul 05, 1983

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;224MG/100ML;300MG/100ML
N019630 007 Apr 28, 1982

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;224MG/100ML;300MG/100ML
N019630 002 Apr 28, 1982

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP
B BRAUN
10GM/100ML;37MG/100ML;200MG/100ML
N019630 031 Feb 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP
B BRAUN
10GM/100ML;37MG/100ML;450MG/100ML
N019630 037 Feb 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP
B BRAUN
10GM/100ML;37MG/100ML;900MG/100ML
N019630 043 Feb 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;37MG/100ML;110MG/100ML
N019630 001 Feb 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;37MG/100ML;200MG/100ML
N019630 007 Feb 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP
B BRAUN
5GM/100ML;37MG/100ML;330MG/100ML
N019630 013 Feb 17, 1988
### DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE INJECTABLE; INJECTION

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<tr>
<th>Potassium Chloride</th>
<th>Dextrose</th>
<th>Sodium Chloride</th>
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*Note: B BRAUN codes are used to identify the specific product.*
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE
INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
+ ICU MEDICAL INC 5GM/100ML; 74.5MG/100ML; 225MG/100ML N018365 002 Jul 05, 1983
+ 5GM/100ML; 149MG/100ML; 225MG/100ML N018365 006 Mar 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 74.5MG/100ML; 300MG/100ML N01876 001 Jan 17, 1986
5GM/100ML; 149MG/100ML; 300MG/100ML N01876 006 Mar 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 75MG/100ML; 900MG/100ML N019308 004 Apr 05, 1985
5GM/100ML; 150MG/100ML; 900MG/100ML N019308 002 Apr 05, 1985

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 224MG/100ML; 225MG/100ML N018365 008 Mar 28, 1988
5GM/100ML; 298MG/100ML; 225MG/100ML N018365 009 Mar 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 224MG/100ML; 300MG/100ML N018876 007 Mar 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 900MG/100ML N019308 006 Apr 05, 1985

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 149MG/100ML; 225MG/100ML N018365 001
5GM/100ML; 298MG/100ML; 225MG/100ML N018365 002 Apr 05, 1985

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 298MG/100ML; 300MG/100ML N018876 008 Mar 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 900MG/100ML N019308 005 Apr 05, 1985

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 224MG/100ML; 225MG/100ML N018365 004 Jul 05, 1983

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ICU MEDICAL INC 5GM/100ML; 224MG/100ML; 300MG/100ML N018876 003 Jan 17, 1986

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 900MG/100ML N019308 004 Apr 05, 1985

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 150MG/100ML; 450MG/100ML N018008 004

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 300MG/100ML; 900MG/100ML N019308 001 Apr 05, 1985

DEXTROSE AND SODIUM CHLORIDE
INJECTABLE; INJECTION

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
B BRAUN 2.5GM/100ML; 450MG/100ML N019631 004 Feb 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 200MG/100ML N019631 007 Feb 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 330MG/100ML N019631 008 Feb 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 450MG/100ML N019631 009 Feb 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 900MG/100ML N019631 010 Feb 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 200MG/100ML N016697 001

DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 330MG/100ML N016689 001

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 450MG/100ML N016687 001

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML; 900MG/100ML N016683 001

DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
B BRAUN 10GM/100ML; 110MG/100ML N019631 011 Feb 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
B BRAUN 10GM/100ML; 200MG/100ML N019631 012 Feb 24, 1988
### Prescription Drug Product List

#### Dextrose; Sodium Chloride

**Injectable; Injection**

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<th>NDC Number</th>
<th>Date Approved</th>
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<tbody>
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<td>Dextrose 10% and Sodium Chloride 0.33% in Plastic Container B Braun</td>
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<td>Feb 24, 1988</td>
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<td>Dextrose 2.5% and Sodium Chloride 0.33% in Plastic Container B Braun</td>
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#### Diatrizoate Meglumine

**Solution; Urethral**

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**Solution; Oral, Rectal**

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<td>MD-Gastroview + Liebel-Flarsheim 66%; 10%</td>
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#### DIAZEPAM

**Concentrate; Oral**

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<td>0204433 001</td>
<td>Apr 14, 2014</td>
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<td>Diazepam INTENSOL               + West-Ward Pharms 5mg/ml</td>
<td>071415 001</td>
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**Gel; Rectal**

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<td>Diastat + Valeant Pharms 2.5mg/0.5ml (5mg/ml) North</td>
<td>020648 001</td>
<td>Jul 29, 1997</td>
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<td>Diastat Acudial + Valeant Pharms 10mg/2ml (5mg/ml) North</td>
<td>020648 007</td>
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<td>+! Hospira 20mg/4ml (5mg/ml)</td>
<td>020648 006</td>
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**Injectable; Injection**

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**Solution; Oral**

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**Tablet; Oral**

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<td>Nov 01, 1985</td>
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DILTIAZEM HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL

| AB2  | APOTEX | 120MG | A074943 003 | Dec 19, 2000 |
| AB2  | 180MG  | A074943 002 | Dec 19, 2000 |
| AB2  | 240MG  | A074943 001 | Aug 06, 1998 |
| AB2  | MYLAN  | 120MG | A075124 002 | Mar 18, 1998 |
| AB2  | 180MG  | A075124 003 | Mar 18, 1998 |
| AB2  | 240MG  | A075124 001 | Mar 18, 1998 |

| AB3  | CARDIZEM CD | 120MG | N020062 001 | Aug 10, 1992 |
| AB3  | + VALEANT INTL | 180MG | N020062 002 | Dec 27, 1991 |
| AB3  | + | 240MG | N020062 003 | Dec 27, 1991 |
| AB3  | + | 300MG | N020062 004 | Dec 27, 1991 |
| AB3  | +! | 360MG | N020062 005 | Aug 24, 1999 |

| AB3  | CARTIA XT | 120MG | A074752 002 | Jul 09, 1998 |
| AB3  | 180MG  | A074752 001 | Jul 09, 1998 |
| AB3  | 240MG  | A074752 003 | Jul 09, 1998 |
| AB3  | 300MG  | A074752 004 | Jul 09, 1998 |

<p>| AB3  | DILTIAZEM HYDROCHLORIDE | 360MG | A202463 001 | Dec 07, 2012 |
| AB3  | ACTAVIS ELIZABETH PAR PHARM 120MG | A074984 001 | Dec 20, 1999 |
| AB3  | 180MG  | A074984 002 | Dec 20, 1999 |
| AB3  | 240MG  | A074984 003 | Dec 20, 1999 |
| AB3  | 300MG  | A074984 004 | Dec 20, 1999 |
| AB3  | 360MG  | A209766 001 | May 30, 2018 |
| AB3  | SUN PHARM IND S LTD | 120MG | A203023 001 | Jun 08, 2017 |
| AB3  | 180MG  | A203023 002 | Jun 08, 2017 |
| AB3  | 240MG  | A203023 003 | Jun 08, 2017 |
| AB3  | 300MG  | A203023 004 | Jun 08, 2017 |
| AB3  | 360MG  | A203023 005 | Jun 08, 2017 |
| AB3  | SUN PHARMA GLOBAL | 120MG | A090492 001 | Oct 28, 2011 |
| AB3  | 180MG  | A090492 002 | Oct 28, 2011 |
| AB3  | 240MG  | A090492 003 | Oct 28, 2011 |
| AB3  | 300MG  | A090492 004 | Oct 28, 2011 |
| AB3  | 360MG  | A090492 005 | Oct 28, 2011 |
| AB3  | 360MG  | A090492 006 | Oct 28, 2011 |
| AB3  | TWI PHARMS | 120MG | A05231 001 | Aug 30, 2018 |
| AB3  | 180MG  | A05231 002 | Aug 30, 2018 |
| AB3  | 240MG  | A05231 003 | Aug 30, 2018 |
| AB3  | 300MG  | A05231 004 | Aug 30, 2018 |
| AB3  | 360MG  | A05231 005 | Aug 30, 2018 |
| AB3  | VALEANT PHARMS NORTH | 120MG | A075116 001 | Dec 23, 1999 |
| AB3  | 180MG  | A075116 002 | Dec 23, 1999 |
| AB3  | 240MG  | A075116 003 | Dec 23, 1999 |
| AB3  | 300MG  | A075116 004 | Dec 23, 1999 |
| AB3  | 360MG  | A075116 005 | Dec 23, 1999 |
| AB3  | ZYDUS PHARMS USA INC | 120MG | A206534 001 | Aug 08, 2017 |
| AB3  | 180MG  | A206534 002 | Aug 08, 2017 |
| AB3  | 240MG  | A206534 003 | Aug 08, 2017 |
| AB3  | 300MG  | A206534 004 | Aug 08, 2017 |
| AB3  | 360MG  | A206534 005 | Aug 08, 2017 |
| AB4  | SANOZ | 120MG | A091022 001 | Sep 28, 2012 |
| AB4  | 180MG  | A091022 002 | Sep 28, 2012 |
| AB4  | 240MG  | A091022 003 | Sep 28, 2012 |
| AB4  | 300MG  | A091022 004 | Sep 28, 2012 |
| AB4  | 360MG  | A091022 005 | Sep 28, 2012 |
| AB4  | 420MG  | A091022 006 | Sep 28, 2012 |
| AB4  | SUN PHARMA GLOBAL | 120MG | A090421 001 | Aug 08, 2017 |
| AB4  | 180MG  | A090421 002 | Aug 08, 2017 |
| AB4  | 240MG  | A090421 003 | Aug 08, 2017 |
| AB4  | 300MG  | A090421 004 | Aug 08, 2017 |
| AB4  | 360MG  | A090421 005 | Aug 08, 2017 |
| AB4  | ZYDUS PHARMS USA INC | 120MG | A206641 001 | Aug 11, 2017 |
| AB4  | 180MG  | A206641 002 | Aug 11, 2017 |
| AB4  | 240MG  | A206641 003 | Aug 11, 2017 |
| AB4  | 300MG  | A206641 004 | Aug 11, 2017 |
| AB4  | 360MG  | A206641 005 | Aug 11, 2017 |
| AB4  | 420MG  | A206641 006 | Aug 11, 2017 |</p>
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<td>APOTEX INC</td>
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## Dipyridamole

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## Disopyramide Phosphate

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## Disulfiram

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## Divalproex Sodium

**Capsule, Delayed Rel Pellets; Oral**

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![Image of the table](image-url)
### DIVALPROEX SODIUM

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### DEPAKOTE ER

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### DOBUTAMINE HYDROCHLORIDE

**INJECTABLE; INJECTION**

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### DOBUTAMINE HYDROCHLORIDE IN DEXTROSE 5% IN PLASTIC CONTAINER

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INJECTABLE; INJECTION

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AP + ACCORD HLTCARE 20MG/ML (20MG/ML) N201195 003 Apr 20, 2012
AP + 80MG/4ML (20MG/ML) N201195 004 Apr 20, 2012
AP +! 160MG/8ML (20MG/ML) N201195 005 Apr 20, 2012
AP ACTAVIS LLC 20MG/ML (20MG/ML) N203551 001 Apr 12, 2013
AP 80MG/4ML (20MG/ML) N203551 002 Apr 12, 2013
AP AMNEAL PHARMS CO 20MG/ML (20MG/ML) A209640 001 Jan 19, 2018
AP 80MG/4ML (20MG/ML) A209640 002 Jan 19, 2018
AP 160MG/8ML (20MG/ML) A209640 003 Jan 19, 2018
AP CIPLA 20MG/2ML (10MG/ML) A209634 001 Aug 24, 2018
AP 80MG/4ML (20MG/ML) A209634 002 Aug 24, 2018
AP 160MG/8ML (20MG/ML) A209634 003 Aug 24, 2018
AP + ACCORD HLTCARE 40MG/2ML (20MG/ML) A209634 004 Aug 24, 2018
AP + 80MG/4ML (20MG/ML) A209634 005 Aug 24, 2018
AP ACTAVIS LLC 20MG/ML (20MG/ML) A206177 001 Jan 20, 2017
AP 80MG/4ML (20MG/ML) A206177 002 Jan 20, 2017
AP DR REDDYS LABS LTD 20MG/ML (20MG/ML) A204193 001 Nov 05, 2014
AP 80MG/4ML (20MG/ML) A204193 002 Nov 05, 2014
AP EAGLE PHARMS 20MG/ML (20MG/ML) N205934 001 Dec 22, 2015
AP 80MG/4ML (20MG/ML) N205934 002 Dec 22, 2015
AP +! HOSPIRA INC 20MG/2ML (10MG/ML) N022234 001 Mar 08, 2011
AP +! 80MG/4ML (10MG/ML) N022234 002 Mar 08, 2011
AP +! INGENUS PHARMS LLC 160MG/16ML (10MG/ML) A207563 001 Aug 31, 2017
AP 80MG/8ML (10MG/ML) A207563 002 Aug 31, 2017
AP 160MG/16ML (10MG/ML) A207563 003 Aug 31, 2017
AP JIANGSU HENGRUI MED 20MG/ML (20MG/ML) A207252 001 Aug 09, 2017
AP 80MG/4ML (20MG/ML) A207252 002 Aug 09, 2017
AP 160MG/8ML (20MG/ML) A207252 003 Aug 09, 2017
AP MYLAN LABS LTD 20MG/2ML (10MG/ML) A210072 001 Jul 02, 2018
AP 80MG/8ML (10MG/ML) A210072 002 Jul 02, 2018
AP SANDOZ 20MG/2ML (10MG/ML) N201525 001 Jun 29, 2011
AP 80MG/8ML (10MG/ML) N201525 002 Jun 29, 2011
AP 160MG/16ML (10MG/ML) N201525 003 Jun 29, 2011
AP TEVA PHARMS USA 20MG/ML (20MG/ML) A203877 001 Sep 16, 2015
AP 80MG/4ML (20MG/ML) A203877 002 Sep 16, 2015

TAXOTERE
AP +! SANOFI AVENTIS US 20MG/ML (20MG/ML) N204449 003 Aug 03, 2010
AP +! 80MG/4ML (20MG/ML) N204449 004 Aug 02, 2010
AP +! 160MG/8ML (20MG/ML) N204449 005 Apr 13, 2012

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AP +! HOSPIRA INC 140MG/7ML (20MG/ML) N203551 003 Apr 12, 2013
AP +! DFB ONCOLOGY LTD 200MG/10ML (20MG/ML) A206177 001 Jan 20, 2017
AP HOSPIRA INC 20MG/ML (20MG/ML) N202234 004 Jun 23, 2016
AP 80MG/4ML (20MG/ML) N202234 005 Jun 23, 2016
AP JIANGSU HENGRUI MED 40MG/ML A203170 001 Feb 15, 2017

DOCETAXEL
INJECTABLE; INJECTION

DOFETILIDE
CAPSULE; ORAL

DOFETILIDE
AP MYLAN LABS LTD 160MG/16ML (10MG/ML) A208859 001 Apr 30, 2018

DOPETILIDE
AP BIONPHERMA INC 0.125MG A208625 001 Apr 10, 2018
AP 0.25MG A208625 002 Apr 10, 2018
AP 0.5MG A208625 003 Apr 10, 2018
AP MAYNE PHARMA INC 0.125MG A207058 001 Jun 06, 2016
AP 0.25MG A207058 002 Jun 06, 2016
AP 0.5MG A207058 003 Jun 06, 2016
AP PAR PHARM INC 0.125MG A208519 001 Oct 09, 2018
AP 0.25MG A208519 002 Oct 09, 2018
AP 0.5MG A208519 003 Oct 09, 2018
AP SIGMAHARM LABS LLC 0.125MG A207746 001 Mar 26, 2018
AP 0.25MG A207746 002 Mar 26, 2018
AP 0.5MG A207746 003 Mar 26, 2018
AP SUN PHARMA GLOBAL 0.125MG A210466 001 Oct 09, 2018
AP 0.25MG A210466 002 Oct 09, 2018
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DONEPEZIL HYDROCHLORIDE

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DOPAMINE HYDROCHLORIDE

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DOPAMINE HYDROCHLORIDE AND DEXTROSE 5% IN PLASTIC CONTAINER

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DOPAMINE HYDROCHLORIDE AND DEXTROSE 5% IN PLASTIC CONTAINER

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DORAVIRINE

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### DOXAZOSIN MESYLATE

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<tr>
<td><strong>AB</strong> TEVA</td>
<td>1 mg</td>
<td>A075536 001</td>
<td>Oct 18, 2000</td>
</tr>
<tr>
<td><strong>AB</strong> TEVA</td>
<td>2 mg</td>
<td>A075536 002</td>
<td>Oct 18, 2000</td>
</tr>
<tr>
<td><strong>AB</strong> TEVA</td>
<td>4 mg</td>
<td>A075536 003</td>
<td>Oct 18, 2000</td>
</tr>
<tr>
<td><strong>AB</strong> TEVA</td>
<td>8 mg</td>
<td>A075536 004</td>
<td>Oct 18, 2000</td>
</tr>
<tr>
<td><strong>AB</strong> ZYLDUS PHARMS USA INC</td>
<td>1 mg</td>
<td>A208719 001</td>
<td>Jul 07, 2017</td>
</tr>
<tr>
<td><strong>AB</strong> ZYLDUS PHARMS USA INC</td>
<td>2 mg</td>
<td>A208719 002</td>
<td>Jul 07, 2017</td>
</tr>
<tr>
<td><strong>AB</strong> ZYLDUS PHARMS USA INC</td>
<td>4 mg</td>
<td>A208719 003</td>
<td>Jul 07, 2017</td>
</tr>
<tr>
<td><strong>AB</strong> ZYLDUS PHARMS USA INC</td>
<td>8 mg</td>
<td>A208719 004</td>
<td>Jul 07, 2017</td>
</tr>
</tbody>
</table>

**Tablet, Extended Release, Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Regulatory Code</th>
<th>Manufacturing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CARDURA XL</strong></td>
<td>4 mg</td>
<td>N021269 001</td>
<td>Feb 22, 2005</td>
</tr>
<tr>
<td><strong>CARDURA XL</strong></td>
<td>8 mg</td>
<td>N021269 002</td>
<td>Feb 22, 2005</td>
</tr>
</tbody>
</table>

### DOXEPIN HYDROCHLORIDE

**Capsule, Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Regulatory Code</th>
<th>Manufacturing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AB</strong> AMNEAL PHARMS CO</td>
<td>10 mg</td>
<td>A207482 001</td>
<td>Jun 28, 2017</td>
</tr>
<tr>
<td><strong>AB</strong> AMNEAL PHARMS CO</td>
<td>25 mg</td>
<td>A207482 002</td>
<td>Jun 28, 2017</td>
</tr>
<tr>
<td><strong>AB</strong> MYLAN PHARMS INC</td>
<td>50 mg</td>
<td>A070791 001</td>
<td>May 13, 1986</td>
</tr>
<tr>
<td><strong>AB</strong> PAR PHARM</td>
<td>50 mg</td>
<td>A071422 001</td>
<td>Nov 09, 1987</td>
</tr>
<tr>
<td><strong>AB</strong> WOCKHARDT BIO AG</td>
<td>150 mg</td>
<td>A071669 001</td>
<td>Nov 09, 1987</td>
</tr>
</tbody>
</table>

**Cream, Topical**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Regulatory Code</th>
<th>Manufacturing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TEVA PHARMS</strong></td>
<td>5%</td>
<td>N020126 001</td>
<td>Apr 01, 1994</td>
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</table>

**Tablet, Oral**

<table>
<thead>
<tr>
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<th>Strength</th>
<th>Regulatory Code</th>
<th>Manufacturing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SILENOR</strong></td>
<td>3 mg</td>
<td>N022036 001</td>
<td>Mar 17, 2010</td>
</tr>
<tr>
<td><strong>SILENOR</strong></td>
<td>6 mg</td>
<td>N022036 002</td>
<td>Mar 17, 2010</td>
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### DOXERCALCIFEROL

**Capsule, Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Regulatory Code</th>
<th>Manufacturing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RISING PHARMS</strong></td>
<td>0.5 mcg</td>
<td>A201518 001</td>
<td>Sep 09, 2016</td>
</tr>
<tr>
<td><strong>RISING PHARMS</strong></td>
<td>1 mcg</td>
<td>A201518 002</td>
<td>Sep 09, 2016</td>
</tr>
<tr>
<td><strong>WEST-NARD PHARMS INT</strong></td>
<td>2.5 mcg</td>
<td>A091433 001</td>
<td>Sep 23, 2011</td>
</tr>
<tr>
<td><strong>HECTOROL</strong></td>
<td>1 mcg</td>
<td>A091433 002</td>
<td>Jan 14, 2014</td>
</tr>
<tr>
<td><strong>HECTOROL</strong></td>
<td>2.5 mcg</td>
<td>A091433 003</td>
<td>Jan 14, 2014</td>
</tr>
<tr>
<td><strong>SANOFI</strong></td>
<td>0.5 mcg</td>
<td>N020862 002</td>
<td>Apr 23, 2004</td>
</tr>
<tr>
<td><strong>SANOFI</strong></td>
<td>1 mcg</td>
<td>N020862 003</td>
<td>Jul 13, 2009</td>
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<tr>
<td><strong>SANOFI</strong></td>
<td>2.5 mcg</td>
<td>N020862 004</td>
<td>Jun 09, 1999</td>
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</table>

**Injectable, Injection**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Regulatory Code</th>
<th>Manufacturing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AKORN INC</strong></td>
<td>2 mcg/ml</td>
<td>A203929 001</td>
<td>Mar 28, 2016</td>
</tr>
<tr>
<td><strong>AKORN INC</strong></td>
<td>4 mcg/ml</td>
<td>A203929 002</td>
<td>May 07, 2015</td>
</tr>
<tr>
<td><strong>AMNEAL PHARMS CO</strong></td>
<td>2 mcg/ml</td>
<td>A208974 001</td>
<td>May 24, 2017</td>
</tr>
<tr>
<td><strong>HIMI PHARMS</strong></td>
<td>4 mcg/ml</td>
<td>A208974 002</td>
<td>May 24, 2017</td>
</tr>
<tr>
<td><strong>HIMI PHARMS</strong></td>
<td>4 mcg/ml</td>
<td>A208975 001</td>
<td>May 24, 2017</td>
</tr>
<tr>
<td><strong>WOSPRA INC</strong></td>
<td>4 mcg/ml</td>
<td>A208614 001</td>
<td>Jul 24, 2018</td>
</tr>
</tbody>
</table>
### DOXERCALCIFEROL

**INJECTABLE; INJECTION**

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPIN LTD</td>
<td>4MCG/2ML (2MCG/ML)</td>
<td>Nov 01, 2018</td>
</tr>
<tr>
<td>SANDOX INC</td>
<td>4MCG/2ML (2MCG/ML)</td>
<td>May 05, 2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feb 04, 2014</td>
</tr>
<tr>
<td>SANOFI</td>
<td>2MCG/ML (2MCG/ML)</td>
<td>Apr 06, 2000</td>
</tr>
<tr>
<td>DOXERCALCIFEROL</td>
<td>4MCG/2ML (2MCG/ML)</td>
<td>Apr 06, 2000</td>
</tr>
<tr>
<td>HOSPIRA INC</td>
<td>10MCG/5ML (2MCG/ML)</td>
<td>Jul 24, 2018</td>
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</table>

### DOXORUBICIN HYDROCHLORIDE

**INJECTABLE; INJECTION**

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTAVIS INC</td>
<td>2MG/ML</td>
<td>Jun 27, 2014</td>
</tr>
<tr>
<td>AMNEAL PHARMS CO</td>
<td>200MG/100ML</td>
<td>Jun 27, 2014</td>
</tr>
<tr>
<td>FRESENIUS KABI USA</td>
<td>2MG/ML</td>
<td>Feb 14, 2012</td>
</tr>
<tr>
<td>GLAND PHARMA LTD</td>
<td>2MG/ML</td>
<td>Aug 11, 2017</td>
</tr>
<tr>
<td>MYLAN LABS LTD</td>
<td>2MCG/ML</td>
<td>Oct 28, 2011</td>
</tr>
<tr>
<td>PHARMACHEMIE BV</td>
<td>2MCG/ML</td>
<td>Feb 28, 1995</td>
</tr>
<tr>
<td>PHARMACIA AND UPJOHN</td>
<td>2MCG/ML</td>
<td>Dec 23, 1987</td>
</tr>
<tr>
<td>SAGENT PHARMS</td>
<td>200MG/100ML</td>
<td>May 03, 1988</td>
</tr>
<tr>
<td>SUN PHARMA GLOBAL</td>
<td>20MG/10ML (2MG/ML)</td>
<td>Mar 17, 1989</td>
</tr>
<tr>
<td>WEST-NARD PHARM INT</td>
<td>2MCG/ML</td>
<td>Mar 17, 1989</td>
</tr>
<tr>
<td>JANSSEN RES AND DEV</td>
<td>200MG/100ML</td>
<td>Nov 17, 1995</td>
</tr>
<tr>
<td>IMPAX LABS LTD</td>
<td>50MCG/25ML (2MG/ML)</td>
<td>Jun 13, 2000</td>
</tr>
<tr>
<td>DR REDDIS LABS LTD</td>
<td>200MG/100ML</td>
<td>May 15, 2017</td>
</tr>
<tr>
<td>SUN PHARMA GLOBAL</td>
<td>200MG/100ML</td>
<td>Feb 04, 2013</td>
</tr>
<tr>
<td>PHARMACIA AND UPJOHN</td>
<td>150MCG/75ML</td>
<td>Mar 28, 2011</td>
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### DOXIL (LIPOSOMAL)

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>JANSSEN RES AND DEV</td>
<td>200MG/100ML</td>
<td>Nov 17, 1995</td>
</tr>
<tr>
<td></td>
<td>50MCG/25ML (2MG/ML)</td>
<td>Jun 13, 2000</td>
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### DOXORUBICIN HYDROCHLORIDE (LIPOSOMAL)

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>DR REDDIS LABS LTD</td>
<td>200MG/100ML</td>
<td>May 15, 2017</td>
</tr>
<tr>
<td>SUN PHARMA GLOBAL</td>
<td>200MG/100ML</td>
<td>Feb 04, 2013</td>
</tr>
</tbody>
</table>

### DOXYCYCLINE

**CAPSULE; ORAL**

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALEMBIC PHARMS LTD</td>
<td>EQ 75MG BASE</td>
<td>Jul 28, 2017</td>
</tr>
<tr>
<td>G AND W LABS INC</td>
<td>EQ 50MG BASE</td>
<td>May 28, 2015</td>
</tr>
<tr>
<td>IMPAX LABS INC</td>
<td>EQ 75MG BASE</td>
<td>May 28, 2015</td>
</tr>
<tr>
<td>LUPIN LTD</td>
<td>EQ 75MG BASE</td>
<td>May 28, 2015</td>
</tr>
<tr>
<td>MAYNE PHARMA INC</td>
<td>EQ 50MG BASE</td>
<td>Sep 29, 2017</td>
</tr>
<tr>
<td>MYLAN PHARMS INC</td>
<td>EQ 150MG BASE</td>
<td>Sep 29, 2017</td>
</tr>
<tr>
<td>PAR PHARM</td>
<td>EQ 50MG BASE</td>
<td>Dec 01, 2000</td>
</tr>
<tr>
<td></td>
<td>EQ 100MG BASE</td>
<td>Dec 01, 2000</td>
</tr>
<tr>
<td></td>
<td>EQ 150MG BASE</td>
<td>Sep 29, 2017</td>
</tr>
<tr>
<td>SUN PHARMA ND LTD</td>
<td>EQ 50MG BASE</td>
<td>Nov 22, 2000</td>
</tr>
<tr>
<td></td>
<td>EQ 75MG BASE</td>
<td>Sep 10, 2003</td>
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</tbody>
</table>
DOXYCYCLINE
CAPSULE;ORAL

DOXYCYCLINE
AB
ZYDUS PHARMS USA INC
EQ 100MG BASE
A065053 002 Nov 22, 2000
AB
EQ 50MG BASE
A205115 001 Feb 18, 2016
AB
EQ 75MG BASE
A205115 003 Feb 18, 2016
MONODOX
AB
AQUA PHARMS
EQ 50MG BASE
N050641 002 Feb 10, 1992
AB
EQ 75MG BASE
N050641 003 Oct 18, 2006
AB
ORACEA
N050641 001 Dec 29, 1989
+! GALDERMA LABS LP FOR SUSPENSION;ORAL
40MG
N050805 005 May 26, 2006

DOXYCYCLINE
AB
CHARTWELL LIFE SCI LTD
EQ 25MG BASE/5ML
A065454 001 Jul 16, 2008
AB
LUPIN LTD
EQ 25MG BASE/5ML
A201678 001 Mar 18, 2013
VIBRAMYCIN
AB
PFIZER
EQ 25MG BASE/5ML
N050006 001
AB
TABLET;ORAL

DOXYCYCLINE
AB
HERITAGE PHARMS INC
EQ 50MG BASE
A091608 001 Dec 20, 2011
AB
EQ 75MG BASE
A091608 002 Dec 20, 2011
AB
EQ 100MG BASE
A091608 003 Dec 20, 2011
AB
EQ 150MG BASE
A091608 004 Dec 20, 2011
AB
LANNETT CO INC
EQ 50MG BASE
A065285 001 Dec 08, 2005
AB
EQ 75MG BASE
A065285 002 Dec 08, 2005
AB
EQ 100MG BASE
A065285 003 Dec 08, 2005
AB
EQ 150MG BASE
A065285 004 Dec 08, 2005
AB
MYLAN
EQ 50MG BASE
A065377 001 Nov 07, 2006
AB
EQ 75MG BASE
A065377 002 Nov 07, 2006
AB
EQ 100MG BASE
A065377 003 Nov 07, 2006
AB
EQ 150MG BASE
A065427 001 Jun 07, 2007
AB
PAR PHARM
EQ 50MG BASE
A065070 001 Dec 15, 2000
AB
EQ 75MG BASE
A065070 002 Dec 15, 2000
AB
EQ 100MG BASE
A065070 003 Dec 15, 2000
AB
EQ 150MG BASE
A065070 004 Dec 15, 2000
AB
SUN PHARM INDs LTD
EQ 50MG BASE
A065356 001 May 31, 2006
AB
EQ 75MG BASE
A065356 002 May 31, 2006
AB
EQ 100MG BASE
A065356 003 May 31, 2006
AB
EQ 150MG BASE
A065356 004 Jul 29, 2010
AB
ZYDUS PHARMS USA INC
EQ 50MG BASE
A090982 001 Sep 28, 2017
AB
EQ 75MG BASE
A209582 002 Sep 28, 2017
AB
EQ 100MG BASE
A209582 003 Sep 28, 2017
AB
EQ 150MG BASE
A209582 004 Sep 28, 2017

DOXYCYCLINE CALCIUM
SUSPENSION;ORAL
VIBRAMYCIN
+! PFIZER
EQ 50MG BASE/5ML
N050480 001

DOXYCYCLINE HYCLATE
CAPSULE;ORAL

DOXYCYCLINE HYCLATE
AB
ACTAVIS LABS FL INC
EQ 50MG BASE
A062031 002 Oct 13, 1982
AB
EQ 100MG BASE
A062031 001
AB
AJANTA PHARMA LTD
EQ 50MG BASE
A211012 001 Sep 24, 2018
AB
EQ 100MG BASE
A211012 002 Sep 24, 2018
AB
ALEMBIC PHARMAS LTD
EQ 50MG BASE
A210527 001 Jun 13, 2018
AB
EQ 100MG BASE
A210527 002 Jun 13, 2018
AB
AMNEAL PHARMS
EQ 100MG BASE
A207289 001 Jun 27, 2016
AB
CHARITNELL LIFE SCI LTD
EQ 50MG BASE
A062030 001 Sep 11, 1984
AB
EQ 100MG BASE
A062030 002 Sep 11, 1984
AB
HIKMA INTL PHARMS
EQ 50MG BASE
A062396 001 Nov 07, 1984
AB
EQ 100MG BASE
A062396 002 Nov 07, 1984
AB
MYLAN
EQ 50MG BASE
A062337 001 May 07, 1984
AB
EQ 100MG BASE
A062337 002 May 07, 1984
AB
SUN PHARM INDUSTRIES
EQ 50MG BASE
A062676 001 Jul 10, 1986
AB
EQ 100MG BASE
A062676 002 Jul 10, 1986
AB
ZYDUS PHARMS USA INC
EQ 50MG BASE
A207774 001 May 31, 2018
DOXYCYCLINE HYCLATE
CAPSULE; ORAL

DOXYCYCLINE HYCLATE
AB EQ 100MG BASE A20774 002 May 31, 2018

VIBRAMYCIN
AB EQ 100MG BASE N05007 002

INJECTABLE; INJECTION

DOXY 100
AP EQ 100MG BASE/VIAL A062475 001 Dec 09, 1983

DOXY 200
AP EQ 200MG BASE/VIAL A062475 002 Dec 09, 1983

MYLAN LABS LTD
AP EQ 100MG BASE/VIAL A062421 001 Feb 02, 1983

WEST-WARD PHARMS INT
AP EQ 100MG BASE/VIAL A062569 001 Mar 09, 1988

ZYDUS PHARMS USA INC
AP EQ 100MG BASE/VIAL A207757 001 Sep 28, 2017

DOXYCYCLINE SYSTEM, EXTENDED RELEASE; PERIODONTAL

ATRIDOX
INT INC EQ 200MG BASE/VIAL A207757 002 Sep 28, 2017

TABLET; ORAL

ACTICLATE
AB +! AQUA PHARMS LLC EQ 75MG BASE N205931 001 Jul 25, 2014
AB +! DOXYCYCLINE HYCLATE EQ 150MG BASE N205931 002 Jul 25, 2014

ACTAVIS LABS FL INC
AB EQ 100MG BASE A090134 003 May 22, 2018
AB EQ 75MG BASE A090134 001 Dec 14, 2011
AB EQ 100MG BASE A090134 002 Dec 14, 2011

AMNEAL PHARMS CO
AB EQ 75MG BASE A029372 001 Feb 06, 2006
AB EQ 150MG BASE A029372 002 Oct 06, 2017

CARIBE HOLDINGS
AB EQ 100MG BASE A062269 002 Nov 09, 1982

CHARTWELL LIFE SCI
AB EQ 100MG BASE A062505 001 Sep 11, 1984

EMCURE PHARMS LTD
AB EQ 100MG BASE A209969 001 Nov 09, 1982

HIKMA INTL PHARMS
AB EQ 100MG BASE A065134 001 May 13, 2005

IVAX SUB TEVA PHARMS
AB EQ 20MG BASE A065163 001 May 13, 2005

LANNETT CO INC
AB EQ 20MG BASE A065277 001 Nov 09, 1982

LARKEN LABS
AB EQ 20MG BASE A065287 001 Feb 05, 2006
AB EQ 75MG BASE A065287 002 May 13, 2005

LUPIN LTD
AB EQ 150MG BASE A208818 001 May 13, 2005

MAYNE PHARMA INC
AB EQ 75MG BASE A029372 001 Feb 05, 2006
AB EQ 150MG BASE A029372 002 Oct 06, 2017

MYLAN
AB EQ 100MG BASE A062432 001 Feb 05, 2006

NOVEL LABS INC
AB EQ 100MG BASE A207538 001 May 13, 2005

SUN PHARM INDUSTRIES
AB EQ 20MG BASE A065134 002 May 13, 2005

ZYDUS PHARMS USA INC
AB EQ 100MG BASE A207773 001 Oct 03, 2017

TABLET, DELAYED RELEASE; ORAL

DORYX
AB + MAYNE PHARMA EQ 50MG BASE N050795 006 Dec 19, 2014
AB + EQ 75MG BASE N050795 001 May 06, 2005
AB + EQ 100MG BASE N050795 002 May 06, 2005
AB + EQ 150MG BASE N050795 003 Jun 20, 2008
AB +! EQ 200MG BASE N050795 005 Apr 11, 2013

DOXYCYCLINE HYCLATE
AB ACTAVIS ELIZABETH EQ 50MG BASE A090134 003 May 22, 2018
AB EQ 75MG BASE A090134 001 Dec 14, 2011
AB EQ 100MG BASE A090134 002 Dec 14, 2011

HERITAGE PHARMS INC
AB EQ 75MG BASE A200856 001 Apr 30, 2013
AB EQ 100MG BASE A200856 002 Apr 30, 2013

MYLAN
AB EQ 50MG BASE A090431 003 May 22, 2018
AB EQ 75MG BASE A090431 001 Dec 29, 2010
AB EQ 100MG BASE A090431 002 Dec 29, 2010

PRINSTON INC
AB EQ 150MG BASE A207494 001 Nov 13, 2018
AB EQ 200MG BASE A207494 002 Nov 13, 2018

ZYDUS PHARMS USA
AB EQ 50MG BASE A206772 001 Dec 21, 2018
<table>
<thead>
<tr>
<th>DOXYCYCLINE HYCLATE</th>
<th>TABLET, DELAYED RELEASE; ORAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB INC</td>
<td>EQ 100MG BASE</td>
</tr>
<tr>
<td>AB DORYX MPC</td>
<td>EQ 150MG BASE</td>
</tr>
<tr>
<td>+! MAYNE PHARMA</td>
<td>EQ 120MG BASE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOXYCYCLINE HYCLATE</th>
<th>INC</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB INC</td>
<td></td>
</tr>
<tr>
<td>AB DORYX MPC</td>
<td></td>
</tr>
<tr>
<td>+! MAYNE PHARMA</td>
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</tr>
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</table>

<table>
<thead>
<tr>
<th>DOXYLAMINE SUCINATE; PYRIDOXINE HYDROCHLORIDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TABLET, DELAYED RELEASE; ORAL</td>
</tr>
<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>AB DUCHESNAY</td>
</tr>
<tr>
<td>AB ACTAVIS LABS FL INC</td>
</tr>
<tr>
<td>AB PAR PHARM INC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOXYLAMINE SUCINATE AND PYRIDOXINE HYDROCHLORIDE</th>
</tr>
</thead>
</table>
| TABLET, EXTENDED RELEASE; ORAL;
| BONJESTA                                         |
| +! DUCHESNAY                                     | 20MG:20MG | N209661 001 Nov 07, 2016 |

<table>
<thead>
<tr>
<th>DROXABINOL</th>
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| DROSPERONE; ETHINYL ESTRADIOL | LO-ZUMANDIMINE |
| 3MG:0.02MG                    | A209632 001 Feb 27, 2018 |
| DROSPERONE; ETHINYL ESTRADIOL | LORNA       |
| 3MG:0.02MG                    | A079221 001 Mar 28, 2011 |
### DROSPIRENONE; ETHINYL ESTRADIOL

**TABLET; ORAL**

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### DROSPIRENONE AND ETHINYL ESTRADIOL

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### DROXIDOPA

**CAPSULE; ORAL**

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### DULOXETINE HYDROCHLORIDE

**CAPSULE, DELAYED REL PELLETS; ORAL**

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### Duloxetine Hydrochloride

**Capsule, Delayed Rel Pellets; Oral**

#### Duloxetine Hydrochloride LTD

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### Dutasteride

**Capsule; Oral**

#### Avodart

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#### Dutasteride

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N208351 001 Mar 01, 2016

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N202123 001 Aug 10, 2011

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AB + 133MG; 200MG A209721 002 Aug 22, 2018
AB + 167MG; 250MG A209721 003 Aug 22, 2018
AB +! 200MG; 300MG A209721 004 Aug 22, 2018

AB AIROBINDO PHARMA LTD
200MG; 300MG A090513 001 Jan 26, 2018

AB MYLAN PHARMS INC
200MG; 300MG A206436 001 Apr 09, 2018
AB +! GILEAD
100MG; 150MG N021752 002 Mar 10, 2016
AB + 133MG; 200MG N021752 003 Mar 10, 2016
AB + 167MG; 250MG N021752 004 Mar 10, 2016
AB +! 200MG; 300MG N021752 001 Aug 02, 2004

TRACTA
FOR SOLUTION; ORAL
EPANED KIT
+! SILVERGATE PHARMS 1MG/ML N204308 001 Aug 13, 2013

EPANED SOLUTION; ORAL
+! SILVERGATE PHARMS 1MG/ML N208686 001 Sep 20, 2016

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AB 5MG A075178 001 Mar 23, 2001
AB 10MG A075178 003 Mar 23, 2001
AB 20MG A075178 004 Mar 23, 2001

AB MYLAN 2.5MG A075480 002 Aug 22, 2000
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AB 10MG A075480 003 Aug 22, 2000
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AB 5MG A075496 002 Aug 22, 2000
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AB 20MG A075496 005 Aug 22, 2000
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AB 20MG A075657 004 Jan 23, 2001
AB TEVA 2.5MG A075479 001 Aug 22, 2000
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AB 10MG A075479 003 Aug 22, 2000
AB 20MG A075479 004 Aug 22, 2000
AB WOCKHARDT LTD 2.5MG A075483 001 Aug 22, 2000
AB 5MG A075483 002 Aug 22, 2000
AB 10MG A075483 003 Aug 22, 2000
AB 20MG A075483 004 Aug 22, 2000

VASOTEC
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ENOXAPARIN SODIUM (PRESERVATIVE FREE)

AP 100MG/ML (100MG/ML) A076726 005 Jun 23, 2014
AP 120MG/0.8ML (150MG/ML) A076726 006 Jun 23, 2014
AP 150MG/ML (150MG/ML) A076726 007 Jun 23, 2014

LOVENOX (PRESERVATIVE FREE)

AP + SANOFI AVENTIS US 30MG/0.3ML (100MG/ML) N020164 001 Mar 29, 1993
AP + 40MG/0.4ML (100MG/ML) N020164 002 Jan 30, 1998
AP + 60MG/0.6ML (100MG/ML) N020164 003 Mar 27, 1998
AP + 80MG/0.8ML (100MG/ML) N020164 004 Mar 27, 1998
AP +! 100MG/ML (100MG/ML) N020164 005 Mar 27, 1998
AP + 120MG/0.8ML (150MG/ML) N020164 007 Jun 02, 2000
AP + 150MG/ML (150MG/ML) N020164 008 Jun 02, 2000

ENTACAPONE
TABLET; ORAL
COMTAN

AB +! ORION PHARMA 200MG N020796 001 Oct 19, 1999

ENTACAPONE

AB AJANTA PHARMA LTD 200MG A205792 001 Aug 31, 2017
AB AUROBINDO PHARMA LTD 200MG A203437 001 Jun 19, 2015
AB MACLEODS PHARMS LTD 200MG A207210 001 Jun 05, 2017
AB SUN PHARMA GLOBAL 200MG A090690 001 Jul 16, 2012
AB SUNSHINE LAKE 200MG A206669 001 Oct 03, 2018
AB WOCKHARDT LTD 200MG A078941 001 Aug 16, 2012

ENTECAVIR
SOLUTION; ORAL
BARACLUDE

AB +! BRISTOL MYERS SQUIBB 0.05MG/ML N021798 001 Mar 29, 2005

BARACLUDE
TABLET; ORAL

AB + BRISTOL MYERS SQUIBB 0.5MG N021797 001 Mar 29, 2005
AB +! 1MG N021797 002 Mar 29, 2005

ENTECAVIR

AB ACCORD HLTHCARE 0.5MG A205824 001 Aug 25, 2017
AB AMNEAL PHARMS 0.5MG A206652 001 Nov 12, 2015
AB AUROBINDO PHARMA LTD 0.5MG A206652 002 Nov 12, 2015
AB BRECKENRIDGE PHARM 1MG A206217 001 Aug 26, 2015
AB CASI PHARMS INC 0.5MG A208721 001 Mar 15, 2018
AB CIPLA 1MG A206740 001 Aug 21, 2015
AB CIPLA 1MG A208721 002 Mar 15, 2018
AB HETERO LABS LTD V 0.5MG A206872 002 Dec 06, 2016
AB PAR PHARM INC 0.5MG A206294 001 Nov 23, 2016
AB PRINSTON INC 0.5MG A206294 002 Nov 23, 2016
AB TEVA PHARMS USA 0.5MG A202122 001 Aug 26, 2014
AB ZYDUS PHARMS USA INC 0.5MG A206745 001 Jun 23, 2017
AB 1MG A206745 002 Jun 23, 2017

ENZALUTAMIDE
CAPSULE; ORAL
XTANDI

AB +! ASTELLAS 40MG N203415 001 Aug 31, 2012
EPHEDRINE SULFATE
SOLUTION; INTRAVENOUS

AKOVAZ
AP +! FLAMEL IRELAND LTD 50MG/ML (50MG/ML) N208289 001 Apr 29, 2016
CORPEDRA
AP PAR STERILE PRODUCTS 50MG/ML (50MG/ML) N208943 001 Jan 27, 2017
EPHEDRINE SULFATE
AP AKORN INC 50MG/ML (50MG/ML) N208609 001 Mar 01, 2017
AP SANDOZ INC 50MG/ML (50MG/ML) A209784 001 Aug 23, 2017

EPINASTINE HYDROCHLORIDE
SOLUTION/DROPS; OPHTHALMIC

ELESTAT
AT +! ALLERGAN 0.05% N021565 001 Oct 16, 2003

EPINEPHrine
INJECTABLE; INTRAMUSCULAR, SUBCUTANEOUS

EPINEPHrine (AUTOJECTOR)
AB TEVA PHARMS USA 0.15MG/DELIVERY A090589 002 Aug 16, 2018
AB 0.3MG/DELIVERY A090589 001 Aug 16, 2018

EPINTEN
AB +! MYLAN SPECIALITY LP 0.3MG/DELIVERY N019430 001 Dec 22, 1987
EPINTEN JR.
AB +! MYLAN SPECIALITY LP 0.15MG/DELIVERY N019430 002 Dec 22, 1987

ADRENACLICK
BX +! IMPAX EQ 0.15MG/DELIVERY N020800 003 Nov 25, 2009
BX +! EQ 0.3MG/DELIVERY N020800 004 Nov 25, 2009

EPINEPHrine BITARTRATE; LIDOCAINE HYDROCHLORIDE
INJECTABLE; INJECTION

LIGNOSPAN FORTE
+! DEPROCO EQ 0.02MG BASE/ML; 2% A088389 001 Jan 22, 1985
LIGNOSPAN STANDARD
+! DEPROCO EQ 0.01MG BASE/ML; 2% A088390 001 Jan 22, 1985

LIGNOSPAN FORTE DENTAL
+! DENTSPLY PHARM 0.005MG/ML; 4% N021383 001

PRIOCAINE HYDROCHLORIDE AND EPINEPHrine BITARTRATE
INJECTABLE; INJECTION

CITANEST FORTE DENTAL
AP +! SEPTODONT INC 0.005MG/ML; 4% A078959 001 Aug 30, 2011
| EPINEPHRINE; LIDOCAINE HYDROCHLORIDE |  |
| INJECTABLE; INJECTION |  |
| LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE |  |
| HOSPIRA | 0.005MG/ML: 0.5% | A089635 001 | Jun 21, 1988 |
| HOSPIRA | 0.005MG/ML: 1.5% | A088571 001 | Sep 13, 1985 |
| HOSPIRA | 0.005MG/ML: 1.5% | A089564 001 | Jun 21, 1988 |
| HOSPIRA | 0.005MG/ML: 2% | A089651 001 | Jun 21, 1988 |
| HOSPIRA | 0.01MG/ML: 1.5% | A089644 001 | Jun 21, 1988 |
| HOSPIRA | 0.01MG/ML: 2% | A089648 001 | Jun 21, 1988 |
| FRESENIUS KABI USA | 0.005MG/ML: 0.5% | N006488 012 |
| FRESENIUS KABI USA | 0.005MG/ML: 1.5% | N006488 017 |
| FRESENIUS KABI USA | 0.005MG/ML: 2% | N006488 019 | Nov 13, 1986 |
| FRESENIUS KABI USA | 0.01MG/ML: 1% | N006488 004 |
| FRESENIUS KABI USA | 0.02MG/ML: 2% | N006488 005 |
| FRESENIUS KABI USA | 0.005MG/ML: 1% | N006488 018 | Nov 13, 1986 |

| EPIRUBICIN HYDROCHLORIDE |  |
| INJECTABLE; INJECTION |  |
| ELLENCE | 200MG/100ML (2MG/ML) | N050778 001 | Sep 15, 1999 |
| ELLENCE | 50MG/25ML (2MG/ML) | N050778 002 | Sep 15, 1999 |
| ACTAVIS TOTOWA | 10MG/5ML (2MG/ML) | A065445 001 | Sep 18, 2008 |
| ACTAVIS TOTOWA | 50MG/25ML (2MG/ML) | A065445 002 | Sep 18, 2008 |
| ACTAVIS TOTOWA | 200MG/100ML (2MG/ML) | A065445 003 | Sep 18, 2008 |
| AKORN INC | 50MG/25ML (2MG/ML) | A090163 001 | Jun 24, 2009 |
| FRESENIUS KABI USA | 200MG/100ML (2MG/ML) | A065408 001 | Oct 15, 2007 |
| FRESENIUS KABI USA | 50MG/25ML (2MG/ML) | A065408 002 | Oct 15, 2007 |
| FRESENIUS KABI USA | 150MG/75ML (2MG/ML) | A065408 003 | Oct 15, 2007 |
| FRESENIUS KABI USA | 200MG/100ML (2MG/ML) | A065408 004 | Oct 15, 2007 |
| FRESENIUS KABI USA | 200MG/100ML (2MG/ML) | A065411 001 | Aug 20, 2007 |
| FRESENIUS KABI USA | 50MG/25ML (2MG/ML) | A065411 002 | Aug 20, 2007 |
| HISUN PHARM HANGZHOU | 200MG/100ML (2MG/ML) | A090078 001 | Mar 25, 2010 |
| HOSPIRA | 200MG/100ML (2MG/ML) | A090075 002 | Mar 25, 2010 |
| HOSPIRA | 10MG/5ML (2MG/ML) | A065343 001 | Apr 19, 2007 |
| HOSPIRA | 150MG/75ML (2MG/ML) | A065343 001 | Apr 19, 2007 |
| HOSPIRA | 200MG/100ML (2MG/ML) | A065343 004 | Apr 19, 2007 |
| IMPAX LABS INC | 50MG/25ML (2MG/ML) | A065331 001 | Aug 09, 2007 |
| MYLAN LABS LTD | 50MG/25ML (2MG/ML) | A065331 002 | Aug 09, 2007 |
| WEST-WARD PHARMS INT | 50MG/25ML (2MG/ML) | A065289 001 | Jun 27, 2007 |
| WEST-WARD PHARMS INT | 200MG/100ML (2MG/ML) | A065289 002 | Jun 27, 2007 |

| EPLERENONE |  |
| TABLET; ORAL |  |
| EPLERENONE | 25MG | A026922 001 | Jul 13, 2017 |
| ACCORD HLTHCARE | 25MG | A026922 002 | Jul 13, 2017 |
| APOTEX | 25MG | A078482 001 | Jul 30, 2008 |
| APOTEX | 50MG | A078482 002 | Jul 30, 2008 |
| BRECKENRIDGE PHARM | 25MG | A028283 001 | Sep 14, 2018 |
| MYLAN PHARMS INC | 25MG | A028283 002 | Sep 14, 2018 |
| SANDOZ | 25MG | A078510 001 | Aug 01, 2008 |
| SANDOZ | 25MG | A078510 002 | Aug 01, 2008 |
| INSPIRA | 25MG | N021437 001 | Sep 27, 2002 |
| GD SEARLE LLC | 25MG | N021437 002 | Sep 27, 2002 |

| EPOPROSTENOL SODIUM |  |
| INJECTABLE; INJECTION |  |
| TEVA PHARM USA | EQ 0.5MG BASE/VIAL | A078396 001 | Apr 23, 2008 |
| TEVA PHARM USA | EQ 1.5MG BASE/VIAL | A078396 002 | Apr 23, 2008 |
| GLAXOSMITHKLINE LLC | EQ 0.5MG BASE/VIAL | N020444 001 | Sep 20, 1995 |
| GLAXOSMITHKLINE LLC | EQ 1.5MG BASE/VIAL | N020444 002 | Sep 20, 1995 |
### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

#### PRESCRIPTION DRUG PRODUCT LIST

- **EPOPROSTENOL SODIUM**
  - **Injectable; Injection**
  - **VELETRI**
    - + ACTELION PHARMS LTD EQ 0.5MG BASE/VIAL N022260 002 Jun 28, 2012
    - +! EQ 1.5MG BASE/VIAL N022260 001 Jun 27, 2008

- **EPROSARTAN MESYLATE**
  - **Tablet; Oral**
  - **EPROSARTAN MESYLATE**
    - AB MYLAN PHARMS INC EQ 400MG BASE A202012 001 Nov 16, 2011
    - AB ! EQ 600MG BASE A202012 002 Nov 16, 2011

- **EPTIFIBATIDE**
  - **Injectable; Injection**
  - **EPTIFIBATIDE**
    - AP ACCORD HLTHCARE 2MG/ML A205557 001 Nov 06, 2017
    - AP AKORN 75MG/100ML A205557 002 Nov 06, 2017
    - AP AKORN 75MG/100ML A204589 001 Apr 18, 2017
    - AP AMNEAL PHARMS 2MG/ML A205581 001 Dec 08, 2016
    - AP AUROBINDO PHARMA LTD 2MG/ML A206127 001 Dec 08, 2015
    - AP CELYX PHARMS 75MG/100ML A206127 002 Dec 08, 2015
    - AP CELYX PHARMS 75MG/100ML A208554 001 Nov 23, 2018
    - AP MYSAN LABS LTD 2MG/ML A208554 002 Nov 23, 2018
    - AP MYSAN LABS LTD 75MG/100ML A203258 001 Jul 20, 2018
    - AP MYSAN LABS LTD 75MG/100ML A203258 002 Jul 20, 2018
    - AP SAGENT PHARMA 2MG/ML A204693 001 Mar 07, 2018
    - AP SAGENT PHARMA 75MG/100ML A204693 002 Mar 07, 2018
    - AP TEVA PHARMS USA 2MG/ML A090554 001 Jun 12, 2015
    - INTEGRILIN
      - AP +! SCHERING 2MG/ML A020718 001 May 18, 1998
      - AP +! 75MG/100ML A020718 002 May 18, 1998
    - ERVACYCLINE DIHYDROCHLORIDE
      - Powder; Intravenous
      - XERAVA
        - +! TETRAPHASE PHARMS EQ 50MG BASE/VIAL N211109 001 Aug 27, 2018
    - ERGOCALCIFEROL
      - Capsule; Oral
      - DRISDOL
        - AA +! US PHARM HOLDINGS 50,000 IU A003444 001
      - ERGOCALCIFEROL
        - AA ORIT LABS LLC 50,000 IU A040833 001 May 20, 2009
        - AA PURACAP PHARM LLC 50000IU A204476 001 Dec 07, 2018
        - AA SIGMAPHARM LABS LLC 50,000 IU A204476 002 Dec 07, 2018
        - AA STRIDES PHARMA 50,000 IU A090455 001 Aug 03, 2010
        - A STRIDES PHARMA IND S 50,000 IU A090455 002 Dec 29, 2009
    - VITAMIN D
      - AA +! BIONPHARMA INC 50,000 IU A080704 001
    - ERGOLOID MESYLATES
      - Tablet; Oral
      - ERGOLOID MESYLATES
        - ! SUN PHARM INDUSTRIES 1MG A081113 001 Oct 31, 1991
    - ERGOTAMINE TARTRATE
      - Tablet; Sublingual
      - ERGOMAR
        - ! TERSERA THERAPS LLC 2MG A087693 001 Feb 24, 1983
    - ERIEBULIN MESYLATE
      - Solution; Intravenous
      - HALAVEN
        - +! EISAI INC 1MG/2ML (0.5MG/ML) N201532 001 Nov 15, 2010
    - ERLOTINIB HYDROCHLORIDE
      - Tablet; Oral
      - TARCEVA
        - + OSI PHARMS EQ 25MG BASE N021743 001 Nov 18, 2004
        - + EQ 100MG BASE N021743 002 Nov 18, 2004
        - +! EQ 150MG BASE N021743 003 Nov 18, 2004
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<td>+ MERCK SHARP DOHME</td>
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CREAM; TOPICAL, VAGINAL
PREMARIN
+! WYETH PHARMS 0.625MG/GM N020216 001
INJECTABLE; INJECTION
PREMARIN
+! WYETH PHARMS 25MG/VIAL N010402 001
TABLET; ORAL
PREMARIN
+ WYETH PHARMS 0.3MG N004782 003
+ 0.45MG N004782 006 Jul 16, 2003
+! 0.625MG N004782 004
+! 0.9MG N004782 005 Jan 26, 1984
+! 1.25MG N004782 001

ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE
TABLET; ORAL-28
PREMPHASE 14/14
+! WYETH PHARMS 0.625MG, 0.625MG; N/A, 5MG N020527 002 Nov 17, 1995
PREMPRO
+! WYETH PHARMS 0.3MG; 1.5MG
+! 0.45MG; 1.5MG N020527 005 Jun 04, 2003
+! 0.625MG; 2.5MG
+! 0.625MG; 5MG N020527 001 Nov 17, 1995

ESTROGENS, ESTERIFIED
TABLET; ORAL
MENEST
MONARCH PHARMS 0.3MG A084951 001
0.625MG A084948 001
1.25MG A084950 001
2.5MG A084949 001

ESTROPIPATATE
TABLET; ORAL
ESTROPIPATATE
MYLAN 0.75MG A040359 001 Aug 26, 1999
1.5MG A040359 002 Aug 26, 1999
OGEN 5
PHARMACIA AND UPJOHN 6MG A083220 004

ESZOPICLONE
TABLET; ORAL
ESZOPICLONE
AB AUROBINDO PHARMA LTD 1MG A208451 001 Sep 15, 2016
AB 2MG A208451 002 Sep 15, 2016
AB 3MG A208451 003 Sep 15, 2016
AB DR REDDYS LABS LTD 1MG A091024 001 Apr 15, 2014
AB 2MG A091024 002 Apr 15, 2014
AB 3MG A091024 003 Apr 15, 2014
AB GLENMARK GENERICS 1MG A091166 001 Apr 15, 2014
AB 2MG A091166 002 Apr 15, 2014
AB 3MG A091166 003 Apr 15, 2014
AB LUPIN LTD 1MG A091244 001 Sep 13, 2011
AB 2MG A091244 002 Sep 13, 2011
AB 3MG A091244 003 Sep 13, 2011
AB MACLEODS PHARMS LTD 1MG A202929 001 Jan 30, 2015
AB 2MG A202929 002 Jan 30, 2015
AB 3MG A202929 003 Jan 30, 2015
AB MYLAN PHARMS INC 1MG A091153 001 Mar 26, 2013
AB 2MG A091153 002 Mar 26, 2013
AB 3MG A091153 003 Mar 26, 2013
AB ORCHID HLTHCARE 1MG A091153 001 Jun 10, 2014
AB 2MG A091153 002 Jun 10, 2014
AB 3MG A091153 003 Jun 10, 2014
AB SUN PHARMA GLOBAL 1MG A091153 001 Apr 03, 2013
AB 2MG A091153 002 Apr 03, 2013
AB 3MG A091153 003 Apr 03, 2013
AB TEVA 1MG A091153 001 May 23, 2011
AB 2MG A091153 002 May 23, 2011
AB 3MG A091153 003 May 23, 2011
AB WEST-WARD PHARMS INT
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| AB GLENMARK GENERICS 0.03MG; 0.15MG |
| DAYSEE 0.03MG; 0.01MG; 0.15MG N/A |
| AB LUPIN LTD 0.03MG; 0.15MG |
| FAVOGIN 0.02MG; 0.15MG 0.025MG; 0.15MG 0.03MG 0.15MG |
| ICLEVIA 0.03MG 0.15MG |
| AB AUROBINDO PHARMA LTD 0.03MG; 0.15MG |
| INTROVALE 0.03MG; 0.15MG |
| AB LABS LEON FARMA 0.03MG; 0.01MG; 0.15MG N/A |
| JAMIESSE 0.03MG; 0.01MG; 0.15MG N/A |
| LEVONORGESTREL AND ETHINYL ESTRADIOL |
| AB AMNEAL PHARMS 0.03MG 0.15MG |
| AB GLENMARK GENERICS 0.02MG; 0.05MG |
| AB GLENMARK PHARMS LTD 0.05MG; 0.15MG |
| AB LUPIN LTD 0.02MG; 0.15MG 0.03MG; 0.15MG |
| AB MYLAN LABS LTD 0.03MG; 0.15MG |
| AB WATSON LABS 0.02MG; 0.09MG |
| LO SIMPESSE 0.02MG; 0.1MG 0.01MG N/A |
| AB AUROBINDO PHARMA LTD 0.02MG; 0.1MG 0.01MG N/A |
| LOSEASONIQUE 0.02MG; 0.1MG 0.01MG N/A |
| AB TEVA BRANDED PHARM 0.02MG; 0.1MG 0.01MG N/A |
| AB QUARTETTE 0.02MG; 0.15MG 0.025MG; 0.15MG 0.03MG 0.15MG 0.01MG N/A |
| AB AUROBINDO PHARMA LTD 0.02MG; 0.15MG 0.03MG; 0.15MG |
| AB WATSON LABS 0.03MG; 0.15MG |
| AB QUASENSE 0.03MG; 0.15MG |
| SEASONALE 0.03MG; 0.01MG; 0.15MG N/A |
| AB TEVA BRANDED PHARM 0.03MG; 0.15MG |
| SEASONIQUE 0.03MG; 0.01MG; 0.15MG N/A |
| AB TEVA BRANDED PHARM 0.03MG 0.01MG; 0.15MG N/A |
| AB NOVAST LABS 0.03MG; 0.15MG |
| AB AUROBINDO PHARMA LTD 0.03MG; 0.01MG; 0.15MG N/A |
| TABLET; ORAL-28 |
| BALCOTRA 0.03MG; 0.15MG |
| ALTAVERA 0.03MG 0.15MG |
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| AB AUROBINDO PHARMA LTD 0.03MG 0.15MG |
| ELIPFEM 0.03MG 0.04MG 0.03MG; 0.05MG 0.075MG 0.1 0.25MG |
| ENPRESSE-28 0.03MG 0.04MG 0.03MG; 0.05MG 0.075MG 0.1 0.25MG |
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| AB LUPIN LTD 0.03MG; 0.15MG |

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| ETHINYL ESTRADIOL; NORELGESTROM FIBRINOL 
**AB** MYLAN TECHNOLOGIES 0.035MG/24HR; 0.15MG/24HR | A200910 001 Apr 16, 2014 |
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<td>ETHINYL ESTRADIOL; NORGESTREL TABLET; ORAL-21 CRYSELLE</td>
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ETHINYL ESTRADIOL; NORGESTREL
TABLET; ORAL-28
OESTREL 0.5/50-28
  ! WATSON LABS 0.05MG; 0.5MG A075406 002 Dec 15, 1999

ETHINYL ESTRADIOL; SEGESTERONE ACETATE
RING; VAGINAL
ANNOVERA
  ! THERAPEUTICSMD INC 0.013MG/24HR; 0.15MG/24HR N209627 001 Aug 10, 2018

ETHIOPIRED OIL
OIL; INTRALYMPHATIC, INTRAUTERINE
LIPIODOL
  ! GUERBET EQ 4.8GM IODINE/10ML (EQ 480MG IODINE/ML) N009190 001

ETHIONAMIDE
TABLET; ORAL
TRECATOR
  ! WYETH PHARMS 250MG A040686 001 May 28, 2008

ETHOSUXIMIDE
CAPSULE; ORAL
ETHOSUXIMIDE
  AB AKORN 250MG A040686 001 May 28, 2008
  AB BIONPHARMA INC 250MG A040430 001 Oct 28, 2002
  AB HERITAGE PHARMS INC 250MG A200892 001 Sep 25, 2012

ZARONTIN
  AB +! PARKE DAVIS 250MG N013026 002

ETHOSUXIMIDE
SYRUP; ORAL
ETHOSUXIMIDE
  AA MIKART 250MG/5ML A040506 001 Dec 22, 2003
  AA PHARM ASSOC 250MG/5ML A040253 001 Nov 22, 2000
  AA TEVA PHARMS 250MG/5ML A081306 001 Jul 30, 1993

ZARONTIN
  AA +! PARKE-DAVIS 250MG/5ML A080258 001

ETHOTOIN
TABLET; ORAL
PEGANONE
  +! RECORDATI RARE 250MG N010841 001

ETIDRONATE DISODIUM
TABLET; ORAL
ETIDRONATE DISODIUM
MYLAN
  200MG A075800 001 Jan 24, 2003
  ! 400MG A075800 002 Jan 24, 2003

ETODOLAC
CAPSULE; ORAL
ETODOLAC
  AB ANI PHARMS INC 200MG A075126 001 Sep 16, 1999
  AB 300MG A075126 002 Sep 16, 1999
  AB APOTEX 200MG A075419 001 Jul 28, 2000
  AB 300MG A075419 002 Jul 28, 2000
  AB TARO 200MG A075078 001 Apr 30, 1998
  AB 300MG A075078 002 Apr 30, 1998

ETODOLAC TABLET; ORAL
ETODOLAC
  AB AMNEAL PHARMS CO 400MG A208834 001 Jun 07, 2018
  AB 500MG A208834 002 Jun 07, 2018
  AB APOTEX INC 400MG A076004 001 Dec 03, 2002
  AB 500MG A076004 002 Dec 03, 2002
  AB EDENBRIDGE PHARMS 400MG A209888 001 Nov 30, 2018
  AB 500MG A209888 002 Nov 30, 2018
  AB SANDOZ 400MG A074903 001 Apr 11, 1997
  AB 500MG A074903 002 Apr 19, 1999
  AB TARO PHARM IND 400MG A075074 001 Mar 11, 1998
  AB 500MG A075074 002 Apr 25, 2000
  AB TEVA 400MG A075009 001 Nov 26, 1997
  AB 500MG A075009 002 Dec 28, 1999

ETODOLAC TABLET, EXTENDED RELEASE; ORAL
ETODOLAC
  AB TARO 400MG A076174 001 Mar 13, 2003
  AB 500MG A076174 002 Mar 13, 2003
  AB 600MG A076174 003 Mar 13, 2003
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<tr>
<th>Name</th>
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<tr>
<td><strong>ETODOLAC</strong></td>
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<td><strong>TEVA</strong></td>
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<td><strong>ETOMIDATE</strong></td>
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<td><strong>HOSPIRA</strong></td>
<td>2MG/ML</td>
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<td><strong>AUROBINDO PHARMA LTD</strong></td>
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<td><strong>EMCURE PHARMS LTD</strong></td>
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<td><strong>GLAND PHARMA LTD</strong></td>
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<td><strong>HIKMA FARMACEUTICA</strong></td>
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<td><strong>LUITPOLD</strong></td>
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<td><strong>MYLAN LABS LTD</strong></td>
<td>2MG/ML</td>
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<td><strong>PAR STERILE PRODUCTS</strong></td>
<td>2MG/ML</td>
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<td><strong>WEST-WARD PHARMS</strong></td>
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<td><strong>ZYDUS PHARMS USA INC</strong></td>
<td>2MG/ML</td>
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<td><strong>ETONOGESTREL</strong></td>
<td>Implant; Implantation</td>
<td><strong>ORGANON USA INC</strong></td>
<td>68MG/IMPLANT</td>
<td>N021529 002</td>
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<td><strong>MYLAN</strong></td>
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<td><strong>ETOPOSIDE</strong></td>
<td>Capsule; Oral</td>
<td><strong>ACCORD HLTHCARE</strong></td>
<td>20MG/ML</td>
<td>A074513 001</td>
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<td><strong>FRESENIUS KABI USA</strong></td>
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<td><strong>TEVA PHARMS USA</strong></td>
<td>20MG/ML</td>
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<td><strong>ETOPOSIDE PHOSPHATE</strong></td>
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<td><strong>BRISTOL MYERS</strong></td>
<td>EQ 100MG BASE/VIAL</td>
<td>N020457 001</td>
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<td><strong>ETRAVIRINE</strong></td>
<td>Tablet; Oral</td>
<td><strong>JANSSEN R AND D</strong></td>
<td>25MG</td>
<td>N022187 003</td>
<td>Mar 26, 2012</td>
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<td><strong>JANSSEN R AND D</strong></td>
<td>100MG</td>
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<td><strong>EVEROLIMUS</strong></td>
<td>Tablet; Oral</td>
<td><strong>NOVARTIS</strong></td>
<td>0.25MG</td>
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<td><strong>NOVARTIS</strong></td>
<td>0.5MG</td>
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<td><strong>NOVARTIS</strong></td>
<td>0.75MG</td>
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<td><strong>AFINITOR</strong></td>
<td>2.5MG</td>
<td>N022334 003</td>
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<td><strong>AFINITOR</strong></td>
<td>5MG</td>
<td>N022334 004</td>
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### Everolimus

**Tablet; Oral**

**Afinitor**

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<td>7.5mg</td>
<td>N022334 004</td>
<td>Mar 30, 2012</td>
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<td>+</td>
<td>10mg</td>
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**Tablet, for Suspension; Oral**

**Afinitor Disperz**

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<td>Novartis Pharm</td>
<td>2mg</td>
<td>N023985 001</td>
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<td>+</td>
<td>3mg</td>
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### Exemestane

**Tablet; Oral**

**Aromasin**

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<td>Pharamcia and Upjohn</td>
<td>25mg</td>
<td>N020753 001</td>
<td>Oct 21, 1999</td>
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**Exemestane**

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<td>AlvoGen Malta</td>
<td>25mg</td>
<td>A200898 001</td>
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<td>Amneal Pharma</td>
<td>25mg</td>
<td>A204621 001</td>
<td>Dec 28, 2018</td>
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<td>Cipla</td>
<td>25mg</td>
<td>A210323 001</td>
<td>Apr 27, 2018</td>
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<td>Mylan Pharma</td>
<td>25mg</td>
<td>A203315 001</td>
<td>Mar 10, 2017</td>
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<td>Upsher Smith Labs</td>
<td>25mg</td>
<td>A209208 001</td>
<td>Jul 26, 2017</td>
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<td>West-Ward Pharma</td>
<td>25mg</td>
<td>A077431 001</td>
<td>Apr 01, 2011</td>
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<td>Zydus Pharma USA Inc</td>
<td>25mg</td>
<td>A202602 001</td>
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### Exenatide

**Suspension, Extended Release; Subcutaneous**

**Bydureon BCise**

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<tr>
<td>AstraZeneca AB</td>
<td>2mg/0.85ml (2mg/0.85ml)</td>
<td>N029210 001</td>
<td>Oct 20, 2017</td>
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**Exenatide Synthetic**

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<tr>
<td>AstraZeneca AB</td>
<td>2mg/vial</td>
<td>N022200 001</td>
<td>Jan 27, 2012</td>
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<td>Bydureon Pen</td>
<td>2mg</td>
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**Injectable; Subcutaneous**

**Byetta**

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<td>AstraZeneca AB</td>
<td>300mcg/1.2ml (250mcg/ml)</td>
<td>N021773 001</td>
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<td>600mcg/2.4ml (250mcg/ml)</td>
<td>N021773 002</td>
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### Ezetimibe

**Tablet; Oral**

**Ezetimibe**

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<td>Accord HLTHCare</td>
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<td>Alkem Labs Ltd</td>
<td>10mg</td>
<td>A209234 001</td>
<td>Dec 21, 2017</td>
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<td>Amneal Pharma</td>
<td>10mg</td>
<td>A208803 001</td>
<td>Jun 12, 2017</td>
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<td>Apotex Inc</td>
<td>10mg</td>
<td>A208332 001</td>
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<td>Aurobindo Pharma Ltd</td>
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<td>Aug 25, 2017</td>
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<td>Glenmark Pharma Ltd</td>
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<td>Ohm Labs Inc</td>
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**Zetia**

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<td>MSD Intl Gmbh</td>
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### Ezetimibe; Simvastatin

**Tablet; Oral**

**Ezetimibe and Simvastatin**

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### EZETIMIBE; SIMVASTATIN

**Tablet; Oral**

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**AB**

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### FAMCICLOVIR

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### FAMOTIDINE

**FOR SUSPENSION; ORAL**

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<td>NOVEL LABS INC</td>
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**Injectable; Injection**

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### FAMOTIDINE PRESERVATIVE FREE

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**FAMOTIDINE PRESERVATIVE FREE IN PLASTIC CONTAINER**

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### Famotidine

**Tablet, Oral**

**Famotidine**

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### Fexofenadine; Ibuprofen

**Tablet, Oral**

**DUEXIS +! HORIZON 26.6MG;800MG**

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### Felbamate

**Suspension, Oral**

**Felbamate**

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### Felodipine

**Tablet, Extended Release, Oral**

**Felodipine**

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FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

FENTANYL-62
MYLAN TECHNOLOGIES 62.5MCG/HR A076258 007 Dec 29, 2014

FENTANYL-87
MYLAN TECHNOLOGIES 87.5MCG/HR A076258 008 Dec 29, 2014

SPRAY; SUBLINGUAL

SUBSYS
  + INSYS DEV CO INC 0.1MG N202788 001 Jan 04, 2012
  + 0.2MG N202788 002 Jan 04, 2012
  +! 0.4MG N202788 003 Jan 04, 2012
  + 0.6MG N202788 004 Jan 04, 2012
  + 0.8MG N202788 005 Jan 04, 2012
  + 1.2MG N202788 006 Aug 30, 2012
  + 1.6MG N202788 007 Aug 30, 2012

FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE
AP HOSPIRA Eq 0.05MG BASE/ML N019115 001 Jan 12, 1985

FENTANYL CITRATE PRESERVATIVE FREE
AP HOSPIRA Eq 0.05MG BASE/ML A072786 001 Sep 24, 1991
AP +! WEST-NARD PHARMS INT Eq 0.05MG BASE/ML N019101 001 Jul 11, 1984

SUBLIMAZE PRESERVATIVE FREE
AP +! AKORN Eq 0.05MG BASE/ML N016619 001

SPRAY, METERED; NASAL

LAZANDA
  + ELEFSEE PHARMS INTL Eq 0.1MG BASE N022569 001 Jun 30, 2011
  + Eq 0.3MG BASE N022569 003 Dec 21, 2015
  +! Eq 0.4MG BASE N022569 002 Jun 30, 2011

TABLET; BUCCAL, SUBLINGUAL

FENTORA
  + CEPHALON Eq 0.1MG BASE N021947 001 Sep 25, 2006
  + Eq 0.2MG BASE N021947 002 Sep 25, 2006
  +! Eq 0.4MG BASE N021947 003 Sep 25, 2006
  + Eq 0.6MG BASE N021947 004 Sep 25, 2006
  + Eq 0.8MG BASE N021947 005 Sep 25, 2006

TABLET; SUBLINGUAL

ABSTRAL
  AB + SENTRYL THERAPS INC Eq 0.1MG BASE N022510 001 Jan 07, 2011
  AB + Eq 0.2MG BASE N022510 002 Jan 07, 2011
  AB + Eq 0.3MG BASE N022510 003 Jan 07, 2011
  AB +! Eq 0.4MG BASE N022510 004 Jan 07, 2011
  AB + Eq 0.6MG BASE N022510 005 Jan 07, 2011
  AB + Eq 0.8MG BASE N022510 006 Jan 07, 2011

FENTANYL CITRATE

AB ACTAVIS LABS FL INC Eq 0.1MG BASE A207338 001 Nov 17, 2017
AB Eq 0.2MG BASE A207338 002 Nov 17, 2017
AB Eq 0.3MG BASE A207338 003 Nov 17, 2017
AB Eq 0.4MG BASE A207338 004 Nov 17, 2017
AB Eq 0.6MG BASE A207338 005 Nov 17, 2017
AB Eq 0.8MG BASE A207338 006 Nov 17, 2017

TROCHE/ LOZENGE; TRANSMUCOSAL

ACTIQ
  AB + CEPHALON Eq 0.2MG BASE N020747 001 Nov 04, 1998
  AB +! Eq 0.4MG BASE N020747 002 Nov 04, 1998
  AB + Eq 0.6MG BASE N020747 003 Nov 04, 1998
  AB + Eq 0.8MG BASE N020747 004 Nov 04, 1998
  AB + Eq 1.2MG BASE N020747 005 Nov 04, 1998
  AB + Eq 1.6MG BASE N020747 006 Nov 04, 1998

FENTANYL CITRATE

AB SPECX LLC Eq 0.2MG BASE A078907 001 Oct 30, 2009
AB Eq 0.4MG BASE A078907 002 Oct 30, 2009
AB Eq 0.6MG BASE A078907 003 Oct 30, 2009
AB Eq 0.8MG BASE A078907 004 Oct 30, 2009
AB Eq 1.2MG BASE A078907 005 Oct 30, 2009
AB Eq 1.6MG BASE A078907 006 Oct 30, 2009
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<td>750MG IRON/15ML (50MG IRON/ML) N203565 001 Jul 25, 2013</td>
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<td>Ferric Citrate</td>
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<td>Ferric Hexacyanoferrate (II)</td>
<td>Capsule; Oral</td>
<td>RADIOGARDASE (PRUSSIAN BLUE) +! HEYL CHEMISCH</td>
<td>500MG N021626 001 Oct 02, 2003</td>
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<td>Ferric Pyrophosphate Citrate</td>
<td>For Solution; Intravenous</td>
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<td>272MG IRON/PACKET N208551 001 Apr 25, 2016</td>
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<td>Ferumoxytol</td>
<td>Solution; Intravenous</td>
<td>TRIFERIC +! ROCKWELL MEDICAL INC</td>
<td>27.2MG IRON/5ML (5.44MG IRON/ML) N206317 001 Jan 23, 2015</td>
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<td>Fexofenadine Hydrochloride</td>
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<td>XTORO +! MERLION PHARMS GMBH 0.3%</td>
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FLECAINIDE ACETATE
TABLET; ORAL
TAMBOCOR
+ 150MG N018830 003 Jun 03, 1988

FLIBANSERIN
TABLET; ORAL
ADDYI
+! SPROUT PHARMS 100MG N022526 001 Aug 18, 2015

FLORBETABEN F-18
SOLUTION; INTRAVENOUS
NEURACEQ
+! LIFE MOLECULAR 30ML (1.4-135mCi/ML) N204677 001 Mar 19, 2014

FLORBETAPIR F-18
SOLUTION; INTRAVENOUS
AMYVID
+! AVID RADIOPHARM INC
10-30ML (13.5-51mCi/ML) N202008 002 Apr 06, 2012
+! 10-50ML (13.5-51mCi/ML) N202008 003 Apr 06, 2012

FLOXURIDINE
INJECTABLE; INJECTION
FLOXURIDINE
AP FRESENIUS KABI USA 500MG/VIAL A075837 001 Feb 22, 2001
AP LUITPOLD 500MG/VIAL A203008 001 Nov 22, 2017
AP WEST-WARD PHARMS 500MG/VIAL A076246 001 Jul 29, 2004

FLUCICLOVINE F-18
SOLUTION; INTRAVENOUS
AXUMIN
+! BLUE EARTH 9-221mCi/ML N208054 001 May 27, 2016

FLUCONAZOLE
FOR SUSPENSION; ORAL
DIFLUCAN
AB + PFIZER 50MG/5ML N020090 001 Dec 23, 1993
AB +! 200MG/5ML N020090 002 Dec 23, 1993

FLUCONAZOLE
AB AUROBINDO PHARMA LTD 50MG/5ML A079150 001 Sep 18, 2009
AB IVAX SUB TEVA PHARMS 50MG/5ML A077523 001 Sep 12, 2007
AB WEST-WARD PHARMS INT 200MG/5ML A076246 001 Jul 29, 2004
AB 200MG/5ML A076246 002 Jul 29, 2004

FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER
HIMRA FARMACEUTICA 200MG/100ML (2MG/ML) A078764 001 Jan 30, 2012
HIMRA FARMACEUTICA 200MG/200ML (2MG/ML) A078764 002 Jan 30, 2012
HOSPIRA 200MG/100ML (2MG/ML) A076303 001 Jul 29, 2004
HOSPIRA 200MG/200ML (2MG/ML) A076303 002 Jul 29, 2004
RENAISSANCE SSA LLC 200MG/100ML (2MG/ML) A077988 001 May 26, 2010
RENAISSANCE SSA LLC 200MG/200ML (2MG/ML) A077988 002 May 26, 2010

FLUCONAZOLE IN SODIUM CHLORIDE 0.9%
BAXTER HLTCARE CORP 200MG/100ML (2MG/ML) A077947 001 May 26, 2010
BAXTER HLTCARE CORP 400MG/200ML (2MG/ML) A076947 002 May 26, 2010
FRESENIUS KABI USA 200MG/100ML (2MG/ML) A076145 001 Jul 29, 2004
FRESENIUS KABI USA 400MG/200ML (2MG/ML) A076145 002 Jul 29, 2004
HIMRA FARMACEUTICA 200MG/100ML (2MG/ML) A076736 001 Aug 23, 2005
HIMRA FARMACEUTICA 200MG/200ML (2MG/ML) A076087 001 Jul 29, 2004
WEST-WARD PHARMS INT 200MG/100ML (2MG/ML) A076087 002 Jul 29, 2004
WEST-WARD PHARMS INT 400MG/200ML (2MG/ML) A076087 003 Jul 29, 2004

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
BAXTER HLTCARE 200MG/100ML (2MG/ML) A076766 001 Jul 29, 2004
BAXTER HLTCARE 400MG/200ML (2MG/ML) A076766 002 Jul 29, 2004
HIMRA FARMACEUTICA 200MG/100ML (2MG/ML) A078698 001 Jan 30, 2012
HIMRA FARMACEUTICA 400MG/200ML (2MG/ML) A078698 002 Jan 30, 2012
HOSPIRA 200MG/100ML (2MG/ML) A076303 001 Jul 29, 2004
HOSPIRA 400MG/200ML (2MG/ML) A076303 002 Jul 29, 2004
INFORLIFE 200MG/100ML (2MG/ML) A079104 001 Jul 30, 2009
INFORLIFE 400MG/200ML (2MG/ML) A079104 002 Jul 30, 2009
### FLUCONAZOLE

**INJECTABLE; INJECTION**

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**TABLET; ORAL**

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### FLUCYTOSINE

**CAPSULE; ORAL**

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**PRESCRIPTION DRUG PRODUCT LIST**

3-190 (of 452)
## FLUCYTOSINE
**Capsule; Oral**

### FLUCYTOSINE

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## FLUDARABINE PHOSPHATE
**Injectable; Injection**

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## FLUDEOXYGLUCOSE F-18
**Injectable; Intravenous**

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<td><strong>AB</strong> Novel Labs Inc 0.05%</td>
<td>A207538 001 Jul 31, 2017</td>
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<tr>
<td><strong>AB</strong> Teva 0.05%</td>
<td>A073481 001 Dec 27, 1991</td>
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<td><strong>AB</strong> Taro 0.05%</td>
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<td><strong>AT</strong> G and W Labs Inc 0.05%</td>
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<td><strong>AT</strong> Glasshouse Pharms 0.05%</td>
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<td><strong>AT</strong> Macleods Pharms Ltd 0.05%</td>
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<td><strong>AP</strong> Akorn Eq 500mg Base/5ml (Eq 100mg Base/ml)</td>
<td>N022186 001 Aug 08, 2008</td>
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<td><strong>AP</strong> Alcon Labs Inc Eq 500mg Base/5ml (Eq 100mg Base/ml)</td>
<td>N021980 001 Mar 28, 2006</td>
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<td><strong>AP</strong> Novartis Pharms Corp 0.1%</td>
<td>N019079 001 Apr 06, 1984</td>
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| **SOLUTION; TOPICAL** | **EFUDEX** | | | |
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| AT | VALEANT PHARM INTL | 5% | N016831 | 2000 |

| **FLUOXETINE HYDROCHLORIDE** | **CAPSULE; ORAL** | | | |
| AB | ALEMBIC PHARMS LTD | EQ 40MG BASE | A09223 | Mar 19, 2009 |
| AB | AUROBINDO PHARMA | EQ 40MG BASE | A07619 | Jan 31, 2008 |
| AB | HERITAGE PHARMS INC | EQ 40MG BASE | A201336 | Oct 01, 2012 |
| AB | IVAX SUB TEVA PHARMS | EQ 40MG BASE | A075425 | Sep 28, 2004 |
| AB | MARKSANS PHARMA | EQ 40MG BASE | A075465 | Aug 02, 2001 |
| AB | PAR PHARM | EQ 40MG BASE | A076928 | Dec 16, 2004 |
| AB | SANDOZ | EQ 40MG BASE | A075049 | Jan 30, 2002 |
| AB | SCIEGEN PHARMS INC | EQ 40MG BASE | A204597 | Mar 16, 2015 |
| AB | SUN PHARM INDUS LTD | EQ 40MG BASE | A076990 | Dec 13, 2004 |
| AB | TEVA | EQ 40MG BASE | A075452 | Jan 29, 2002 |
| PROZAC | ELI LILLY AND CO | EQ 40MG BASE | N018936 | Jun 15, 1999 |
| AB1 | ALEMBIC PHARMS LTD | EQ 10MG BASE | A09223 | Mar 19, 2009 |
| AB1 | ALEMBIC PHARMS LTD | EQ 20MG BASE | A09223 | Mar 19, 2009 |
| AB1 | AUROBINDO PHARMA | EQ 10MG BASE | A07619 | Jan 31, 2008 |
| AB1 | AUROBINDO PHARMA | EQ 20MG BASE | A07619 | Jan 31, 2008 |
| AB1 | BARR | EQ 10MG BASE | A074803 | Jan 30, 2002 |
| AB1 | BARR | EQ 20MG BASE | A074803 | Jan 30, 2002 |
| AB1 | HERITAGE PHARMS INC | EQ 10MG BASE | A201336 | Oct 01, 2012 |
| AB1 | HERITAGE PHARMS INC | EQ 20MG BASE | A201336 | Oct 01, 2012 |
| AB1 | IVAX SUB TEVA PHARMS | EQ 10MG BASE | A075425 | Jan 30, 2002 |
| AB1 | IVAX SUB TEVA PHARMS | EQ 20MG BASE | A075425 | Jan 30, 2002 |
| AB1 | LANDELA PHARM | EQ 10MG BASE | A075464 | Jan 30, 2002 |
| AB1 | LANDELA PHARM | EQ 20MG BASE | A075464 | Jan 30, 2002 |
| AB1 | MARKSANS PHARMA | EQ 10MG BASE | A075465 | Jan 29, 2002 |
| AB1 | MARKSANS PHARMA | EQ 20MG BASE | A075465 | Jan 29, 2002 |
| AB1 | SANDOZ | EQ 10MG BASE | A075449 | Aug 02, 2001 |
| AB1 | SANDOZ | EQ 20MG BASE | A075449 | Aug 02, 2001 |
| AB1 | SCIEGEN PHARMS INC | EQ 10MG BASE | A204597 | Mar 16, 2015 |
| AB1 | SCIEGEN PHARMS INC | EQ 20MG BASE | A204597 | Mar 16, 2015 |
| AB1 | SPECX LLC | EQ 10MG BASE | A075658 | Jan 29, 2002 |
| AB1 | SPECX LLC | EQ 20MG BASE | A075658 | Jan 29, 2002 |
| AB1 | TEVA | EQ 10MG BASE | A075452 | Jan 29, 2002 |
| AB1 | TEVA | EQ 20MG BASE | A075452 | Jan 29, 2002 |
| AB1 | TEVA PHARMS USA | EQ 10MG BASE | A076001 | Jan 29, 2002 |
| AB1 | TEVA PHARMS USA | EQ 20MG BASE | A076001 | Jan 29, 2002 |

| PROZAC | ELI LILLY AND CO | EQ 10MG BASE | N018936 |
| AB1 | ELI LILLY AND CO | EQ 20MG BASE | N018936 | Dec 23, 1992 |
| AB1 | ELI LILLY AND CO | EQ 10MG BASE | N018936 | Dec 29, 1987 |
# 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

## PRESCRIPTION DRUG PRODUCT LIST

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## FLUOXETINE HYDROCHLORIDE; OLanzAPINE

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<td><strong>AB</strong></td>
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**Notes:**
- The table above lists the various formulations of FLUOXETINE HYDROCHLORIDE and their associated companies, bases, and release dates.
- Each formulation is categorized by its type (capsule, delayed release pellets, solution, tablet) and includes the company name and the specific base and release date information.
- FLUOXETINE HYDROCHLORIDE and OLanzAPINE combinations are also listed with associated companies and release dates.
- The table is sorted by base strength to facilitate easy comparison between formulations.

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**Source:** 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

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**Disclaimer:**
- The information provided is for educational purposes only and should not be used as a substitute for professional medical advice.
- Always consult a healthcare provider for medical advice.
- The above data is subject to change and may not include all available formulations.

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**FLUOXYMESTERONE**  
TABLET; ORAL  
FLUOXYMESTERONE  
USL PHARMA 10MG A088342 001 Oct 21, 1983

**FLUPHENAZINE DECANOATE**  
INJECTABLE; INJECTION  
FLUPHENAZINE DECANOATE  
A0 AUROBINDO PHARMA 25MG/ML A207733 001 Oct 17, 2017  
A0 FRESENIUS KABI USA 25MG/ML A071413 001 Jul 14, 1987  
A0 MYLAN LABS LTD 25MG/ML A075918 001 Aug 17, 2001  
A0 PAR STERILE PRODUCTS 25MG/ML A203732 001 Jul 03, 2014  
A0 WEST-WARD PHARMACEUTICALS INT 25MG/ML A074531 001 Aug 30, 1996

**FLUPHENAZINE HYDROCHLORIDE**  
CONCENTRATE; ORAL  
FLUPHENAZINE HYDROCHLORIDE  
PHARM ASSOC 5MG/ML A074725 001 Sep 16, 1996  
ELIXIR; ORAL  
FLUPHENAZINE HYDROCHLORIDE  
PHARM ASSOC 2.5MG/5ML A040146 001 Aug 21, 1996  
INJECTABLE; INJECTION  
FLUPHENAZINE HYDROCHLORIDE  
FRESENIUS KABI USA 2.5MG/ML A089556 001 Apr 16, 1987  
TABLET; ORAL  
FLUPHENAZINE HYDROCHLORIDE  
AB LANNETT CO INC 1MG A089743 002 Aug 25, 1988  
AB 2.5MG A089743 003 Aug 25, 1988  
AB 5MG A089743 004 Aug 25, 1988  
AB 10MG A089743 001 Aug 25, 1988  
AB MYLAN 1MG A089804 002 Aug 12, 1988  
AB 2.5MG A089804 003 Aug 12, 1988  
AB 5MG A089804 004 Aug 12, 1988  
AB 10MG A089804 001 Aug 12, 1988  
AB SANDOZ 1MG A089586 002 Oct 16, 1987  
AB 2.5MG A089586 003 Oct 16, 1987  
AB 5MG A089586 004 Oct 16, 1987  
AB 10MG A089586 001 Oct 16, 1987

**FLURAN DRENOLIDE**  
CREAM; TOPICAL  
CORDRAN SP  
AT AQUA PHARMA LLC 0.05% N012806 002  
AT CINTEX SVCS 0.05% A205342 001 Apr 13, 2016  
AT CORDRAN SP +! AQUA PHARMS 0.025% N012806 003  
AT CORDRAN +! AQUA PHARMS 0.05% N013790 001  
AT CINTEX SVCS 0.05% A205343 001 Dec 22, 2016  
AT PERRIGO UK FINCO 0.05% A207133 001 Aug 30, 2016  
AT CORDRAN +! AQUA PHARMS 0.05% N012806 001  
AT TELIGENT PHARMA INC 0.05% A207851 001 Dec 30, 2016  
AT CORDRAN +! AQUA PHARMS LLC 0.004MG/SQ CM N016455 001

**FLURAZEPAM HYDROCHLORIDE**  
CAPSULE; ORAL  
FLURAZEPAM HYDROCHLORIDE  
MYLAN PHARMA INC 15MG A070345 002 Nov 27, 1985  
! 30MG A070345 001 Nov 27, 1985
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<th>Manufacturer</th>
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<td>Flutamide</td>
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<td>Actavis Labs FL Inc</td>
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<td>Flutemetamol F-18</td>
<td>Injectable; Intravenous</td>
<td>GE Healthcare</td>
<td>121.5mCi/30ml (4.05mCi/ML)</td>
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<td>Arnuity ELLIpta</td>
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<td>Fluticasone Propionate</td>
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<td>Flovent Diskus 100</td>
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### Fluticasone Propionate

#### Powder; Inhalation

- FLOVENT DISKUS 250
  - GLAXO GRP LTD
  - 0.25mg/Inh
  - N020833 003
  - Sep 29, 2000
- FLOVENT DISKUS 50
  - GLAXO GRP LTD
  - 0.05mg/Inh
  - N020833 001
  - Sep 29, 2000

#### Spray, Metered; Nasal

- FLOVENT DISKUS 250
  - GLAXO GRP LTD
  - 0.05mg/Inh
  - N020833 003
  - Sep 29, 2000
- FLOVENT DISKUS 50
  - GLAXO GRP LTD
  - 0.05mg/Inh
  - N020833 001
  - Sep 29, 2000
- SPRAY, METERED; NASAL
  - FLUTICASONE PROPIONATE
  - APOTEX INC
  - 0.05mg/spray
  - A077538 001
  - Sep 12, 2007
  - Hi Tech Pharma
  - 0.05mg/spray
  - A077570 001
  - Jan 16, 2008
  - West-Ward Pharm
  - 0.05mg/spray
  - A076504 001
  - Feb 22, 2006
  - XHANCE
  - OPTINOSE US INC
  - 0.093mg
  - N209022 001
  - Sep 18, 2017

### Fluticasone Propionate; Salmeterol Xinafoate

#### Aerosol, Metered; Inhalation

- ADVAIR HFA
  - GLAXO GRP LTD
  - 0.045mg/Inh; EQ 0.021mg BASE/Inh
  - N021254 001
  - Jun 08, 2006
  - 0.115mg/Inh; EQ 0.021mg BASE/Inh
  - N021254 002
  - Jun 08, 2006
  - 0.230mg; EQ 0.014mg BASE/Inh
  - N021254 003
  - Jun 08, 2006

### Fluvastatin Sodium

#### Capsule; Oral

- FLUVASTATIN SODIUM
  - MYLAN PHARMS INC
  - EQ 20mg BASE
  - A090595 001
  - Apr 11, 2012
  - EQ 40mg BASE
  - A090595 002
  - Apr 11, 2012
  - TEVA PHARMS
  - EQ 20mg BASE
  - A078407 001
  - Jun 12, 2012
  - EQ 40mg BASE
  - A078407 002
  - Jun 12, 2012

#### Tablet, Extended Release; Oral

- LESCOL XL
  - NOVARTIS
  - EQ 80mg BASE
  - A024548 001
  - Sep 11, 2015
  - TEVA PHARMS USA
  - EQ 80mg BASE
  - A079011 001
  - Jan 27, 2016

### Fluvoxamine Maleate

#### Capsule, Extended Release; Oral

- FLUVOXAMINE MALEATE
  - ACTAVIS ELIZABETH
  - 100mg
  - A091482 001
  - Apr 23, 2013
  - 150mg
  - A091482 002
  - Nov 18, 2013
  - ANCHEN PHARMS
  - 100mg
  - A091476 001
  - Mar 13, 2013
  - 150mg
  - A091476 002
  - Mar 13, 2013
  - TORRENT PHARMS LTD
  - 100mg
  - A203240 001
  - Oct 31, 2014
  - 150mg
  - A203240 002
  - Oct 31, 2014

#### Tablet; Oral

- FLUVOXAMINE MALEATE
  - ANI PHARMS INC
  - 25mg
  - A075897 001
  - Jan 25, 2001
  - 50mg
  - A075897 002
  - Jan 25, 2001
  - 100mg
  - A075897 003
  - Jan 25, 2001
  - APOTEX
  - 25mg
  - A075902 001
  - May 07, 2001
  - 50mg
  - A075902 002
  - May 07, 2001
  - 100mg
  - A075902 003
  - May 07, 2001
  - MYLAN
  - 25mg
  - A075889 001
  - Nov 29, 2000
  - 50mg
  - A075889 002
  - Nov 29, 2000
  - 100mg
  - A075889 003
  - Nov 29, 2000
  - TEVA
  - 25mg
  - A075893 001
  - Sep 10, 2002
  - 50mg
  - A075893 002
  - Sep 10, 2002
  - 100mg
  - A075893 003
  - Sep 10, 2002
  - UPsher SMITH LABS
  - 25mg
  - A075888 001
  - Nov 29, 2000
  - 50mg
  - A075888 002
  - Nov 29, 2000
  - 100mg
  - A075888 003
  - Nov 29, 2000
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FORMOTEROL FUMARATE
SOLUTION; INHALATION
PERFOROMIST
+! MYLAN SPECLT 0.02MG/2ML N022007 001 May 11, 2007

FORMOTEROL FUMARATE; GLYCOPYRROLATE
AEROSOL, METERED; INHALATION
BEVESPI AEROSPHERE
+! ASTRazeneca PHARMS 0.0048MG/INH; 0.0090MG/INH N208294 001 Apr 25, 2016

FORMOTEROL FUMARATE; MOMETASONE Furoate
AEROSOL, METERED; INHALATION
DULERA
+! MERck SHARP DOHme 0.005MG/INH; 0.1MG/INH N022518 001 Jun 22, 2010
+! 0.005MG/INH; 0.2MG/INH N022518 002 Jun 22, 2010

FOSAMPRENAVIR Calcium
SUSPENSION; ORAL
LEXIVA
+! VIIV HLTHCARE EQ 50MG BASE/ML N022116 001 Jun 14, 2007
TABLET; ORAL

FOSAMPRENAVIR Calcium
AB MYLAN PHARMS INC EQ 700MG BASE A204060 001 Apr 15, 2016
LEXIVA
AB +! VIIV HLTHCARE EQ 700MG BASE N021548 001 Oct 20, 2003

Fosaprepitant Dimeglumine
POWDER; INTRAVENOUS
EMEND
AP +! MERck AND CO INC EQ 150MG BASE/VIAL N022023 002 Nov 12, 2010
Fosaprepitant Dimeglumine
AP FRESENIUS KABI USA EQ 150MG BASE/VIAL A206197 001 Jun 09, 2016

Foscarnet Sodium
Injectable; Injection
Foscavir
+! CLINIGEN HLTHCARE 2.4GM/100ML N020068 001 Sep 27, 1991

Fosfomycin Tromethamine
For Solution; Oral
Monurol
+! ZAMBON SPA EQ 3GM BASE/PACKET N050717 001 Dec 19, 1996

Fosinopril Sodium
Tablet; Oral

Fosinopril Sodium
AB APOTEX INC 10MG A076906 001 May 17, 2005
AB 20MG A076906 002 May 17, 2005
AB 40MG A076906 003 May 17, 2005
AB Aurobindo Pharma LTD 10MG A091163 001 Mar 30, 2011
AB 20MG A091163 002 Mar 30, 2011
AB 40MG A091163 003 Apr 20, 2005
AB Invagen Pharms 10MG A077222 001 Apr 20, 2005
AB 20MG A077222 002 Apr 20, 2005
AB 40MG A077222 003 Apr 20, 2005
AB Prinston Inc 10MG A205670 001 Aug 29, 2016
AB 20MG A205670 002 Aug 29, 2016
AB 40MG A205670 003 Aug 29, 2016
AB TEVA 10MG A076139 001 Nov 25, 2003
AB 20MG A076139 002 Nov 25, 2003
AB ! 40MG A076139 003 Nov 25, 2003
AB Upsher Smith Labs 10MG A076483 001 Apr 23, 2004
AB 20MG A076483 002 Apr 23, 2004
AB 40MG A076483 003 Apr 23, 2004

Fosinopril Sodium; Hydrochlorothiazide
Tablet; Oral

Fosinopril Sodium and Hydrochlorothiazide
AB Aurobindo Pharma 10MG;12.5MG A079245 001 Jul 09, 2009
AB 20MG;12.5MG A079245 002 Jul 09, 2009
AB Emcure Pharms Ltd 10MG;12.5MG A079025 001 Sep 17, 2010
AB ! 20MG;12.5MG A079025 002 Sep 17, 2010
AB Invagen Pharms 10MG;12.5MG A090228 001 Jul 09, 2009
AB 20MG;12.5MG A090228 002 Jul 09, 2009
AB Sandoz 10MG;12.5MG A076961 001 Sep 28, 2005
AB 20MG;12.5MG A076961 002 Sep 28, 2005
### Fosnetupitant Chloride Hydrochloride; Palonosetron Hydrochloride

**Powder; Intravenous**

**Akyneze**

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<th>Approvals</th>
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<td><strong>AKYNZEO</strong></td>
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### Fosphenytoin Sodium

**Injectable; Injection**

**Cerebyx**

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### Fostamatinib Disodium

**Tablet; Oral**

**Tavalisse**

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### Frovatriptan Succinate

**Tablet; Oral**

**Frova**

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### Fulvestrant

**Injectable; Intramuscular**

**Faslodex**

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### Furosemide

**Injectable; Injection**

**Furosemide**

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### Tablet; Oral

**Furosemide**

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### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**PRESCRIPTION DRUG PRODUCT LIST**

#### 3-205 (of 452)

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### Ganirelix Acetate

**Injectable; Injection**

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### Gatifloxacin

**Solution/Drops; Ophthalmic**

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<td>Lupin Ltd</td>
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<td>A202653 001</td>
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<td>Mylan Pharm Inc</td>
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<td>Sandog Inc</td>
<td>0.5%</td>
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<td>Allergan</td>
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### Gefitinib

**Tablet; Oral**

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### Gemcitabine Hydrochloride

**Injectable; Injection**

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<td>Accord Hlthcare</td>
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**39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST**

**PRESCRIPTION DRUG PRODUCT LIST**

3-208 (of 452)
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### GLIMEPIRIDE

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### GLIPIZIDE

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### GLIPIZIDE

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<td><strong>Glynase</strong></td>
<td><strong>TABLET; ORAL</strong></td>
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<tr>
<td><strong>AB</strong></td>
<td><strong>+! PHARMACIA AND UPJOHN</strong></td>
<td><strong>1.5MG</strong></td>
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### Glyburide

**Tablet; Oral**

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<tr>
<th>Brand</th>
<th>Strength</th>
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<th>Approval Date</th>
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<tbody>
<tr>
<td>Aurobindo Pharma</td>
<td>1.25 mg</td>
<td>A077537</td>
<td>Oct 18, 2007</td>
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<tr>
<td>Aurobindo Pharma</td>
<td>2.5 mg</td>
<td>A077537</td>
<td>Oct 18, 2007</td>
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<td>Cadila Pharms Ltd</td>
<td>1.25 mg</td>
<td>A020379</td>
<td>Jan 04, 2019</td>
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<td>Jan 04, 2019</td>
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<td>Epic Pharma LLC</td>
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<td>A076257</td>
<td>Jun 27, 2002</td>
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<td>Epic Pharma LLC</td>
<td>2.5 mg</td>
<td>A076257</td>
<td>Jun 27, 2002</td>
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<tr>
<td>Heritage Pharma LLC</td>
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<td>Feb 28, 2011</td>
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<td>Heritage Pharma LLC</td>
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<td>A090937</td>
<td>Feb 28, 2011</td>
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<tr>
<td>Pharmedax Inc</td>
<td>1.25 mg</td>
<td>A020381</td>
<td>Apr 14, 2016</td>
</tr>
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<td>Pharmedax Inc</td>
<td>2.5 mg</td>
<td>A020381</td>
<td>Apr 14, 2016</td>
</tr>
<tr>
<td>Teva</td>
<td>1.25 mg</td>
<td>A074388</td>
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<td>Teva</td>
<td>2.5 mg</td>
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<td>Aug 29, 1995</td>
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<tr>
<td>Zydus Pharms USA Inc</td>
<td>1.25 mg</td>
<td>A020674</td>
<td>May 10, 2016</td>
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<td>Zydus Pharms USA Inc</td>
<td>2.5 mg</td>
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### Diabeta

**Tablet; Oral**

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<tr>
<td>Sanofi Aventis US</td>
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<td>May 01, 1984</td>
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<td>Sanofi Aventis US</td>
<td>2.5 mg</td>
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### Glyburide and Metformin Hydrochloride

**Tablet; Oral**

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<td>Actavis Elizabeth</td>
<td>2.5 mg:500 mg</td>
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<td>Actavis Elizabeth</td>
<td>5 mg:500 mg</td>
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<tr>
<td>Aurobindo Pharma</td>
<td>1.25 mg:250 mg</td>
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<td>Aurobindo Pharma</td>
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<td>Heritage Pharma Inc</td>
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<td>Heritage Pharma Inc</td>
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<td>Impax Labs Inc</td>
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<td>Impax Labs Inc</td>
<td>2.5 mg:500 mg</td>
<td>A076348</td>
<td>Feb 18, 2004</td>
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<tr>
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<td>1.25 mg:250 mg</td>
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<td>Feb 29, 2016</td>
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<tr>
<td>Zydus Pharms USA Inc</td>
<td>2.5 mg:500 mg</td>
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### Glycerol Phenylbutyrate

**Liquid; Oral**

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<td>Horizon Theraps Inc</td>
<td>1.1 gm/ml</td>
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### Glycine

**Solution; Irrigation**

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<tr>
<td>Baxter Healthcare</td>
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<td>N017865</td>
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<td>Baxter Healthcare</td>
<td>1.5%</td>
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<td>Baxter Healthcare</td>
<td>1.5%</td>
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<td>GLYCOPRROLATE INJECTABLE; INJECTION</td>
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<td>LUITPOLD</td>
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<td>0.2MG/ML</td>
<td>PRINSTON INC</td>
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<td>SOMERSET THERAPS LLC</td>
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<td>SEEBRI</td>
<td>SUNOVION PHARMS INC</td>
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<td>SUNOVION RESP</td>
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<td>GLYRX-PF</td>
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<td>CUVPOSA</td>
<td>MERZ PHARMS</td>
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<td>GLYCOPRROLATE</td>
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<td>GLYCOPRROLATE; INDACATEROL MALEATE</td>
<td>POWDER; INHALATION</td>
<td>UTIBRON</td>
<td>SUNOVION PHARMS INC</td>
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<tr>
<td>GLYCOPRROLONIUM TOSYLATE</td>
<td>CLOTH; TOPICAL</td>
<td>QBREXZA</td>
<td>DERMIRA INC</td>
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<td>CHORIONOTROPIN, CHORIONIC</td>
<td>INJECTABLE; INJECTION</td>
<td>CHORIONIC GONADOTROPIN</td>
<td>FERRING</td>
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<td>10,000 UNITS/VIAL</td>
<td>FRESENIUS KABI USA</td>
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<td>10,000 UNITS/VIAL</td>
<td>ORGANON USA INC</td>
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</tbody>
</table>
**Goserelin Acetate**

**Implant; Implantation**

+! **Zoladex**

EQ 3.6MG BASE

N019726 001 Dec 29, 1989

+! EQ 10.8MG BASE

N020578 001 Jan 11, 1996

**Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate**

**Solution/Drops; Ophthalmic**

**Neomycin and Polymyxin B Sulfates and Gramicidin**

<table>
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<tr>
<th>AT</th>
<th>AMRING PHARMS</th>
<th>0.025MG/ML</th>
<th>EQ 1.75MG BASE/ML</th>
<th>10,000 UNITS/ML</th>
<th>A065187 001 Oct 28, 2005</th>
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<tr>
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<td>EQ 1.75MG BASE/ML</td>
<td>10,000 UNITS/ML</td>
<td>A064047 001 Jan 31, 1996</td>
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**Granisetron**

**Film, Extended Release; Transdermal**

**Sancuso**

+! **Kyowa Kirin** 3.1MG/24HR

N022198 001 Sep 12, 2008

**Injection, Extended Release; Subcutaneous**

**Sustol**

+! **Heron Theraps Inc** 10MG/0.4ML (10MG/0.4ML)

N022445 001 Aug 09, 2016

**Granisetron Hydrochloride**

**Injectable; Injection**

**Granisetron Hydrochloride Preservative Free**

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<thead>
<tr>
<th>AP</th>
<th>AKORN INC</th>
<th>EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)</th>
<th>A079119 001 Sep 10, 2009</th>
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<tr>
<td>AP</td>
<td>AUROBINDO PHARMA LTD</td>
<td>EQ 4MG BASE/4ML (EQ 1MG BASE/ML)</td>
<td>A078989 001 Apr 09, 2010</td>
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**Granisetron Hydrochloride Tablet; Oral**

**Granisetron Hydrochloride Preservative Free**

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<tr>
<th>AP</th>
<th>APOTEX INC</th>
<th>EQ 1MG BASE</th>
<th>A078843 001 Feb 27, 2008</th>
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<tbody>
<tr>
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<td>CHARTWELL MOLECULAR</td>
<td>EQ 1MG BASE</td>
<td>A078037 001 Feb 27, 2008</td>
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<td>AP</td>
<td>DR REDDYS LABS LTD</td>
<td>EQ 1MG BASE</td>
<td>A078444 001 Feb 27, 2008</td>
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<td>AP</td>
<td>MYLAN</td>
<td>EQ 1MG BASE</td>
<td>A078500 001 Feb 27, 2008</td>
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<td>NATCO PHARMA</td>
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<td>A078380 001 Feb 27, 2008</td>
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</tr>
<tr>
<td>GRANISETRON HYDROCHLORIDE</td>
<td>TABLET; ORAL</td>
<td>1MG Base</td>
<td>ORCHID HLC</td>
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<td></td>
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<td>Taro Pharm</td>
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<td>WEST-WARD PHARMS</td>
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<td>GRANISETRON HYDROCHLORIDE</td>
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<td>1MG Base</td>
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<td>SUSPENSION; ORAL</td>
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<td>ACTAVIS MID</td>
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<td>TABLET; ORAL</td>
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<td>SOLUTION; ORAL</td>
<td>200MG/5ML; 2.5MG/5ML</td>
<td>SOVEREIGN PHARMS</td>
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<td>GUANABENZ ACETATE</td>
<td>TABLET; ORAL</td>
<td>4MG Base</td>
<td>ANI PHARMS INC</td>
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<td>1MG Base</td>
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<td>GUANFACINE HYDROCHLORIDE</td>
<td>TABLET; ORAL</td>
<td>2MG Base</td>
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<td>3MG Base</td>
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<td>4MG Base</td>
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<td>MANUFACTURER</td>
<td>FORMULATION</td>
<td>NDC NUMBER</td>
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<td>EQ 3mg Base</td>
<td>A202568 003</td>
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<td>EQ 1mg Base</td>
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<td>EQ 1mg Base</td>
<td>A201382 001</td>
</tr>
<tr>
<td></td>
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<td>MERCK SHARP DOHME</td>
<td>125mg Base</td>
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<td>Halcinonide</td>
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<td>0.1% Cream</td>
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<td>Taro</td>
<td>0.05% Cream</td>
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<td>FOUGERA PHARMS</td>
<td>0.05% Aerosol</td>
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### Heparin Sodium

**Injectable; Injection**

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<tbody>
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<td>AP Sandoz</td>
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<td>AP +! BAXTER HEALTHCARE</td>
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<tr>
<td>AP +! B BRAUN</td>
<td>200 Units/100mL</td>
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**Heparin Sodium 1,000 Units and Sodium Chloride 0.9% in Plastic Container**

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**Heparin Sodium 10,000 Units in Dextrose 5% in Plastic Container**

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**Heparin Sodium 2,000 Units and Sodium Chloride 0.9% in Plastic Container**

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**Heparin Sodium 20,000 Units in Dextrose 5% in Plastic Container**

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**Heparin Sodium 25,000 Units in Dextrose 5% in Plastic Container**

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<td>AP HOSPIRA</td>
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**Heparin Sodium Preservative Free**

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**Heparin Sodium 12,500 Units in Dextrose 5% in Plastic Container**

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**Hexachlorophene Sponge; Topical**

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**PRE-OP**

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<tr>
<td>Hexaminolevulinate Hydrochloride</td>
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<td>Histrelin Acetate</td>
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## HYDROCHLOROTHIAZIDE
### TABLET; ORAL

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## HYDROCHLOROTHIAZIDE; IRBESARTAN
### TABLET; ORAL

**AVALIDE**

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## HYDROCHLOROTHIAZIDE; LIXINOPRIL
### TABLET; ORAL

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### Hydrochlorothiazide; Lisinopril

**Tablet; Oral**

**Lisinopril and Hydrochlorothiazide**

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<td>Sun Pharm Inds Ltd</td>
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<td>Watson Labs</td>
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### Hydrochlorothiazide; Losartan Potassium

**Tablet; Oral**

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<td>Alembic Pharm Ltd</td>
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<td>Aurobindo Pharma</td>
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<td>Cadista Pharmas</td>
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<td>Ipca Labs Ltd</td>
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<td>Macleods Pharm Ltd</td>
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### Hydrochlorothiazide; Methyldopa

**Tablet; Oral**

**Methyldopa and Hydrochlorothiazide**

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### Hydrochlorothiazide; Methyldopa

**Tablet; Oral**

**Methyldopa and Hydrochlorothiazide**

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HYDROCORTISONE ACETATE
AEROSOL, METERED;RECTAL
CORTIFOAM

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HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMIXIN B SULFATE
CREAM;TOPICAL
CORTISPORIN

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HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE
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EFIFOAM

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<p>| HYDROXOCOBALAMIN | INJECTABLE; INJECTION | ACTAVIS LLC | A085998 | 001 |     |             |</p>
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### Ibandronate Sodium

**Tablet; Oral**

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<td>A078997 001</td>
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<td>A078998 001</td>
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<td>A078996 001</td>
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### Ibrutinib

**Capsule; Oral**

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<td>A074978 001</td>
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**Tablet; Oral**

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### Ibuprofen

**Solution; Intravenous**

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<td>A071059 001</td>
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**Suspension; Oral**

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<td>A078558 002</td>
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<td>A078558 003</td>
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**Tablet; Oral**

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**Granules India Ltd**

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**Perrigo R and D**

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**Shandong Xinhua**

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**Strides Pharma**

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**39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST**

**PRESCRIPTION DRUG PRODUCT LIST**

3-232 (of 452)
### Approved Drug Product List

#### Prescription Drug Product List

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Formulation</th>
<th>Manufacturer</th>
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<th>Date Approved</th>
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<td><strong>Ibuprofen Lysine</strong></td>
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<td><strong>Ibuprofen; Oxycodone Hydrochloride</strong></td>
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<td>AB +! X-Gen Pharms Inc</td>
<td>A202402 001</td>
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<td><strong>Ibutilide Fumarate</strong></td>
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<td><strong>Icatibant Acetate</strong></td>
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<td><strong>FIRAZYR</strong></td>
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<td><strong>Icodextrin</strong></td>
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<td><strong>Icosapent Ethyl</strong></td>
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<td><strong>Idarubicin Hydrochloride</strong></td>
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*Note: The above list includes a subset of products, and the full list can be found in the referenced documents.*
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<td>IFOSFAMIDE</td>
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<td>DR REDDYS LABS LTD</td>
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<td>A206547 001 Aug 13, 2018</td>
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<td>MYLAN PHARMS INC</td>
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<td>SUN PHARMA GLOBAL</td>
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<td>TEVA PHARMS USA</td>
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<td>AB EQ 400MG BASE</td>
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<td>IMIGLUCERASE</td>
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<td>200 UNITS/VIAL</td>
<td>N020367 001 May 23, 1994</td>
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<td>AB 400 UNITS/VIAL</td>
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<td>IMIPRAMINE HYDROCHLORIDE</td>
<td>TABLET; ORAL</td>
<td>+ GENZYME</td>
<td>200 UNITS/VIAL</td>
<td>N020367 001 May 23, 1994</td>
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<td>75mg Hydrochloride</td>
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<td>100mg Hydrochloride</td>
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<td>IMIQUIMOD</td>
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<td>5%</td>
<td>N020723</td>
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<td>INAMRINONE LACTATE</td>
<td>Injectable; Injection</td>
<td>5mg Base/ML</td>
<td>A075513</td>
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<td>INDACATEROL MALEATE</td>
<td>Powder; Inhalation</td>
<td>75mcg Base</td>
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<td>200mg Base</td>
<td>N020685</td>
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<td>400mg Base</td>
<td>N020685</td>
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<td>INDOLEUM IN-111 CHLORIDE</td>
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<td>INDICLOR</td>
<td>N019862 001 Dec 29, 1992</td>
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<td>+! GE HEALTHCARE</td>
<td>2mCi/0.2ML</td>
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<td>N019841 001 Sep 27, 1994</td>
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<tr>
<td>+! MALLINKRODT NUCLEAR</td>
<td>5mCi/0.5ML</td>
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<th>INDIUM IN-111 OXYQUINOLINE</th>
<th>INJECTABLE; INJECTION</th>
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<td>MPI INDIUM DTPA IN 111</td>
<td>N017707 001 Feb 18, 1982</td>
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<td>+! GE HEALTHCARE</td>
<td>1mCi/ML</td>
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<table>
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<tr>
<td>MPI INDIUM DTPA IN 111</td>
<td>N020314 001 Jun 02, 1994</td>
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<td>+! MALLINKRODT NUCLEAR</td>
<td>3mCi/ML</td>
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<tr>
<th>INDOCYANINE GREEN</th>
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<tr>
<td>IC-GREEN AP</td>
<td>25mg/vial</td>
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<tr>
<td>+! AKORN</td>
<td>N011525 001</td>
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<th>INDOCYANINE GREEN</th>
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<tr>
<td>AP</td>
<td>DIAGNOSTIC GREEN 25mg/vial</td>
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<th>INDOMETHACIN</th>
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<tr>
<td>AB GLENMARK GENERICS</td>
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<td>AB 50mg</td>
<td>A091276 001 Dec 22, 2010</td>
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<td>AB HERITAGE PHARMS INC</td>
<td>25mg</td>
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<tr>
<td>AB 50mg</td>
<td>A091276 002 Dec 22, 2010</td>
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<td>AB HETERO LABS LTD III</td>
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<td>AB 50mg</td>
<td>N018851 001 May 18, 1984</td>
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<td>AB HETERO LABS LTD III</td>
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<td>AB 75mg</td>
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<td>A091240 002 Apr 12, 2011</td>
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<td>AB IVAX SUB TEVA PHARMS</td>
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<td>AB 25mg</td>
<td>A070719 001 Feb 12, 1986</td>
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<td>AB JUBILANT GENERICS</td>
<td>25mg</td>
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<tr>
<td>AB 50mg</td>
<td>A070756 001 Feb 12, 1986</td>
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<td>AB MYLAN</td>
<td>A205215 001 Aug 25, 2017</td>
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<td>AB MYLAN</td>
<td>A205215 002 Aug 25, 2017</td>
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<td>AB SANDOZ</td>
<td>A070624 001 Sep 04, 1985</td>
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<tr>
<td>AB SUN PHARM INDS INC</td>
<td>25mg</td>
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<td>AB 50mg</td>
<td>A091401 001 Mar 28, 2013</td>
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<tr>
<td>AB ZYDUS PHARMS USA INC</td>
<td>25mg</td>
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<td>AB 50mg</td>
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<th>TIVORBEX</th>
<th>CAPSULE, EXTENDED RELEASE; ORAL</th>
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<tr>
<td>+! IROKO PHARMS LLC</td>
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<td>+! 40mg</td>
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<th>INDOMETHACIN</th>
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<tr>
<td>AB AMNEAL PHARMS</td>
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<tr>
<td>AB AVANTHI INC</td>
<td>75mg</td>
</tr>
<tr>
<td>AB CHARTWELL RX</td>
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<td>AB HETERO LABS LTD III</td>
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<tr>
<td>AB JUBILANT GENERICS</td>
<td>75mg</td>
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<tr>
<td>AB MYLAN PHARMS INC</td>
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<td>AB NOVAST LABS</td>
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<td>AB SANDOZ</td>
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<td>AB ZYDUS PHARMS USA INC</td>
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| IROKO PHARMS LLC | 75mg |
| AB 50mg | A079175 001 Mar 06, 2009 |
| AB 20mg | A200529 001 Nov 30, 2010 |
| AB 40mg | A200529 002 Nov 30, 2010 |
| AB 50mg | A020107 001 Jun 22, 2017 |
| AB 30mg | A202106 001 Oct 05, 2015 |
| AB 40mg | A202106 002 Oct 05, 2015 |
| AB 50mg | A020107 002 May 08, 2017 |
| AB 60mg | A074464 001 May 28, 1998 |
| AB 75mg | A022711 001 Sep 25, 2017 |
### INDOMETHACIN

**Injectable; Injection**

- Indomethacin
  - Fresenius Kabi USA
    - EQ 1MG BASE/VIAL
    - N022536 001 Mar 17, 2010
  - G and W Labs
    - 50MG
    - A073314 001 Aug 31, 1992
  - IROKO PharmS
    - 25MG/5ML
    - N018332 001 Oct 10, 1985

**Suppository; Rectal**

- Indomethacin
  - FRESENIUS KABI USA
    - N018878 001 Jan 30, 1985

### INDOCIN

**Injectable; Injection**

- Indomethacin Sodium
  - Recordati Rare
    - EQ 1MG BASE/VIAL
    - N018878 001 Jan 30, 1985

**Suspension; Oral**

- Indocin
  - IROKO PharmS
    - N018878 001 Jan 30, 1985

### INGENOL MEBUTATE

**Gel; Topical**

- Perrigo UK Finco
  - 0.015%
    - A209018 001 Jan 07, 2019
  - 0.05%
    - A209019 001 Jan 09, 2019

- Picato
  - LEGO Labs
    - 0.015%
      - N202833 001 Jan 23, 2012
    - 0.05%
      - N202833 002 Jan 23, 2012

### INOTERSEN SODIUM

**Solution; Subcutaneous**

- Tegsedi
  - Akcea Theraps
    - EQ 284MG BASE/1.5ML (EQ 189.3MG BASE/ML)
      - N211172 001 Oct 05, 2018

### INSULIN ASPART

**Solution; Intravenous, Subcutaneous**

- Fiasp
  - Novo Nordisk Inc
    - 1000 UNITS/10ML (100 UNITS/ML)
      - N208751 001 Sep 29, 2017

- Fiasp FlexTouch
  - Novo Nordisk Inc
    - 300 UNITS/3ML (100 UNITS/ML)
      - N208751 002 Sep 29, 2017

### INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

**Injectable; Subcutaneous**

- Novolog Mix 70/30
  - Novo Nordisk Inc
    - 700 UNITS/10ML; 300 UNITS/10ML (70 UNITS/ML; 30 UNITS/ML)
      - N021172 001 Nov 01, 2001

- Novolog Mix 70/30 Flexpen
  - Novo Nordisk Inc
    - 210 UNITS/3ML; 90 UNITS/3ML (70 UNITS/ML; 30 UNITS/ML)
      - N021172 004 May 03, 2002

### INSULIN ASPART RECOMBINANT

**Injectable; Subcutaneous**

- Novolog
  - Novo Nordisk Inc
    - 1000 UNITS/10ML (100 UNITS/ML)
      - N020986 001 Jun 07, 2000

- Novolog Flexpen
  - Novo Nordisk Inc
    - 300 UNITS/3ML (100 UNITS/ML)
      - N020986 003 Jan 19, 2001

- Novolog Penfill
  - Novo Nordisk Inc
    - 300 UNITS/3ML (100 UNITS/ML)
      - N020986 002 Jun 07, 2000

### INSULIN ASPART; INSULIN DEGLUDEC

**Solution; Subcutaneous**

- Ryzodeg 70/30
  - Novo
    - 90 UNITS/3ML; 210 UNITS/3ML (30 UNITS/ML; 70 UNITS/ML)
      - N203313 001 Sep 25, 2015

### INSULIN DEGLUDEC

**Solution; Subcutaneous**

- Tesiba
  - Novo
    - 300 UNITS/3ML (100 UNITS/ML)
      - N203314 001 Sep 25, 2015
    - 600 UNITS/3ML (200 UNITS/ML)
      - N203314 002 Sep 25, 2015
INSULIN DEGLUDEC; LIRAGLUTIDE
SOLUTION; SUBCUTANEOUS
XULTOPHY 100/3,6
+! NOVO
300 UNITS/3ML; 10.8MG/3ML (100 UNITS/ML; 3.6MG/ML)
N208583 001 Nov 21, 2016

INSULIN DETEMIR RECOMBINANT
INJECTABLE; SUBCUTANEOUS
LEVEMIR
+! NOVO NORDISK INC
1000 UNITS/10ML (100 UNITS/ML)
N021536 001 Jun 16, 2005

INSULIN GLARGINE
SOLUTION; SUBCUTANEOUS
BASAGLAR
ELI LILLY AND CO
300 UNITS/3ML (100 UNITS/ML)
N205692 001 Dec 16, 2015

INSULIN GLARGINE RECOMBINANT
INJECTABLE; INJECTION
LANTUS
+! SANOFI AVENTIS US
100 UNITS/ML
N021081 001 Apr 20, 2000

INSULIN GLULISINE RECOMBINANT
INJECTABLE; INTRAVENOUS, SUBCUTANEOUS
APIGKA
+! SANOFI AVENTIS US
1000 UNITS/10ML (100 UNITS/ML)
N021629 001 Apr 16, 1999

INSULIN HUMAN
SOLUTION; SUBCUTANEOUS
HUMULIN R
+! LILLY
10000 UNITS/20ML (500 UNITS/ML)
N018780 004 Mar 31, 1994

INSULIN LEPRO
SOLUTION; INTRAVENOUS, SUBCUTANEOUS
ADMELOG
+! SANOFI-AVENTIS US
300 UNITS/3ML (100 UNITS/ML)
N209196 003 Oct 19, 2018

INSULIN LISPRO
PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT
INJECTABLE; INJECTION
HUMALOG MIX 50/50
+! LILLY
50 UNITS/ML; 50 UNITS/ML
N202091 001 Dec 22, 1999

INSULIN LISPRO RECOMBINANT
INJECTABLE; INJECTION
HUMALOG
+! LILLY
100 UNITS/ML
N20563 001 Jun 14, 1996

HUMALOG KWIKPEN
+! LILLY
100 UNITS/ML
N20563 003 Sep 06, 2007

HUMALOG SOLOSTAR
+! LILLY
50 UNITS/ML; 50 UNITS/ML
N202018 002 Sep 06, 2007

HUMALOG KWIKPEN
+! LILLY
50 UNITS/ML; 50 UNITS/ML
N202018 002 Sep 06, 2007

HUMALOG MIX 50/50 KWIKPEN
+! LILLY
50 UNITS/ML; 50 UNITS/ML
N202018 002 Sep 06, 2007

HUMALOG MIX 75/25
+! LILLY
75 UNITS/ML; 25 UNITS/ML
N202101 001 Dec 22, 1999

HUMALOG MIX 75/25 KWIKPEN
+! LILLY
75 UNITS/ML; 25 UNITS/ML
N202101 002 Sep 06, 2007
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<td>N022472 001</td>
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<td>AFREZZA</td>
<td>GE HEALTHCARE</td>
<td>15mCi/ML</td>
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<td>Jul 30, 2018</td>
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<td>IOBENGUANE I-131</td>
<td>PROGENICS PHARMS</td>
<td>10mCi/5ML (2mCi/ML)</td>
<td>N022290 001</td>
<td>Sep 19, 2008</td>
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<td>IOBENGUANE SULFATE I-123</td>
<td>GE HEALTHCARE</td>
<td>5mCi/2.5ML (2mCi/ML)</td>
<td>N022454 001</td>
<td>Jan 14, 2011</td>
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<td>IODIXANOL</td>
<td>INTERPHARMA PRAHA AS</td>
<td>9.7GM/BOT</td>
<td>N205383 001</td>
<td>Mar 26, 2015</td>
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<td>OMNIPAQUE 140</td>
<td>GE HEALTHCARE</td>
<td>30.2%</td>
<td>N018956 005</td>
<td>Nov 30, 1988</td>
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<td>OMNIPAQUE 350</td>
<td>GE HEALTHCARE</td>
<td>75.5%</td>
<td>N018956 004</td>
<td>Dec 26, 1985</td>
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<td>OMNIPAQUE 180</td>
<td>GE HEALTHCARE</td>
<td>38.8%</td>
<td>N018956 001</td>
<td>Dec 26, 1985</td>
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<td>OMNIPAQUE 240</td>
<td>GE HEALTHCARE</td>
<td>51.8%</td>
<td>N018956 002</td>
<td>Dec 26, 1985</td>
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<td>OMNIPAQUE 300</td>
<td>GE HEALTHCARE</td>
<td>64.7%</td>
<td>N018956 003</td>
<td>Dec 26, 1985</td>
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<td>OMNIPAQUE 12</td>
<td>GE HEALTHCARE</td>
<td>2.6%</td>
<td>N018956 009</td>
<td>Apr 17, 2018</td>
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<td>IOPAMIDOL</td>
<td>BRACCO</td>
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<td>N018735 002</td>
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<td>ISOVUE-300</td>
<td>BRACCO</td>
<td>76%</td>
<td>N018735 003</td>
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<td>SCANLUX-300</td>
<td>SANOCHEMIA CORP USA</td>
<td>61%</td>
<td>A090394 001</td>
<td>Jun 18, 2010</td>
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<p>| ISOVUE-250                      | BRACCO               | 51%  | N018735 007 | Jul 06, 1992 |</p>
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### Additional Information

- **IPRATROPIUM BROMIDE**
  - Manufacturer: West-Ward Pharms
  - Formulation: NASAL SPRAY
  - NDC Number: A076664
  - Date: Nov 05, 2003

- **IRBESARTAN**
  - Manufacturer: Sanofi Aventis US
  - Formulation: TABLET; ORAL
  - NDC Numbers: A076664
  - Date: Sep 30, 1997

- **IRBESARTAN**
  - Manufacturer: Macleod's Pharms Ltd
  - Formulation: TABLET; ORAL
  - NDC Numbers: A204740
  - Date: Oct 15, 2012
IRINOTECAN HYDROCHLORIDE
INJECTABLE; INJECTION

CAMPPOSAR
AP +! PFIZER INC
400MG/2ML (20MG/ML) N020571 001 Jun 14, 1996
AP +! 1000MG/5ML (20MG/ML) N020571 002 Jun 14, 1996
AP +! 3000MG/15ML (20MG/ML) N020571 003 Aug 05, 2010

IRINOTECAN HYDROCHLORIDE
INJECTABLE; INJECTION

ACCORD HLT CARE
AP 400MG/2ML (20MG/ML) A079068 001 Nov 21, 2008
AP 1000MG/5ML (20MG/ML) A079068 002 Nov 21, 2008
AP ACTAVIS TOTOWA
400MG/2ML (20MG/ML) A078589 001 Feb 27, 2008
AP 1000MG/5ML (20MG/ML) A078589 002 Feb 27, 2008
AP AKORN
500MG/25ML (20MG/ML) A078589 003 Nov 18, 2015
AP 400MG/2ML (20MG/ML) A090726 001 Sep 16, 2009
AP 1000MG/5ML (20MG/ML) A090726 002 Sep 16, 2009
AP CIPLA LTD
400MG/2ML (20MG/ML) A077219 001 Feb 20, 2008
AP 1000MG/5ML (20MG/ML) A077219 002 Feb 20, 2008
AP EMCURE PHARMS LTD
400MG/2ML (20MG/ML) A200771 001 Sep 16, 2012
AP 1000MG/5ML (20MG/ML) A200771 002 Sep 16, 2012
AP FRESENIUS KABI
400MG/2ML (20MG/ML) A078188 001 Feb 27, 2008
AP FRESENIUS KABI USA
1000MG/5ML (20MG/ML) A077776 001 Feb 27, 2008
AP HIKMA FARMACEUTICA
1000MG/5ML (20MG/ML) A091032 001 Dec 20, 2010
AP HISUN PHARM
400MG/2ML (20MG/ML) A090016 001 Jan 28, 2009
AP HANGZHOU
1000MG/5ML (20MG/ML) A090016 002 Jan 28, 2009
AP HOSPIRA
400MG/2ML (20MG/ML) A077776 002 Feb 27, 2008
AP 1000MG/5ML (20MG/ML) A077776 003 Feb 27, 2008
AP INGENUS PHARMS LLC
500MG/25ML (20MG/ML) A078796 001 Feb 27, 2008
AP 400MG/2ML (20MG/ML) A206935 001 May 26, 2017
AP 1000MG/5ML (20MG/ML) A206935 002 May 26, 2017
AP INTAS PHARMS USA
400MG/2ML (20MG/ML) A203054 001 Aug 31, 2008
AP 1000MG/5ML (20MG/ML) A203054 002 Aug 31, 2008
AP JIANGSU HENGRI MED
400MG/2ML (20MG/ML) A090675 001 Dec 16, 2011
AP 1000MG/5ML (20MG/ML) A090675 002 Dec 16, 2011
AP MUSTAFA NEVIAT ILAC
400MG/2ML (20MG/ML) A090393 001 May 13, 2011
AP 400MG/2ML (20MG/ML) A090393 002 May 13, 2011
AP NEOPHARMA
400MG/2ML (20MG/ML) A078953 001 Apr 15, 2010
AP 1000MG/5ML (20MG/ML) A078953 002 Apr 15, 2010
AP PLIVA LACHEMA
400MG/2ML (20MG/ML) A078122 001 Oct 31, 2008
AP 1000MG/5ML (20MG/ML) A078122 002 Oct 31, 2008
AP QILU PHARM CO LTD
400MG/2ML (20MG/ML) A203380 001 May 03, 2016
AP 1000MG/5ML (20MG/ML) A203380 002 May 03, 2016
AP SHILPA MEDICARE LTD
300MG/15ML (20MG/ML) A203380 003 May 03, 2016
AP 400MG/2ML (20MG/ML) A208718 001 Dec 28, 2018
AP TEVA PHARMS USA
1000MG/5ML (20MG/ML) A090101 001 Feb 27, 2008
AP 1000MG/5ML (20MG/ML) A090101 002 Feb 27, 2008
AP WEST-WARD PHARMS INT
500MG/25ML (20MG/ML) A090101 003 Nov 26, 2008
AP 400MG/2ML (20MG/ML) A078753 001 Dec 24, 2008

INOYIDE
INJECTABLE, LIPOSOMAL; INTRAVENOUS
AP +! IPSEN INC
EQ 43MG BASE/10ML (EQ 4.3MG BASE/ML) N207793 001 Oct 22, 2015

IRON DEXTRAN
INJECTABLE; INJECTION

DUXFERM
BP LUITPOLD
EQ 50MG IRON/ML N040024 001 Feb 23, 1996
BP +! ALLERGAN SALES LLC
EQ 50MG IRON/ML N017441 001
BP PROFERDEX
BP NEW RIVER
EQ 50MG IRON/ML N017807 001

IRON SUCROSE
INJECTABLE; INTRAVENOUS
VENOFER
AP +! LUITPOLD
EQ 50MG BASE/2.5ML (EQ 20MG BASE/ML) N021135 002 Mar 20, 2005
AP +! 1000MG BASE/5ML (EQ 20MG BASE/ML) N021135 001 Nov 06, 2000
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# ISOSORBIDE DINITRATE

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**INJECTABLE; INJECTION**

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# ISOTRETINOIN

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CAPSULE; ORAL

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AB 20MG A076485 002 Jan 19, 2012
AB 30MG A076485 004 Aug 25, 2015
AB 40MG A076485 003 Jan 19, 2012

ZENATANE
AB DR REDDYS LABS LTD 10MG A202099 001 Mar 25, 2013
AB 20MG A202099 002 Mar 25, 2013
AB 30MG A202099 004 Feb 23, 2015
AB 40MG A202099 003 Mar 25, 2013

ABSORICA
BX + SUN PHARM IND INC 10MG N021951 001 May 25, 2012
BX + 20MG N021951 002 May 25, 2012
BX + 30MG N021951 003 May 25, 2012
BX + 40MG N021951 004 Aug 15, 2014
BX + 25MG N021951 005 Aug 15, 2014
BX + 35MG N021951 006 Aug 15, 2014

ISRADIPINE
CAPSULE; ORAL

ISRADIPINE
AB ELITE LABS INC 2.5MG A077169 001 Apr 24, 2006
AB 5MG A077169 002 Apr 24, 2006
AB WATSON LABS TEVA 2.5MG A077317 001 Jan 05, 2006
AB 5MG A077317 002 Jan 05, 2006

ITRACONAZOLE
CAPSULE; ORAL

ITRACONAZOLE
AB ACCORD HLTCARE 100MG A205991 001 May 26, 2016
AB ALEMBIC PHARMS LTD 100MG A206741 001 Dec 13, 2016
AB ALKEM LABS LTD 100MG A208591 001 Jun 12, 2017
AB AMNEAL PHARMS 100MG A205080 001 Sep 26, 2016
AB JUBILANT GENERICS 100MG A203446 001 Feb 23, 2017
AB MYLAN PHARMS INC 100MG A200463 001 Jul 20, 2012
AB PAR PHARM INC 100MG A205724 001 Dec 13, 2016
AB SANKEN 100MG A076104 001 May 28, 2004
AB TORRENT PHARMS LTD 100MG A209460 001 Aug 24, 2018
AB ZYDUS PHARMS USA INC 100MG A204672 001 Sep 19, 2017

SPORANOX
AB +! JANSSEN PHARMS 100MG N020083 001 Sep 11, 1992
TOLSURA
+! MAYNE PHARMA INTL 65MG N208901 001 Dec 11, 2018

ITRACONAZOLE
SOLUTION; ORAL

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AA AMNEAL PHARMS 10MG/ML A205573 001 Oct 30, 2015

SPORANOX
AA +! JANSSEN PHARMS 10MG/ML N020657 001 Feb 21, 1997
TABLET; ORAL
ONMEL
+! SEBELA IRELAND LTD 200MG N022484 001 Apr 29, 2010

IVARRADINE HYDROCHLORIDE
TABLET; ORAL

IVARRADINE HYDROCHLORIDE
+! AMGEN INC Eq 5MG BASE N206143 001 Apr 15, 2015
+! Eq 7.5MG BASE N206143 002 Apr 15, 2015

IVACAFTR
GRANULE; ORAL
KALYDECO
+ VERTEX PHARMS INC 50MG/PACKET N207925 001 Mar 17, 2015
+! 75MG/PACKET N207925 002 Mar 17, 2015
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KALYDECO
+! VERTEX PHARMS 150MG N203188 001 Jan 31, 2012
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KETOCONAZOLE

SHAMPOO; TOPICAL

KETOCONAZOLE

AB

KETOCONAZOLE

AP

KETOCONAZOLE

AT

ACULAR

AT

ACULAR LS

ACUVAAIL

SPRAY, METERED; NASAL
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### Lamivudine; Tenofovir Disoproxil Fumarate

**Tablet; Oral**

**Cimduo**

+! MYLAN LABS LTD 300MG;300MG  N022141 001  Feb 28, 2018

**Temixys**

CELLTRION 300MG;300MG  N211284 001  Nov 16, 2018

### Lamivudine; Zidovudine

**Tablet; Oral**

**Combivir**

+! VIV HLTHCARE 150MG;300MG  N020857 001  Sep 26, 1997

**Lamivudine and Zidovudine**

AUROBINDO PHARMA LTD 150MG;300MG  A077558 001  May 05, 2017

CIPLA 150MG;300MG  A202418 001  May 15, 2012

HETERO LABS LTD III 150MG;300MG  A079124 001  Sep 17, 2015

HETERO LABS LTD V 150MG;300MG  A203259 001  Feb 03, 2014

LUPIN LTD 150MG;300MG  A090246 001  May 15, 2012

MACLEODS PHARMS LTD 150MG;300MG  A090679 001  Aug 29, 2018

MYLAN PHARMS INC 150MG;300MG  A204005 001  Aug 28, 2014

SHANGHAI DESANO 150MG;300MG  A206375 001  Apr 10, 2018

STRIDES PHARMA 150MG;300MG  A079128 001  May 13, 2015

### Lamotrigine

**Tablet; Oral**

**Lamictal**

+! GLAXOSMITHKLINE LLC 25MG  N020241 005  Dec 27, 1994

+ 100MG  N020241 001  Dec 27, 1994

+ 150MG  N020241 002  Dec 27, 1994

+ 200MG  N020241 004  Dec 27, 1994

**Lamotrigine**

ALEMBIC PHARMS LTD 25MG  A090607 001  Jan 13, 2011

+ 100MG  A090607 002  Jan 13, 2011

+ 150MG  A090607 003  Jan 13, 2011

+ 200MG  A090607 004  Jan 13, 2011

ALKEM LABS LTD 25MG  A200694 001  Jun 14, 2013

+ 100MG  A200694 002  Jun 14, 2013

+ 150MG  A200694 003  Jun 14, 2013

+ 200MG  A200694 004  Jun 14, 2013

APOTEX INC 25MG  A078625 001  Jan 27, 2009

+ 100MG  A078625 002  Jan 27, 2009

+ 150MG  A078625 003  Jan 27, 2009

+ 200MG  A078625 004  Jan 27, 2009

AUROBINDO PHARMA 25MG  A078956 001  Jan 27, 2009

+ 100MG  A078956 002  Jan 27, 2009

+ 150MG  A078956 003  Jan 27, 2009

+ 200MG  A078956 004  Jan 27, 2009

CIPLA 25MG  A078956 001  Jan 27, 2009

+ 100MG  A078956 002  Jan 27, 2009

+ 150MG  A078956 003  Jan 27, 2009

+ 200MG  A078956 004  Jan 27, 2009

GLENMARK GENERICS 25MG  A077783 001  Nov 01, 2010

+ 100MG  A077783 002  Nov 01, 2010

+ 150MG  A077783 003  Nov 01, 2010

+ 200MG  A077783 004  Nov 01, 2010

JUBILANT CADISTA 25MG  A078691 001  Jun 01, 2010

+ 100MG  A078691 002  Jun 01, 2010

+ 150MG  A078691 003  Jun 01, 2010

+ 200MG  A078691 004  Jun 01, 2010

LUPIN LTD 25MG  A078691 001  Jun 01, 2010

+ 100MG  A078691 002  Jun 01, 2010

+ 150MG  A078691 003  Jun 01, 2010

+ 200MG  A078691 004  Jun 01, 2010

MYLAN 25MG  A077420 001  Jan 27, 2009

+ 100MG  A077420 002  Jan 27, 2009

+ 150MG  A077420 003  Jan 27, 2009

+ 200MG  A077420 004  Jan 27, 2009

TARO PHARM IND 25MG  A078525 001  Jan 27, 2009

+ 100MG  A078525 002  Jan 27, 2009
### LAMOTRIGINE

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# LAMOTRIGINE

**Tablet, Extended Release; Oral**

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# LAMICTAL ODT

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# LANREOTIDE ACETATE

**Solution; Subcutaneous**

**Somatuline Depot**

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# LANSOPRAZOLE

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LETRAZOLE
TABLET; ORAL
LETRAZOLE
AB EUGIA PHARMA 2.5MG A211717 001 Jan 11, 2019
AB FRESENIUS KABI 2.5MG A090491 001 Jun 03, 2011
AB ONCOL HIKMA PHARMS 2.5MG A203796 001 Jun 03, 2016
AB JIANGSU HENGRIUI MED 2.5MG A202716 001 May 16, 2013
AB NATCO PHARMA LTD 2.5MG A200161 001 Jun 03, 2011
AB TEVA PHARMAS 2.5MG A090289 001 Jun 03, 2011
AB VINTAGE PHARMS LLC 2.5MG A090789 001 Jun 03, 2011
AB WEST-WARD PHARMS 2.5MG A090838 001 Jun 03, 2011

LETRAZOLE; KIROCCILIB SUCCINATE
TABLET, TABLET; ORAL
KISQALI FEMARA CO-PACK (COPACKAGED) +!
NOVARTIS PHARMS 2.5MG, N/A; N/A, EQ 200MG BASE N209935 001 May 04, 2017

LEUCOVORIN CALCIUM
INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
AP FRESENIUS KABI USA EQ 10MG BASE/ML A207226 001 Jul 27, 2018
AP INGENUS PHARMS LLC EQ 10MG BASE/VIAL A210917 001 Nov 23, 2018
AP TEVA PHARMAS USA EQ 100MG BASE/VIAL A081277 001 Sep 28, 1993
AP ! WEST-WARD PHARMS EQ 50MG BASE/VIAL A089384 001 Sep 14, 1987
AP ! EQ 100MG BASE/VIAL A089717 001 Mar 28, 1988

LEUCOVORIN CALCIUM PRESERVATIVE FREE
LEUCOVORIN CALCIUM
AP FRESENIUS KABI USA EQ 200MG BASE/VIAL A040258 001 Feb 26, 1999
AP MYLAN LABS LTD EQ 500MG BASE/VIAL A040286 001 Feb 26, 1999
AP SAGENT PHARMS EQ 100MG BASE/VIAL A041714 001 Jun 12, 1997
AP ! WEST-WARD PHARMS EQ 50MG BASE/VIAL A089384 001 Sep 14, 1987
AP ! EQ 100MG BASE/VIAL A089717 001 Mar 28, 1988

LEUCOVORIN CALCIUM
TABLET; ORAL
LEUCOVORIN CALCIUM
AB BARR EQ 5MG BASE A071198 001 Sep 24, 1987
AB EQ 25MG BASE A071199 001 Sep 24, 1987
AB WEST-WARD PHARMS EQ 5MG BASE A072733 001 Feb 22, 1993
AB ! EQ 25MG BASE A072736 001 Feb 22, 1993

LEUPROLIDE ACETATE
FOR SUSPENSION; INTRAMUSCULAR
LUPRON DEPOT KIT
+! GP-PHARM SA 22.5MG/VIAL N205054 001 Aug 28, 2018
LEUPROLIDE ACETATE
AP ! SANDOZ 1MG/0.2ML A074728 001 Aug 04, 1998
AP SUN PHARMA GLOBAL 1MG/0.2ML A078885 001 Mar 09, 2009
AP TEVA PHARMAS USA 1MG/0.2ML A075471 001 Oct 25, 2000
LUPRON DEPOT
+! ABBVIE ENDOCRINE INC 3.75MG N020011 002 Oct 26, 1995
+! 7.5MG/VIAL N019732 001 Jan 26, 1989
+! 11.25MG/VIAL N020708 001 Mar 07, 1997
+ 22.5MG/VIAL N020517 001 Dec 22, 1995
+! 30MG/VIAL N020517 002 May 30, 1997
+! 45MG/VIAL N020517 003 Jun 17, 2011
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<td>N020263 002</td>
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<td>+! AbbVie Endocrine Inc</td>
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<td>+! AbbVie Endocrine Inc</td>
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<td>N020263 007</td>
<td>Aug 15, 2011</td>
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<td>+! AbbVie Endocrine Inc</td>
<td>30MG/VIAL</td>
<td>N020263 008</td>
<td>Aug 15, 2011</td>
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<td>7.5MG/VIAL</td>
<td>N021343 001</td>
<td>Jan 23, 2002</td>
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<td>+! TOLMAR THERAP</td>
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<td>Leuprolide Acetate; Nor ethindrone Acetate</td>
<td>3.75MG/VIAL, N/A; N/A, 5MG</td>
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<td>+! AbbVie Endocrine Inc</td>
<td>11.25MG/VIAL, N/A; N/A, 5MG</td>
<td>N203696 002</td>
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<td>A207628 001</td>
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<td>+! AUROBINDO PHARMA LTD</td>
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<td>A207625 001</td>
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<td>+! CIPLA</td>
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<td>A077756 001</td>
<td>Apr 09, 2008</td>
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LEVETIRACETAM
INJECTABLE; IV (INFUSION)

LEVETIRACETAM
AP LUITPOLD 500MG/5ML (100MG/ML) A202143 001 Jan 31, 2012
AP MYLAN LABS LTD 500MG/5ML (100MG/ML) A203308 001 Sep 16, 2016
AP SAGENT PHARMS 500MG/5ML (100MG/ML) A091627 001 Jun 26, 2013
AP SUN PHARM INDOS LTD 500MG/5ML (100MG/ML) A090754 001 Jun 16, 2010
AP X GEN PHARMS 500MG/5ML (100MG/ML) A091489 001 Aug 05, 2011
LEVETIRACETAM IN SODIUM CHLORIDE
AP AUROBINDO PHARMA LTD 500MG/100ML (5MG/ML) A207160 001 Jan 04, 2017
AP 1000MG/100ML (10MG/ML) A207160 002 Jan 04, 2017
AP 1500MG/100ML (15MG/ML) A207160 003 Jan 04, 2017
AP GLAND PHARMA LTD 500MG/100ML (5MG/ML) A206880 001 Oct 25, 2017
AP 1000MG/100ML (10MG/ML) A206880 002 Oct 25, 2017
AP 1500MG/100ML (15MG/ML) A206880 003 Oct 25, 2017
AP + HQ SPECIALITY PHARMA 500MG/100ML (5MG/ML) N202543 001 Nov 09, 2011
AP + 1000MG/100ML (10MG/ML) N202543 002 Nov 09, 2011
AP + 1500MG/100ML (15MG/ML) N202543 003 Nov 09, 2011
SOLUTION; ORAL
KEPPRA
AA + UCB INC 100MG/ML N021505 001 Jul 15, 2003
LEVETIRACETAM
AA ACTAVIS MID 100MG/ML A078976 001 Jan 15, 2009
ATLANTIC
AA AMNEAL PHARMS 100MG/ML A090992 001 Oct 27, 2009
AA AUROBINDO PHARMA LTD 100MG/ML A079063 001 Jan 15, 2009
AA BRECKENRIDGE PHARM 100MG/ML A079120 001 Jan 15, 2009
AA HETER LABS LTD III 100MG/ML A020352 001 Feb 28, 2013
AA HI-TECH PHARMACAL 100MG/ML A090601 001 Feb 28, 2012
AA LANNETT CO INC 100MG/ML A090079 001 Apr 11, 2012
AA 100MG/ML A090263 001 Apr 03, 2009
AA LUPIN LTD 100MG/ML A090839 001 Oct 17, 2011
AA ORIT LABS LLC 100MG/ML A020357 001 May 09, 2013
AA PHARM ASSOC 100MG/ML A020157 001 Jun 04, 2015
AA Taro 100MG/ML A078774 001 Feb 10, 2009
AA TOLMAR 100MG/ML A079107 001 Jan 15, 2009
AA TRIS PHARMA INC 100MG/ML A090461 001 Sep 30, 2010
AA WOCKHARDT BIO AG 100MG/ML A090028 001 Mar 03, 2010
TABLET; ORAL
KEPPRA
AB + UCB INC 250MG N021035 001 Nov 30, 1999
AB + 500MG N021035 002 Nov 30, 1999
AB + 750MG N021035 003 Nov 30, 1999
AB + 1GM N021035 004 Jan 06, 2006
LEVETIRACETAM
AB ACCORD HLTHCARE 250MG A090843 001 Feb 14, 2011
AB 500MG A090843 002 Feb 14, 2011
AB 750MG A090843 003 Feb 14, 2011
AB 1GM A090843 004 Feb 14, 2011
AB ACI HEALTHCARE LTD 250MG A078042 001 Jan 15, 2009
AB 500MG A078042 002 Jan 15, 2009
AB 750MG A078042 003 Jan 15, 2009
AB 1GM A078042 004 Jan 15, 2009
AB ACIC PHARMS 250MG A090767 001 Jul 28, 2010
AB 500MG A090767 002 Jul 28, 2010
AB 750MG A090767 003 Jul 28, 2010
AB 1GM A090767 004 Jul 28, 2010
AB APOTEX INC 250MG A078869 001 Mar 13, 2009
AB 500MG A078869 002 Mar 13, 2009
AB 750MG A078869 003 Mar 13, 2009
AB 1GM A078869 004 Mar 13, 2009
AB AUROBINDO PHARMA 250MG A078993 001 Jan 15, 2009
AB 500MG A078993 002 Jan 15, 2009
AB 750MG A078993 003 Jan 15, 2009
AB 1GM A078993 004 Jan 15, 2009
AB BRECKENRIDGE PHARM 250MG A078993 001 Jan 15, 2009
AB 500MG A078993 002 Jan 15, 2009
AB 750MG A078993 003 Jan 15, 2009
AB 1GM A078993 004 Jan 15, 2009
AB CHARTWELL RX 250MG A201293 001 Jun 14, 2011
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POWDER; INTRAVENOUS
FUSILEV
AP +! SPECTRUM PHARMS EQ 50MG BASE/VIAL N202140 001 Mar 07, 2008
LEVOLEUCOVORIN CALCIUM
AP ACTAVIS LLC EQ 50MG BASE/VIAL A206516 001 Feb 13, 2017
AP AMNEAL PHARMAS CO EQ 50MG BASE/VIAL A207547 001 Feb 13, 2017
AP + INT WEST-WARD PHARMS EQ 50MG BASE/VIAL A206263 001 Jun 16, 2016
AP +! ACTAVIS LLC EQ 175MG BASE/VIAL N208723 001 Sep 29, 2016
LEVONE
AP AMNEAL PHARMAS CO EQ 50MG BASE/VIAL A207548 001 Sep 08, 2017
AP GLAND PHARMA LTD EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) A210892 001 Sep 08, 2017
AP INGENUS PHARMS LLC EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) A210623 001 May 03, 2018
AP MYLAN TEOANTA EQ 250MG BASE/25ML (EQ 10MG BASE/ML) A203576 001 Oct 20, 2015
AP SANDOZ INC EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) A203563 001 Mar 09, 2015
AP EQ 250MG BASE/25ML (EQ 10MG BASE/ML) A203563 002 Mar 09, 2015
LEVOMILNACIPRAN HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL
FETZIMA + ALLERGAN SALES LLC EQ 20MG BASE N204168 001 Jul 25, 2013
AP EQ 40MG BASE N204168 002 Jul 25, 2013
AP EQ 80MG BASE N204168 003 Jul 25, 2013
AP +! EQ 120MG BASE N204168 004 Jul 25, 2013
LEVONORGESTREL
INTRAUTERINE DEVICE; INTRAUTERINE
KYLEENA +! BAYER HLTHCARE 19.5MG N208224 001 Sep 16, 2016
LILETTA MEDICINES360 52MG A206229 001 Feb 26, 2015
MIKRENA +! BAYER HLTHCARE 52MG N201225 001 Dec 06, 2000
SKYLA +! BAYER HLTHCARE 13.5MG N203159 001 Jan 09, 2013
TABLET; ORAL
LEVONORGESTREL
AB LOTUS PHARM CO LTD 0.75MG A202684 001 Sep 02, 2016
AB MYLAN LABS LTD 0.75MG A202740 001 Sep 02, 2016
AB + PERRIGO R AND D 0.75MG A090740 001 Dec 30, 2010
LEVORPHANOL TARTRATE
TABLET; ORAL
LEVORPHANOL TARTRATE
AB + SENTRYL THERAPS INC 2MG A074278 001 Mar 31, 2000
AB VIRTUS PHARMS 2MG A211484 001 Dec 13, 2018
AB SENTRYL THERAPS INC 3MG A074278 002 Jun 18, 2018
LEVOTHYROXINE SODIUM
CAPSULE; ORAL
TIROSINT + INSTITUT 0.013MG N201924 013 Aug 01, 2007
+ 0.025MG N201924 002 Oct 13, 2006
+ 0.050MG N201924 003 Oct 13, 2006
+ 0.075MG N201924 004 Oct 13, 2006
+ 0.088MG N201924 010 Oct 02, 2009
+ 0.1MG N201924 005 Oct 13, 2006
+ 0.112MG N201924 008 Oct 02, 2009
+ 0.125MG N201924 006 Oct 13, 2006
+ 0.137MG N201924 009 Oct 02, 2009
+ 0.15MG N201924 007 Oct 13, 2006
+ 0.175MG N201924 011 Apr 25, 2017
+! 0.200MG N201924 012 Apr 25, 2017
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**Note:** See current Annual Edition, 1.8 Description of Special Situations, Levothyroxine Sodium
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TABLET; ORAL
JENTADUETO
+ BOEHRINGER 2.5MG; 500MG N201281 001 Jan 30, 2012
+ 2.5MG; 850MG N201281 002 Jan 30, 2012
+! 2.5MG; 1GM N201281 003 Jan 30, 2012
TABLET, EXTENDED RELEASE; ORAL
JENTADUETO XR
+ BOEHRINGER 2.5MG; 1GM N208026 001 May 27, 2016
+! 5MG; 1GM N208026 002 May 27, 2016
LINCOMYCIN HYDROCHLORIDE
INJECTABLE; INJECTION
LINCOMYCIN
AP +! PHARMACIA AND UPJOHN EQ 300MG BASE/ML N050317 001
LINCOMYCIN
AP X-GEN PHARMS INC EQ 300MG BASE/ML A201746 001 Jun 04, 2015
LINDANE
LOTION; TOPICAL
LINDANE
OLTA PHARMS 1% A087313 001
LINDANE SHAMPOO; TOPICAL
OLTA PHARMS 1% A087266 001
WOCKHARDT BIO AG 1% A088191 001 Sep 18, 1984
LINEZOLID FOR SUSPENSION; ORAL
LINEZOLID SOLUTION; INTRAVENOUS
LINEZOLID IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
LINEZOLID IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
+! HOSPIRA INC 600MG/300ML (2MG/ML) N206473 001 Jun 18, 2015
TABLET; ORAL
LINEZOLID
AP AUROBINDO PHARMA LTD 600MG/300ML (2MG/ML) A206917 001 Aug 04, 2016
AP FRESENIUS KABI USA 600MG/300ML (2MG/ML) A204764 001 Mar 15, 2016
AP HOSPIRA INC 600MG/300ML (2MG/ML) A205442 001 Jul 07, 2015
AP HOSPITALITY PHARMA 200MG/100ML (2MG/ML) A207001 001 Jul 07, 2017
AP MYLAN LABS LTD 600MG/300ML (2MG/ML) A207002 002 Jul 07, 2017
AP NANG KUANG PHARM CO 200MG/100ML (2MG/ML) A205154 001 Dec 06, 2017
AP TEVA PHARMS 600MG/300ML (2MG/ML) A200222 001 Jun 27, 2012
LINEZOLID IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
+! HOSPIRA INC 600MG/300ML (2MG/ML) N206473 001 Jun 18, 2015
TABLET; ORAL
LINEZOLID
AP ALEMIC PHARMS LTD 600MG A205233 001 Dec 21, 2015
AP ALKEM LABS LTD 600MG A205517 001 Dec 21, 2015
AP AMNEAL PHARMS 600MG A204536 001 Dec 21, 2015
AP GATE PHARMS 600MG A091210 001 Feb 05, 2016
AP GLENMARK PHARMS 600MG A078987 001 Dec 21, 2015
AP HETERO LABS LTD V 600MG A204239 001 Dec 21, 2015
AP MYLAN PHARMS INC 600MG A78846 001 Dec 21, 2015
AP NOVEL LABS INC 600MG A207526 001 Aug 22, 2016
AP TEVA PHARMS USA 600MG A207861 001 May 18, 2015
AP ZYDUS PHARMS USA INC 600MG A206997 001 Feb 22, 2017
LINEZOLID

TABLET; ORAL

ZYVOX

AB +! PHARMACIA AND UPJOHN 600MG N02130 002 Apr 18, 2000

LIOTHYRONINE SODIUM

INJECTABLE; INJECTION

LIOTHYRONINE SODIUM

AP X GEN PHARMS EQ 0.01MG BASE/ML A076923 001 Aug 17, 2005

TRIOSTAT

AP +! PAR STERILE PRODUCTS EQ 0.01MG BASE/ML N020105 001 Dec 31, 1991

TABLET; ORAL

CYTOMEL

AB + KING PHARMS EQ 0.005MG BASE N010379 001

AB + EQ 0.025MG BASE N010379 002

AB +! EQ 0.05MG BASE N010379 003

LIOTHYRONINE SODIUM

AB MAYNE PHARMA INC EQ 0.005MG BASE A09097 001 Mar 20, 2009

AB EQ 0.025MG BASE A09097 002 Mar 20, 2009

AB EQ 0.05MG BASE A09097 003 Mar 20, 2009

AB MYLAN EQ 0.005MG BASE A090326 001 Jul 14, 2009

AB EQ 0.025MG BASE A090326 002 Jul 14, 2009

AB EQ 0.05MG BASE A090326 003 Jul 14, 2009

AB SIGMAPHARM LABS LLC EQ 0.005MG BASE A200825 001 Nov 29, 2012

AB EQ 0.025MG BASE A200825 002 Nov 29, 2012

AB EQ 0.05MG BASE A200825 003 Dec 31, 2012

AB SUN PHARM INDUS LTD EQ 0.005MG BASE A091382 001 Apr 20, 2016

AB EQ 0.025MG BASE A091382 002 Apr 20, 2016

AB EQ 0.05MG BASE A091382 003 Apr 20, 2016

AB TEVA PHARS USA EQ 0.005MG BASE A211510 001 Oct 26, 2014

AB EQ 0.025MG BASE A211510 002 Oct 26, 2014

AB EQ 0.05MG BASE A211510 003 Oct 26, 2014

LIRAGLUTIDE RECOMBINANT

SOLUTION; SUBCUTANEOUS

SAXENDA

+! NOVO 18MG/3ML (6MG/ML) N206321 001 Dec 23, 2014

VICTOZA

+! NOVO NORDISK INC 18MG/3ML (6MG/ML) N022341 001 Jan 25, 2010

LISDEXAMFETAMINE DIMESYLATE

CAPSULE; ORAL

VYVANSE

+ SHIRE DEVELOPMENT 10MG N021977 007 Oct 30, 2014

+ 20MG N021977 004 Dec 10, 2007

+ 30MG N021977 001 Feb 23, 2007

+ 40MG N021977 005 Dec 10, 2007

+ 50MG N021977 002 Feb 23, 2007

+ 60MG N021977 006 Dec 10, 2007

+! 70MG N021977 003 Feb 23, 2007

TABLET, CHEWABLE; ORAL

VYVANSE

+ SHIRE DEVELOPMENT 10MG N020510 001 Jan 28, 2017

+ 20MG N020510 002 Jan 28, 2017

+ 30MG N020510 003 Jan 28, 2017

+ 40MG N020510 004 Jan 28, 2017

+ 50MG N020510 005 Jan 28, 2017

+ 60MG N020510 006 Jan 28, 2017

LISINOPRIL

SOLUTION; ORAL

QBRELIS

+! SILVERGATE PHARMS 1MG/ML N208401 001 Jul 29, 2016

TABLET; ORAL

LISINOPRIL

AB ACCORD HLTCARE 2.5MG A202554 001 Jul 30, 2013

AB 5MG A202554 002 Jul 30, 2013

AB 10MG A202554 003 Jul 30, 2013

AB 20MG A202554 004 Jul 30, 2013

AB 30MG A202554 005 Jul 30, 2013

AB 40MG A202554 006 Jul 30, 2013

AB APOTEX INC 2.5MG A076102 001 Sep 30, 2002

AB 5MG A076102 002 Sep 30, 2002
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<th>Strength</th>
<th>Code</th>
<th>Date</th>
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<td>Feb 22, 2006</td>
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<td>Casipharm Inc</td>
<td>2.5MG</td>
<td>A075994 001</td>
<td>Jul 01, 2002</td>
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<td>Lisinopril</td>
<td>Wockhardt</td>
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<tr>
<td>Lithium Carbonate Capsule; Oral</td>
<td>Lisinopril</td>
<td>Wockhardt</td>
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<td>Lisinopril</td>
<td>Sun Pharm Inds Inc</td>
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<td>West-Ward Pharms Int</td>
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<td>EQ 300mg Carbonate/5ml</td>
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<td>Formulation</td>
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<td>Lixisenatide</td>
<td>Solution; Subcutaneous</td>
<td>+ Sanofi-Aventis US</td>
<td>0.15mg/3ml (0.05mg/ml)</td>
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<td>+</td>
<td>0.3mg/3ml (0.1mg/ml)</td>
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<td>Lodoxamide Tromethamine</td>
<td>Solution/Drops; Ophthalmic</td>
<td>+ Novartis Pharms Corp</td>
<td>EQ 0.1% Base</td>
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<tr>
<td>Loxididine Hydrochloride</td>
<td>Tablet; Oral</td>
<td>Lucemira</td>
<td>+ US WorldMeds LLC</td>
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<td>Capsule; Oral</td>
<td>Juxtapid</td>
<td>+ Aegerion</td>
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<td>Gleostine</td>
<td>+ Corden Pharma</td>
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<td>TEVA</td>
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<td>Solution; Oral</td>
<td>Kaletra</td>
<td>+ ABBVIE</td>
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<td>Kaletra</td>
<td>+ ABBVIE</td>
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<td>+</td>
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<td>ANDA REPOSITORY</td>
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<td>HI-TECH PHARMA CO</td>
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LURASIDONE HYDROCHLORIDE

TABLET; ORAL

LURASIDONE HYDROCHLORIDE

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LUSUTROMBOPAG

TABLET; ORAL

MULPLETA

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<tbody>
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LUTETIUM DOTATATE LU-177 SOLUTION; INTRAVENOUS

LUTATHERA

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MACIMORELIN ACETATE FOR SOLUTION; ORAL

MACRILEN

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<tbody>
<tr>
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<td>N205598 001</td>
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MACITENTAN TABLET; ORAL

OPSUMIT

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MAFENIDE ACETATE CREAM; TOPICAL

SULFAMYLON

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MAFENIDE ACETATE INJECTABLE; INJECTION

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SULFAMYLON

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MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE INJECTABLE; INJECTION

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<td>30MG/100ML; 37MG/100ML; 0.82MG/100ML; 370MG/1000ML</td>
<td>N019696 001</td>
<td>Sep 29, 1989</td>
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<td>10MG/100ML; 530MG/100ML; 500MG/100ML; 12MG/100ML</td>
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MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE INJECTABLE; INJECTION

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Code</th>
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<td>B BRAUN</td>
<td>30MG/100ML; 37MG/100ML; 0.82MG/100ML; 370MG/1000ML</td>
<td>N019711 001</td>
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<td>NORMOSOL-R IN PLASTIC CONTAINER</td>
<td>30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML</td>
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<tr>
<td>ICU MEDICAL INC</td>
<td>30MG/100ML; 37MG/100ML; 526MG/100ML</td>
<td>N017586 001</td>
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NORMOSOL-R IN PLASTIC CONTAINER
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION

PLASMA-LYTE 148 IN WATER IN PLASTIC CONTAINER +!
BAXTER HLTHCARE 30MG/100ML; 37MG/100ML; 368MG/100ML; 526MG N017378 001/100ML; 502MG/100ML

PLASMA-LYTE A IN PLASTIC CONTAINER +!
BAXTER HLTHCARE 30MG/100ML; 37MG/100ML; 368MG/100ML; 526MG N017378 002 Nov 22, 1982/100ML; 502MG/100ML

SOLUTION; IRRIGATION

PHYSIOLYTE IN PLASTIC CONTAINER +!
B BRAUN 30MG/100ML; 37MG/100ML; 370MG/100ML; 530MG N019024 001 Jun 08, 1984/100ML; 500MG/100ML

PHYSIOSOL IN PLASTIC CONTAINER +!
ICU MEDICAL INC 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG N017637 002 Jul 08, 1982/100ML; 502MG/100ML

MAGNESIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

SOLUTION; INJECTION

NORMOCARB HF 25 +!
DIALYSIS SUPS 0.21GM/100ML; 2.8GM/100ML; 9.07GM/100ML N021910 001 Jul 26, 2006

NORMOCARB HF 35 +!
DIALYSIS SUPS 0.21GM/100ML; 3.97GM/100ML; 8.3GM/100ML N021910 002 Jul 26, 2006

MAGNESIUM SULFATE

INJECTABLE; INJECTION

MAGNESIUM SULFATE IN DEXTROSE 5% IN PLASTIC CONTAINER +!
FRESENIUS KABI USA 1GM/100ML A206486 001 Mar 07, 2016

MAGNESIUM SULFATE IN PLASTIC CONTAINER +!
FRESENIUS KABI USA 4GM/100ML (40MG/ML) A206485 001 Mar 15, 2016

MAGNESIUM SULFATE

SOLUTION; INTRAMUSCULAR, INTRAVENOUS

MAGNESIUM SULFATE +!
FRESENIUS KABI USA 5GM/10ML (500MG/ML) A206039 001 Dec 18, 2014

MAGNESIUM SULFATE +!
FRESENIUS KABI USA 5GM/10ML (500MG/ML) N019316 001 Sep 08, 1986

MAGNESIUM SULFATE +!
FRESENIUS KABI USA 10GM/20ML (500MG/ML) N019316 003 Jan 29, 2016

MAGNESIUM SULFATE +!
HOSPIRA INC 10GM/20ML (500MG/ML) A202411 001 May 14, 2015

MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION

TIS-U-SOL

BAXTER HLTHCARE 20MG/100ML; 40MG/100ML; 6.25MG/100ML; 800MG/100ML; 8.75MG/100ML N018508 001 Feb 19, 1982

TIS-U-SOL IN PLASTIC CONTAINER

BAXTER HLTHCARE 20MG/100ML; 40MG/100ML; 6.25MG/100ML; 800MG/100ML; 8.75MG/100ML N018336 001
### Prescription Drug Product List

#### Magnesium Sulfate; Potassium Sulfate; Sodium Sulfate

**Powder; Oral**

**Colprep Kit**

+! GatorPharms

1.6GM/BOT; 3.13GM/BOT; 17.5GM/BOT

N204553 001 Dec 27, 2016

**Solution; Oral**

**Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate**

**AA**

Novel Labs Inc

1.6GM/BOT; 3.13GM/BOT; 17.5GM/BOT

A202511 001 Feb 23, 2017

**AA**

Braintree Labs

1.6GM/BOT; 3.13GM/BOT; 17.5GM/BOT

N022372 001 Aug 05, 2010

#### Malathion

**Lotion; Topical**

**Malathion**

AT

Suvfen Life

0.5%

A091559 001 May 23, 2012

AT

Taro Pharm Inds Ltd

0.5%

N018613 001 Aug 02, 1982

#### Manganese Chloride

**Injectable; Injection**

Manganese Chloride in Plastic Container

+! Hospira

EQ 0.1MG Manganese/ML

N018962 001 Jun 26, 1986

#### Mannitol

**Injectable; Injection**

**Mannitol 10% in Plastic Container**

AP

B Braun

10GM/100ML

N020006 002 Jul 26, 1993

AP

Mannitol 15% in Plastic Container

B Braun

15GM/100ML

N020006 003 Jul 26, 1993

AP

Mannitol 20% in Plastic Container

B Braun

20GM/100ML

N020006 004 Jul 26, 1993

AP

ICU Medical Inc

20GM/100ML

N019603 004 Jan 08, 1990

**Mannitol 25%**

AP

Prexenius Kabi USA

12.5GM/50ML

A080677 001

AP

Hospira

12.5GM/50ML

N016269 006 Aug 25, 1994

AP

Intl Medication

12.5GM/50ML

A083051 001

AP

Luitpold

12.5GM/50ML

A087409 001 Jan 21, 1982

AP

Mannitol 5% in Plastic Container

B Braun

5GM/100ML

N020006 001 Jul 26, 1993

AP

Osmotrol 10% in Water

Baxter Hlthcare

10GM/100ML

N013684 002

AP

Osmotrol 10% in Water in Plastic Container

Baxter Hlthcare

10GM/100ML

N013684 006

AP

Osmotrol 15% in Water

Baxter Hlthcare

15GM/100ML

N013684 004

AP

Osmotrol 15% in Water in Plastic Container

Baxter Hlthcare

15GM/100ML

N013684 008

AP

Osmotrol 20% in Water

Baxter Hlthcare

20GM/100ML

N013684 003

AP

Osmotrol 20% in Water in Plastic Container

Baxter Hlthcare

20GM/100ML

N013684 007

AP

Osmotrol 5% in Water

Baxter Hlthcare

5GM/100ML

N013684 001

AP

Osmotrol 5% in Water in Plastic Container

Baxter Hlthcare

5GM/100ML

N013684 005

#### Mapprotoline Hydrochloride

**Tablet; Oral**

Mapprotoline Hydrochloride

Mylan

25MG

A072285 002 Oct 03, 1988

! 50MG

A072285 001 Oct 03, 1988

! 75MG

A072285 003 Oct 03, 1988
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<th>Type</th>
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<th>NDC Code</th>
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<td>TABLET; ORAL</td>
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<td>MEBENDAZOLE</td>
<td>TABLET, CHEWABLE; ORAL</td>
<td>100MG</td>
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<td>MECAMYLAMINE HYDROCHLORIDE</td>
<td>TABLET; ORAL</td>
<td>2.5MG</td>
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<td>NEXGEN PHARMA</td>
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<td>MECASERMIN RECOMBINANT</td>
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<td>40MG/4ML</td>
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<td>INCRELEX</td>
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<td>(10MG/ML)</td>
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<td>MECHLORETHAMINE HYDROCHLORIDE</td>
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<td>EQ 0.016% BASE</td>
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<td>valchlor</td>
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<td>MECLOFENAMATE SODIUM</td>
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<td>INJECTABLE; INJECTION</td>
<td>150MG/ML</td>
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<td>Nov 28, 2017</td>
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<td>MEGESTROL ACETATE</td>
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<td>PROCTER &amp; GAMBLE</td>
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<td>MICRO LABS</td>
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<td><strong>AB</strong></td>
<td>+ BOEHRINGER</td>
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**Tablet, Extended Release; Oral**

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**Tablet; Oral**

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### Metformin Hydrochloride; Saxagliptin Hydrochloride

**Tablet, Extended Release; Oral**

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### Methacholine Chloride

**For Solution; Inhalation**

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### Methadone Hydrochloride

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### Methadone Hydrochloride Intensol

**Concentrate; Oral**

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### Methadone Hydrochloride Intensol

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### Methadone Hydrochloride Intensol

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### Methadone Hydrochloride Intensol

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### METHOTREXATE

#### SOLUTION; SUBCUTANEOUS

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#### METHOTREXATE SOLUTION; ORAL

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#### METHOTREXATE SODIUM

#### INJECTABLE; INJECTION

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#### METHOTREXATE SODIUM PRESERVATIVE FREE

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#### METHOTREXATE SODIUM INJECTABLE; INJECTION

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### METOTREXATE SODIUM INJECTABLE; INJECTION

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<td>ProvePharm SAS</td>
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METHYLALTREXONE BROMIDE
SOLUTION; SUBCUTANEOUS
RELISTOR
+! SALIX PHARMS 8MG/0.4ML (8MG/0.4ML) N021964 002 Sep 27, 2010
+! 12MG/0.6ML (12MG/0.6ML) N021964 001 Apr 24, 2008
+! 12MG/0.6ML (12MG/0.6ML) N021964 003 Sep 27, 2010
TABLET; ORAL
RELISTOR
+! SALIX PHARMS INC 150MG N208271 001 Jul 19, 2016

METHYLPHENIDATE
FILM, EXTENDED RELEASE; TRANSDERMAL
DAYTRANA
+ NOVEN PHARMS INC 10MG/9HR (1.1MG/HR) N021514 001 Apr 06, 2006
+ 15MG/9HR (1.6MG/HR) N021514 002 Apr 06, 2006
+ 20MG/9HR (2.2MG/HR) N021514 003 Apr 06, 2006
+! 30MG/9HR (3.3MG/HR) N021514 004 Apr 06, 2006
TABLET, ORALLY DISINTEGRATING, EXTENDED RELEASE; ORAL
COTEMPLA XR-ODT
+ NEOS THERAPS INC 8.6MG N205489 001 Jun 19, 2017
+ 17.3MG N205489 002 Jun 19, 2017
+ 25.9MG N205489 003 Jun 19, 2017

METHYLPHENIDATE HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL
AB1
BARR LABS INC 10MG A079031 004 Oct 15, 2014
AB1 20MG A079031 001 Jul 13, 2012
AB1 30MG A079031 002 Jul 13, 2012
AB1 40MG A079031 003 Jul 13, 2012
AB1 MAYNE PHARMA 10MG A200886 001 Feb 26, 2018
AB1 20MG A078458 001 Dec 01, 2011
AB1 30MG A078458 002 Dec 01, 2011
AB1 40MG A078458 003 Dec 01, 2011
RITALIN LA
AB1 + NOVARTIS 10MG N021284 004 Apr 10, 2004
AB1 + 20MG N021284 001 Jun 05, 2002
AB1 + 30MG N021284 002 Jun 05, 2002
METADATE CD
AB2 + LANNETT CO INC 10MG N021259 003 May 27, 2003
AB2 + 20MG N021259 001 Jun 19, 2003
AB2 + 30MG N021259 002 Jun 19, 2003
AB2 + 40MG N021259 003 Feb 19, 2006
AB2 + 50MG N021259 004 Feb 19, 2006
AB2 +! 60MG N021259 005 Feb 19, 2006
METHYLPHENIDATE HYDROCHLORIDE
AB2 IMPAX LABS INC 10MG A205105 004 Jul 28, 2016
AB2 20MG A205105 001 Jul 28, 2016
AB2 30MG A205105 002 Jul 28, 2016
AB2 40MG A205105 003 Jul 28, 2016
AB2 50MG A205105 004 Jul 28, 2016
AB2 60MG A205105 005 Jul 28, 2016
AB2 SPECGX LLC 10MG A203583 001 Sep 29, 2015
AB2 20MG A203583 002 Sep 29, 2015
AB2 30MG A203583 003 Sep 29, 2015
AB2 40MG A203583 004 Sep 29, 2015
AB2 50MG A203583 005 Sep 29, 2015
AB2 60MG A203583 006 Sep 29, 2015
AB2 TEVA PHARMS 10MG A007707 003 Jul 19, 2012
AB2 20MG A007707 002 Jul 19, 2012
AB2 30MG A007707 003 Jul 19, 2012
AB2 40MG A007873 001 Jul 19, 2012
AB2 50MG A007873 002 Jul 19, 2012
AB2 60MG A007873 003 Jul 19, 2012
APTENSIO XR
AB3 + RHODES PHARMS 10MG N205831 001 Apr 17, 2015
AB3 + 15MG N205831 002 Apr 17, 2015
AB3 + 20MG N205831 003 Apr 17, 2015
AB3 + 30MG N205831 004 Apr 17, 2015
AB3 + 40MG N205831 005 Apr 17, 2015
AB3 + 50MG N205831 006 Apr 17, 2015
AB3 +! 60MG N205831 007 Apr 17, 2015
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*Please note that this is a sample of the data provided in the document.*
### Methylenidate Hydrochloride

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### Methylprednisolone

**Tablet; Oral**

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**Tablet; Injectable; Inj**

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**Methylprednisolone Acetate**

**Injectable; Injection**

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**Methylprednisolone Sodium Succinate**

**Injectable; Injection**

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<td>METOLAZONE</td>
<td>Tablet; Oral</td>
<td>2.5 mg</td>
<td>MYLAN</td>
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<tr>
<td>METOLAZONE</td>
<td>Tablet; Oral</td>
<td>5 mg</td>
<td>MYLAN</td>
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<td>10 mg</td>
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<td>ZAROXOLYN</td>
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### METOPROLOL TARTRATE

**INJECTABLE; INJECTION**

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<td>HO SPIRA</td>
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<td>AEL MIEC</td>
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<td>A075160 001</td>
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<td>LI UPTOLD</td>
<td>1 MG/ML</td>
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<td>MY LAN ASI</td>
<td>1 MG/ML</td>
<td>A099317 001</td>
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<td>SAN DOX INC</td>
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### METOPROLOL TARTRATE

**TABLET; ORAL**

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### METRONIDAZOLE

**CAPSULE; ORAL**

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<td>ALEMBIC PHARMS LTD</td>
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<td>FOGUERA PHARMS</td>
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<td>A076408 001</td>
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<td>G AND W LABS</td>
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<td>A077549 001</td>
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<td>VALEANT PHARMS</td>
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### METRONIDAZOLE

**CREAM; TOPICAL**

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<td>FOGUERA PHARMS</td>
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### METRONIDAZOLE

**GEL; TOPICAL**

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<td>T O L M A R</td>
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METRONIDAZOLE

**GEL;TOPICAL**

AB 1% A090903 001 Jul 22, 2011

**GEL;VAGINAL**

**METROGEL-VAGINAL**

AB 0.75% N020208 001 Aug 17, 1992

**METRONIDAZOLE**

AB 0.75% A077264 001 Oct 31, 2006

BX 0.75% N021806 001 May 20, 2005

NUVESSA +! CHEMO RESEARCH SL 1.3% N205223 001 Mar 24, 2014

**INJECTABLE;INJECTION**

**FLAGYL I.V. RTU IN PLASTIC CONTAINER**

AP 500MG/100ML N018657 001

AP 500MG/100ML N018900 001 Sep 29, 1983

AP 500MG/100ML N018900 002 Nov 18, 1983

AP 500MG/100ML A205535 001 May 09, 2017

**METROLOTION**

AB 0.75% N020901 001 Nov 24, 1998

**TABLET;ORAL**

**FLAGYL**

AB 250MG N012623 001

AB 500MG N012623 003

AB ALEMBIC PHARMS LTD 250MG A079067 001 Mar 13, 2009

AB A079067 002 Mar 13, 2009

AB AUROBINDO PHARMA LTD 250MG A203974 001 May 29, 2015

AB 500MG A203974 002 May 29, 2015

AB CADILA PHARMS LTD 250MG A079794 001 Dec 12, 2017

AB 500MG A079794 002 Dec 12, 2017

AB FLAMINGO PHARMS 250MG A207309 001 May 16, 2016

AB 500MG A207309 002 May 16, 2016

AB HERITAGE PHARMS INC 250MG A205245 001 Sep 23, 2015

AB 250MG A205245 002 Sep 23, 2015

AB INNOCENIX 250MG A070772 001 Jul 16, 1986

AB 500MG A070772 002 Jul 16, 1986

AB LUPIN LTD 250MG A209096 001 Sep 12, 2017

AB 500MG A209096 002 Sep 12, 2017

AB ORIT LABS LLC 250MG A208681 001 Jun 20, 2017

AB 500MG A208681 002 Jun 20, 2017

AB PLIVA 500MG A070033 001 Dec 06, 1984

AB STRIDES PHARMA 250MG A208162 002 May 25, 2016

AB 500MG A208162 002 May 25, 2016

AB STRIDES VIVIMED 250MG A070040 001 Jan 29, 1985

AB 500MG A070039 001 Jan 29, 1985

AB TEVA PHARMS USA 250MG A070027 001 Nov 06, 1984

AB UNICHEM LABS LTD 250MG A203458 001 Jan 22, 2014

AB 500MG A203458 002 Jan 22, 2014

AB WATSON LABS 250MG A070035 001 Dec 20, 1984

AB WATSON LABS INC 500MG A070044 001 Feb 08, 1985

AB ZYDUS PHARMS USA INC 250MG A206560 001 Nov 16, 2016

AB 500MG A206560 002 Nov 16, 2016

**METYRAPONE**

**CAPSULE;ORAL**

**METOPIRONE**

+! LABORATORIE HRA 250MG N012911 002 Aug 09, 1996
METYROSINE
CAPSULE; ORAL
DEMSEN
+! ATON PHARMA VPN
250MG N017871 001

MEXILETINE HYDROCHLORIDE
CAPSULE; ORAL

TEVA
150MG A074377 001 May 16, 1995
200MG A074377 002 May 16, 1995
250MG A074377 003 May 16, 1995

MICAFUNGIN SODIUM
INJECTABLE; INTRAVENOUS

MYCAMINE
+! ASTELLAS
EQ 50MG BASE/VIAL N021506 002 Mar 16, 2005
+! EQ 100MG BASE/VIAL N021506 003 Jun 27, 2006

MICONAZOLE
TABLET; BUCCAL

ORAVIG
+! MIDATECH PHARMA US
50MG N022404 001 Apr 16, 2010

MICONAZOLE NITRATE
SUPPOSITORY; VAGINAL

MICRONAL NITRATE
AB
ACTAVIS PHARMA
200MG A073508 001 Nov 19, 1993

MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE

OINTMENT; TOPICAL

VISION
+! MYLAN PHARMS INC
0.25%; 81.35%; 15% N021026 001 Feb 16, 2006

MIDAZOLAM HYDROCHLORIDE
INJECTABLE; INJECTION

MIDAZOLAM HYDROCHLORIDE

AP
AKORN INC
EQ 1MG BASE/ML A075494 001 Jun 30, 2000
AP EQ 5MG BASE/ML A075494 002 Jun 30, 2000
AP FRESENIUS KABI
EQ 1MG BASE/ML A075154 001 Jun 20, 2000
AP EQ 5MG BASE/ML A075154 002 Jun 20, 2000
AP GLAND PHARMA LTD
EQ 1MG BASE/ML A090696 001 Feb 29, 2012
AP HOSPIRA
EQ 1MG BASE/ML A075293 001 Jun 20, 2000
AP EQ 5MG BASE/ML A075293 002 Jun 20, 2000
AP HOSPIRA
EQ 1MG BASE/ML A075856 001 Jun 13, 2002
AP EQ 5MG BASE/ML A075856 002 Jun 13, 2002
AP WEST-WARD PHARMS
INT
EQ 1MG BASE/ML A075243 001 Jun 23, 2000
AP EQ 1MG BASE/ML A075243 002 Jun 23, 2000
AP EQ 1MG BASE/ML A075243 003 Jun 23, 2000
AP EQ 5MG BASE/ML A075243 004 Jun 23, 2000
AP FRESENIUS KABI USA
EQ 1MG BASE/ML A203460 001 Aug 22, 2014
AP EQ 5MG BASE/ML A203460 002 Aug 22, 2014
AP HOSPIRA
EQ 1MG BASE/ML A075857 001 Jul 22, 2002
AP EQ 5MG BASE/ML A075857 002 Jul 22, 2002
AP MYLAN ASI
EQ 1MG BASE/ML A090315 001 Nov 29, 2010
AP EQ 5MG BASE/ML A090315 002 Nov 29, 2010

MIDAZOLAM HYDROCHLORIDE PRESERVATIVE FRER

AP FRESENIUS KABI USA
EQ 1MG BASE/ML A090316 001 May 04, 2011
AP EQ 5MG BASE/ML A090316 002 May 04, 2011

MIDAZOLAM HYDROCHLORIDE

AP SAGENT STRIDES
EQ 1MG BASE/ML A090316 001 May 04, 2011
AP EQ 5MG BASE/ML A090316 002 May 04, 2011

MIDAZOLAM HYDROCHLORIDE

AP FRESENIUS KABI USA
EQ 5MG BASE/ML A208878 001 Mar 28, 2017

SEIZALAM
+! MERIDIAN MEDCL
TECHN
EQ 50MG BASE/10ML (EQ 5MG BASE/ML) N209566 001 Sep 14, 2018
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### MILNACIPRAN HYDROCHLORIDE

**TABLET; ORAL**

**SAVELLA**

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### MILRINONE LACTATE

**INJECTABLE; INJECTION**

#### MILRINONE LACTATE

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### MILTEFOSINE

**CAPSULE; ORAL**

**IMPAVIDO**

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### MINOCYCLINE HYDROCHLORIDE

**CAPSULE; ORAL**

#### DYNACIN

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### MINOCIN

**INJECTABLE; INJECTION**

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#### POWDER, EXTENDED RELEASE; DENTAL

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### MOEXIPRIL HYDROCHLORIDE

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### MOLINDONE HYDROCHLORIDE

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### SINGULAIR

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### MONTELUKAST SODIUM

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## MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

### KADIAN
- **AB +!** ALLERGAN SALES LLC
  - 10MG
  - N020616 008 Apr 20, 2007
- **AB +**
  - 20MG
  - N020616 001 Jul 03, 1996
- **AB +**
  - 30MG
  - N020616 004 Mar 09, 2001
- **AB +**
  - 40MG
  - N020616 009 Jul 09, 2012
- **AB +**
  - 50MG
  - N020616 002 Jul 03, 1996
- **AB +**
  - 60MG
  - N020616 005 Mar 09, 2001
- **AB +**
  - 70MG
  - N020616 010 Jul 09, 2012
- **AB +**
  - 80MG
  - N020616 006 Oct 27, 2006
- **AB +!**
  - 100MG
  - N020616 003 Jul 03, 1996

### MORPHINE SULFATE
- **AB**
  - IMPAX LABS INC
  - 20MG
  - A200411 001 Apr 12, 2016
- **AB**
  - PAR PHARM INC
  - 20MG
  - A200812 001 Nov 10, 2011
- **AB**
  - TEVA PHARMS USA
  - 20MG
  - A200718 001 Dec 29, 2014
- **AB**
  - UPSHER SMITH LABS
  - 100MG
  - A20104 001 Jun 03, 2013

### KADIAN
- **+**
  - ALLERGAN SALES LLC
  - 130MG
  - N020616 011 Jul 09, 2012
- **+**
  - 150MG
  - N020616 012 Jul 09, 2012
- **+!**
  - 200MG
  - N020616 007 Feb 27, 2007

### MORPHINE SULFATE
- **ACTAVIS ELIZABETH**
  - 30MG
  - A079040 001 Jan 16, 2013
  - A079040 002 Jan 16, 2013
  - A079040 003 Jan 16, 2013
  - A079040 004 Jan 16, 2013
  - A079040 005 Jan 16, 2013
- **!**
  - 120MG
  - A079040 006 Jan 16, 2013

### INJECTABLE; INJECTION

#### ASTRAMORPH PF
- **AP**
  - FRESENIUS KABI USA
  - 0.5MG/ML
  - A071050 001 Oct 07, 1986
- **AP**
  - 0.5MG/ML
  - A071051 001 Oct 07, 1986
- **AP**
  - 1MG/ML
  - A071052 001 Oct 07, 1986
- **AP**
  - 1MG/ML
  - A071053 001 Oct 07, 1986

#### DURAMORPH PF
- **AP +!**
  - WEST-WARD PHARMS INT
  - 0.5MG/ML
  - N018565 001 Sep 18, 1984
- **AP +!**
  - 1MG/ML
  - N018565 002 Sep 18, 1984
- **AP +!**
  - WEST-WARD PHARMS INT
  - 10MG/ML
  - N018565 003 Jul 19, 1991
- **AP +!**
  - 25MG/ML
  - N018565 004 Jul 19, 1991

#### MITIGO
- **AP**
  - PIRAMAL CRITICAL
  - 10MG/ML
  - A204345 001 Jul 16, 2018
- **AP**
  - 25MG/ML
  - A204343 002 Jul 16, 2018

#### MORPHINE SULFATE
- **AP**
  - EUROHITH INTL SARL
  - 4MG/ML
  - A205758 001 May 21, 2015
  - A205758 002 May 21, 2015
  - A205758 003 May 21, 2015
- **AP**
  - HOSPIRA
  - 0.5MG/ML
  - A071849 001 May 11, 1988
### MORPHINE SULFATE

#### INJECTABLE; INJECTION

**MORPHINE SULFATE**

| AP | 0.5MG/ML | A073509 001 | Sep 30, 1992 |
| AP | 1MG/ML | A071850 001 | May 11, 1988 |
| AP | 1.5MG/ML | A073510 001 | Sep 30, 1992 |
| AP | 4MG/ML | N202515 002 | Nov 14, 2011 |
| AP | 8MG/ML | N202515 003 | Nov 14, 2011 |
| AP | 10MG/ML | N202515 004 | Nov 14, 2011 |
| AP | 1MG/ML | A071850 002 | May 11, 1988 |
| AP | 1.5MG/ML | A073510 002 | Sep 30, 1992 |
| AP | 4MG/ML | N202515 002 | Nov 14, 2011 |
| AP | 8MG/ML | N202515 003 | Nov 14, 2011 |
| AP | 10MG/ML | N202515 004 | Nov 14, 2011 |

**HOSPIRA INC**

- 4MG/ML N202515 001 Nov 14, 2011
- 8MG/ML N202515 002 Oct 27, 2006
- 15MG/ML N019999 001 Jul 12, 1990

**ICU MEDICAL INC**

- 2MG/ML N019916 001 Oct 30, 1992
- 5MG/ML N019916 002 Oct 27, 2006

**MERIDIAN MEDICAL**

- 2MG/ML N202515 001 Nov 14, 2011
- 5MG/ML N202515 002 Oct 30, 2013
- 8MG/ML N202515 003 Oct 30, 2013
- 10MG/ML N202515 004 Oct 30, 2013

**HOSPIRA INC**

- 2MG/ML N202515 001 Nov 14, 2011
- 8MG/ML N202515 002 Oct 27, 2006
- 15MG/ML N019999 001 Jul 12, 1990

**TECHNICAL SOLUTION; INTRAMUSCULAR, INTRAVENOUS**

**MORPHINE SULFATE**

- 2MG/ML (2MG/ML) N204223 001 Oct 30, 2013
- 4MG/ML (4MG/ML) N204223 002 Oct 30, 2013
- 5MG/ML (5MG/ML) N204223 003 Oct 30, 2013
- 8MG/ML (8MG/ML) N204223 004 Oct 30, 2013
- 10MG/ML (10MG/ML) N204223 005 Oct 30, 2013

**SOLUTION; ORAL**

**MORPHINE SULFATE**

- 10MG/5ML A205509 001 Apr 17, 2018
- 20MG/5ML A205509 002 Apr 17, 2018
- 100MG/5ML A205509 003 Apr 17, 2018

**ANI PHARM INC**

- 100MG/5ML A205509 004 Apr 17, 2018

**HI-TECH PHARMACEUTICALS**

- 100MG/5ML A208809 001 Oct 27, 2006

**LANNETT CO INC**

- 2MG/5ML N022195 001 Jan 05, 2012
- 100MG/5ML N022195 002 Jan 05, 2012

**PADOCK PHARMACEUTICALS**

- 100MG/5ML N201517 001 Jan 05, 2012

**WEST-WARD PHARMACEUTICALS**

- 2MG/5ML N022195 002 Jan 05, 2012
- 100MG/5ML N022195 003 Jan 05, 2012

**ACTAVIS ELIZABETH**

- 15MG A203849 001 Apr 06, 2015
- 30MG A203849 002 Apr 06, 2015

**DAVA PHARMACEUTICALS INC**

- 15MG A075407 001 Nov 14, 2011

**MAYNE PHARMACEUTICALS INC**

- 15MG A075407 002 Nov 14, 2011
- 30MG A075407 003 Nov 14, 2011
- 60MG A075407 004 Nov 14, 2011

**MYLAN PHARMACEUTICALS INC**

- 15MG A076733 001 Jan 05, 2012
- 30MG A076733 002 Jan 05, 2012

**NESHER PHARMACEUTICALS INC**

- 15MG A076720 001 Jan 05, 2012
- 30MG A076720 002 Jan 05, 2012
- 60MG A076720 003 Jan 05, 2012

**LANNETT CO INC**

- 100MG/5ML N201517 001 Jan 05, 2012

**TRIS PHARMACEUTICALS INC**

- 15MG A206308 001 Jan 05, 2012
- 30MG A206308 002 Jan 05, 2012
- 60MG A206308 003 Jan 05, 2012
- 100MG A206308 004 Jan 05, 2012
- 200MG A206308 005 Jan 05, 2012

**WEST-WARD PHARMACEUTICALS**

- 15MG A206308 006 Jan 05, 2012
- 30MG A206308 007 Jan 05, 2012
- 60MG A206308 008 Jan 05, 2012
- 100MG A206308 009 Jan 05, 2012
- 200MG A206308 010 Jan 05, 2012

**VISTAPHARM**

- 15MG A206308 011 Jan 05, 2012
- 30MG A206308 012 Jan 05, 2012
- 60MG A206308 013 Jan 05, 2012
- 100MG A206308 014 Jan 05, 2012
- 200MG A206308 015 Jan 05, 2012

**WEST-WARD PHARMACEUTICALS**

- 10MG/5ML N022195 001 Jan 05, 2012
- 20MG/5ML N022195 002 Jan 05, 2012
- 30MG N022195 003 Jan 05, 2012
- 100MG N022195 004 Jan 05, 2012

**TABLET; ORAL**

**MORPHINE SULFATE**

- 30MG N022207 001 Jan 05, 2012
- 30MG N022207 002 Jan 05, 2012
- 30MG N022207 003 Jan 05, 2012
- 30MG N022207 004 Jan 05, 2012

**TABLET, EXTENDED RELEASE; ORAL**

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- 15MG A203849 001 Apr 06, 2015
- 30MG A203849 002 Apr 06, 2015
- 60MG A203849 003 Apr 06, 2015
- 200MG A203849 004 Apr 06, 2015

**DAVA PHARMACEUTICALS INC**

- 15MG A075407 001 May 18, 2016
- 30MG A075407 002 May 18, 2016
- 60MG A075407 003 May 18, 2016

**MAYNE PHARMACEUTICALS INC**

- 15MG A075407 004 May 18, 2016
- 30MG A075407 005 May 18, 2016
- 60MG A075407 006 May 18, 2016
### MORPHINE SULFATE

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### MOXIDECTIN

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### MOXIFLOXACIN HYDROCHLORIDE

**SOLUTION; INTRAVENOUS**

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<td>EQ 400MG BASE/250ML (EQ 1.6MG BASE/ML)</td>
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<td>AT1 MYLAN LABS LTD</td>
<td>IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER</td>
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**SOLUTION/DROPS; OPHTHALMIC**

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MOXIFLOXACIN HYDROCHLORIDE
SOLUTION/DROPS;OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE
LTD

AT1
LUPIN LTD
EQ 0.5% BASE
A202867 001
Sep 04, 2014

AT1
WATSON LABS INC
EQ 0.5% BASE
A202525 001
Mar 06, 2015

AT1
+! NOVARTIS PHARMS CORP
EQ 0.5% BASE
N021598 001
Apr 15, 2003

MOXEZA

AT2
LUPIN LTD
EQ 0.5% BASE
A204079 001
May 28, 2015

MOXIFLOXACIN HYDROCHLORIDE
TABLET;ORAL

AVELOX

AT1
BAYER HLTHCARE
EQ 400MG BASE
N021085 001
Dec 10, 1999

MOXIFLOXACIN HYDROCHLORIDE
AB
AUROBINDO PHARMA LTD
EQ 400MG BASE
A202632 001
Mar 04, 2014

MOXIFLOXACIN HYDROCHLORIDE
AB
CROSSMEDIKA SA
EQ 400MG BASE
A205348 001
Jan 14, 2016

MOXIFLOXACIN HYDROCHLORIDE
AB
DR REDDYS LABS LTD
EQ 400MG BASE
A076938 001
Mar 04, 2014

MOXIFLOXACIN HYDROCHLORIDE
AB
MYLAN PHARMS INC
EQ 400MG BASE
A208682 001
Sep 22, 2017

MOXIFLOXACIN HYDROCHLORIDE
AB
NOVEL LABS INC
EQ 400MG BASE
A207285 001
Feb 13, 2017

MOXIFLOXACIN HYDROCHLORIDE
AB
SUNSHINE LAKE
EQ 400MG BASE
A206295 001
Sep 28, 2018

MOXIFLOXACIN HYDROCHLORIDE
AB
TEVA PHARMS USA
EQ 400MG BASE
A077437 001
Feb 18, 2014

MOXIFLOXACIN HYDROCHLORIDE
AB
TORRENT PHARMS LTD
EQ 400MG BASE
A200160 001
Apr 03, 2014

MUPIROCIN
OINTMENT;TOPICAL

MUPIROCIN
AB
FOUGERA PHARMS
2%
A065192 001
Nov 30, 2005

MUPIROCIN
AB
GLENMARK PHARMS
2%
A090480 001
Jun 08, 2011

MUPIROCIN
AB
PERRIGO NEW YORK
2%
A065123 001
Nov 07, 2003

MUPIROCIN
AB
TARO
2%
A065170 001
Sep 23, 2005

MUPIROCIN
AB
TEVA
2%
A065085 001
Nov 07, 2003

MUPIROCIN CALCIUM
CREAM;TOPICAL

MUPIROCIN
AB
GLENMARK PHARMS INC
EQ 2% BASE
A201587 001
Jan 24, 2013

MYCOPHENOLATE MOFETIL
CAPSULE;ORAL

CELLCEPT
AB
ROCHE PALO
250MG
N050722 001
May 03, 1995

MYCOPHENOLATE MOFETIL
AB
ACCORD HLTHCARE
250MG
A090253 001
May 04, 2009

MYCOPHENOLATE MOFETIL
AB
ALKEM LABS LTD
250MG
A200197 001
Jun 13, 2013

MYCOPHENOLATE MOFETIL
AB
MYLAN
250MG
A065521 001
May 04, 2009

MYCOPHENOLATE MOFETIL
AB
SANDOZ
250MG
A065379 001
Oct 15, 2008

MYCOPHENOLATE MOFETIL
AB
STRIDES PHARMA
250MG
A090486 001
Oct 08, 2010

MYCOPHENOLATE MOFETIL
AB
TEVA PHARMS
250MG
A065491 001
May 06, 2009

MYCOPHENOLATE MOFETIL
AB
VINTAGE PHARMS LLC
250MG
A090111 001
Dec 22, 2009

MYCOPHENOLATE MOFETIL
AB
WEST-WARD PHARMS INT
250MG
A065410 001
Jul 29, 2008

MYCOPHENOLATE MOFETIL
SUSPENSION;ORAL

CELLCEPT
AB
ROCHE PALO
200MG/ML
N050759 001
Oct 01, 1998

MYCOPHENOLATE MOFETIL
AB
ALKEM LABS LTD
200MG/ML
A203005 001
Nov 14, 2014

CEPHERONE
CAPSULE;ORAL

CEPHERONE
AB
ROCHE PALO
500MG
N050723 001
Jun 19, 1997

CEPHERONE
AB
ACCORD HLTHCARE
500MG
A065416 001
May 04, 2009

CEPHERONE
AB
ALKEM LABS LTD
500MG
A091249 001
Nov 04, 2011

CEPHERONE
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MYLAN
500MG
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May 04, 2009

CEPHERONE
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OXFORD PHARMS
500MG
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Jul 16, 2010
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**NAFARELIN ACETATE**

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**NAFTIFINE HYDROCHLORIDE**

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**NAFTIN**

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**SEBELA IRELAND LTD**

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**NALBUPHINE HYDROCHLORIDE**
*Injectable; Injection*

| AP | HOSPIRA | 10MG/ML | A070914 001 | Feb 03, 1989 |
| AP | 10MG/ML | A070916 001 | Feb 03, 1989 |
| AP | 20MG/ML | A070918 001 | Feb 03, 1989 |
| AP | MYLAN LABS LTD | 10MG/ML | A207595 001 | Jan 11, 2019 |
| AP | 20MG/ML | A207598 002 | Jan 11, 2019 |

**NALDEMEDINE TOSYLATE**
*Tablet; Oral*

+! SHIONOGI INC | EQ 0.2MG BASE | N208854 001 | Mar 23, 2017 |

**NALOXEGOL OXALATE**
*Tablet; Oral*

+! ASTRazeneca phARMS | EQ 12.5MG BASE | N204760 001 | Sep 16, 2014 |
+! EQ 25MG BASE | N204760 002 | Sep 16, 2014 |

**NALOXONE HYDROCHLORIDE**
*Injectable; Injection*

| AP | WEST-WARD PHARMS INT | 0.4MG/ML | A070299 001 | Sep 24, 1986 |

**NALOXONE HYDROCHLORIDE**
*Tablet; Oral*

| AP | AKORN | 0.4MG/ML | A208871 001 | Feb 28, 2017 |
| AP | 0.4MG/ML | A208872 001 | Mar 14, 2017 |
| AP | HOSPIRA | 0.4MG/ML | A070172 001 | Sep 24, 1986 |
| AP | 0.4MG/ML | A070254 001 | Jan 07, 1987 |
| AP | 0.4MG/ML | A070256 001 | Jan 07, 1987 |
| AP | HOSPIRA | 0.4MG/ML | A070257 001 | Jan 07, 1987 |
| AP | INTL MEDICATION | 0.4MG/ML | A070639 001 | Sep 24, 1986 |
| AP | MYLAN INSTITUTIONAL | 0.4MG/ML | A204997 001 | Mar 06, 2014 |
| AP | 0.4MG/ML | A205014 001 | Jun 29, 2016 |
| AP | RENAISSANCE SSA LLC | 0.4MG/ML | A207846 001 | Dec 17, 2018 |
| AP | SOMERSET THERAPS LLC | 0.4MG/ML | A207633 001 | Aug 08, 2017 |
| AP | 0.4MG/ML | A207634 001 | Jul 26, 2017 |
| ! INTL MEDICATION | 1MG/ML | A072076 001 | Mar 24, 1988 |

**EVOZIO**
*Spray, Metered; Nasal*

| +! KALEO INC | 2MG/0.4ML (2MG/0.4ML) | N209862 001 | Oct 19, 2016 |
| NARCAN | +! ADAPT | 4MG/Spray | N208411 001 | Nov 18, 2015 |

**NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE**
*Tablet; Oral*

| AB | GAVIS PHARMS | EQ 0.5MG BASE: EQ 50MG BASE | A075735 001 | Jul 11, 2001 |
| AB | SUN PHARM INDs LTD | EQ 0.5MG BASE: EQ 50MG BASE | A075523 001 | Mar 17, 2000 |
| AB | WATSON LABS | EQ 0.5MG BASE: EQ 50MG BASE | A074736 001 | Jan 21, 1997 |

**NALTREXONE**
*For Suspension, Extended Release; Intramuscular*

| VIVITROL | 380MG/Vial | N021897 001 | Apr 13, 2006 |

**NALTREXONE HYDROCHLORIDE**
*Tablet; Oral*

<p>| AB | ACCORD HLTCARE | 50MG | A091205 001 | Aug 17, 2011 |
| AB | APOTEX INC | 50MG | A207905 001 | Jul 21, 2017 |
| AB | BARR | 50MG | A074938 001 | May 08, 1998 |
| AB | ELITE LABS | 50MG | A075274 001 | May 26, 1999 |
| AB | SPECGX LLC | 50MG | A076264 002 | Mar 22, 2002 |
| AB | SUN PHARMA GLOBAL | 50MG | A090356 001 | Feb 24, 2012 |
| SPECGX LLC | 50MG | A076264 001 | Mar 22, 2002 |
| SPECGX LLC | 100MG | A076264 003 | Mar 22, 2002 |</p>
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### Niacin

**Tablet; Oral**

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**Capsule; Oral**

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### Nicardipine Hydrochloride

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### Cardene In 0.83% Sodium Chloride In Plastic Container

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**Inhalant; Oral**

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<td>Powder, Sublingual</td>
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### Nizatidine

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<tbody>
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<td>Capsule, Oral</td>
<td>Ani Pharma</td>
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### Noradrenaline bitartrate

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<th>Date Approved</th>
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<tbody>
<tr>
<td>Tablet, Oral-28</td>
<td>Aurobindo Pharma</td>
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### Noradrenaline bitartrate

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### Noradrenaline bitartrate

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### Noradrenaline bitartrate

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### NORETHINDRONE

**TABLET; ORAL - 28**

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**NORETHINDRONE ACETATE**

**TABLET; ORAL**

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**NORTRIPTYLINE HYDROCHLORIDE**

**CAPSULE; ORAL**

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**SOLUTION; ORAL**

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**NUSINERSEN SODIUM**

**SOLUTION; INTRATHECAL**

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**NYSTATIN**

**CREAM; TOPICAL**

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### OBETICHOLIC ACID
**Tablet; Oral**

OCALIVA
+ Intercept Pharms Inc 5mg N207999 001 May 27, 2016
+
**10mg**
N207999 002 May 27, 2016

### OCTREOTIDE ACETATE
**Injectable; Injection**

**OCTREOTIDE ACETATE**

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### OFLOXACIN
**SOLUTION/DROPS; OPHTHALMIC**

**OCUFLOX**

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**OFLOXACIN**

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**SOLUTION/DROPS; OTIC**

**OFLOXACIN**

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### OFLOXACIN

**SOLUTION/DRIPS;OTIC**

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**TABLET;ORAL**

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### OLANZAPINE

**INJECTABLE; INTRAMUSCULAR**

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39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST
PRESCRIPTION DRUG PRODUCT LIST
## Olmesartan Medoxomil

**Tablet; Oral**

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## Olodaterol Hydrochloride

**Spray, Metered; Inhalation**

Striverdi Respimat +!

Boehringer

Eq 0.0025mg Base/Inh

Ingeleim

N203108

## Olodaterol Hydrochloride; Tiotropium Bromide

**Spray, Metered; Inhalation**

Stiolto Respimat +!

Boehringer

Eq 0.0025mg Base/Inh; Eq 0.0025mg

Ingeleim

N206756

## Olopatadine Hydrochloride

**Solution/Drops; Ophthalmic**

## Olodaterol Hydrochloride

**Spray, Metered; Inhalation**

Striverdi Respimat +!

Boehringer

Eq 0.0025mg Base/Inh

Ingeleim

N203108

## Olopatadine Hydrochloride

**Solution/Drops; Ophthalmic**

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<td>Ondansetron Hydrochloride</td>
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<td>AA  +!  Novartis Pharma Corp</td>
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<td>AB  Apotex</td>
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<td>AB  Aurobindo Pharma</td>
<td>EQ 4mg Base  A078530 002 Jun 25, 2007</td>
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<td>AB  Casi Pharma Inc</td>
<td>EQ 24mg Base A078539 003 Jul 31, 2007</td>
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<td>AB  Dr Reddy's Ltd</td>
<td>EQ 4mg Base  A076183 003 Dec 26, 2006</td>
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<td>AB  Glenmark Generics</td>
<td>EQ 4mg Base  A077535 002 Jun 25, 2007</td>
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<td>AB  IPCA Labs Ltd</td>
<td>EQ 4mg Base  A02776 001 Jan 23, 2014</td>
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<td>AB  Mylan</td>
<td>EQ 8mg Base  A076930 001 Jun 25, 2007</td>
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<td>AB  Natco Pharma Ltd</td>
<td>EQ 4mg Base  A077851 001 Jun 25, 2007</td>
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<tr>
<td>AB  Pliva Hrvatska Doo</td>
<td>EQ 8mg Base  A077112 002 Jun 25, 2007</td>
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<tr>
<td>AB  Sun Pharma Inds (IN)</td>
<td>EQ 24mg Base A077050 002 Jun 25, 2007</td>
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<td>AB  Teva</td>
<td>EQ 8mg Base  A076252 001 Jun 25, 2007</td>
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| Oritavancin Diphosphate | Powder; Intravenous ORBactiv +! MELINTA Therap | EQ 400mg Base/Vial N206334 001 Aug 06, 2014 |

| Orlistat | Capsule; Oral XENICAL +! CHEPLAPHARM 120mg N020766 001 Apr 23, 1999 |

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<th>Orphenadrine Citrate</th>
<th>Injectable; Injection</th>
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<tr>
<td>AP  +  Akorn</td>
<td>30mg/mL A040484 001 May 24, 2006</td>
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<td>AP  +  Sagent Pharma</td>
<td>30mg/mL A090585 001 Aug 30, 2011</td>
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<td>AP  +  Watson Labs</td>
<td>30mg/mL A084778 001 Mar 15, 1982</td>
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<td>AP  +  West-Ward Pharma INT</td>
<td>30mg/mL A040463 001 Mar 04, 2003</td>
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<td>100mg A040249 001 Jan 29, 1999</td>
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<td>AP  +  Gavis Pharma</td>
<td>100mg A040284 001 Jun 19, 1998</td>
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<tr>
<td>AP  +  Impax Pharma</td>
<td>100mg A040368 001 Jun 23, 2000</td>
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<td>AP  +  Invagen Pharma</td>
<td>100mg A041158 001 Jul 27, 2012</td>
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<td>AB  +  Sandoz</td>
<td>100mg A040327 001 Feb 15, 2000</td>
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OSELTAMIVIR PHOSPHATE
CAPSULE; ORAL

AB AMNEAL PHARMS
EQ 30MG BASE A209093 001 May 17, 2017
AB EQ 45MG BASE A209093 002 May 17, 2017
AB EQ 75MG BASE A209093 003 May 17, 2017
AB HETERO LABS LTD III
EQ 30MG BASE A209438 001 Feb 23, 2018
AB EQ 45MG BASE A209438 002 Feb 23, 2018
AB EQ 75MG BASE A209438 003 Feb 23, 2018
AB LUPIN ATLANTIS
EQ 30MG BASE A208348 001 Jan 09, 2018
AB EQ 45MG BASE A208348 002 Jan 09, 2018
AB EQ 75MG BASE A208348 003 Jan 09, 2018
AB MACLEODS PHARMS LTD
EQ 30MG BASE A209421 001 Jun 08, 2018
AB EQ 45MG BASE A209421 002 Jun 08, 2018
AB EQ 75MG BASE A209421 003 Jun 08, 2018
AB AMNEAL PHARMS NY
EQ 6MG BASE/ML A210186 001 Feb 27, 2018
AB LUPIN ATLANTIS
EQ 6MG BASE/ML A208347 001 Feb 20, 2018
AB NESHER PHARMS
EQ 6MG BASE/ML A209113 001 Sep 14, 2017
AB STRIDES PHARMA
EQ 6MG BASE/ML A209421 001 Jun 08, 2018
AB TADIFLU
AB + ROCHE
EQ 30MG BASE N021087 003 Jul 02, 2007
AB + ROCHE
EQ 45MG BASE N021087 002 Jul 02, 2007
AB +! ROCHE
EQ 75MG BASE N021087 001 Oct 27, 1999

OSIMERTINIB MESYLATE
TABLET; ORAL
TARGRISSO
+ ASTRazeneca PHARMS
EQ 40MG BASE N208065 001 Nov 13, 2015
+! ASTRazeneca PHARMS
EQ 80MG BASE N208065 002 Nov 13, 2015

OXACillin SODIUM
INJECTABLE; INJECTION

OXACillin SODIUM
AP AUROBINDO PHARMA LTD
EQ 1GM BASE/VIAL A201539 001 Jan 18, 2013
AP EQ 2GM BASE/VIAL A201539 002 Jan 18, 2013
AP HOSPIRA INC
EQ 1GM BASE/VIAL A203950 001 Dec 11, 2015
AP EQ 2GM BASE/VIAL A203950 002 Dec 11, 2015
AP RENAISSANCE SSA LLC
EQ 1GM BASE/VIAL A206681 001 Sep 11, 2017
AP EQ 2GM BASE/VIAL A206681 002 Sep 11, 2017
AP EQ 10GM BASE/VIAL A206760 001 Oct 26, 2017
AP ! SAGENT PHARMS
EQ 1GM BASE/VIAL A091246 001 Mar 30, 2012
AP ! SAGENT PHARMS
EQ 2GM BASE/VIAL A091246 002 Mar 30, 2012
AP ! WOCKHARDT BIO AG
EQ 1GM BASE/VIAL A207147 001 Jul 31, 2017
AP EQ 2GM BASE/VIAL A207147 002 Jul 31, 2017
AP EQ 10GM BASE/VIAL A207148 001 Nov 24, 2017

BACTOCILL IN PLASTIC CONTAINER
+! BAXTER HLTHCARE
EQ 20MG BASE/ML N050640 001 Oct 26, 1989
+! EQ 40MG BASE/ML N050640 002 Oct 26, 1989
### Oxaliplatin

**Injectable; IV (Infusion)**

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### Oxandrolone

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### Oxaprozin

**Tablet; Oral**

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<td>APOTEX INC</td>
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**Oxaprozin**

**Tablet; Oral**

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<td>IVAX Sub Teva</td>
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<td>Sandoz</td>
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<td>Sun Pharm Inds Inc</td>
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<td>A075844 001</td>
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<td>Teva</td>
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**Oxazepam**

**Capsule; Oral**

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<tbody>
<tr>
<td>Actavis Elizabeth</td>
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<td>Sandoz</td>
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**Oxcarbazepine**

**Suspension; Oral**

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<tbody>
<tr>
<td>Amneal Pharmaceuticals</td>
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<td>A202961 001</td>
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<tr>
<td>Sun Pharm Inds Ltd</td>
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<td>A078734 001</td>
<td>Jun 26, 2009</td>
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<tr>
<td>West-Ward Pharm Int</td>
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**Trileptal**

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<tr>
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**Oxcarbazepine**

**Tablet; Oral**

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<td>600mg</td>
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**Trileptal**

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**Oxiconazole Nitrate**

**Cream; Topical**

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**Oxistat**

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<tr>
<td>Fougere Pharm</td>
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**Oxistat**

<table>
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<tr>
<td>Fougere Pharm</td>
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OXYBUTYNIN
FILM, EXTENDED RELEASE; TRANSDERMAL
OXYTROL
+! ALLERGAN SALES LLC 3.9MG/24HR N021351 002 Feb 26, 2003

OXYBUTYNIN CHLORIDE
GEL; TRANSDERMAL
GELNIQUE
AB +! ALLERGAN SALES LLC 10% (100MG/PACKET) N022204 001 Jan 27, 2009

OXYCODONE
CAPSULE, EXTENDED RELEASE; ORAL
XTAMPZA ER
+ COLLEGIUM PHARM INC 9MG N208090 001 Apr 26, 2016
+ 13.5MG N208090 002 Apr 26, 2016
+ 18MG N208090 003 Apr 26, 2016
+ 27MG N208090 004 Apr 26, 2016
+! 36MG N208090 005 Apr 26, 2016

OXYCODONE HYDROCHLORIDE
CAPSULE; ORAL
OXYCODONE HYDROCHLORIDE
AB ANI PHARMS INC 5MG A205177 001 Mar 31, 2016
AB AVANTHI INC 5MG A202773 001 Aug 17, 2015
AB +! GENUS LIFESCIENCES 5MG N200534 001 Oct 20, 2010
AB LANNETT CO INC 5MG A203823 001 Jul 26, 2012
AB MAYNE PHARMA INC 5MG A202332 002 Jun 26, 2017
AB NOVEL LABS INC 5MG A203107 003 Jun 26, 2017

DITROPAN XL
TABLET, EXTENDED RELEASE; ORAL
AB +! JANSEN PHARM 5MG N020897 001 Dec 16, 1998
AB + 10MG N020897 002 Dec 16, 1998

OXYCODONE
CAPSULE, EXTENDED RELEASE; ORAL
XTAMPZA ER
+ COLLEGIUM PHARM INC 9MG N208090 001 Apr 26, 2016
+ 13.5MG N208090 002 Apr 26, 2016
+ 18MG N208090 003 Apr 26, 2016
+ 27MG N208090 004 Apr 26, 2016
+! 36MG N208090 005 Apr 26, 2016

OXYCODONE HYDROCHLORIDE
CAPSULE; ORAL
OXYCODONE HYDROCHLORIDE
AB ANI PHARMS INC 5MG A205177 001 Mar 31, 2016
AB AVANTHI INC 5MG A202773 001 Aug 17, 2015
AB +! GENUS LIFESCIENCES 5MG N200534 001 Oct 20, 2010
AB LANNETT CO INC 5MG A203823 001 Jul 26, 2012
AB MAYNE PHARMA INC 5MG A202332 002 Jun 26, 2017
AB NOVEL LABS INC 5MG A203107 003 Jun 26, 2017
# Oxydione Hydrochloride

## Solution; Oral

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<tbody>
<tr>
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<tr>
<td>ABHI LLC</td>
<td>100mg/5ml</td>
<td>A208593 002</td>
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<td>ANI PHARMS INC</td>
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<td>A204975 001</td>
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<td>ASCENT PHARMS INC</td>
<td>5mg/5ml</td>
<td>A203447 001</td>
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<td>100mg/5ml</td>
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<td>Nov 09, 2017</td>
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<td>GENUS LIFESCIENCES</td>
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<td>N200535 002</td>
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<tr>
<td>HI-TECH PHARMACAL</td>
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<td>A208795 001</td>
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<tr>
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<td>NOVEL LABS INC</td>
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<td>PHARM ASSOC</td>
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<td>A204603 001</td>
<td>Apr 29, 2015</td>
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<td>WES PHARMA INC</td>
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<td>WOCKHARDT BIO AG</td>
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## Tablet; Oral

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<tr>
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<td>ALVOGEN MALTA</td>
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<td>AVLTHI INC</td>
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<td>EPIC PHARMA LLC</td>
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<td>NEXHER PHARMS</td>
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**Note:** Dates represent the approval or expiration dates of the drug products listed.
### OXYCODONE HYDROCHLORIDE

**Oral Tablet**

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**Roxicodone**

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**Roxycodone + General**

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**Oxacodone + General**

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### OXYMETAZOLINE HYDROCHLORIDE

**Cream Topical**

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**Spray Topical**

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<td>ST RENATUS</td>
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<td></td>
<td>0.4%</td>
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<td>Apr 05, 2010</td>
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<tr>
<td></td>
<td>0.6%</td>
<td>N022272 005</td>
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<td>0.8%</td>
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### OXYMETHOLONE

**Oral Tablet**

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<td>MYLAN SPECIALITY LP</td>
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### OXYMORPHONE HYDROCHLORIDE

**Oral Tablet**

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<tbody>
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**Oral Capsule**

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<tbody>
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<td>10MG</td>
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<tr>
<td>AUROLIFE PHARMA LLC</td>
<td>5MG</td>
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<td>AVANTHI INC</td>
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<td>EPIC PHARMA LLC</td>
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<td>A201187 002</td>
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<td>SPECGX LLC</td>
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<td>10MG</td>
<td>A202321 002</td>
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### OXYMORPHONE HYDROCHLORIDE

**Oral Tablet**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
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<th>Date Approved</th>
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<tbody>
<tr>
<td><strong>TEVA</strong></td>
<td>5MG</td>
<td>A091443 002</td>
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<td><strong>TEVA</strong></td>
<td>10MG</td>
<td>A091443 001</td>
<td>Feb 15, 2011</td>
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<td><strong>WEST-WARD PHARMS</strong></td>
<td>5MG</td>
<td>A090964 001</td>
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<tr>
<td><strong>AB</strong></td>
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**Extended Release Tablet**

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<tbody>
<tr>
<td><strong>ACTAVIS ELIZABETH</strong></td>
<td>5MG</td>
<td>A079046 003</td>
<td>Jul 11, 2013</td>
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<tr>
<td><strong>ACTAVIS ELIZABETH</strong></td>
<td>7.5MG</td>
<td>A079046 001</td>
<td>Dec 13, 2010</td>
</tr>
<tr>
<td><strong>ACTAVIS ELIZABETH</strong></td>
<td>10MG</td>
<td>A079046 004</td>
<td>Jul 11, 2013</td>
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<tr>
<td><strong>ACTAVIS ELIZABETH</strong></td>
<td>15MG</td>
<td>A079046 002</td>
<td>Dec 13, 2010</td>
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<tr>
<td><strong>ACTAVIS ELIZABETH</strong></td>
<td>20MG</td>
<td>A079046 005</td>
<td>Jul 11, 2013</td>
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<td><strong>ACTAVIS ELIZABETH</strong></td>
<td>30MG</td>
<td>A079046 006</td>
<td>Jul 11, 2013</td>
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<td><strong>IMPAX LABS</strong></td>
<td>5MG</td>
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<td>A202946 003</td>
<td>Jun 14, 2010</td>
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<td><strong>IMPAX LABS</strong></td>
<td>15MG</td>
<td>A202946 004</td>
<td>Dec 21, 2010</td>
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<tr>
<td><strong>IMPAX LABS</strong></td>
<td>20MG</td>
<td>A202946 005</td>
<td>Jun 14, 2010</td>
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<td>A202946 006</td>
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<tr>
<td><strong>WEST-WARD PHARMS</strong></td>
<td>5MG</td>
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<td><strong>WEST-WARD PHARMS</strong></td>
<td>7.5MG</td>
<td>A200822 003</td>
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<td>A200822 004</td>
<td>Jul 15, 2013</td>
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<td><strong>WEST-WARD PHARMS</strong></td>
<td>15MG</td>
<td>A200822 005</td>
<td>Jul 15, 2013</td>
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<td><strong>WEST-WARD PHARMS</strong></td>
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<td><strong>WEST-WARD PHARMS</strong></td>
<td>40MG</td>
<td>A200822 008</td>
<td>Jul 15, 2013</td>
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### OXYTOCIN

**Injectable Injection**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FRESENIUS KABI USA</strong></td>
<td>10USP UNITS/ML (10USP UNITS/ML)</td>
<td>N018248 001</td>
<td>Jul 27, 2007</td>
</tr>
<tr>
<td><strong>FRESENIUS KABI USA</strong></td>
<td>100USP UNITS/10ML (10USP UNITS/ML)</td>
<td>N018248 002</td>
<td>Jul 27, 2007</td>
</tr>
<tr>
<td><strong>HIKMA FARMACEUTICA</strong></td>
<td>10USP UNITS/ML (10USP UNITS/ML)</td>
<td>A091676 001</td>
<td>Jul 13, 2018</td>
</tr>
<tr>
<td><strong>HIKMA FARMACEUTICA</strong></td>
<td>100USP UNITS/10ML (10USP UNITS/ML)</td>
<td>A091676 002</td>
<td>Jul 13, 2018</td>
</tr>
<tr>
<td><strong>WEST-WARD PHARMS</strong></td>
<td>10USP UNITS/10ML (10USP UNITS/ML)</td>
<td>N018243 001</td>
<td>Jan 10, 2007</td>
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<tr>
<td><strong>WEST-WARD PHARMS</strong></td>
<td>100USP UNITS/10ML (10USP UNITS/ML)</td>
<td>N018243 002</td>
<td>Jul 27, 2007</td>
</tr>
<tr>
<td><strong>PAR STERILE PRODUCTS</strong></td>
<td>100USP UNITS/10ML (10USP UNITS/ML)</td>
<td>N018261 001</td>
<td>Jul 27, 2007</td>
</tr>
<tr>
<td><strong>PAR STERILE PRODUCTS</strong></td>
<td>300USP UNITS/30ML (10USP UNITS/ML)</td>
<td>N018248 003</td>
<td>Sep 01, 2012</td>
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## API: Pacitaxel

**For Suspension; IV (Infusion)**

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<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
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<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td><strong>ABRAXANE</strong></td>
<td>100MG/VIAL</td>
<td>N021660 001</td>
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**For Injectable; Injection**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td><strong>GLAND PHARMA LTD</strong></td>
<td>6MG/ML</td>
<td>A207326 001</td>
<td>Aug 23, 2016</td>
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</table>
### PACLITAXEL

**INJECTABLE; INJECTION**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength (mg/ml)</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCORD HEALTHCARE</td>
<td>6MG/ML</td>
<td>A205720 001</td>
<td>Aug 17, 2018</td>
</tr>
<tr>
<td>ACTAVIS TOTONA</td>
<td>6MG/ML</td>
<td>A091130 001</td>
<td>Dec 09, 2009</td>
</tr>
<tr>
<td>FRESENIUS KABI USA</td>
<td>6MG/ML</td>
<td>A077574 001</td>
<td>Nov 27, 2006</td>
</tr>
<tr>
<td>HOSPIRA</td>
<td>6MG/ML</td>
<td>A076131 001</td>
<td>May 08, 2002</td>
</tr>
<tr>
<td>MYLAN LABS LTD</td>
<td>6MG/ML</td>
<td>A091540 001</td>
<td>Sep 29, 2011</td>
</tr>
<tr>
<td>SANDOZ INC</td>
<td>6MG/ML</td>
<td>A078167 001</td>
<td>Dec 26, 2007</td>
</tr>
<tr>
<td>TEVA PHARMS</td>
<td>6MG/ML</td>
<td>A075184 001</td>
<td>Jan 25, 2002</td>
</tr>
<tr>
<td>WEST-WARD PHARMS</td>
<td>6MG/ML</td>
<td>A075190 001</td>
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### TAXOL

<table>
<thead>
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<th>Strength (mg/ml)</th>
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<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>HQ SPCLT PHARMA</td>
<td>6MG/ML</td>
<td>N020262 001</td>
<td>Dec 29, 1992</td>
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### PALBOCICLIB

**CAPSULE; ORAL**

<table>
<thead>
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<th>Strength (mg)</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFIZER INC</td>
<td>75MG</td>
<td>N207103 001</td>
<td>Feb 03, 2015</td>
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<td>100MG</td>
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<td>N207103 003</td>
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### PALIPERIDONE

**TABLET, EXTENDED RELEASE; ORAL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength (mg)</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>JANSSEN PHARMS</td>
<td>1.5MG</td>
<td>N021999 006</td>
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<td>3MG</td>
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<td></td>
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<td></td>
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### PALIPERIDONE PALMITATE

**SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength (mg/ml)</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>JANSSEN PHARMS</td>
<td>39MG/0.25ML</td>
<td>N022264 001</td>
<td>Jul 31, 2009</td>
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<td></td>
<td>78MG/0.5ML</td>
<td>N022264 002</td>
<td>Jul 31, 2009</td>
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<tr>
<td></td>
<td>117MG/0.75ML</td>
<td>N022264 003</td>
<td>Jul 31, 2009</td>
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<tr>
<td></td>
<td>156MG/1.5ML</td>
<td>N022264 004</td>
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<tr>
<td></td>
<td>234MG/1.75ML</td>
<td>N022264 005</td>
<td>Jul 31, 2009</td>
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### PALONOSETRON HYDROCHLORIDE

**INJECTABLE; INTRAVENOUS**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength (mg/ml)</th>
<th>NDC Number</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>HELSINN HLTHCARE</td>
<td>EQ 0.075MG BASE/1.5ML</td>
<td>N021372 002</td>
<td>Feb 29, 2008</td>
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<td>EQ 0.25MG BASE/5ML</td>
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### PALONOSETRON HYDROCHLORIDE

<table>
<thead>
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<th>Strength (mg/ml)</th>
<th>NDC Number</th>
<th>Date Approved</th>
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<tbody>
<tr>
<td>AKOBINDO PHARMA LTD</td>
<td>EQ 0.25MG BASE/5ML</td>
<td>A204702 001</td>
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<tr>
<td>CIPLA</td>
<td>EQ 0.25MG BASE/5ML</td>
<td>A206396 001</td>
<td>Sep 19, 2018</td>
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<tr>
<td>DR REDDYS LABS LTD</td>
<td>EQ 0.075MG BASE/1.5ML</td>
<td>A201533 002</td>
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<tr>
<td>FRESENIUS KABI USA</td>
<td>EQ 0.25MG BASE/5ML</td>
<td>A201533 001</td>
<td>Apr 21, 2016</td>
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<tr>
<td>HOSPIRA INC</td>
<td>EQ 0.25MG BASE/5ML</td>
<td>A207005 001</td>
<td>Sep 19, 2018</td>
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<tr>
<td></td>
<td>EQ 0.075MG BASE/1.5ML</td>
<td>A207005 002</td>
<td>Sep 19, 2018</td>
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</table>
### PALONOSETRON HYDROCHLORIDE

#### INJECTABLE; INTRAVENOUS

<table>
<thead>
<tr>
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<th>Product Description</th>
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<th>Date Approved</th>
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<tbody>
<tr>
<td>MYLAN INSTITUTIONAL</td>
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<td>A206416</td>
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<tr>
<td>QILU PHARM CO LTD</td>
<td>INJECTABLE; INTRAVENOUS</td>
<td>A205648</td>
<td>Sep 19, 2018</td>
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<tr>
<td>SAGENT PHARMS</td>
<td>INJECTABLE; INTRAVENOUS</td>
<td>A205870</td>
<td>Sep 19, 2018</td>
</tr>
<tr>
<td>SANDOZ INC</td>
<td>INJECTABLE; INTRAVENOUS</td>
<td>A204289</td>
<td>Sep 19, 2018</td>
</tr>
<tr>
<td>TEVA PHARMS USA</td>
<td>INJECTABLE; INTRAVENOUS</td>
<td>A202521</td>
<td>Oct 13, 2015</td>
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<tr>
<td>VIRTUS PHARM</td>
<td>INJECTABLE; INTRAVENOUS</td>
<td>A209287</td>
<td>Sep 19, 2018</td>
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### PAMIDRONATE DISODIUM

#### INJECTABLE; INJECTION

<table>
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<th>Product Description</th>
<th>NDC Code</th>
<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>AREVA PHARMS</td>
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<td>A077433</td>
<td>Nov 26, 2008</td>
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<tr>
<td>FRESENIUS KABI USA</td>
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<td>A075773</td>
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<td>HOSPIRA</td>
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<td>Jun 27, 2002</td>
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<td>LUITPOLD</td>
<td>INJECTABLE; INJECTION</td>
<td>A078942</td>
<td>Jul 25, 2008</td>
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<tr>
<td>MYLAN LABS LTD</td>
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<td>PLIVA LACHEMA</td>
<td>INJECTABLE; INJECTION</td>
<td>A078156</td>
<td>Aug 19, 2008</td>
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<tr>
<td>SUN PHARMA GLOBAL</td>
<td>INJECTABLE; INJECTION</td>
<td>A077703</td>
<td>Aug 19, 2008</td>
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<tr>
<td>WEST-WARD PHARMS</td>
<td>INJECTABLE; INJECTION</td>
<td>A075290</td>
<td>Apr 30, 2001</td>
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</table>

### PANCRELIPASE (AMYLASE; LIPASE; PROTEASE)

#### CAPSULE, DELAYED RELEASE; ORAL

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Description</th>
<th>NDC Code</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABBVIE</td>
<td>CAPSULE, DELAYED RELEASE; ORAL</td>
<td>N020725</td>
<td>Apr 30, 2009</td>
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<tr>
<td>VIVUS INC</td>
<td>CAPSULE, DELAYED RELEASE; ORAL</td>
<td>N022523</td>
<td>Mar 04, 2002</td>
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### CREON

<table>
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<th>Product Description</th>
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<tbody>
<tr>
<td>ABBVIE</td>
<td>CREON</td>
<td>N020725</td>
<td>Apr 30, 2009</td>
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<tr>
<td>VIVUS INC</td>
<td>CREON</td>
<td>N022523</td>
<td>Mar 04, 2002</td>
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### PANCREAZE

<table>
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<th>Manufacturer</th>
<th>Product Description</th>
<th>NDC Code</th>
<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>ABBVIE</td>
<td>PANCREAZE</td>
<td>N020725</td>
<td>Apr 30, 2009</td>
</tr>
<tr>
<td>VIVUS INC</td>
<td>PANCREAZE</td>
<td>N022523</td>
<td>Mar 04, 2002</td>
</tr>
</tbody>
</table>
### Pancrelipase (Amylase; Lipase; Protease)

**Capsule, Delayed Release; Oral**

**Pertzye**
- Digestive Care Inc
  - 30,250 USP units; 8,000 USP units
  - 60,500 USP units; 16,000 USP units
  - 15,125 USP units; 4,000 USP units
  - 90,750 USP units; 24,000 USP units
  - N022175 001 (May 17, 2012)
  - N022175 002 (May 17, 2012)
  - N022175 003 (Oct 06, 2016)
  - N022175 004 (Jul 13, 2017)

**Zempep**
- Forest Labs Inc
  - 168,000 USP units; 40,000 USP units
  - 14,000 USP units; 3,000 USP units
  - 24,000 USP units; 5,000 USP units
  - 42,000 USP units; 10,000 USP units
  - 63,000 USP units; 15,000 USP units
  - 84,000 USP units; 20,000 USP units
  - 105,000 USP units; 25,000 USP units
  - N022175 001 (Mar 25, 2014)
  - N022175 005 (Jun 15, 2011)
  - N022175 006 (Oct 06, 2016)
  - N022175 007 (Mar 25, 2014)
  - N022175 008 (Aug 27, 2009)

**Tablet; Oral**

**Viokace**
- Forest Labs Inc
  - 39,150 USP units; 10,440 USP units
  - 78,300 USP units; 20,880 USP units
  - N022175 001 (Mar 01, 2012)
  - N022175 002 (Mar 01, 2012)

### Pancuronium Bromide

**Inj ectable; Injection**

**AP**
- Hospira
  - 1mg/ml
  - A072320 001 (Jan 19, 1989)

**AP**
- Teva Pharms USA
  - 1mg/ml
  - A072759 001 (Jul 31, 1990)

**PANOBINOSTAT Lactate**

**Capsule; Oral**

**Farydak**
- Novartis Pharms Corp
  - Eq 10mg Base
  - N205353 001 (Feb 23, 2015)

**Pantoprazole Sodium**

**For Suspension, Delayed Release; Oral**

**Protonix**
- Wyeth Pharms
  - Eq 40mg Base
  - N022020 001 (Nov 14, 2007)

**Inj ectable; IV (Infusion)**

**Pantoprazole Sodium**

**AP**
- Akorn Inc
  - Eq 40mg Base/Vial
  - A079197 001 (Nov 08, 2012)

**AP**
- Aurobindo Pharma Ltd
  - Eq 40mg Base/Vial
  - A205675 001 (Mar 30, 2016)

**AP**
- Mylan Labs Ltd
  - Eq 40mg Base/Vial
  - A208580 001 (May 04, 2018)

**AP**
- Sandoz Inc
  - Eq 40mg Base/Vial
  - A090296 001 (Jul 14, 2015)

**Protonix IV**
- Wyeth Pharms
  - Eq 40mg Base/Vial
  - N020988 001 (Mar 22, 2001)

**Powder; IV (Infusion)**

**Pantoprazole Sodium**
- Exela Pharma SCS LLC
  - Eq 40mg Base/Vial
  - N209463 001 (Jun 30, 2017)

**Tablet, Delayed Release; Oral**

**Pantoprazole Sodium**
- Actavis Totowa
  - Eq 20mg Base
  - A090797 001 (Feb 07, 2011)

- Amneal Pharms
  - Eq 20mg Base
  - A090787 002 (Feb 07, 2011)

- Apotex Inc
  - Eq 20mg Base
  - A205119 001 (Jan 26, 2016)

- Aurobindo Pharma Ltd
  - Eq 20mg Base
  - A090807 001 (May 02, 2012)

- Dr Reddys Labs Ltd
  - Eq 20mg Base
  - A077619 001 (Jan 19, 2011)
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### PAROMOMYCIN SULFATE
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### PAROXETINE HYDROCHLORIDE
**SUSPENSION; ORAL**

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**FAXIL**

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**Paroxetine Mesylate**

**Capsule; Oral**

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**Pexeva**

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**Pasireotide Diaspaptate**

**Solution; Subcutaneous**

<table>
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<th>Date</th>
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</thead>
<tbody>
<tr>
<td>NOVARTIS</td>
<td>0.3mg/ML</td>
<td>200677 001</td>
<td>Dec 14, 2012</td>
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<tr>
<td></td>
<td>0.6mg/ML</td>
<td>200677 002</td>
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<td>0.9mg/ML</td>
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**Pasireotide Pamiate**

**For Suspension; Intramuscular**

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<th>Date</th>
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<tbody>
<tr>
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<td>10mg/ML</td>
<td>203255 004</td>
<td>Jun 29, 2018</td>
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<td>20mg/ML</td>
<td>203255 005</td>
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<td>30mg/ML</td>
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<td>40mg/ML</td>
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**Patiromer Sorbitex Calcium**

**Powder; Oral**

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<td>RELYPSA INC</td>
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<td>25.2gm</td>
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**Patisiran Sodium**

**Solution; Intravenous**

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<td>ALNYLAM PHARMS INC</td>
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**Pazopanib Hydrochloride**

**Tablet; Oral**

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<td>PEGADEMASE BOVINE</td>
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<tr>
<td>PEGAPTANIB SODIUM</td>
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<td>PHARMACIA AND UPJOHN</td>
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<td>MYLAN PHARMS INC</td>
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<td>PENTETEATE CALCIUM TRISODIUM</td>
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<tr>
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<td>AP RENAISSANCE SSA LLC</td>
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<td>A206404 001 May 23, 2016</td>
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3-349 (of 452)
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<td>PENTOXIFYLLINE</td>
<td>TABLET, EXTENDED RELEASE; ORAL</td>
<td>PENTOXIFYLLINE</td>
<td>AB APOTEX 400MG</td>
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<td>AB MYLAN 400MG</td>
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<td>PENTOXIFYLLINE</td>
<td>AB VALEANT PHARMS 400MG</td>
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<td>PENTOXIL</td>
<td>AB UPSHER SMITH LABS 400MG</td>
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<td>RAPIVAB</td>
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<td>FYCOMPA</td>
<td>+! EISAI INC 0.5MG/ML</td>
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<tr>
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<td>FYCOMPA</td>
<td>+ EISAI INC 2MG</td>
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<td>FYCOMPA</td>
<td>+ 4MG</td>
<td>Oct 22, 2012</td>
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<td>Oct 22, 2012</td>
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<td>Nov 10, 2009</td>
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<td>AB 8MG</td>
<td>Nov 10, 2009</td>
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<td>AB AUROBINDO PHARMA 2MG</td>
<td>Nov 10, 2009</td>
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<td>Nov 10, 2009</td>
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<td>AB 8MG</td>
<td>Nov 10, 2009</td>
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<td>ELIMITE</td>
<td>AB MYLAN PHARMS INC 5%</td>
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<td>AB ACTAVIS LABS 5%</td>
<td>Jan 23, 1998</td>
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<td>PERMETHRIN</td>
<td>AB PERRIGO NEW YORK 5%</td>
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<td>AB 4MG</td>
<td>Apr 14, 2017</td>
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<td>PERPHENAZINE</td>
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<td>Apr 14, 2017</td>
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<td>PERPHENAZINE</td>
<td>AB SANDOZ 2MG</td>
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<td>PERPHENAZINE</td>
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<td>Dec 31, 1998</td>
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<td>PERPHENAZINE</td>
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<td>AB 4MG</td>
<td>Oct 17, 2016</td>
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PILOCARPINE HYDROCHLORIDE
TABLET; ORAL

PILOCARPINE HYDROCHLORIDE
7.5MG
AB PERRIGO PHARMA INTL
5MG

SALAGEN
AB + EISAI INC
3MG
AB +! 7.5MG

PIMAVANSENER TARTRATE
capsule; oral
NUPLAZID
AB +! ACADEIA PHARMS INC
34MG BASE
N210793 001
6 Jun 28, 2018

AB +! ACADEIA PHARMS INC
10MG BASE
N207318 002
6 Jun 28, 2018

AB +! ACADEIA PHARMS INC
17MG BASE
N207318 001
4 Apr 29, 2016

PIMECROLIMUS
cream; topical
ELIDEL
AB +! VALENT BERMUDA
1%
N021302 001
Dec 13, 2001

AB +! ACTAVIS LABS UT INC
1%
N209345 001
Dec 27, 2018

PIMOZIDE
TABLET; ORAL
ORAP
AB + TEVA
1MG
N017473 003
Aug 27, 1997

AB +! TEVA
2MG
N017473 002
Jul 31, 1984

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Sep 28, 2015

AB 2MG
A204521 002
Sep 28, 2015

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Mar 29, 1993

AB 10MG
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AB MYLAN PHARMS INC
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AB SUN PHARM INDUSTRIES
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AB ZYDUS PHARMS USA INC
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Aug 18, 2017

AB 10MG
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Aug 18, 2017

PIOGLITAZONE HYDROCHLORIDE
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AB + TAKEDA PHARMS USA
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Jul 15, 1999

AB + EQ 30MG BASE
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Jul 15, 1999

AB +! EQ 45MG BASE
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AB ACCORD HLTCARE
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<th>POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE SOLUTION/DROPS; OPHTHALMIC</th>
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<tr>
<td><strong>POLYTRIM</strong></td>
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<td>ALLERGAN 10,000 UNITS/ML; EQ 1MG BASE/ML N050567 001 Oct 20, 1988</td>
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<tr>
<td>POMALYST + CELGENE 1MG N204026 001 Feb 08, 2013</td>
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<td>+ 2MG N204026 002 Feb 08, 2013</td>
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<td>+ 3MG N204026 003 Feb 08, 2013</td>
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<td>+ 4MG N204026 004 Feb 08, 2013</td>
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<tr>
<td>ICLUSIG + ARIAD EQ 15MG BASE N203469 001 Dec 14, 2012</td>
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<td>+ EQ 30MG BASE N203469 003 Apr 23, 2015</td>
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<td>+! EQ 45MG BASE N203469 002 Dec 14, 2012</td>
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<tr>
<th>PORACTANT ALFA SUSPENSION; INTRATRACHEAL</th>
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<td>CUROSURF + CHIESI USA INC 80MG/ML N020744 001 Nov 18, 1999</td>
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<tr>
<th>PORFIMER SODIUM INJECTABLE; INJECTION</th>
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<td>PHOTOFRIN CONCORDIA LABS INC 75MG/VIAL N020451 001 Dec 27, 1995</td>
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**POSACONAZOLE**

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<tr>
<td><strong>SOLUTION; INTRAVENOUS</strong></td>
<td><strong>NOXAFIL</strong></td>
<td>300MG/16.7ML (18MG/ML)</td>
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<td><strong>NOXAFIL</strong></td>
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<td><strong>TABLET, DELAYED RELEASE; ORAL</strong></td>
<td><strong>NOXAFIL</strong></td>
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**POTASSIUM ACETATE**

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<td><strong>INJECTABLE; INJECTION</strong></td>
<td><strong>NOXAFIL</strong></td>
<td>2MEQ/ML</td>
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<td><strong>SUSPENSION; ORAL</strong></td>
<td><strong>SCHERING</strong></td>
<td>40MG/ML</td>
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<td><strong>TABLET, DELAYED RELEASE; ORAL</strong></td>
<td><strong>MERCK SHARP DOHME</strong></td>
<td>100MG</td>
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**POTASSIUM CHLORIDE**

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<td><strong>CAPSULE, EXTENDED RELEASE; ORAL</strong></td>
<td><strong>KLOR-CON</strong></td>
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<td><strong>SOLUTION; ORAL</strong></td>
<td><strong>KLOR-CON</strong></td>
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<td>2MEQ/ML</td>
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<td><strong>SOLUTION; ORAL</strong></td>
<td><strong>B BRAHN</strong></td>
<td>2MEQ/ML</td>
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<td><strong>SOLUTION; ORAL</strong></td>
<td><strong>PRESENIUS KABI USA</strong></td>
<td>2MEQ/ML</td>
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<td><strong>SOLUTION; ORAL</strong></td>
<td><strong>BAXTER HLTHCARE</strong></td>
<td>14.9MG/ML</td>
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<td><strong>SOLUTION; ORAL</strong></td>
<td><strong>ICU MEDICAL INC</strong></td>
<td>14.9MG/ML</td>
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<td><strong>ICU MEDICAL INC</strong></td>
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<td><strong>ICU MEDICAL INC</strong></td>
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### Prescription Drug Product List

#### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**POTASSIUM CHLORIDE**

**INJECTABLE; INJECTION**

**POTASSIUM CHLORIDE IN PLASTIC CONTAINER**

| Brand | Company | Strength | Code | Date
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<td>2MEQ/ML</td>
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<td>2.24GM/100ML</td>
<td>N019904</td>
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**SOLUTION; ORAL**

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<tr>
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<td>AMNEAL PHARMS LLC</td>
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<td>APOTEX INC</td>
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**TABLET, EXTENDED RELEASE; ORAL**

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<td>AB1</td>
<td>UPSHER SMITH LABS</td>
<td>10MEQ</td>
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<td>ACTAVIS LABS FL INC</td>
<td>10MEQ</td>
<td>A075604</td>
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<td>ACTAVIS LABS FL INC</td>
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<td>GLENMARK PHARMAS LTD</td>
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<td>A203562</td>
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**K-TAB**

| Brand | Company | Strength | Code | Date
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<td>AB2</td>
<td>MYLAN PHARMS INC</td>
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<td>AB2</td>
<td>NOVEL LABS INC</td>
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<td>AB2</td>
<td>PADDOCK LLC</td>
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<td>SIGMAHARM LABS LLC</td>
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<td>STRIDES PHARMA</td>
<td>8MEQ</td>
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<td>AB2</td>
<td>VITRUVIAS THERAP</td>
<td>20MEQ</td>
<td>A209688</td>
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<tr>
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<td>YICHANG HUMANWELL</td>
<td>8MEQ</td>
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<tr>
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<td>YICHANG HUMANWELL</td>
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**K-TAB**

| Brand | Company | Strength | Code | Date
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<td>N019123</td>
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**POTASSIUM CHLORIDE; SODIUM CHLORIDE**

**INJECTABLE; INJECTION**

| Brand | Company | Strength | Code | Date
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<tr>
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<td>149MG/100ML; 450MG/100ML</td>
<td>A078446</td>
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<td>BAXTER HLTHCARE</td>
<td>150MG/100ML; 450MG/100ML</td>
<td>N017648</td>
<td>Nov 26, 2002</td>
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<tr>
<td>AP</td>
<td>B BRAUN</td>
<td>150MG/100ML; 900MG/100ML</td>
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<td>POTASSIUM CHLORIDE; SODIUM CHLORIDE INJECTABLE; INJECTION</td>
<td>POTASSIUM CHLORIDE 0.3% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</td>
<td>AP + BAXTER HLTHCARE</td>
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Injectable; Subcutaneous

+ AstraZeneca AB
EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML) N021332 002 Sep 25, 2007
EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML) N021332 003 Sep 25, 2007

Prasterone
Insert; Vaginal

+ AMAG Pharma Inc
6.5MG N208470 001 Nov 16, 2016

Prasugrel Hydrochloride
Tablet; Oral

Effient

+ Eli Lilly and Co
EQ 5MG BASE N022307 001 Jul 10, 2009
EQ 10MG BASE N022307 002 Jul 10, 2009

Prasugrel

ACCORD Healthcare
EQ 5MG BASE A205987 001 Feb 02, 2018
EQ 10MG BASE A205987 002 Feb 02, 2018

AMNEAL Pharma
EQ 5MG BASE A205913 001 Jun 19, 2018
EQ 10MG BASE A205913 002 Jun 19, 2018

Aurobindo Pharma Ltd
EQ 5MG BASE A205888 001 Oct 16, 2017

Parexel

+ HEC Pharma
EQ 10MG BASE A206021 001 Jan 16, 2019
EQ 10MG BASE A206021 002 Jan 16, 2019

Mylan Pharma Inc
EQ 10MG BASE A205927 001 Jul 12, 2017
EQ 10MG BASE A205927 002 Jul 12, 2017

Pancera Biotech Ltd
EQ 5MG BASE A205897 001 Oct 16, 2017
EQ 10MG BASE A205897 002 Oct 16, 2017

US Pharma Windlas
EQ 5MG BASE A205790 001 Oct 16, 2017
EQ 10MG BASE A205790 002 Oct 16, 2017

Praavastatin Sodium
Tablet; Oral

Praavachol

+ Bristol Myers Squibb
20MG N019998 003 Oct 31, 1991

Praavastatin Sodium

ACCORD Healthcare
10MG A207068 001 Nov 17, 2016
20MG A207068 002 Nov 17, 2016
40MG A207068 003 Nov 17, 2016
80MG A207068 004 Nov 17, 2016

ApotheX Inc
10MG A077904 001 Oct 23, 2006
20MG A077904 002 Oct 23, 2006
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Aurobindo Pharma Ltd
10MG A203367 001 Feb 02, 2017

Dr Reddy's Labs Inc
10MG A076714 001 Oct 23, 2006
20MG A076714 002 Oct 23, 2006
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80MG A076714 004 Dec 28, 2007

Glenmark Generics
10MG A077987 001 May 11, 2007
20MG A077987 002 May 11, 2007
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80MG A077987 004 Dec 28, 2007

Hisun Pharma Hangzhou
20MG A206061 001 Nov 23, 2018

Lupin Pharma
40MG A206061 002 Nov 23, 2018
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Praavastatin Sodium
Tablet; Oral

Praavastatin Sodium

ACCORD Healthcare
20MG A207068 005 Dec 28, 2007

ApotheX Inc
20MG A077904 005 Dec 28, 2007

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20MG A206061 004 Dec 28, 2007

Lupin Pharma
40MG A077917 001 Jan 08, 2008
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<td>Apr 30, 2008</td>
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<tr>
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<td>80mg</td>
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</tr>
<tr>
<td>AB TEVA PHARMS</td>
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</tr>
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<td>AB</td>
<td>80mg</td>
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### PRAZICUANTEL

**Tablet; Oral**

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<th>Strength</th>
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<td>600mg</td>
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### PRAZOSIN HYDROCHLORIDE

**Capsule; Oral**

**MiniPress**

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<tbody>
<tr>
<td>1</td>
<td>EQ 1mg base</td>
<td>A017442</td>
<td>Nov 27, 2017</td>
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<tr>
<td>2</td>
<td>EQ 2mg base</td>
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<td>3</td>
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### PREDNICARBATE

**Cream; Topical**

**Dermatop E Emollient**

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<tbody>
<tr>
<td>0.1%</td>
<td>Valeant Bermuda</td>
<td>A020279</td>
<td>Oct 29, 1993</td>
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### PREDNICARBATE

**Ointment; Topical**

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<tr>
<td>0.1%</td>
<td>Valeant Pharmaceuticals North</td>
<td>A077287</td>
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### PREDNISOLON

**SYRUP; Oral**

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PREDNISOLONE
TABLET; ORAL
PREDNISOLONE
! WATSON LABS 5MG A080354 001

PREDNISOLONE ACETATE
SUSPENSION/DROPS; OPHTHALMIC
OMNIPRED
AB NOVARTIS PHARMS 1% N017469 001
PRED FORTE
AB ! ALLERGAN 1% N017011 001
PRED MILD
! ALLERGAN 0.12% N017100 001

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM
OINTMENT; OPHTHALMIC
BLEPHAMIDE S.O.P.
! ALLERGAN 0.2%; 10% A087748 001 Dec 03, 1986
SUSPENSION; OPHTHALMIC
BLEPHAMIDE
! ALLERGAN 0.2%; 10% N012813 002

PREDNISOLONE SODIUM PHOSPHATE
SOLUTION; ORAL
PEDIAPRED
AA +! SETON PHARM EQ 5MG BASE/5ML N019157 001 May 28, 1986
PREDNISOLONE SODIUM PHOSPHATE
SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM
SOLUTION/DROPS; OPHTHALMIC
! BAUSCH AND LOMB EQ 0.9% PHOSPHATE A040070 001 Jul 29, 1994
TABLET, ORALLY DISINTEGRATING; ORAL
ORAPRED ODT
AB + CONCORDIA PHARMS INC EQ 10MG BASE N021959 001 Jun 01, 2006
AB + EQ 15MG BASE N021959 002 Jun 01, 2006
AB +! EQ 30MG BASE N021959 003 Jun 01, 2006
PREDNISOLONE SODIUM PHOSPHATE
SOLUTION; ORAL
PREDNISONE
SOLUTION; ORAL
PREDNISONE
! WEST-WARD PHARMS INT 5MG/5ML A088703 001 Nov 08, 1984
PREDNISONE INTENSOL
! WEST-WARD PHARMS INT 5MG/ML A088810 001 Feb 20, 1985
TABLET; ORAL
PREDNISONE
AB GENEYORK PHARMS 1MG A211496 001 Dec 28, 2018
AB 2.5MG A211495 001 Dec 07, 2018
AB 5MG A211495 002 Dec 07, 2018
AB 10MG A210525 001 Dec 04, 2018
AB 20MG A210525 002 Dec 04, 2018
AB 50MG A210525 003 Dec 04, 2018
AB HIKMA PHARMS 50MG A098446 001 Jun 01, 1984
### Prednisone

**Tablet; Oral**

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<td>Jubilant Cadista</td>
<td>1 mg</td>
<td>A040611 001</td>
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<td>5 mg</td>
<td>A040362 002</td>
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<td>10 mg</td>
<td>A040362 003</td>
<td>Aug 29, 2001</td>
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<td>Mutual Pharm</td>
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<td>A089245 001</td>
<td>Jun 29, 2005</td>
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<tr>
<td>Nyland Pharms Inc</td>
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<td>A088802 001</td>
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<td></td>
<td>10 mg</td>
<td>A088832 001</td>
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<tr>
<td>Sun Pharm Industries</td>
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<tr>
<td>Vintage Pharms</td>
<td>20 mg</td>
<td>A089247 001</td>
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<td>5 mg</td>
<td>A040581 001</td>
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<td>10 mg</td>
<td>A040582 003</td>
<td>Jul 12, 2002</td>
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<td>A040392 001</td>
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<td>10 mg</td>
<td>A085162 001</td>
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<td>20 mg</td>
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<td>Westward Pharm Inc</td>
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<td>2.5 mg</td>
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<td></td>
<td>5 mg</td>
<td>A084122 001</td>
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<td></td>
<td>10 mg</td>
<td>A087342 001</td>
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<td>20 mg</td>
<td>A084283 001</td>
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**Tablet, Delayed Release; Oral**

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<tbody>
<tr>
<td>Actavis Labs FL Inc</td>
<td>1 mg</td>
<td>A204867 001</td>
<td>Apr 25, 2017</td>
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<td></td>
<td>2 mg</td>
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<td></td>
<td>5 mg</td>
<td>A204867 003</td>
<td>Apr 25, 2017</td>
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<tr>
<td>Horsus</td>
<td>1 mg</td>
<td>N202020 001</td>
<td>Jul 26, 2012</td>
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<td></td>
<td>2 mg</td>
<td>N202020 002</td>
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<td></td>
<td>5 mg</td>
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### Pregabalin

**Capsule; Oral**

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<tbody>
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<td>25 mg</td>
<td>N021446 001</td>
<td>Dec 30, 2004</td>
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<tr>
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<td>50 mg</td>
<td>N021446 002</td>
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<td></td>
<td>75 mg</td>
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<td>100 mg</td>
<td>N021446 004</td>
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<td></td>
<td>150 mg</td>
<td>N021446 005</td>
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<td></td>
<td>200 mg</td>
<td>N021446 006</td>
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<td></td>
<td>225 mg</td>
<td>N021446 007</td>
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<td>300 mg</td>
<td>N021446 008</td>
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<td>+ PF Prism CV</td>
<td>20 mg/ML</td>
<td>N022488 001</td>
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**Tablet, Extended Release; Oral**

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<tr>
<td>+ PF Prism CV</td>
<td>82.5 mg</td>
<td>N209501 001</td>
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<td></td>
<td>165 mg</td>
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### Prilocaine Hydrochloride

**Injectable; Injection**

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<td>Septodont Inc</td>
<td>4%</td>
<td>A079235 001</td>
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### Primaquine Phosphate

**Tablet; Oral**

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</thead>
<tbody>
<tr>
<td>+ Sanofi Aventis US</td>
<td>EQ 15 mg base</td>
<td>N008316 001</td>
<td>Feb 03, 2014</td>
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<tr>
<td>+ Alvogen Inc</td>
<td>EQ 15 mg base</td>
<td>A203924 001</td>
<td>Feb 25, 2014</td>
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<tr>
<td>+ Bayshore Pharm LLC</td>
<td>EQ 15 mg base</td>
<td>A204476 001</td>
<td>Jun 23, 2016</td>
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<tr>
<td>+ Novast Labs</td>
<td>EQ 15 mg base</td>
<td>A206043 001</td>
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<td>PRIMIDONE</td>
<td>TABLET; ORAL</td>
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<tr>
<td><strong>MYSOLINE</strong></td>
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<td>Valeant</td>
<td>50MG</td>
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<td>Hikma Intl Pharm</td>
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<td>Lannett</td>
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<td>+</td>
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<td><strong>AB</strong></td>
<td>! Mylan</td>
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<td>Watson Labs Teva</td>
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<td>500MG/ML</td>
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<tr>
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### PROMETHAZINE HYDROCHLORIDE

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### PROPAFENONE HYDROCHLORIDE

**Capsule, Extended Release; Oral**

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### RYTHMOL SR

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### PROPANETHYLNE BROMIDE

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**Solution/Drops; Ophthalmic**

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### PROPOFOL

**Injectable; Injection**

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### PROPRANOLOL HYDROCHLORide

**Capsule, Extended Release; Oral**

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### HEMANGEOL

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### PROTAMINE SULFATE

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### Quetiapine Fumarate

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### Quinapril Hydrochloride

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| RADION RA-223 DICHLORIDE | \( BX \) Bayer HLTHCARE | 162mCi/6ML (27mCi/ML) | N020971 001 | May 15, 2013 |

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| AB | RANITIDINE | EQ 300MG BASE | A210681 002 | Nov 23, 2018 |

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| AB | RANITIDINE HYDROCHLORIDE | EQ 300MG BASE | A209859 002 | Sep 27, 2018 |
| AB | RANITIDINE HYDROCHLORIDE | EQ 150MG BASE | A211058 001 | Jul 16, 2018 |
| AB | RANITIDINE HYDROCHLORIDE | EQ 300MG BASE | A211058 002 | Jul 16, 2018 |
| AB | RANITIDINE HYDROCHLORIDE | EQ 150MG BASE | A075742 001 | Nov 29, 2000 |
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| AB | RANITIDINE HYDROCHLORIDE | EQ 150MG BASE | A074456 001 | Oct 22, 1997 |
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| AP | RANITIDINE HYDROCHLORIDE | EQ 25MG BASE/ML | A079076 001 | Jun 09, 2016 |
| AP | RANITIDINE HYDROCHLORIDE | EQ 25MG BASE/ML | A074777 001 | Mar 02, 2005 |
| AP | RANITIDINE HYDROCHLORIDE | EQ 25MG BASE/ML | A077458 001 | Feb 16, 2006 |
| AP | RANITIDINE HYDROCHLORIDE | EQ 25MG BASE/ML | A091534 001 | Feb 22, 2013 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A076124 001 | Feb 21, 2007 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A078312 001 | Sep 02, 2008 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A090054 001 | Nov 15, 2010 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A090623 001 | Jul 28, 2010 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A090102 001 | May 26, 2009 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A078684 001 | Aug 27, 2009 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A091078 001 | Mar 22, 2011 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A078890 001 | Jul 01, 2010 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A091288 001 | Dec 09, 2010 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A091091 001 | Sep 20, 2011 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A077405 001 | Sep 21, 2007 |
| AA | RANITIDINE HYDROCHLORIDE | EQ 15MG BASE/ML | A077476 001 | Jun 13, 2011 |

| AA | ACTAVIS MID ATLANTIC | EQ 15MG BASE/ML | A076124 001 | Feb 21, 2007 |
| AA | AMNEAL PHARMS | EQ 15MG BASE/ML | A078312 001 | Sep 02, 2008 |
| AA | ANDA REPOSITORY | EQ 15MG BASE/ML | A090054 001 | Nov 15, 2010 |
| AA | AUROBINDO PHARMA LTD | EQ 15MG BASE/ML | A090623 001 | Jul 28, 2010 |
| AA | BIO PHARM INC | EQ 15MG BASE/ML | A090102 001 | May 26, 2009 |
| AA | BRECKENRIDGE PHARM | EQ 15MG BASE/ML | A078684 001 | Aug 27, 2009 |
| AA | HI TECH PHARMA | EQ 15MG BASE/ML | A091078 001 | Mar 22, 2011 |
| AA | LANNETT CO INC | EQ 15MG BASE/ML | A078890 001 | Jul 01, 2010 |
| AA | NOSTRUM LABS INC | EQ 15MG BASE/ML | A091288 001 | Dec 09, 2010 |
| AA | TARO | EQ 15MG BASE/ML | A077405 001 | Sep 21, 2007 |
| AA | TARO | EQ 15MG BASE/ML | A077476 001 | Jun 13, 2011 |

<p>| AB | VIVIMED GLOBAL | EQ 15MG BASE | A075165 001 | Sep 30, 2000 |
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| AB | VIVIMED GLOBAL | EQ 15MG BASE | A078542 001 | Nov 19, 2008 |
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| AB | VIVIMED GLOBAL | EQ 15MG BASE | A075165 002 | Sep 30, 2000 |
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| AB | VIVIMED GLOBAL | EQ 15MG BASE | A078542 002 | Nov 19, 2008 |
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### Riociguat
**TABLET; ORAL**
**ADEMPAS**
+ **BAYER HLTHCARE**
  + 0.5MG N204819 001 Oct 08, 2013
  + 1MG N204819 002 Oct 08, 2013
  + 1.5MG N204819 003 Oct 08, 2013
  + 2MG N204819 004 Oct 08, 2013
  + 2.5MG N204819 005 Oct 08, 2013

### Risedronate Sodium
**TABLET; ORAL**
**ACTONEL**
+ **APIL**
  + 5MG N020835 002 Apr 14, 2000
  + 30MG N020835 001 Mar 27, 1998
  + 35MG N020835 003 May 25, 2002
  + 150MG N020835 005 Apr 22, 2008

**AUROBINDO PHARMA LTD**
+ 5MG A090877 001 Nov 30, 2015
+ 30MG A090877 002 Nov 30, 2015
+ 35MG A090877 003 Nov 30, 2015
+ 150MG A206768 001 Apr 22, 2016

**MACLEODS PHARMS LTD**
+ 5MG A203533 001 Nov 30, 2015
+ 30MG A203533 002 Dec 09, 2015
+ 35MG A203533 003 Nov 29, 2016

**MYLAN PHARMS INC**
+ 5MG A200477 001 Nov 30, 2015
+ 30MG A200477 002 Nov 30, 2015
+ 35MG A200477 003 Nov 30, 2015
+ 75MG A200477 004 Jun 10, 2014
+ 150MG A200477 005 Jun 10, 2014

**SUN PHARMA GLOBAL**
+ 5MG A090886 001 Jun 10, 2014
+ 30MG A090886 002 Jun 10, 2014
+ 35MG A090886 003 Jun 10, 2014
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**TEVA PHARMS USA**
+ 5MG A077132 001 Oct 05, 2007
+ 30MG A077132 002 Oct 05, 2007
+ 35MG A077132 003 Oct 05, 2007
+ 150MG A079215 001 Jun 13, 2014

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**TABLET, DELAYED RELEASE; ORAL**
**ATEVILIA**
+ **APIL**
  + 35MG N022560 001 Oct 08, 2010

**TEVA PHARMS USA**
+ 35MG A203217 001 May 18, 2015

**ZYDUS PHARMS USA INC**
+ 35MG A203822 001 Sep 11, 2018

### Risperidone
**FOR SUSPENSION, EXTENDED RELEASE; SUBCUTANEOUS**
**PERSERIS KIT**
+ **INDIVIOR INC**
  + 90MG N210655 001 Jul 27, 2018
  + 120MG N210655 002 Jul 27, 2018

**INJECTABLE; INTRAMUSCULAR**
**RISPERDAL CONSTA**
+ **JANSSEN PHARMS**
  + 12.5MG/VIAL N021346 004 Apr 12, 2007
  + 25MG/VIAL N021346 001 Oct 29, 2003
  + 37.5MG/VIAL N021346 002 Oct 29, 2003
  + 50MG/VIAL N021346 003 Oct 29, 2003

**SOLUTION; ORAL**
**RISPERDAL**
+ **JANSSEN PHARMS**
  + 1MG/ML N020588 001 Jun 10, 1996

**RISPERIDONE**
**AMNEAL PHARMS**
+ 1MG/ML A091384 001 May 25, 2011

**ANI PHARMS INC**
+ 1MG/ML A076440 001 Jun 10, 2014

**APOTEX INC**
+ 1MG/ML A077719 001 Jul 29, 2009

**AUROBINDO PHARMA LTD**
+ 1MG/ML A078452 001 Sep 04, 2009

**BIO PHARM INC**
+ 1MG/ML A078909 001 Sep 04, 2009

**LANNETT CO INC**
+ 1MG/ML A079059 001 Dec 12, 2012

**TARO**
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**TRIS PHARMA INC**
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<td>AB, SUN PHARM INDs LTD</td>
<td>0.5mg, 1mg, 2mg</td>
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<td>Powder; oral</td>
<td>AB, AMNEAL PHARMS LLC</td>
<td>100mg</td>
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<td>RIVAROXABAN</td>
<td>Tablet; oral</td>
<td>AB, KARELTO</td>
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<td>Capsule; oral</td>
<td>AB, NOVARTIS</td>
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### RIVASTIGMINE TARTRATE
**Capsule; Oral**

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<td>AB DR REDDYS LABS INC</td>
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<td>AB MACLEODS PHARMS LTD</td>
<td>EQ 1.5MG</td>
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<td>AB MACLEODS PHARMS LTD</td>
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<td>AB WATSON LABS</td>
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### RIZATRIPTAN BENZOATE
**Tablet; Oral**

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<td>AB AUROBINDO PHARMA LTD</td>
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<td>A020490</td>
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<td>AB ECI PHARMS LLC</td>
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RIZATRIPTAN BENZOATE
TABLET; ORAL

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UNICHEM LABS LTD
EQ 10MG BASE
A077263 002 Dec 31, 2012
AB
UNICHEM LABS LTD
EQ 5MG BASE
A207836 001 Mar 07, 2017
AB
UNICHEM LABS LTD
EQ 10MG BASE
A207836 002 Mar 07, 2017

MAXALT-MLT
AB
AUROBINDO PHARMA LTD
EQ 10MG BASE
N020865 002 Jun 29, 1998
AB
AUROBINDO PHARMA LTD
EQ 5MG BASE
A203062 001 Jul 01, 2013
AB
GLENMARK PHARMAS LTD
EQ 10MG BASE
A201914 002 Jul 01, 2013
AB
JUBILANT GENERICS
EQ 5MG BASE
A203334 001 Oct 16, 2015
AB
MACLEODS PHARMS LTD
EQ 10MG BASE
A203146 001 Sep 19, 2014
AB
MYLAN PHARMS INC
EQ 10MG BASE
A203146 002 Sep 19, 2014
AB
AUROBINDO PHARMA LTD
EQ 5MG BASE
A078173 001 Dec 31, 2012
AB
AUROBINDO PHARMA LTD
EQ 10MG BASE
A078173 002 Dec 31, 2012
AB
PANACEA BIOTEC LTD
EQ 10MG BASE
A204722 001 Jan 11, 2017
AB
SANDOZ
EQ 10MG BASE
A078739 001 Jul 01, 2013
AB
SANDOZ
EQ 10MG BASE
A078739 002 Jul 01, 2013
AB
UNICHEM LABS LTD
EQ 5MG BASE
A207835 001 Mar 07, 2017
AB
UNICHEM LABS LTD
EQ 10MG BASE
A207835 002 Mar 07, 2017

ROCURONIUM BROMIDE
INJECTABLE; INJECTION

ROCURONIUM BROMIDE
AP
AUROBINDO PHARMA LTD
50MG/5ML (10MG/ML)
A206206 001 Apr 12, 2017
AP
AUROBINDO PHARMA LTD
100MG/10ML (10MG/ML)
A206206 002 Apr 12, 2017
AP
FRESENIUS KABI USA
50MG/5ML (10MG/ML)
A078651 001 Dec 29, 2008
AP
GLAND PHARMA LTD
100MG/10ML (10MG/ML)
A078651 002 Dec 29, 2008
AP
HOSPIRA
50MG/5ML (10MG/ML)
A205656 001 Apr 04, 2018
AP
HOSPIRA
100MG/10ML (10MG/ML)
A205656 002 Apr 04, 2018
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MYLAN INSTITUTIONAL
50MG/5ML (10MG/ML)
A079199 001 Nov 26, 2008
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MYLAN INSTITUTIONAL
100MG/10ML (10MG/ML)
A079199 002 Nov 26, 2008
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SAGENT PHARMS
50MG/5ML (10MG/ML)
A091458 001 Jul 28, 2010
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SAGENT PHARMS
100MG/10ML (10MG/ML)
A091458 002 Jul 28, 2010
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SAGENT PHARMS
50MG/5ML (10MG/ML)
A079195 001 Dec 05, 2008
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SAGENT PHARMS
100MG/10ML (10MG/ML)
A079195 002 Dec 05, 2008
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TAMARANG
50MG/5ML (10MG/ML)
A091118 001 Aug 27, 2012
AP
TAMARANG
100MG/10ML (10MG/ML)
A091118 002 Aug 27, 2012
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TEVA PHARMS
50MG/5ML (10MG/ML)
A078717 001 Nov 26, 2008
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TEVA PHARMS
100MG/10ML (10MG/ML)
A078717 002 Nov 26, 2008
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WEST WARD PHARM CORP
50MG/5ML (10MG/ML)
A204679 001 Feb 28, 2017
AP
WEST WARD PHARM CORP
100MG/10ML (10MG/ML)
A204679 002 Feb 28, 2017

ROFLUMILAST
TABLET; ORAL

DALIRESP
AB
ASTRAZENECA PHARMS
500MCG
N022522 001 Feb 28, 2011
AB
ASTRAZENECA PHARMS
500MCG
A208236 001 Oct 03, 2018
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ASTRAZENECA PHARMS
500MCG
A208236 002 Oct 03, 2018
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HETER LABS LTD III
500MCG
A208213 001 Nov 23, 2018
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HETER LABS LTD III
500MCG
A208213 002 Nov 23, 2018
AB
HETER LABS LTD III
500MCG
A208278 001 Aug 06, 2018
AB
HETER LABS LTD III
500MCG
A208278 002 Aug 06, 2018
AB
TERSERA THERAPS LLC
EQ 90MG BASE
N206500 001 Sep 01, 2015
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# Prescription Drug Product List

## Ropinirole Hydrochloride

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## Ropivacaine Hydrochloride

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ROTIGOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

NEUPRO

+ UCB INC 1MG/24HR N021829 004 Apr 02, 2012
+ UCB INC 2MG/24HR N021829 001 May 09, 2007
+ UCB INC 3MG/24HR N021829 005 Apr 02, 2012
+ UCB INC 4MG/24HR N021829 002 May 09, 2007
+ UCB INC 6MG/24HR N021829 003 May 09, 2007
+ UCB INC 8MG/24HR N021829 006 Apr 02, 2012

RUBIDIUM CHLORIDE RB-82

INJECTABLE; INJECTION

CARDIOGEN-RB-82

BRACCO N/A N019414 001 Dec 29, 1989
SOLUTION; INTRAVENOUS

RUBY-FILL

JUBILANT DRAXIMAGE N/A N202153 001 Sep 30, 2016

RUCAPARIB CAMSYLATE

TABLET; ORAL

RUBRACA

+ CLOVIS ONCOLOGY INC EQ 200MG BASE N209115 001 Dec 19, 2016
+ EQ 250MG BASE N209115 003 May 01, 2017
+ EQ 300MG BASE N209115 002 Dec 19, 2016

RUFINAMIDE

SUSPENSION; ORAL

BANZEL

+ EISAI INC 40MG/ML N201367 001 Mar 03, 2011

TABLET; ORAL

BANZEL

AB + EISAI INC 200MG N021911 002 Nov 14, 2008
AB + 400MG N021911 003 Nov 14, 2008

RUFINAMIDE

AB GLENMARK PHARMS LTD 200MG A205075 001 May 16, 2016
AB 400MG A205075 002 May 16, 2016
AB MYLAN PHARMS INC 200MG A205095 001 May 16, 2016
AB 400MG A205095 002 May 16, 2016
AB WEST-WARD PHARMS 200MG A204988 001 May 16, 2016
INT AB 400MG A204988 002 May 16, 2016

RUXOLITINIB PHOSPHATE

TABLET; ORAL

JAKAFI

+ INCYTE CORP EQ 5MG BASE N202192 001 Nov 16, 2011
+ EQ 10MG BASE N202192 002 Nov 16, 2011
+ EQ 15MG BASE N202192 003 Nov 16, 2011
+ EQ 20MG BASE N202192 004 Nov 16, 2011
+ EQ 25MG BASE N202192 005 Nov 16, 2011

SACROSIDASE

SOLUTION; ORAL

SUCRAID

+ QOL MEDCL 8,500 IU/ML N020772 001 Apr 09, 1998

SACUBITRIL; VALSARTAN

TABLET; ORAL

ENTRESTO

+ NOVARTIS PHARMS CORP 24MG; 26MG N207620 001 Jul 07, 2015
+ 49MG; 51MG N207620 002 Jul 07, 2015
+ 97MG; 103MG N207620 003 Jul 07, 2015

SAFINAMIDE MESYLATE

TABLET; ORAL

XADAGO

+ US WORLDMEDS LLC 50MG N207145 001 Mar 21, 2017
+ 100MG N207145 002 Mar 21, 2017

SALMETEROL XINAFOATE

POWDER; INHALATION

SEREVENT

+ GLAXOSMITHKLINE EQ 0.05MG BASE/INH N020692 001 Sep 19, 1997
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### Selenium Sulfide

**Lotion/Shampoo; Topical**

**AT! Perrigo New York**
- 2.5%
  - [A089996](#) 001 Jan 10, 1991

**AT! Wockhardt Bio AG**
- 2.5%
  - [A088228](#) 001 Sep 01, 1983

### Selalexipag

**Tablet; Oral**

**Uptravi**
- + Actelion Pharm Ltd 0.2mg [N207947](#) 001 Dec 21, 2015
- + 0.4mg [N207947](#) 002 Dec 21, 2015
- + 0.6mg [N207947](#) 003 Dec 21, 2015
- + 0.8mg [N207947](#) 004 Dec 21, 2015
- + 1mg [N207947](#) 005 Dec 21, 2015
- + 1.2mg [N207947](#) 006 Dec 21, 2015
- + 1.4mg [N207947](#) 007 Dec 21, 2015
- + 1.6mg [N207947](#) 008 Dec 21, 2015

### Semaglutide

**Solution; Subcutaneous**

**Ozempic**
- + Novo 2mg/1.5ml (1.34mg/ml) [N209637](#) 001 Dec 05, 2017

### Sertaconazole Nitrate

**Cream; Topical**

**Ertaczo**
- + Valeant Luxembourg 2% [N021385](#) 001 Dec 10, 2003

### Sertraline Hydrochloride

**Concentrate; Oral**

**Sertraline Hydrochloride**
- **AA! Aurobindo Pharma**
  - EQ 20mg [A078861](#) 001 Oct 31, 2008
- **Zoloft**
  - **AA! Pfizer**
    - EQ 20mg [N020990](#) 001 Dec 07, 1999

### Sertraline Hydrochloride

**Tablet; Oral**

**Sertraline Hydrochloride**
- **AA! Accord Hlthcare**
  - EQ 25mg [A202825](#) 001 Nov 07, 2014
- **AB! Apotex Inc**
  - EQ 25mg [A076882](#) 001 Feb 06, 2007
- **AB! Aurobindo Pharma**
  - EQ 25mg [A077206](#) 001 Feb 06, 2007
  - EQ 50mg [A077206](#) 002 Feb 06, 2007
  - EQ 100mg [A077206](#) 003 Feb 06, 2007
- **AB! Austarpharma LLC**
  - EQ 25mg [A077670](#) 001 Feb 06, 2007
- **AB! Invagen Pharms**
  - EQ 25mg [A077977](#) 001 Feb 06, 2007
- **AB! Lupin**
  - EQ 25mg [A077977](#) 002 Feb 06, 2007
  - EQ 50mg [A077977](#) 003 Feb 06, 2007
- **AB! Mylan Pharms Inc**
  - EQ 25mg [A078626](#) 001 Jan 31, 2008
  - EQ 50mg [A078626](#) 002 Jan 31, 2008
- **AB! Oxford Pharms**
  - EQ 25mg [A078175](#) 001 Jul 21, 2010
  - EQ 50mg [A078175](#) 002 Jul 21, 2010
- **AB! Sun Pharm Inds Ltd**
  - EQ 25mg [A077977](#) 001 Feb 06, 2007
  - EQ 50mg [A077977](#) 002 Feb 06, 2007
- **AB! Teva**
  - EQ 25mg [A076465](#) 001 Aug 11, 2006
  - EQ 50mg [A076465](#) 002 Aug 11, 2006
- **AB! Torrent Pharms**
  - EQ 25mg [A077765](#) 001 Feb 06, 2007
  - EQ 50mg [A077765](#) 002 Feb 06, 2007
- **AB! Wockhardt**
  - EQ 25mg [A077803](#) 001 Jan 08, 2008
  - EQ 50mg [A077803](#) 002 Jan 08, 2008
- **AB! Zydus Pharms Usa**
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<td></td>
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<td></td>
<td>10MG</td>
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<tr>
<td></td>
<td></td>
<td>AB</td>
<td></td>
<td>20MG</td>
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<td></td>
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<td>40MG</td>
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### SIMVASTATIN

**TABLET; ORAL**

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### ZOCOR

**INJECTABLE; INJECTION**

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### SINCALIDE

**OINTMENT; TOPICAL**

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<td>0.005MG/VIAL</td>
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### SINECATECHINS

**TABLET; ORAL**

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<th>Expiration Date</th>
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<tbody>
<tr>
<td>AB</td>
<td>0.5MG</td>
<td>N021110 004</td>
<td>Jan 25, 2010</td>
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<td>N021110 001</td>
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### SIROLIMUS

**SOLUTION; ORAL**

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<th>Approval Number</th>
<th>Expiration Date</th>
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<tr>
<td>AB</td>
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### SIROLIMUS

**TABLET; ORAL**

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## 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**PRESCRIPTION DRUG PRODUCT LIST**

### SIROLIMUS

**TABLET; ORAL**

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<td>RAPAMUNE</td>
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### SITAGLIPTIN PHOSPHATE

**TABLET; ORAL**

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<td>N021995 001</td>
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<td>JANUVIA</td>
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### SODIUM ACETATE

**INJECTABLE; INJECTION**

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<td>FRESENIUS KABI USA</td>
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### SODIUM BENZOATE; SODIUM PHENYLACETATE

**SOLUTION; INTRAVENOUS**

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</thead>
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<tr>
<td>AILEX PHARMS LLC</td>
<td>10%;10% (5GM/50ML;5GM/50ML)</td>
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<td>NAVINTA LLC</td>
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<td>A205880 001</td>
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### SODIUM BICARBONATE

**INJECTABLE; INJECTION**

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<td>0.9MEQ/ML</td>
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<td>9MG/ML</td>
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### SODIUM CHLORIDE

**INJECTABLE; INJECTION**

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<tr>
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<td>5MG/ML</td>
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<td>9MG/ML</td>
<td>N020178 002</td>
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<td>900MG/100ML</td>
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### SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

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<tr>
<td>HOSPIRA</td>
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### SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP
JUBILANT
HOLLISTERSTR
9MG/ML
A203352 001 May 18, 2016
AP
LABORATORIOS GRIPOLS
900MG/100ML
A207956 001 May 25, 2017
AP
TARO
9MG/ML
A077407 001 Aug 11, 2006

SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

AP
B BRAUN
3GM/100ML
N019635 003 Mar 09, 1988
AP
BAXTER HLTHCARE
3GM/100ML
N019022 001 Nov 01, 1983

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

AP
B BRAUN
5GM/100ML
N019635 004 Mar 09, 1988
AP
BAXTER HLTHCARE
5GM/100ML
N019022 002 Nov 01, 1983

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

+ LIEBEL-FLARSHEIM
405MG/50ML (9MG/ML)
N021569 001 Jul 27, 2006
+ 1012.5MG/125ML (9MG/ML)
N021569 002 Jul 27, 2006

SODIUM CHLORIDE IN PLASTIC CONTAINER

+ WEST-WARD PHARMS
9MG/ML
A201833 001 Sep 24, 2013

SOLUTION; IRRIGATION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP
B BRAUN
900MG/100ML
N019635 005 Aug 11, 2016
AP
BAXTER HLTHCARE
900MG/100ML
N019022 003 Nov 01, 1983

SODIUM FERRIC GLUCONATE COMPLEX

INJECTABLE; INJECTION

FERRLECT
AP
SANOFI AVENTIS US
62.5MG/5ML
A029550 001 Feb 18, 1999

SODIUM FLUORIDE F-18

INJECTABLE; INTRAVENOUS

SODIUM FLUORIDE F-18

AP
3D IMAGING DRUG
10-200mCi/ML
A203777 001 Oct 19, 2015
AP
BIOMEDCL RES FDN
10-200mCi/ML
A204351 001 Jan 09, 2015
AP
CARDINAL HEALTH 414
10-200mCi/ML
A203780 001 Jul 20, 1984
AP
ESSENTIAL ISOTOPES
10-200mCi/ML
A204541 001 Oct 29, 2014
AP
GLOBAL ISOTOPES LLC
10-200mCi/ML
A204464 001 Oct 21, 2014
AP
HOT SHOTS NM LLC
10-200mCi/ML
A204530 001 Jul 29, 2005
AP
JUBILANT DRAXIMAGE
10-200mCi/ML
A203936 001 May 19, 2016
AP
KREITCHMAN PET CTR
10-200mCi/ML
A203936 001 May 19, 2016
AP
MIDWEST MEDCL
10-200mCi/ML
A204440 001 Nov 17, 2015
AP
MIPS CRF
10-200mCi/ML
A204517 001 Jul 21, 2015
AP
NMC USA BRONX LLC
10-200mCi/ML
A204513 001 Nov 28, 2014
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PETNET
10-200mCi/ML
A208389 001 Sep 28, 2015
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PRECISION NUCLEAR
10-200mCi/ML
A204542 001 Feb 27, 2015
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SHERTECH LABS LLC
10-200mCi/ML
A204518 001 Sep 22, 2014
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SOFIE
10-200mCi/ML
A203592 001 Aug 18, 2015
AP
SPECTRON MRC LLC
10-200mCi/ML
A203912 001 Apr 22, 2015
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UCSF RODIOPHARM
10-200mCi/ML
A204437 001 Mar 13, 2014
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UNIV UTAH CYCLOTRON
10-200mCi/ML
A204497 001 Apr 20, 2015
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THE FEINSTEIN INST
10-91.5mCi/ML
A204328 001 Jun 28, 2013

SODIUM IODIDE I-123

CAPSULE; ORAL

SODIUM IODIDE I-123

AA
CARDINAL HEALTH 418
100uCi
N018671 001 May 27, 1982
AA
MALLINKRODT NUCLEAR
200uCi
A071908 001 Feb 26, 1989
AA
200uCi
A071910 001 Feb 26, 1989
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<td>Sodium Nitrite; Sodium Thiosulfate</td>
<td>Solution, Solution; Intravenous Nithiotide</td>
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<td>001</td>
<td>Jan 14, 2011</td>
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NDC stands for National Drug Code, which is a unique identifier for human and veterinary drugs distributed in the United States.
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## SOMATROPIN
**INJECTABLE; INJECTION**

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## SOMATROPIN RECOMBINANT
**INJECTABLE; INJECTION**

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## NORDITROPIN FLEXPRO

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<td>Nutropin AQ Nuspin</td>
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<td>BX 10MG/2ML (5MG/ML)</td>
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## SONIDEGIB PHOSPHATE
**CAPSULE; ORAL**

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**TABLET; ORAL**

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<td>AP +! PRESENIIUS</td>
<td>May 28, 1993</td>
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<td>INTRALIPID 20%</td>
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<td>AP +! PRESENIIUS</td>
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<td>AP +! B BRAUN</td>
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<td>Name</td>
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<td>Strength</td>
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<td>SOYBEAN OIL</td>
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<td>NUTRILIPID 20%</td>
<td>B BRAUN</td>
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<td>NATROBA 0.9%</td>
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<td>CAROSPIR 25MG/5ML</td>
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<td>GD SEARLE LLC 100MG</td>
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<td>ACCORD HLTHCARE 25MG</td>
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<td>JUBILANT GENERICS 25MG</td>
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<td>SUN PHARM INDUSTRIES 25MG</td>
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<td>AUROBINDO PHARMA 15MG</td>
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<td>HETERO LABS LTD III 15MG</td>
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<td>BRISTOL-MYERS SQUIBB 1MG/ML</td>
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### Sterile Water for Injection

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<td>Sterile Water for Injection</td>
<td>Hospira</td>
<td>N018802</td>
<td>Oct 27, 1982</td>
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<td>Bacteriostatic Water for Injection</td>
<td>Fresenius Rabi USA</td>
<td>A209689</td>
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<td>Sterile Water for Injection</td>
<td>Westward Pharm</td>
<td>A206369</td>
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### Sterile Water for Ingestion

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<td>Sterile Water in Plastic Container</td>
<td>B Braun</td>
<td>N016734</td>
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<td>Sterile Water in Plastic Container</td>
<td>ICU Medical Inc</td>
<td>N017513</td>
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### Streptomycin Sulfate

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<td>Streptomycin Sulfate</td>
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### Succinylcholine Chloride

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<td>Succinylcholine Chloride</td>
<td>Sandoz Inc</td>
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<td>Succinylcholine Chloride</td>
<td>Hospira</td>
<td>N008845</td>
<td>May 04, 2018</td>
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<td>Succinylcholine Chloride</td>
<td>Amneal Pharms Co</td>
<td>A2111432</td>
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<td>Succinylcholine Chloride</td>
<td>Renaissance SSA LLC</td>
<td>A210231</td>
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<td>Succinylcholine Chloride</td>
<td>Zydus Pharms USA Inc</td>
<td>A209467</td>
<td>May 04, 2018</td>
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</table>
### SUCRALFATE
- **SUSPENSION; ORAL**
  - CARAFATE
    - **PRODUCT:** SUCRALFATE SUSPENSION; ORAL
    - **MANUFACTURER:** ALLERGAN SALES LLC
    - **STRENGTH:** 1GM/10ML
    - **NDC:** N019183 001
    - **DATE:** Dec 16, 1993
  - **TABLET; ORAL**
    - **PRODUCT:** CARAFATE
    - **MANUFACTURER:** TEVA
    - **STRENGTH:** 1GM
    - **NDC:** A070848 001
    - **DATE:** Mar 29, 1996

### SUCROFERRIC OXYHYDROXIDE
- **TABLET, CHEWABLE; ORAL**
  - VELPHORO
    - **PRODUCT:** SUCROFERRIC OXYHYDROXIDE TABLET, CHEWABLE; ORAL
    - **MANUFACTURER:** VIFOR FRESENIUS
    - **STRENGTH:** 500MG
    - **NDC:** N205109 001
    - **DATE:** Nov 27, 2013

### SUFENTANIL CITRATE
- **INJECTABLE; INJECTION**
  - CARAFATE
    - **PRODUCT:** SUFENTANIL CITRATE
    - **MANUFACTURER:** AKORN
      - **STRENGTH:** EQ 0.05MG BASE/ML
        - **NDC:** N019050 001
        - **DATE:** May 04, 1984
    - **MANUFACTURER:** Hospira
      - **STRENGTH:** EQ 0.05MG BASE/ML
        - **NDC:** A074534 001
        - **DATE:** Dec 11, 1996
    - **MANUFACTURER:** WEST-WARD PHARMS
      - **STRENGTH:** EQ 0.05MG BASE/ML
        - **NDC:** A074413 001
        - **DATE:** Dec 15, 1995

### SUHAMADEX SODIUM
- **SOLUTION; INTRAVENOUS**
  - BRIDION
    - **PRODUCT:** SUHAMADEX SODIUM SOLUTION; INTRAVENOUS
    - **MANUFACTURER:** ORGANON SUB MERCK
      - **STRENGTH:** EQ 200MG BASE/2ML (EQ 100MG BASE/ML)
        - **NDC:** N022225 002
        - **DATE:** Dec 15, 2015
    - **MANUFACTURER:** ORGANON SUB MERCK
      - **STRENGTH:** EQ 500MG BASE/5ML (EQ 100MG BASE/ML)
        - **NDC:** N022225 001
        - **DATE:** Dec 15, 2015

### SULCONAZOLE NITRATE
- **CREAM, TOPICAL**
  - EXELDERM
    - **PRODUCT:** SULCONAZOLE NITRATE CREAM, TOPICAL
    - **MANUFACTURER:** JOURNEY
      - **STRENGTH:** 1%
        - **NDC:** N018737 001
        - **DATE:** Feb 28, 1989
    - **MANUFACTURER:** JOURNEY
      - **STRENGTH:** 1%
        - **NDC:** N018738 001
        - **DATE:** Aug 30, 1985

### SULFACETAMIDE SODIUM
- **LOTION, TOPICAL**
  - KLARON
    - **PRODUCT:** SULFACETAMIDE SODIUM LOTION, TOPICAL
    - **MANUFACTURER:** VALEANT PHARMS
      - **STRENGTH:** 10%
        - **NDC:** N019931 001
        - **DATE:** Dec 23, 1996
  - **AB**
    - **PRODUCT:** SULFACETAMIDE SODIUM OINTMENT; OPHTHALMIC
      - **MANUFACTURER:** SULFACETAMIDE SODIUM OINTMENT; OPHTHALMIC
        - **MANUFACTURER:** SULFACETAMIDE SODIUM OINTMENT; OPHTHALMIC
          - **MANUFACTURER:** PERRIGO CO
            - **STRENGTH:** 10%
              - **NDC:** A078668 001
              - **DATE:** May 28, 2009
          - **MANUFACTURER:** TARO
            - **STRENGTH:** 10%
              - **NDC:** A078669 001
              - **DATE:** May 28, 2009
          - **MANUFACTURER:** Sandoz Inc
            - **STRENGTH:** 10%
              - **NDC:** A080029 001

### SULFADIAZINE
- **TABLET, ORAL**
  - SULFADIAZINE TABLET, ORAL
    - **PRODUCT:** SULFADIAZINE TABLET, ORAL
    - **MANUFACTURER:** SANDOZ INC
      - **STRENGTH:** 500MG
        - **NDC:** A040091 001
        - **DATE:** Jul 29, 1994

### SULFAMETHOXAZOLE; TRIMETHOPRIM
- **INJECTABLE; INJECTION**
  - SULFAMETHOXAZOLE AND TRIMETHOPRIM INJECTABLE; INJECTION
    - **PRODUCT:** SULFAMETHOXAZOLE AND TRIMETHOPRIM INJECTABLE; INJECTION
    - **MANUFACTURER:** TEVA PHARMS USA
      - **STRENGTH:** 80MG/ML; 16MG/ML
        - **NDC:** A073303 001
        - **DATE:** Oct 31, 1991
    - **MANUFACTURER:** TEVA PHARMS USA
      - **STRENGTH:** 80MG/ML; 16MG/ML
        - **NDC:** A026607 001
        - **DATE:** Aug 30, 2017
  - **SUSPENSION; ORAL**
    - **PRODUCT:** SULFAMETHOXAZOLE AND TRIMETHOPRIM SUSPENSION; ORAL
    - **MANUFACTURER:** AUROBINDO PHARMA
      - **STRENGTH:** 200MG/5ML; 40MG/5ML
        - **NDC:** A091348 001
        - **DATE:** Jun 08, 2010
    - **MANUFACTURER:** HI TECH PHARMA
      - **STRENGTH:** 200MG/5ML; 40MG/5ML
        - **NDC:** A074650 001
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<td>Septra</td>
<td>AB</td>
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<td>+! PHARMACIA AND UPJOHN</td>
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<td>Sulfur hexafluoride Lipid-Type A Microspheres For Suspension; Intravenous Lumason</td>
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<td>N203684</td>
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<td>+! BRACCO</td>
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<td>Sulindac Tablet; Oral</td>
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<td>+ WATSON LABS</td>
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<td>+! WATSON LABS</td>
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*Note: The above list is a sample of the drugs mentioned in the document and may not be exhaustive.*
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### Telotristat Etiprate

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### Temazepam

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### Teriparatide Recombinant Human

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### Tesamorelin Acetate

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### Topiramate<br>**Tablet; Oral**<br><br>#### Topamax<br>**AB**<br>+ JANSSEN PHARMS 25MG N020505 004 Dec 24, 1996<br>+ 50MG N020505 005 Dec 24, 1996<br>+ 100MG N020505 001 Dec 24, 1996<br>+ 200MG N020505 002 Dec 24, 1996<br><br>#### Topiramate<br>**AB**<br>+ ACCORD HLTHCARE 25MG A076311 001 Mar 27, 2009<br>+ 50MG A076311 002 Mar 27, 2009<br>+ 100MG A076311 003 Mar 27, 2009<br>+ 200MG A076311 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>APOTEX INC 25MG A077733 001 Mar 27, 2009<br>50MG A077733 002 Mar 27, 2009<br>100MG A077733 003 Mar 27, 2009<br>200MG A077733 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>AIROBINDO PHARMA 25MG A078462 001 Mar 27, 2009<br>50MG A078462 002 Mar 27, 2009<br>100MG A078462 003 Mar 27, 2009<br>200MG A078462 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>Cipla Ltd 25MG A076343 001 Mar 27, 2009<br>50MG A076343 002 Mar 27, 2009<br>100MG A076343 003 Mar 27, 2009<br>200MG A076343 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>GLENMARK GENERICS 25MG A077627 001 Mar 27, 2009<br>50MG A077627 002 Mar 27, 2009<br>100MG A077627 003 Mar 27, 2009<br>200MG A077627 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>INVAGEN PHARMS 25MG A079162 001 Mar 27, 2009<br>50MG A079162 002 Mar 27, 2009<br>100MG A079162 003 Mar 27, 2009<br>200MG A079162 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>LUPIN 25MG A078410 001 Sep 11, 2013<br>50MG A078410 002 Sep 11, 2013<br>100MG A078410 003 Sep 11, 2013<br>200MG A078410 004 Sep 11, 2013<br><br>#### Topiramate<br>**AB**<br>SUN PHARM INDS LTD 25MG A076327 001 Mar 27, 2009<br>100MG A076327 002 Mar 27, 2009<br>200MG A076327 003 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>SUN PHARMA GLOBAL 25MG A090278 001 Mar 27, 2009<br>50MG A090278 002 Mar 27, 2009<br>100MG A090278 003 Mar 27, 2009<br>200MG A090278 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>TEVA 25MG A076317 001 Mar 27, 2009<br>50MG A076317 002 Mar 27, 2009<br>100MG A076317 003 Mar 27, 2009<br>200MG A076317 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>Torrent phams 25MG A079153 001 Mar 27, 2009<br>50MG A079153 002 Mar 27, 2009<br>100MG A079153 003 Mar 27, 2009<br>200MG A079153 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>Unichem labs ltd 25MG A079162 001 Mar 27, 2009<br>50MG A090162 002 Mar 27, 2009<br>100MG A090162 003 Mar 27, 2009<br>200MG A090162 004 Mar 27, 2009<br><br>#### Topiramate<br>**AB**<br>Upsher Smith Labs 25MG A078499 001 Jan 07, 2010<br>50MG A078499 002 Jan 07, 2010<br>100MG A078499 003 Jan 07, 2010<br>200MG A078499 004 Jan 07, 2010<br><br>#### Topiramate<br>**AB**<br>Zydus pharms usa inc 25MG A078235 001 Mar 27, 2009<br>50MG A078235 002 Mar 27, 2009<br>100MG A078235 003 Mar 27, 2009<br>200MG A078235 004 Mar 27, 2009<br><br>### Topotecan Hydrochloride<br>**Capsule; Oral**<br><br>#### Hycamtin<br>**AB**<br>+ NOVARTIS PHARMS EQ 0.25MG BASE N020981 001 Oct 11, 2007<br>+! EQ 1MG BASE N020981 002 Oct 11, 2007
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# 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

## PRESCRIPTION DRUG PRODUCT LIST

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|                 | MYLAN PHARMS INC          | 0.025%   | A207555 001 |
|                 | POUGERA PHARMS            | 0.025%   | A207555 001 |
|                 | FOUGERA PHARMS            | 0.1%     | A207555 001 |
|                 | MACLEODS PHARMS LTD       | 0.025%   | A209535 001 |
|                 | GLENMARK PHARMS LTD       | 0.025%   | A209535 001 |
|                 | LANNETT CO INC            | 0.025%   | A209535 001 |
|                 | LUPIN ATLANTIS            | 0.025%   | A209535 001 |
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|                 | PERRIGO NEW YORK          | 0.025%   | A209535 001 |
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VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

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VALBENAZINE TOSYLATE

CAPSULE; ORAL

INGREZZA

+ NEUROCRINE

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VALGANCICLOVIR HYDROCHLORIDE

FOR SOLUTION; ORAL

VALCYTE

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VALPROATE SODIUM

INJECTABLE; INJECTION

DEPACON

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VALPROATE SODIUM

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## Valsartan

**Tablet; Oral**

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## Vancomycin Hydrochloride

**Capsule; Oral**

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## FOR Solution; Oral

**Fixvaq Kit**

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## Vancomycin Hydrochloride

**Injectable; Injection**

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<td>AB 20MG</td>
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<tr>
<td>AB CROSSMEDIKAI SA 5MG</td>
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<tr>
<td>AB 10MG</td>
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<td>AB 20MG</td>
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<tr>
<td>AB TEVA PHARMS 2.5MG</td>
</tr>
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<td>AB 5MG</td>
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<tr>
<td>AB 10MG</td>
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<td>AB 20MG</td>
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<tr>
<td>AB ZYDUS PHARMS USA INC 2.5MG</td>
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<td>AB 10MG</td>
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| TABLET, ORALLY DISINTEGRATING; ORAL |
| STAXYN |
| +! BAYER HLTHCARE 10MG | N200179 001 Jun 17, 2010 |

| VARENICLINE TARTRATE |
| TABLET; ORAL |
| CHANTIX          |
| + PF PRISM CV    |
| EQ 0.5MG BASE    | N021928 001 May 10, 2006 |
| +! EQ 1MG BASE   | N021928 002 May 10, 2006 |

<p>| VASOPRESSIN |
| SOLUTION; IV (INFUSION) |
| VASOSTRICT |
| +! PAR STERILE PRODUCTS |
| 20UNITS/ML (20UNITS/ML) | N204485 001 Apr 17, 2014 |</p>
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### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**PRESCRIPTION DRUG PRODUCT LIST**

#### VERAPAMIL HYDROCHLORIDE
- **Tablet, Extended Release; Oral**
  - **AB IVAX SUB TEVA PHARMS**
    - 240MG
    - A078906 001 Sep 17, 2009
    - 120MG
    - A073568 002 Oct 10, 1997
  - **AB MYLAN**
    - 180MG
    - A074330 001 Jan 31, 1994
    - 240MG
    - A073568 001 Jul 31, 1992
    - 120MG
    - A074587 002 Feb 21, 1997
    - 180MG
    - A074587 003 Sep 09, 1997
  - **AB PAR PHARM**
    - 240MG
    - A075072 001 May 25, 1999
    - 120MG
    - A075072 003 May 25, 1999
  - **AB SUN PHARM INDS INC**
    - 180MG
    - A090529 001 Dec 30, 2011
    - 240MG
    - A090529 002 Dec 30, 2011

#### VEREPORFIN
- **Injectable; Injection**
  - **VISUDYNE +! VALEANT LUXEMBOURG**
    - 15MG/VIAL
    - N021119 001 Apr 12, 2000

#### VIGABATRIN
- **For Solution; Oral**
  - **SABRIL**
    - **AA LUNDBECK PHARMS LLC**
      - 500MG/PACKET
      - N022006 001 Aug 21, 2009
    - **AA AMNEAL PHARMS**
      - 500MG/PACKET
      - A210155 001 Mar 13, 2018
    - **AA DR REDDYS LABS LTD**
      - 500MG/PACKET
      - A211481 001 Nov 20, 2018
    - **AA PAR PHARM INC**
      - 500MG/PACKET
      - A208218 001 Apr 27, 2017
    - **AA TEVA PHARMS USA**
      - 500MG/PACKET
      - A209824 001 Apr 23, 2018
  - **VIGADRONE**
    - **AA AUCTA PHARMS**
      - 500MG/PACKET
      - A210196 001 Jun 21, 2018

#### VILAZODONE HYDROCHLORIDE
- **Tablet; Oral**
  - **SABRIL**
    - **AA LUNDBECK PHARMS LLC**
      - 500MG
      - N020427 001 Aug 21, 2009
    - **AA TEVA PHARMS USA**
      - 500MG
      - A209822 001 Jan 14, 2019

#### VINBLASTINE SULFATE
- **Injectable; Injection**
  - **VINBLASTINE SULFATE**
    - **! FRESENIUS KABI USA**
      - 1MG/ML
      - A089515 001 Apr 29, 1987
    - **! WEST-WARD PHARMS**
      - 10MG/VIAL
      - A089395 001 Apr 09, 1987

#### VINCRISTINE SULFATE
- **Injectable; Injection**
  - **VINCRISTINE SULFATE PFS**
    - **AF TEVA PHARMS USA**
      - 1MG/ML
      - A075493 001 Sep 01, 1999
  - **INJECTABLE, LIPOSOMAL; INTRAVENOUS**
    - **MARQIBO KIT**
      - 5MG/5ML (1MG/ML)
      - N020497 001 Aug 09, 2012

#### VINORELBINE TARTRATE
- **Injectable; Injection**
  - **NAVELbine**
    - **AF PIERRE FABRE**
      - EQ 10MG BASE/ML
      - N020388 001 Dec 23, 1994
  - **VINORELINA TARTRATE**
    - **AP ACTAVIS TOTOWA**
      - EQ 10MG BASE/ML
      - A078011 001 Jul 22, 2009
    - **AP DR REDDYS LABS LTD**
      - EQ 10MG BASE/ML
      - A202017 001 Sep 12, 2013
    - **AP FRESENIUS KABI USA**
      - EQ 10MG BASE/ML
      - A076849 001 Apr 18, 2005
    - **AP HOSPIRA**
      - EQ 10MG BASE/ML
      - A076827 001 Jun 02, 2005
    - **AP JIANGSU HANSOH PHARM**
      - EQ 10MG BASE/ML
      - A091106 001 Sep 26, 2012
    - **AP TEVA PHARMS USA**
      - EQ 10MG BASE/ML
      - A076028 001 Feb 03, 2003
    - **AP WEST-WARD PHARMS**
      - EQ 10MG BASE/ML
      - A075992 001 Jun 10, 2003
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## Warfarin Sodium

**Tablet; Oral**

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<th>Date</th>
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### Xenon Xe-133

**Gas; Inhalation**

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<tr>
<td>LANTHEUS MEDCL</td>
<td>10 mCi/VIAL</td>
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<td>MALLINKRODT NUCLEAR</td>
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<td>MALLINKRODT NUCLEAR</td>
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### Zafirlukast

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### Zaleplon

**Capsule; Oral**

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### Zanamivir

**Powder; Inhalation**

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<th>Date</th>
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<tbody>
<tr>
<td>RELENZA</td>
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### Ziconotide Acetate

**Injectable; Intrathecal**

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<th>Brand Name</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Number</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>PRIALT</td>
<td>TESERA THERAPS LLC</td>
<td>100mcg/1ml (100mcg/ml)</td>
<td>N021060 002</td>
<td>Dec 28, 2004</td>
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<tr>
<td></td>
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<td>500mcg/20ml (250mcg/ml)</td>
<td>N021060 001</td>
<td>Dec 28, 2004</td>
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<tr>
<td></td>
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<td>500mcg/5ml (100mcg/ml)</td>
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### Zidovudine

**Capsule; Oral**

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<th>Brand Name</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Number</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>RETROVIR</td>
<td>VIIV HLTHCARE</td>
<td>100mg</td>
<td>N019655 001</td>
<td>Mar 19, 1987</td>
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<tr>
<td>ZIDOVUDINE</td>
<td>AUROBINDO PHARMA LTD</td>
<td>100mg</td>
<td>A078128 001</td>
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<tr>
<td>ZIDOVUDINE</td>
<td>CIPLA LTD</td>
<td>100mg</td>
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**Injection; Injection**

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<th>Strength</th>
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<tbody>
<tr>
<td>RETROVIR</td>
<td>VIIV HLTHCARE</td>
<td>10mg/ml</td>
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<tr>
<td>ZIDOVUDINE</td>
<td>LUITPOLD</td>
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**Syrup; Oral**

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<tr>
<td>RETROVIR</td>
<td>VIIV HLTHCARE</td>
<td>50mg/5ml</td>
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**Tablet; Oral**

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<tbody>
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<td>ZIDOVUDINE</td>
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<td>300mg</td>
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<tr>
<td>ZIDOVUDINE</td>
<td>CIPLA</td>
<td>300mg</td>
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<td>ZIDOVUDINE</td>
<td>HETERO LABS LTD III</td>
<td>300mg</td>
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<td>ZIDOVUDINE</td>
<td>MYLAN PHARMS INC</td>
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<td>ZIDOVUDINE</td>
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### Zileuton

**Tablet; Oral**

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<td>CHIESI USA INC</td>
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**Tablet, Extended Release; Oral**

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<tr>
<td>ZYLEUTON</td>
<td>RISING PHARMS</td>
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<td>ZYLEUTON</td>
<td>CHIESI USA INC</td>
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### Zinc Acetate

**Capsule; Oral**

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<tr>
<td>GALZIN</td>
<td>TEVA EQ 25mg ZINC</td>
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<td>GALZIN</td>
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### Zinc Chloride

**Injectable; Injection**

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<tbody>
<tr>
<td>ZINC CHLORIDE IN PLASTIC CONTAINER</td>
<td>HOSPIRA EQ 1MG ZINC/ML</td>
<td>EQ 1mg Zinc/ml</td>
<td>N018959 001</td>
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### Ziramidone Hydrochloride

**Capsule; Oral**

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**Injection**

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<table>
<thead>
<tr>
<th>Zolpidem Mesylate</th>
<th>Injectable; Intramuscular</th>
<th>Geodon</th>
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<table>
<thead>
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<th>Zoledronic Acid</th>
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<th>Reclast</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Zoledronic Acid</th>
<th>Gland Pharma Ltd</th>
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<tbody>
<tr>
<td>AP</td>
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<table>
<thead>
<tr>
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</thead>
<tbody>
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* Nov 09, 2016
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* Feb 25, 2000
* Dec 14, 2011
* Jun 08, 1994
* Nov 26, 2001
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<td>FAMOTIDINE, CALCIUM CARBONATE, AND MAGNESIUM HYDROXIDE</td>
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CETIRIZINE HYDROCHLORIDE

TABLET; ORAL
CETIRIZINE HYDROCHLORIDE HIVES RELIEF
10MG A079191 002 Apr 15, 2010
ZYRTEC ALLERGY
+! J AND J CONSUMER 10MG N019835 004 Nov 16, 2007

TABLET, CHEWABLE; ORAL
CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY
JUBILANT GENERICS 5MG A091116 001 Feb 19, 2015
10MG A091116 002 Feb 19, 2015
NOVEL LABS INC 5MG A206793 001 Mar 08, 2016
10MG A206793 002 Mar 08, 2016
SANDOZ 5MG A078692 001 Feb 14, 2008
10MG A078692 002 Feb 14, 2008
SUN PHARMA GLOBAL 5MG A090142 001 Aug 30, 2011
10MG A090142 002 Aug 30, 2011

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF
JUBILANT GENERICS 5MG A091116 003 Feb 19, 2015
10MG A091116 004 Feb 19, 2015
SUN PHARMA GLOBAL 5MG A090142 003 Aug 30, 2011
10MG A090142 004 Aug 30, 2011

TABLET, ORALLY DISINTEGRATING; ORAL
CETIRIZINE HYDROCHLORIDE ALLERGY
PERRIGO R AND D 10MG A205490 001 Sep 02, 2015
ZYRTEC ALLERGY
+! J AND J CONSUMER INC 10MG N022578 001 Sep 03, 2010

CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE
TABLET, EXTENDED RELEASE; ORAL
CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE
IVAX SUB TEVA 5MG; 120MG A077170 001 Feb 25, 2008
PERRIGO R AND D 5MG; 120MG A210719 001 Nov 16, 2018
PLD ACQUISITIONS 5MG; 120MG A077991 001 Mar 05, 2008
SUN PHARM IND S LTD 5MG; 120MG A090922 001 Sep 28, 2012
ZYRTEC-D 12 HOUR
+! J AND J CONSUMER INC 5MG; 120MG N021550 002 Nov 09, 2007

CHLORHEXIDINE GLUCONATE
AEROSOL, METERED; TOPICAL
EXIDINE 4% N019127 001 Dec 24, 1984
CLOTH; TOPICAL
CHLORHEXIDINE GLUCONATE 2% N021669 001 Apr 25, 2005
READYPREP CHG
MEDLINE INDUSTRIES 2% N207964 001 Nov 20, 2018
SOLUTION; TOPICAL
BRIAN CARE 4% A071419 001 Dec 17, 1987
SOACO 4% A019258 002 Jul 22, 1986
CHG SCRUB
ECOLAB 4% N019258 001 Jul 22, 1986
CIDA-STAT 4% N019125 001 Dec 24, 1984
EXIDINE 2% N019422 001 Dec 17, 1985
4% N019125 001 Dec 24, 1984
HIBICLENS 4% N017768 001
HIBISTAT 0.5% N018300 001
SPONGE; TOPICAL
BIOSCRUB 4% N019822 001 Mar 31, 1989
GRIFFEN 4% A072525 001 Oct 24, 1989
CHLORHEXIDINE GLUCONATE
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<th>Approval Date 2</th>
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<td>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL SOLUTION; TOPICAL</td>
<td>SOLUPREP</td>
<td>2%; 70% (3ML)</td>
<td>N208288 001 Aug 08, 2018</td>
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<td>SPONGE; TOPICAL</td>
<td>2%; 70% (10.5ML)</td>
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<td>CHLORAPREP WITH TINT</td>
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<td>CHLORAPREP TRIPLE SWABSTICK</td>
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<td>PREVANTICS MAXI SWABSTICK</td>
<td>3.15%; 70% (5.1ML)</td>
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<td>PREVANTICS SWAB</td>
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<td>PREVANTICS SWABSTICK</td>
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<td>A074165 001 Jul 16, 1993</td>
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<td>CLOTRIMAZOLE CREAM; VAGINAL</td>
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### CLOTRIMAZOLE
**Cream; Vaginal**
- **Trivagizole 3 Taro** 2% N021143 001 Apr 12, 2000

### CROMOLYN SODIUM
**Spray, Metered; Nasal**
- **Bausch and Lomb** 5.2mg/spray A075702 001 Jul 03, 2001
- **Perrigo** 5.2mg/spray A075427 001 Dec 12, 2001

### DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN
**Tablet, Extended Release; Oral**
- **Guaifenesin and Dextromethorphan Hydrobromide**
  - **Actavis Labs FL** 30mg; 600mg A091070 001 Aug 31, 2015
  - **Amneal Pharmas** 30mg; 600mg A209692 002 Nov 01, 2018
  - **Aurobindo Pharma Ltd** 30mg; 600mg A206941 001 Mar 17, 2017
  - **Perrigo R and D** 30mg; 600mg A207602 002 Mar 05, 2018

### DEXTROMETHORPHAN POLISTIREX
**Suspension, Extended Release; Oral**
- **Delsym**
  - **Amneal Pharmas LLC** EQ 30mg hydrobromide/5ml A203133 001 Jul 28, 2017
  - **Tris Pharma Inc** EQ 30mg hydrobromide/5ml A091135 001 May 25, 2012

### DIPHENHYDRAMINE CITRATE; IBUPROFEN
**Tablet; Oral**
- **Advil**
  - **PFIZER** 38mg; 200mg N021394 001 Dec 21, 2005
- **Ibuprofen and Dihydroxyamine Citrate**
  - **Dr Reddys Labs Ltd** 38mg; 200mg A090619 001 Jul 08, 2009
  - **Perrigo R and D** 38mg; 200mg A079113 001 Dec 22, 2008

### DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN
**Capsule; Oral**
- **Advil PM**
  - **PFIZER** 25mg; EQ 200mg free acid and potassium salt N021393 001 Dec 21, 2005
- **Ibuprofen and Dihydroxyamine Hydrochloride**
  - **Bionpharma Inc** 25mg; EQ 200mg free acid and potassium salt A090397 001 Nov 22, 2010
  - **Strides Pharma** 25mg; EQ 200mg free acid and potassium salt A200888 001 Mar 05, 2012

### DIPHENHYDRAMINE HYDROCHLORIDE; NAPROXEN SODIUM
**Tablet; Oral**
- **Aleve PM**
  - **Bayer Hlthcare** 25mg; 220mg N205352 001 Jan 17, 2014
- **Naproxen Sodium and Dihydroxyamine Hydrochloride**
  - **Amneal Pharmas Co** 25mg; 220mg A209726 001 Oct 23, 2018

### DOCOSANOL
**Cream; Topical**
- **Abreva**
  - **Glaxosmithkline** 10% N020941 001 Jul 25, 2000
- **Docosanol**
  - **Actavis Labs UT Inc** 10% A208754 001 Nov 19, 2018

### DOXYLAMINE SUCCINATE
**Tablet; Oral**
- **Doxylamine Succinate**
  - **Lnk** 25mg A040564 001 Aug 27, 2004
  - **Perrigo** 25mg A040167 001 Sep 18, 1996
  - **Unisom**
    - **Chattem** 25mg N018066 001
EPINEPHRINE
AEROSOL, METERED; INHALATION
PRIMATENE MIST
+! ARMSTRONG PHARMS 0.125MG/INH N205920 001 Nov 07, 2018

ESOMEPRAZOLE MAGNESIUM
CAPSULE, DELAYED RELEASE; ORAL
ESOMEPRAZOLE MAGNESIUM
AUROBINDO PHARMA LTD EQ 20MG BASE A209339 001 Oct 16, 2017
DR REDDYS LABS LTD EQ 20MG BASE A207673 001 May 15, 2018
PERRIGO R AND D EQ 20MG BASE A207193 001 Aug 18, 2017
NEXIUM 24HR
+! ASTRAZENECA LP EQ 20MG BASE N204655 001 Mar 28, 2014
TABLET, DELAYED RELEASE; ORAL
NEXIUM 24HR
+! ASTRAZENECA LP EQ 20MG BASE N207920 001 Nov 23, 2015

FAMOTIDINE
TABLET; ORAL
FAMOTIDINE
AUROBINDO PHARMA LTD 10MG A206531 001 Apr 26, 2016
DR REDDYS LABS LTD 20MG A206531 002 Apr 26, 2016
IVAX SUB TEVA 10MG A075512 001 Jul 26, 2001
MYLAN 10MG A076574 001 Dec 21, 2001
PERRIGO 10MG A075400 001 Mar 28, 2015
PERRIGO R AND D 10MG A075512 001 Jul 26, 2001
SUN PHARM INDS LTD 20MG A090283 001 Nov 17, 2009
TEVA 10MG A075312 001 May 31, 2001
WOCKHARDT LTD 20MG A090837 001 Aug 04, 2010
PEPCID AC
+ J AND J CONSUMER INC 10MG N020325 001 Apr 28, 1995
+! 20MG N020325 002 Sep 23, 2003
TABLET, CHEWABLE; ORAL
FAMOTIDINE
PERRIGO 10MG A075715 001 Aug 22, 2003
PEPCID AC
+! J AND J CONSUMER INC 20MG N020801 002 Dec 17, 2007

FEXOFENADINE HYDROCHLORIDE
SUSPENSION; ORAL
CHILDREN'S ALLEGRA ALLERGY
+! SANOFI AVENTIS US 30MG/5ML N201373 001 Dec 21, 2001
CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY
ACTAVIS MID 30MG/5ML A203330 001 Nov 18, 2014
ATLANTIC
CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES
! ACTAVIS MID 30MG/5ML A203330 002 Nov 18, 2014
ATLANTIC
TABLET; ORAL
ALLEGRA ALLERGY
+ SANOFI AVENTIS US 60MG N020872 007 Jan 24, 2011
+! 180MG N020872 010 Jan 24, 2011
CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY
AUROLIFE PHARMA LLC 30MG A202039 001 Nov 19, 2014
DR REDDYS LABS LTD 30MG A076502 004 Apr 12, 2011
HETERO LABS LTD V 30MG A204097 001 Aug 19, 2016
MYLAN 30MG A077081 004 Jul 21, 2011
SUN PHARM INDS 30MG A091567 002 Feb 17, 2012
TEVA 30MG A076447 004 Apr 13, 2011
WOCKHARDT LTD 30MG A079112 002 Feb 08, 2012
CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES
DR REDDYS LABS LTD 30MG A076502 005 Apr 12, 2011
MYLAN 30MG A077081 005 Jul 21, 2011
SUN PHARM INDS 30MG A091567 001 Feb 17, 2012
TEVA 30MG A076447 005 Apr 13, 2011
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<td>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE</td>
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<td>TABLET, EXTENDED RELEASE;ORAL</td>
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<td>ALLEGRA-D 12 HOUR ALLERGY AND CONGESTION</td>
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<td>SANOFI AVENTIS US 60MG;120MG N020786 002 Jan 24, 2011</td>
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<td>+!</td>
<td>SANOFI AVENTIS US 180MG;240MG N021704 002 Jan 24, 2011</td>
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<td>AUROBINDO PHARMA</td>
<td>60MG;120MG A209116 001 Oct 30, 2017</td>
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<td>DR REDDYS LABS LTD</td>
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<td>180MG;240MG</td>
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<td>FLUTICASONE FURATE</td>
<td>SPRAY, METERED;NASAL</td>
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<td>FLOMASE SENSIMIST ALLERGY RELIEF</td>
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<td>SPRAY, METERED;NASAL</td>
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<td>WEST-WARD PHARMS</td>
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<td>AMNEAL PHARMS</td>
<td>1.2GM A207342 001 Jul 11, 2018</td>
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<td>GUARDIAN DRUG</td>
<td>1.2GM A209215 001 Sep 06, 2017</td>
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<td>OHM LABS INC</td>
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<td>PERRIGO R AND D</td>
<td>600MG A078912 001 Nov 23, 2011</td>
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### Guaifenesin

**Tablet, Extended Release; Oral**

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### Guaifenesin; Pseudoephedrine Hydrochloride

**Tablet, Extended Release; Oral**

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<tr>
<td>ACTAVIS LABS FL</td>
<td>600mg; 60mg</td>
<td>A091071</td>
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<td>1.2gm; 120mg</td>
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<td>DR REDDYS LABS LTD</td>
<td>600mg; 60mg</td>
<td>A208369</td>
<td>Dec 29, 2017</td>
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### Mucinex D

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<td>1.2gm; 120mg</td>
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### Ibuprofen

**Capsule; Oral**

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<td>+! PFIZER</td>
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**Ibuprofen**

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<td>A2075730</td>
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<td>BIONPHARMA INC</td>
<td>EQ 200mg</td>
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<td>HUMANWELL PURACAP</td>
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**Midol Liquid Gels**

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**Suspension; Oral**

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<td>+! PFIZER</td>
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<td>CHILDREN’S ELIXSURE</td>
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**Ibuprofen**

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<td>APTPHARMA INC</td>
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**Suspension/Drops; Oral**

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<td>40mg/ML</td>
<td>N020603</td>
<td>Jun 10, 1996</td>
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**Ibuprofen**

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<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>NDC Number</th>
<th>Date Approved</th>
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<tbody>
<tr>
<td>GUARDIAN DRUG</td>
<td>40mg/ML</td>
<td>A210755</td>
<td>Sep 26, 2018</td>
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<tr>
<td>L PERRIGO CO</td>
<td>40mg/ML</td>
<td>A075217</td>
<td>Dec 16, 1998</td>
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<tr>
<td>TRIS PHARMA INC</td>
<td>40mg/ML</td>
<td>A079058</td>
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**Pediatric Advil**

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<tbody>
<tr>
<td></td>
<td>100mg/2.5ml</td>
<td>N020812</td>
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**Tablet; Oral**

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<td>200mg</td>
<td>N018989</td>
<td>May 18, 1984</td>
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<td>IBU-TAB 200</td>
<td>200mg</td>
<td>A071057</td>
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**Ibuprofen**

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<tr>
<td>AMNEAL PHARMS</td>
<td>200mg</td>
<td>A079233</td>
<td>Mar 18, 2014</td>
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<tr>
<td>Product Name</td>
<td>Strength</td>
<td>Expiration Date</td>
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<tr>
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<td>IBUPROFEN TABLET; ORAL</td>
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<tr>
<td>AMNEAL PHARMS NY</td>
<td>200MG</td>
<td>A071333 001 Feb 17, 1987</td>
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<tr>
<td>Aurobindo Pharma Ltd</td>
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<td>A072199 001 May 23, 1988</td>
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<td>AVEMA PHARMA</td>
<td>200MG</td>
<td>A075661 001 Dec 12, 2001</td>
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<td>CONTRACT PHARMACAL</td>
<td>200MG</td>
<td>A076117 001 Nov 20, 2001</td>
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<td>DR REDDYS LA</td>
<td>200MG</td>
<td>A079174 001 Dec 10, 2010</td>
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<td>GRANULES INDIA</td>
<td>200MG</td>
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<td>LNK</td>
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<td>Marksans Pharma</td>
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<td>McNeil</td>
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<td>Merro Pharm</td>
<td>200MG</td>
<td>A070985 001 Oct 02, 1987</td>
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<td>OHM</td>
<td>200MG</td>
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<td>PAR PHARM</td>
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<td>Perrigo</td>
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<td>A075995 001 Mar 14, 2002</td>
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<td>Shandong Xinhua</td>
<td>200MG</td>
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<td>Strides Pharma</td>
<td>200MG</td>
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<td>Vintage Pharm</td>
<td>200MG</td>
<td>A071229 001 Apr 01, 1987</td>
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<td>IBUPROFEN OHM LABS</td>
<td>200MG</td>
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<td>Junior Strength Advil Pfizer</td>
<td>100MG</td>
<td>N020267 002 Dec 13, 1996</td>
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<td>Junior Strength Ibuprofen L Perrigo Co</td>
<td>100MG</td>
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<tr>
<td>Junior Strength Motrin J and J Consumer Inc</td>
<td>100MG</td>
<td>N020602 001 Jun 10, 1996</td>
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<tr>
<td>Motrin IB + J and J Consumer Inc</td>
<td>200MG</td>
<td>N019012 003 Dec 17, 1990</td>
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<td>Tab-Profen</td>
<td>200MG</td>
<td>A072095 001 Dec 08, 1987</td>
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<td>IBUPROFEN TABLET, CHEWABLE; ORAL CHILDREN'S ADVIL</td>
<td>50MG</td>
<td>N020944 001 Dec 18, 1998</td>
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<td>IBUPROFEN</td>
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<td>Advil + Pfizer Cons</td>
<td>EQ 200MG</td>
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<td>IBUPROFEN Sodium</td>
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<td>IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE</td>
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<tr>
<td>Advil Congestion Relief</td>
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<tr>
<td>IBUPROFEN and Phenylephrine Hydrochloride</td>
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<tr>
<td>Perrigo R and D</td>
<td>200MG; 10MG</td>
<td>A203200 001 Jul 03, 2014</td>
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</table>
**IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE**

**CAPSULE; ORAL**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>Approval Number</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVIL COLD AND SINUS</td>
<td>Pfizer</td>
<td>EQ 200MG FREE ACID AND POTASSIUM SALT; 30MG</td>
<td>N021374 001</td>
<td>May 30, 2002</td>
</tr>
<tr>
<td>IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE</td>
<td>Aurobindo Pharma, Ltd</td>
<td>EQ 200MG FREE ACID AND POTASSIUM SALT; 30MG</td>
<td>A209235 001</td>
<td>Dec 01, 2017</td>
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**SUSPENSION; ORAL**

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<th>Strength</th>
<th>Approval Number</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHILDREN'S ADVIL COLD</td>
<td>Pfizer</td>
<td>100MG/5ML;15MG/5ML</td>
<td>N021373 001</td>
<td>Apr 18, 2002</td>
</tr>
<tr>
<td>CHILDREN'S MOTRIN COLD</td>
<td>J and J Consumer Inc</td>
<td>100MG/5ML;15MG/5ML</td>
<td>N021128 001</td>
<td>Aug 01, 2000</td>
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<tr>
<td>IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE</td>
<td>Perrigo</td>
<td>100MG/5ML;15MG/5ML</td>
<td>A076478 001</td>
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**TABLET; ORAL**

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<th>Strength</th>
<th>Approval Number</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVIL COLD AND SINUS</td>
<td>Pfizer</td>
<td>200MG;30MG</td>
<td>N019771 001</td>
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**INSULIN RECOMBINANT HUMAN**

<table>
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<th>Manufacturer</th>
<th>Strength</th>
<th>Approval Number</th>
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<tbody>
<tr>
<td>HUMULIN R PEN</td>
<td>Lilly</td>
<td>100 UNITS/ML</td>
<td>N018780 005</td>
<td>Aug 06, 1998</td>
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<tr>
<td>NOVOLIN R</td>
<td>Novo Nordisk Inc</td>
<td>100 UNITS/ML</td>
<td>N019938 001</td>
<td>Jun 25, 1991</td>
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**INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN**

<table>
<thead>
<tr>
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<th>Manufacturer</th>
<th>Strength</th>
<th>Approval Number</th>
<th>Approval Date</th>
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</thead>
<tbody>
<tr>
<td>HUMULIN 70/30 PEN</td>
<td>Lilly</td>
<td>30 UNITS/ML;70 UNITS/ML</td>
<td>N019717 001</td>
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<tr>
<td>HUMULIN 70/30</td>
<td>Lilly</td>
<td>30 UNITS/ML;70 UNITS/ML</td>
<td>N019717 002</td>
<td>Aug 06, 1998</td>
</tr>
<tr>
<td>NOVOLIN 70/30</td>
<td>Novo Nordisk Inc</td>
<td>30 UNITS/ML;70 UNITS/ML</td>
<td>N019991 001</td>
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**INSULIN SUSP ISOPHANE RECOMBINANT HUMAN**

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<tbody>
<tr>
<td>HUMULIN N</td>
<td>Lilly</td>
<td>100 UNITS/ML</td>
<td>N018781 001</td>
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<tr>
<td>NOVOLIN N</td>
<td>Novo Nordisk Inc</td>
<td>100 UNITS/ML</td>
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**IODINE POVACRYLEX; ISOPROPYL ALCOHOL**

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<th>Approval Date</th>
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<tbody>
<tr>
<td>SPONGE; TOPICAL DURAPREP</td>
<td>3M</td>
<td>EQ 0.7% IODINE;74% (6ML)</td>
<td>N021586 001</td>
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<tr>
<td>KETOCONAZOLE SHAMPOO; TOPICAL NIZORAL A-D</td>
<td>Johnson and Johnson</td>
<td>1%</td>
<td>N020310 001</td>
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**KETOTIFEN FUMARATE**

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<th>Approval Date</th>
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<tbody>
<tr>
<td>SOLUTION/DROPS; OPHTHALMIC ALAWAY</td>
<td>Bausch and Lomb</td>
<td>EQ 0.025% BASE</td>
<td>N021996 001</td>
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<tr>
<td>KETOTIFEN FUMARATE</td>
<td>Akorn</td>
<td>EQ 0.025% BASE</td>
<td>A077958 001</td>
<td>Jul 26, 2007</td>
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<tr>
<td>! Alcon Pharmis Ltd</td>
<td>EQ 0.025% BASE</td>
<td>A077200 001</td>
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LANSOPRAZOLE
CAPSULE, DELAYED REL PELLETS; ORAL

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<tbody>
<tr>
<td>DR REDDYS LABS LTD</td>
<td>15MG</td>
<td>May 18, 2012</td>
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<tr>
<td>LANNETT CO INC</td>
<td>15MG</td>
<td>Sep 29, 2017</td>
</tr>
<tr>
<td>MYLAN PHARMS INC</td>
<td>15MG</td>
<td>Jun 01, 2016</td>
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<tr>
<td>NATCO PHARMA LTD</td>
<td>15MG</td>
<td>Jan 13, 2016</td>
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<tr>
<td>PERRIGO R AND D</td>
<td>15MG</td>
<td>May 18, 2012</td>
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<tr>
<td>WOCKHARDT LTD</td>
<td>15MG</td>
<td>May 18, 2012</td>
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<tr>
<td>PREVACID 24 HR</td>
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TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE; ORAL

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<tr>
<td>DEXCEL PHARMA</td>
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LEVOCETIRIZINE DIHYDROCHLORIDE
SOLUTION; ORAL

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<tr>
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<tbody>
<tr>
<td>XYZAL ALLERGY 24HR +! SANOFI AVENTIS US</td>
<td>2.5MG/5ML</td>
<td>Jan 31, 2017</td>
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TABLET; ORAL

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<tr>
<td>DR REDDYS LABS LTD</td>
<td>5MG</td>
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<tr>
<td>MICRO LABS</td>
<td>5MG</td>
<td>Nov 20, 2018</td>
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<tr>
<td>XYZAL ALLERGY 24HR +! SANOFI AVENTIS US</td>
<td>5MG</td>
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LEVONORGESTREL
TABLET; ORAL

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<tr>
<td>AUROBINDO PHARMA LTD</td>
<td>1.5MG</td>
<td>Dec 08, 2015</td>
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<td>Fallback Solo</td>
<td>1.5MG</td>
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<tr>
<td>HER STYLE</td>
<td>1.5MG</td>
<td>Mar 11, 2016</td>
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<tr>
<td>LEVONORGESTREL</td>
<td>1.5MG</td>
<td>Oct 31, 2014</td>
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<tr>
<td>APOTEX INC</td>
<td>1.5MG</td>
<td>Sep 18, 2018</td>
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<tr>
<td>FDN CONSUMER</td>
<td>1.5MG</td>
<td>Jul 12, 2012</td>
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<td>GLENMARK PHARMS LTD</td>
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<td>LOTUS PHARM CO LTD</td>
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<td>Sep 02, 2016</td>
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<td>MYLAN LABS LTD</td>
<td>0.75MG</td>
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<td>NOVEL LABS INC</td>
<td>1.5MG</td>
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<td>OC PHARMA</td>
<td>1.5MG</td>
<td>Feb 22, 2013</td>
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<tr>
<td>! PERRIGO R AND D</td>
<td>0.75MG</td>
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<td>RECKITT BENCKISER</td>
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<td>OPCICON ONE-STEP</td>
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<td>PLAN B ONE-STEP</td>
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LOPERAMIDE HYDROCHLORIDE
CAPSULE; ORAL

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<tr>
<td>LOPERAMIDE HYDROCHLORIDE +! BIONPHARMA INC</td>
<td>1MG</td>
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<td>+! 2MG</td>
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SOLUTION; ORAL

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<tbody>
<tr>
<td>IMODIUM A-D +! J AND J CONSUMER INC</td>
<td>1MG/5ML</td>
<td>Mar 01, 1988</td>
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<tr>
<td>IMODIUM A-D +! J AND J CONSUMER INC</td>
<td>1MG/7.5ML</td>
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<tr>
<td>IMODIUM A-D +! J AND J CONSUMER INC</td>
<td>1MG/7.5ML</td>
<td>May 28, 2011</td>
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SUSPENSION; ORAL
<table>
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<th><strong>TABLET, ORAL</strong></th>
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</thead>
<tbody>
<tr>
<td>IMODIUM A-D</td>
<td>+! J AND J CONSUMER 2MG</td>
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<td>N019860 001 Nov 22, 1989</td>
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<tr>
<td>LOPERAMIDE HYDROCHLORIDE</td>
<td><strong>AUROBINDO PHARMA LTD</strong> 2MG</td>
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<td>A206548 001 Dec 15, 2015</td>
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<td><strong>L PERRIGO CO</strong> 2MG</td>
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<td>A075232 001 Jan 06, 2000</td>
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<td></td>
<td><strong>LANK</strong> 2MG</td>
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<td>A076497 001 Jun 10, 2003</td>
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<td></td>
<td><strong>OHM LABS</strong> 2MG</td>
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<td>A074091 001 Dec 10, 1992</td>
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<th><strong>TABLET, ORAL</strong></th>
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<td>IMODIUM MULTI-SYMPOM RELIEF</td>
<td>+! J AND J CONSUMER 2MG;125MG</td>
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<td>N021140 001 Nov 30, 2000</td>
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<tr>
<td>LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE</td>
<td><strong>PERRIGO R AND D</strong> 2MG;125MG</td>
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<td>A209837 001 Sep 05, 2018</td>
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<tr>
<td></td>
<td><strong>SUN PHARM IND'S LTD</strong> 2MG;125MG</td>
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<td></td>
<td>A077500 001 Sep 06, 2006</td>
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<table>
<thead>
<tr>
<th><strong>LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE</strong></th>
<th><strong>TABLET, CHEWABLE, ORAL</strong></th>
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<tbody>
<tr>
<td>+! PERRIGO</td>
<td>2MG;125MG</td>
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<tr>
<td>A076029 001 Aug 30, 2002</td>
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<th><strong>LORATADINE</strong></th>
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<tr>
<td>CLARITIN</td>
<td>+! BAYER HEALTHCARE 10MG</td>
</tr>
<tr>
<td>Los Angeles, California</td>
<td>N021952 001 Jun 16, 2008</td>
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<tr>
<td>BIONPHARMA INC 10MG</td>
<td>A202538 001 Dec 21, 2018</td>
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<td>MARKSANS PHARMA 10MG</td>
<td>A206214 001 Sep 23, 2016</td>
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<tr>
<td><strong>LORATADINE</strong> +! Taro 1MG/ML</td>
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<td>N021734 001 Oct 04, 2005</td>
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<tr>
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<tr>
<td>+! BAYER HEALTHCARE LLC 10MG</td>
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<td>N019658 002 Nov 27, 2002</td>
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<tr>
<th><strong>CLARITIN HIVES RELIEF</strong></th>
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<tr>
<td>+! BAYER HEALTHCARE LLC 10MG</td>
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<td>AROTIX INC 10MG</td>
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<td>AUROBINDO PHARMA LTD 10MG</td>
<td>A208314 001 Apr 16, 2018</td>
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<td>MYLAN 10MG</td>
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<td>PERRIGO 10MG</td>
<td>A076301 001 Jun 25, 2004</td>
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<td>PLD ACQUISITIONS LLC 10MG</td>
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<td>SUN PHARM IND'S LTD 10MG</td>
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<tr>
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<tr>
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<td>CLARITIN REDITABS</td>
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<td>MICONAZOLE 3 COMBINATION PACK</td>
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<td>MONISTAT 3 COMBINATION PACK</td>
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<td>+! MEDTECH PRODUCTS</td>
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<td>MICONAZOLE 7</td>
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<td>G AND W LABS INC</td>
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<td>PERRIGO</td>
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<td>PERRIGO R AND D</td>
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<td>TARO PHARMS</td>
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<td></td>
<td>MONISTAT 3</td>
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<td></td>
<td>+! MEDTECH PRODUCTS</td>
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<td>MICONAZOLE 7</td>
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<td></td>
<td>+! MEDTECH PRODUCTS</td>
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<td>MONISTAT 1 COMBINATION PACK</td>
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<td>+! MEDTECH PRODUCTS</td>
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MICONAZOLE NITRATE
CRAEM, SUSPODISORY; TOPICAL, VAGINAL
MONISTAT 7 COMBINATION PACK
+! MEDTECH PRODUCTS 2%,100MG N020288 002 Apr 26, 1993
SUPPOSITORY, VAGINAL
MICONAZOLE NITRATE
ACTAVIS PHARMA 100MG A073507 001 Nov 19, 1993
G AND W LABS 100MG A074414 001 Apr 30, 1997
! PERRIGO 100MG A074395 001 Mar 20, 1997
MONISTAT 7
+! MEDTECH PRODUCTS 100MG N018520 002 Feb 15, 1991

MINOXIDIL
AEROSOL, FOAM; TOPICAL
MEN'S ROGAINE
+! JOHNSON AND JOHNSON 5% N021812 001 Jan 20, 2006
MINOXIDIL
PERRIGO ISRAEL 5% A091344 001 Apr 28, 2011
MINOXIDIL (FOR MEN)
TARO PHARM 5% A209074 001 Dec 31, 2018
WATSON LABS INC 5% A208092 001 Feb 17, 2017
MINOXIDIL (FOR WOMEN)
WATSON LABS INC 5% A208092 002 Jul 27, 2017
WOMEN'S ROGAINE
+! JOHNSON AND JOHNSON 5% N021812 002 Feb 28, 2014

SOLUTION; TOPICAL
MINOXIDIL (FOR MEN)
ACTAVIS MID 2% A074588 001 Apr 05, 1996
ATLANTIC
HI TECH PHARMA 2% A074731 001 Dec 24, 1996
L PERRIGO CO 2% A075357 001 Jul 30, 1999
WOCKHARDT BIO AG 2% A074767 001 Feb 28, 1997
MINOXIDIL (FOR WOMEN)
HI TECH PHARMA 2% A074731 002 May 11, 2005
L PERRIGO CO 2% A075357 002 Jul 30, 1999
MINOXIDIL EXTRA STRENGTH (FOR MEN)
ACTAVIS MID 5% A075518 001 Nov 17, 2000
ATLANTIC
AVACOR PRODS 5% A075619 001 Nov 17, 2000
PERRIGO 5% A075598 001 Jun 13, 2001
PERRIGO NEW YORK 5% A075737 001 Mar 15, 2002
WOCKHARDT BIO AG 5% A075438 001 Feb 27, 2003
ROGAINE (FOR MEN)
+! JOHNSON AND JOHNSON 2% N019501 001 Feb 09, 1996
ROGAINE (FOR WOMEN)
+! JOHNSON AND JOHNSON 2% N019501 003 Feb 09, 1996
ROGAINE EXTRA STRENGTH (FOR MEN)
+! JOHNSON AND JOHNSON 5% N020834 001 Nov 14, 1997
THEROXIDIL
KI INC 2% A078176 001 Nov 09, 2007
5% A076239 001 Aug 24, 2004

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE
SOLUTION/DROPS; OPHTHALMIC
NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE
AKORN INC 0.025%; 0.3% A202795 001 Jan 24, 2013
ALTAIRE PHARMS INC 0.02675%; 0.315% A078208 001 Aug 24, 2004
NAPHCONE-A
+! ALCON 0.025%; 0.3% N020226 001 Jun 08, 1994
OPCON-A
+! BAUSCH AND LOMB 0.02675%; 0.315% N020065 001 Jun 08, 1994
VISINE
+! JOHNSON AND JOHNSON 0.025%; 0.3% N020485 001 Jan 31, 1996

NAPROXEN SODIUM
CAPSULE; ORAL
NAPROXEN SODIUM
+! BIONPHARMA INC EQ 200MG BASE N021920 001 Feb 17, 2006
CATALENT EQ 200MG BASE A202807 001 Jan 04, 2019
PURACAP PHARM LLC EQ 200MG BASE A208363 001 Mar 15, 2018
ALEVE
+! BAYER EQ 200MG BASE N020204 002 Jan 11, 1994
### NAPROXEN SODIUM

**TABLET; ORAL**

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<th>Strength</th>
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<td>Aurobindo Pharma LTD</td>
<td>EQ 200MG BASE</td>
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<td>Mar 18, 2016</td>
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<td>Dr Reddys Labs Inc</td>
<td>EQ 200MG BASE</td>
<td>A075168 001</td>
<td>Jul 28, 1998</td>
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<tr>
<td>Granules India</td>
<td>EQ 200MG BASE</td>
<td>A091353 001</td>
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<td>Lnk Intl Inc</td>
<td>EQ 200MG BASE</td>
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<td>Marksans Pharma</td>
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<td>Perrigo</td>
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<td>Sun Pharma Industries Ltd</td>
<td>EQ 200MG BASE</td>
<td>A091183 001</td>
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### NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE

**TABLET, EXTENDED RELEASE; ORAL**

- **ALEVE-D SINUS & COLD**
  - 200MG;120MG
  - Bayer
  - Nov 29, 1999

- **NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE**
  - Dr Reddys Labs Inc
  - EQ 220MG BASE;120MG
  - A077381 001
  - Sep 27, 2006

  - Perrigo
  - EQ 200MG BASE;120MG
  - A076518 001
  - Mar 17, 2004

### NICOTINE

**FILM, EXTENDED RELEASE; TRANSDERMAL**

- **HABITROL**
  - Dr Reddys Labs SA
  - 7MG/24HR
  - Nov 12, 1999

- **NICODERM CQ**
  - Sanofi Aventis US
  - 7MG/24HR
  - Aug 02, 1996

### NICOTINE POLACRILEX

**GUM, CHEWING; BUCCAL**

- **NICORETTE**
  - GlaxoSmithKline
  - EQ 2MG BASE
  - Feb 09, 1996

- **NICORETTE (MINT)**
  - GlaxoSmithKline
  - EQ 2MG BASE
  - Dec 23, 1998

### NOTES
NICOTINE POLACRILEX

**GUM, CHEWING; Buccal**

**EQ 4MG BASE**
- NICOTINE POLACRILEX
  - WATSON LABS
    - EQ 4MG BASE A091354 001 Jul 20, 2011
  - ICORTE + GLAXOSMITHKLINE CONS
    - EQ 2MG BASE N021330 001 Oct 31, 2002
  - NICOTINE POLACRILEX
    - WATSON LABS INC
      - EQ 2MG BASE A090711 001 May 09, 1996
    - WATSON LABS
      - EQ 2MG BASE A090821 001 Jul 10, 2009

**TROCHE/LOZENGE; Oral**

**NICORETTE**
- GLAXOSMITHKLINE CONS
  - NICOTINE POLACRILEX
    - EQ 2MG BASE N022360 001 May 18, 2009
  - NICOTINE POLACRILEX
    - EQ 4MG BASE N022360 002 May 18, 2009

**NIZATIDINE**

**TABLET; Oral**
- AXID AR
  - PERRIGO R AND D
    - EQ 20MG BASE A209206 001 Jun 26, 2018
  - TROPHUS LABS INC
    - EQ 20MG BASE A209190 001 Dec 09, 2010
  - WATSON LABS TEVA
    - EQ 4MG BASE A077007 001 Jan 31, 2006

**OMEPRAZOLE**

**TABLET, DELAYED RELEASE; Oral**

**OMEPRAZOLE MAGNESIUM**

**CAPSULE, DELAYED RELEASE; Oral**

**NIZATIDINE**

**TABLET; Oral**
- AXID AR
  - PERRIGO R AND D
    - EQ 20MG BASE A209206 001 Jun 26, 2018
  - PRILOSEC OTC
    - EQ 20MG BASE A209190 001 Dec 09, 2010
  - WATSON LABS TEVA
    - EQ 4MG BASE A077007 001 Jan 31, 2006

**OMEPRAZOLE; SODIUM BICARBONATE**

**CAPSULE; Oral**

**NIZATIDINE**

**TABLET; Oral**
- AXID AR
  - PERRIGO R AND D
    - EQ 20MG BASE A209206 001 Jun 26, 2018
  - PRILOSEC OTC
    - EQ 20MG BASE A209190 001 Dec 09, 2010
  - WATSON LABS TEVA
    - EQ 4MG BASE A077007 001 Jan 31, 2006
ORLISTAT
CAPSULE; ORAL
ALLI
+! GLAXOSMITHKLINE 60MG CONS

OXYBUTYNIN
FILM, EXTENDED RELEASE; TRANSDERMAL
OXYTROL FOR WOMEN
+! ALLERGAN SALES LLC 3.9MG/24HR N202211 001 Jan 25, 2013

OXYMETAZOLINE HYDROCHLORIDE
SOLUTION/DROPS; OPHTHALMIC
VISINE L.R.
+! JOHNSON AND JOHNSON 0.025% N019407 001 Mar 31, 1989

PERMETHRIN
LOTION; TOPICAL
NIX
+! MEDTECH PRODUCTS 1% N019918 001 May 02, 1990
PERMETHRIN
ACTAVIS MID 1%
ATLANTIC
PERRIGO NEW YORK 1%

POLYETHYLENE GLYCOL 3350
FOR SOLUTION; ORAL
GLYCOLAX
LANNETT CO INC 17GM PACKET A090600 001 Oct 06, 2009
17GM SCOOPFUL A090600 002 Oct 06, 2009
MIRALAX
+! BAYER HEALTHCARE LLC
POLYETHYLENE GLYCOL 3350
ANI PHARMS INC 17GM SCOOPFUL A202850 001 Dec 15, 2015
APNAR PHARMA LP 17GM SCOOPFUL A202071 001 Dec 28, 2012
AUROBINDO PHARMA 17GM SCOOPFUL A209017 001 Apr 09, 2018
MILAN
MYLAN
NEXGEN PHARMA 17GM PACKET A078915 001 Oct 06, 2009
17GM SCOOPFUL A078915 002 Oct 06, 2009
NOVEL LABS INC 17GM SCOOPFUL A090812 001 Oct 07, 2009
NUVO PHARMS INC 17GM SCOOPFUL A206105 001 Oct 28, 2016
PAR PHARM 17GM SCOOPFUL A079214 001 Jan 31, 2013
PERRIGO R AND D
17GM PACKET A090685 002 Oct 06, 2009
STRIDES PHARMA 17GM SCOOPFUL A203928 001 Aug 24, 2016
17GM PACKET A203928 002 Aug 24, 2016

POTASSIUM IODIDE
SOLUTION; ORAL
POTASSIUM IODIDE
MISSION PHARMACAL CO
THYROSHIELD
+! ARCO PHARMS LLC 65MG/ML A206211 001 Mar 24, 2016
TABLET; ORAL
IOSAT
+! ANBEX 65MG N018664 002 May 12, 2011
+! 130MG N018664 001 Oct 14, 1982
THYROSAFE
+! RECIP 65MG A076350 001 Sep 10, 2002

POVIDONE IODINE
SOLUTION; TOPICAL
POVIDONE IODINE
+! ALLEGIANCE HLTHCARE 1% N019522 001 Mar 31, 1989
TABLET; TOPICAL
E-Z SCRUB 201
+! BECTON DICKINSON 20% N019240 001 Nov 29, 1985
E-Z SCRUB 241
+! BECTON DICKINSON 10% N019476 001 Jan 07, 1987
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<td>Niagara Pharms</td>
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<td>SODIUM FLUORIDE; TRICLOSAN</td>
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ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION INJECTABLE; INJECTION
ADSOL IN PLASTIC CONTAINER
FENWAL INC N900223 Dec 27, 1991

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD) INJECTABLE; INJECTION
CPD ANTICOAGULANT IN PL 2209 PLASTIC CONTAINER
FENWAL INC N900224 Dec 27, 1991
MACOPRODUCTIONS SAS CPD/AS-1: MACOPHARMA LEUCOFLEX MTL1 LEUKOREDUCTION SYSTEM FOR BLOOD COMPONENTS KNOWN AS MTL1-WB
MACOPRODUCTIONS SAS N040083 Nov 21, 2005
NONE
TERUMO BCT INC A070025 Jan 06, 2008

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP INJECTABLE; INJECTION
NONE
FENWAL INC N170401 Dec 06, 1977
HAEMONETICS N800222 Aug 23, 1982
TERUMO MEDICAL CORP N781211 Jun 10, 1981

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP WITH: AS-1: DEXTROSE USP; SODIUM CHLORIDE USP; MANNITOL USP; ADENINE INJECTABLE; INJECTION
ADSOL RED BLOOD CELL PRESERVATIVE SOLUTION
FENWAL INC N811104 May 16, 1983

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP WITH: AS-5: DEXTROSE USP; SODIUM CHLORIDE USP; MANNITOL USP; ADENINE INJECTABLE; INJECTION
OPTISOL RED BLOOD CELL PRESERVATIVE SOLUTION
TERUMO MEDICAL CORP N880217 Oct 07, 1988

ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-3: CITRIC ACID USP; MONOBASIC SODIUM PHOSPHATE USP; SODIUM CHLORIDE USP; ADENINE; DEXTROSE USP; SODIUM CITRATE USP INJECTABLE; INJECTION
AS-3 NUTRICEL ADDITIVE SYSTEM
HAEMONETICS 0.042GM/100ML;0.276GM/100ML; N820915 Oct 19, 1984
MANUFACTURING INC 0.410GM/100ML;0.30GM/100ML; 1.10GM/100ML;0.588GM/100ML

ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-2: CITRIC ACID USP; DIBASIC SODIUM PHOSPHATE USP; SODIUM CHLORIDE USP; ADENINE; DEXTROSE USP; SODIUM CITRATE USP INJECTABLE; INJECTION
AS-2 NUTRICEL ADDITIVE SYSTEM
MEDSEP CORP 0.042GM/100ML;0.285GM/100ML; N820915 Sep 22, 1983
0.718GM/100ML;0.017GM/100ML; 0.396GM/100ML;0.588GM/100ML
DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST

ANTICOAGULANT SODIUM CITRATE 4% SOLUTION
INJECTABLE; INJECTION
NONE
HAEMONETICS CORPORATION N980123 Mar 03, 2000
TERUMO BCT N125608 Jun 26, 2018

ANTICOAGULANT SODIUM CITRATE SOLUTION
INJECTABLE; INJECTION
TRICITRASOL
CYTOSOL LABORATORIES INC N010409 Jul 10, 2003

ANTICOAGULANT SODIUM CITRATE SOLUTION USP
INJECTABLE; INJECTION
NONE
FENWAL INC N770923 Jan 20, 1978
TERUMO MEDICAL CORP N781214 Feb 08, 1980

CORD BLOOD STERILE COLLECTION BAG, ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD)
STERILE CORD BLOOD COLLECTION UNIT
NONE
MACOPHARMA N125552 Dec 21, 2016

DEXTRAN 1 IN SODIUM CHLORIDE 0.6%
INJECTABLE; INJECTION
PROMIT
MEDA AB N830715 Oct 30, 1984

DEXTRAN 40, 10% IN DEXTROSE 5%
INJECTABLE; INJECTION
LMD IN GLASS BOTTLE
HOSPIRA INC 10GM/100ML;5GM/100ML A720563 Oct 30, 1992

DEXTRAN 40, 10% IN SODIUM CHLORIDE 0.9%
INJECTABLE; INJECTION
LMD IN PLASTIC CONTAINER
HOSPIRA INC 10GM/100ML;0.9GM/100ML A720562 Oct 30, 1992

HETASTARCH 6% IN LACTATED ELECTROLYTE INJECTION
INJECTABLE; INJECTION
HEXTEND
BIOTIME INC 6GM/100ML N200952 Mar 31, 1999

HETASTARCH 6% IN SODIUM CHLORIDE 0.9%
INJECTABLE; INJECTION
6% HETASTARCH IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
HOSPIRA INC 6GM/100ML;0.9GM/100ML A740193 Jan 30, 1995
HESPAN IN PLASTIC CONTAINER
B BRAUN MEDICAL INC 6GM/100ML;0.9GM/100ML N890105 Apr 04, 1991
NONE
TEVA PARENTERAL MEDICINES INC 6GM/100ML;0.9GM/100ML A740592 Nov 12, 1998
HYDROXYETHYL STARCH 130/0.4 IN 6% SODIUM CHLORIDE 0.9%
STORAGE/PROCESSING SOLUTION ONLY; SHOULD NEVER BE INFUSED DIRECTLY TO THE PATIENT.

NONE

B. BRAUN MEDICAL A110013 Jan 09, 2015

VOLUVEN

FRESENIUS KABI 6GM/100ML;0.9GM/100ML N070012 Dec 27, 2007

DEUTSCHLAND GMBH

ISOPLATE SOLUTION IN THE 500 ML EXCEL CONTAINER
STORAGE/PROCESSING SOLUTION ONLY; SHOULD NEVER BE INFUSED DIRECTLY TO THE PATIENT.

ISOPLATE SOLUTION

HAEMONETICS CORP N90067 Mar 05, 2013

LEUKOCYTE REDUCTION FILTRATION SYSTEM FOR WHOLE BLOOD WITH CPD ANTICOAGULANT AND SOLX ADDITIVE
INJECTABLE; INJECTION

LEUKOSEP HWB-600-XL

HAEMONETICS CORP N110059 Apr 25, 2013

RED BLOOD CELL PROCESSING SOLUTION
STORAGE/PROCESSING SOLUTION ONLY; SHOULD NEVER BE INFUSED DIRECTLY TO THE PATIENT.

REJUVESOL

CITRA LABS LLC N950522 Feb 26, 1997

SODIUM CHLORIDE; SODIUM ACETATE; SODIUM CITRATE DIHYDRATE; SODIUM PHOSPHATE, DIABASIC ANHYDROUS; SODIUM PHOSPHATE MONOBASIC, MONOHYDRATE
STORAGE/PROCESSING SOLUTION ONLY; SHOULD NEVER BE INFUSED DIRECTLY TO THE PATIENT.

INTERSOL SOLUTION

FENWAL INC. 2.26G/500ML; 2.21G/500ML; 1.59G/500ML; 1.53G/500ML; 0.465G/500ML N080041 Dec 09, 2009
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<th>Formulation</th>
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<td>Seclaral</td>
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<td>Mallinckrodt</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>Gilbert Labs</td>
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<td>Hikma Pharms</td>
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<td>Mikart</td>
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<td>Mirror Pharm LLC</td>
<td>A040883</td>
<td>Dec 23, 2008</td>
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<td>Novast Labs</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Discontinued Drug Product List

**See List Footnote**

### Acetaminophen; Clemastine Fumarate; Pseudoephedrine Hydrochloride

**Tablet; Oral**

TAVIST ALLERGY/SINUS/HEADACHE

N021082 001 Mar 01, 2001

### Acetaminophen; Codeine Phosphate

**Capsule; Oral**

ACETAMINOPHEN AND CODEINE PHOSPHATE

- TEVA
  - 300MG; 15MG
  - 300MG; 30MG
  - 300MG; 60MG

- PHENAPHEN W/ CODEINE NO. 2
  - ROBINS AH
    - 325MG; 15MG

- PHENAPHEN W/ CODEINE NO. 3
  - ROBINS AH
    - 325MG; 30MG

- PHENAPHEN W/ CODEINE NO. 4
  - ROBINS AH
    - 325MG; 60MG

- PROVAL #3
  - SOLVAY
    - 325MG; 30MG

- TYLENOL W/ CODEINE NO. 3
  - ORTHO MCNEIL PHARM
    - 300MG; 30MG

- TYLENOL W/ CODEINE NO. 4
  - ORTHO MCNEIL PHARM
    - 300MG; 60MG

**Solution; Oral**

ACETAMINOPHEN AND CODEINE PHOSPHATE

- ACI HEALTHCARE LTD
  - 120MG/5ML; 12MG/5ML

- ACTAVIS MID ATLANTIC
  - DAVA PHARMS INC
    - 120MG/5ML; 12MG/5ML

- TYLENOL W/ CODEINE
  - ORTHO MCNEIL PHARM
    - 120MG/5ML; 12MG/5ML

**Suspension; Oral**

CAPITAL AND CODEINE

- ACTAVIS MID ATLANTIC
  - VALEANT PHARMS LLC
    - 120MG/5ML; 12MG/5ML

**Tablet; Oral**

ACETAMINOPHEN AND CODEINE PHOSPHATE

- ABLE
  - 300MG; 30MG
  - 300MG; 60MG

- AM THERAP
  - 300MG; 15MG
  - 300MG; 30MG
  - 300MG; 60MG
  - 300MG; 15MG
  - 300MG; 30MG
  - 300MG; 60MG
  - 300MG; 60MG

- DURAMED PHARMS BARR
  - 300MG; 15MG
  - 300MG; 15MG
  - 300MG; 30MG
  - 300MG; 30MG
  - 300MG; 60MG
  - 300MG; 60MG
  - 300MG; 60MG

- EVERYLIFE
  - 325MG; 30MG

- FOSUN PHARMA
  - 300MG; 30MG
  - 300MG; 60MG

- HALSEY
  - 300MG; 15MG
  - 300MG; 30MG
  - 300MG; 60MG
  - 300MG; 60MG

- KV PHARM
  - 300MG; 30MG
  - 300MG; 60MG
  - 325MG; 15MG
  - 325MG; 45MG **
  - 325MG; 30MG

- LEADERLE
  - 300MG; 30MG

- MIKART
  - 300MG; 30MG
  - 300MG; 60MG
  - 650MG; 30MG
  - 650MG; 60MG

- MUTUAL PHARM
  - 300MG; 15MG
  - 300MG; 30MG
  - 300MG; 60MG

- PURACAP PHARM
  - 300MG; 30MG

- PUREPAC PHARM
  - 300MG; 30MG
  - 300MG; 60MG

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ACETAMINOPHEN; CODEINE PHOSPHATE

** See List Footnote

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<td>A089080 001 Jul 17, 1986</td>
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<td>RHODES PHARMS</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

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ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE**

**TABLET; ORAL**

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

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**ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE**

**TABLET; ORAL**

TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN

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**ACETAZOLAMIDE**

**TABLET; ORAL**

ACETAZOLAMIDE

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**DIAMOX**

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**ACETAZOLAMIDE SODIUM**

**INJECTABLE; INJECTION**

ACETAZOLAMIDE SODIUM

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**DIAMOX**

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**ACETIC ACID, GLACIAL**

**SOLUTION/DROPS; OTIC**

ACETASOL

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<td>ORLEX</td>
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**ACETIC ACID, GLACIAL; ALUMINUM ACETATE**

**SOLUTION/DROPS; OTIC**

ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE

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<td>PHARMAFAY</td>
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<td>DOMEBO</td>
<td>BAYER PHARMS</td>
<td>2%;0.79%</td>
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**ACETIC ACID, GLACIAL; DESONIDE**

**SOLUTION/DROPS; OTIC**

TRIDESILON

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<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>BAYER PHARMS</td>
<td>2%;0.05%</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<th>Drug Product Name</th>
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<th>Approval Date</th>
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<tr>
<td>ACETIC ACID, GLACIAL; HYDROCORTISONE SOLUTION/DROPS/OTIC</td>
<td>KV PHARM</td>
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<td>WOCKHARDT</td>
<td>2%;1%</td>
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<tr>
<td>ORLEX HC</td>
<td>WARNER CHILCOTT</td>
<td>2%;1%</td>
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<td>ACETIC ACID, GLACIAL; HYDROCORTISONE; NEOMYCIN SULFATE SUSPENSION/DROPS/OTIC</td>
<td>BAYER PHARMS</td>
<td>2%;1%;EQ 0.35% BASE</td>
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<td>ACETOHEXAMIDE TABLET;ORAL</td>
<td>ANI PHARMS INC</td>
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<tr>
<td>DYMELOR</td>
<td>LILLY</td>
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<td>DYMELOR</td>
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<td>ACETYLCYSTEINE W/ ISOPROTERENOL HYDROCHLORIDE SOLUTION;INHALATION</td>
<td>MEAD JOHNSON</td>
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### Acitretin
**Capsule; Oral**

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<td>22.5MG</td>
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### Acrisorcin
**Cream; Topical**

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### Acyclovir
**Capsule; Oral**

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<tr>
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<td>200MG</td>
<td>A074906</td>
<td>001  Aug 26, 1997</td>
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<td>CHARTWELL MOLECULES</td>
<td>200MG</td>
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<td>001  Jun 05, 1997</td>
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<td>200MG</td>
<td>A074674</td>
<td>001  Apr 22, 1997</td>
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<td>LEK PHARM</td>
<td>200MG</td>
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<td>A074727</td>
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<td>TEVA</td>
<td>200MG</td>
<td>A074828</td>
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<tr>
<td>TEVA PHARMS</td>
<td>200MG</td>
<td>A074914</td>
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<tr>
<td>WATSON LABS</td>
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<td>A075101</td>
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<td>400MG</td>
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<td>400MG</td>
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**Tablet; Oral**

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<tr>
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**Acyclovir Sodium**

**Injection; Injection**

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<th>Date</th>
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<tbody>
<tr>
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<td>ACYCLOVIR IN SODIUM CHLORIDE 0.9% PRESERVATIVE FREE</td>
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<td>EQ 1GM BASE/VIAL</td>
<td>A074885</td>
<td>002  Dec 19, 1997</td>
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<tr>
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<td>A074897</td>
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<tr>
<td>APOTHECON</td>
<td>EQ 500MG BASE/VIAL</td>
<td>A074897</td>
<td>002  Feb 27, 1998</td>
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<tr>
<td>ATHENEX INC</td>
<td>EQ 500MG BASE/VIAL</td>
<td>A074596</td>
<td>002  Apr 22, 1997</td>
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<tr>
<td>EUROHLTH INTL SARL</td>
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<td>A074913</td>
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<tr>
<td>FRESENIUS KABI USA</td>
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<td>HIKMA PHARMS</td>
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<td>HOSPIRA</td>
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<tr>
<td>MYLAN LABS LTD</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

#### ACYCLOVIR SODIUM

**INJECTABLE; INJECTION**

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<tbody>
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**ZYDUS PHARMS USA INC**

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**ZOVIRAX**

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<td>+ GLAXOSMITHKLINE EQ 250MG BASE/VIAL</td>
<td>N018603 003</td>
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<td>+ EQ 500MG BASE/VIAL</td>
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<tr>
<td>+ EQ 1GM BASE/VIAL</td>
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#### ADAPALENE

**SOLUTION; TOPICAL**

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**DIFTERIN**

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#### ADENOSINE

**INJECTABLE; INJECTION**

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**ADVANCED ADELAS**

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**TEVA PHARMS USA**

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**WEST-WARD PHARMS INT**

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#### ALBUTEROL

**AEROSOL, METERED; INHALATION**

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<td>0.09MG/INH</td>
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**PLIVA**

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**ARMSTRONG PHARMS**

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**GENPHARM**

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**RADIO-IODINATED (I 125) SERUM ALBUMIN (HUMAN)**

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<td>100uCi/AMP</td>
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**RADIOIODINATED SERUM ALBUMIN (HUMAN) IHSA I 125**

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**AMEDRA PHARMS LLC**

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**ALBENZA**

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**ALBUTEROL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### ALBUTEROL

**AEROSOL, METERED; INHALATION**
- **PROVENTIL**
  - Schering: 0.09mg/inh N017559 001
- **VENTOLIN**
  - GlaxSmithKline: 0.09mg/inh N018473 001

**ALBUTEROL SULFATE**
- **CAPSULE; INHALATION**
  - **VENTOLIN ROTACAPS**
    - GlaxSmithKline: Eq 0.2mg base N019489 001 May 04, 1988
- **SOLUTION; INHALATION**
  - **ALBUTEROL SULFATE**
    - Actavis Mid Atlantic: Eq 0.083% base A073533 001 Sep 26, 1995
    - Apotex Inc: Eq 0.021% base A078623 001 Apr 05, 2010
    - Eq 0.042% base A078623 002 Apr 05, 2010
    - Eq 0.083% base A075717 001 Feb 02, 2007
    - Eq 0.5% base A076391 001 Apr 01, 2003
    - Hi Tech Pharma: Eq 0.083% base A075063 001 Feb 09, 1999
    - Landela Pharm: Eq 0.083% base A077569 001 Apr 04, 2006
    - Mylan Speclt: Eq 0.083% base ** A072652 001 Feb 21, 1992
    - Eq 0.083% base A075129 001 Feb 13, 2001
    - Roxane: Eq 0.083% base A075343 001 Nov 09, 1999
    - Teva Pharm: Eq 0.083% base A076370 001 Nov 24, 2003
    - Watson Labs Inc: Eq 0.083% base A075394 001 Nov 22, 1999
    - Wockhardt Eu Operatn: Eq 0.083% base A073307 001 Nov 27, 1991
  - **PROVENTIL**
    - + Schering: Eq 0.083% base ** N019243 002 Jan 14, 1987
    - + Eq 0.5% base ** N019243 001 Jan 14, 1987
  - **VENTOLIN**
    - + GlaxSmithKline: Eq 0.083% base ** N019773 001 Apr 23, 1992
    - + Eq 0.5% base ** N019269 002 Jan 16, 1987

**SYRUP; ORAL**
- **ALBUTEROL SULFATE**
  - Actavis Mid Atlantic: Eq 2mg base/5ml A075262 001 Mar 30, 1999
  - Movia: Eq 2mg base/5ml A074302 001 Sep 30, 1994
  - Watson Labs: Eq 2mg base/5ml A073165 001 Apr 29, 1993
  - **PROVENTIL**
    - + Schering: Eq 2mg base/5ml ** N019062 001 Jan 19, 1983
  - **VENTOLIN**
    - GlaxSmithKline: Eq 2mg base/5ml ** N019621 001 Jun 10, 1987

**TABLET; ORAL**
- **ALBUTEROL SULFATE**
  - Am Therap: Eq 2mg base A072449 001 Dec 05, 1989
  - Eq 4mg base A072450 001 Dec 05, 1989
  - Copley Pharm: Eq 2mg base A072966 001 Nov 22, 1991
  - Eq 4mg base A072967 001 Nov 22, 1991
  - Dava Pharmcs Inc: Eq 2mg base A072860 002 Dec 20, 1989
  - Eq 4mg base A072860 001 Dec 20, 1989
  - Pliva: Eq 2mg base A072316 001 Dec 05, 1989
  - Eq 4mg base A072317 001 Dec 05, 1989
  - Teva: Eq 2mg base A072619 001 Dec 05, 1989
  - Eq 2mg base A072779 001 Jun 23, 1993
  - Eq 2mg base A072938 001 Mar 30, 1990
  - Eq 4mg base A072620 001 Dec 05, 1989
  - Eq 4mg base A072790 001 Jun 25, 1993
  - Eq 4mg base A072939 001 Mar 30, 1990
  - Ucb Inc: Eq 2mg base A073120 001 Sep 29, 1992
  - Eq 4mg base A073121 001 Sep 29, 1992
  - Warner Chilcott: Eq 2mg base A072817 001 Jan 09, 1990
  - Eq 4mg base A072818 001 Jan 09, 1990
  - Watson Labs: Eq 2mg base A072629 001 Jan 31, 1991
  - Eq 2mg base A072764 001 Aug 28, 1991
  - Eq 4mg base A072630 001 Jan 31, 1991
  - Eq 4mg base A072765 001 Aug 28, 1991
  - Yopharma Co Ltd: Eq 2mg base A072151 001 Dec 05, 1989
  - Eq 4mg base A072152 001 Dec 05, 1989

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### ALBUTEROL SULFATE

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<td>Muro</td>
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## Discontinued Drug Product List

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

### Alendronate Sodium

**Tablet, Oral**

**Fosamax**

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<td>5mg base</td>
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<td>10mg base</td>
<td>Merck and Co Inc</td>
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<td>Sep 29, 1995</td>
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<td>35mg base</td>
<td>Merck and Co Inc</td>
<td>N020560 004</td>
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<td>40mg base</td>
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### Alfuzosin Hydrochloride

**Tablet, Extended Release; Oral**

**Alfuzosin Hydrochloride**

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<td>10mg base</td>
<td>Wockhardt Ltd</td>
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### Alglucerase

**Injectable; Injection**

**Ceredase**

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### Aliskiren Hemifumarate

**Capsule, Pellet; Oral**

**Tekturna**

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### Aliskiren Hemifumarate; Amlodipine Besylate

**Tablet, Oral**

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### Aliskiren Hemifumarate; Amlodipine Besylate; Hydrochlorothiazide

**Tablet, Oral**

**Amturnide**

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<td>N200045 002</td>
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### Aliskiren Hemifumarate; Valsartan

**Tablet, Oral**

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### Alkaervervir

**Tablet, Oral**

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### Allopurinol

**Tablet, Oral**

**Allopurinol**

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<td>Mutual Pharm</td>
<td>A070466 001</td>
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# DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

## ALPRAZOLAM

**SOLUTION, ORAL**

- Roxane 0.5mg/5ml A074314 001 Oct 31, 1993

**TABLET, ORAL**

- Roxane 0.25mg A074085 001 Feb 16, 1994
- 0.5mg A074085 002 Feb 16, 1994
- 1mg A074085 003 Feb 16, 1994
- 2mg A074085 004 Feb 26, 1996

- Ivax Teva Pharmaceuticals 0.25mg A074294 001 Jul 29, 1994
- 0.5mg A074294 002 Jul 29, 1994
- 1mg A074294 003 Jul 29, 1994
- 2mg A074294 004 Jul 29, 1994

- Mylan Pharmaceuticals Inc 0.25mg A074046 001 Oct 19, 1993
- 0.5mg A074046 002 Oct 19, 1993
- 1mg A074046 003 Oct 19, 1993
- 2mg A074046 004 May 07, 1997

- Roxane 0.25mg A074199 001 Oct 19, 1993
- 0.5mg A074199 002 Oct 19, 1993
- 1mg A074199 003 Oct 19, 1993

- Watson Laboratories 0.25mg A074456 001 Aug 31, 1995
- 0.5mg A074479 001 Jan 21, 1997
- 0.5mg A074479 002 Aug 31, 1995
- 1mg A074479 002 Jan 21, 1997
- 1mg A074456 003 Aug 31, 1995
- 1mg A074479 003 Jan 21, 1997

**TABLET, EXTENDED RELEASE, ORAL**

- Actavis Laboratories FL Inc 0.5mg A077198 001 May 13, 2010
- 1mg A077198 002 May 13, 2010
- 2mg A077198 003 May 13, 2010
- 3mg A077198 004 May 13, 2010

- Mylan Laboratories 0.5mg A077968 001 May 24, 2007
- 1mg A077968 002 May 24, 2007
- 2mg A077968 003 May 24, 2007
- 3mg A077968 004 May 24, 2007

- Impax Laboratories 0.5mg A077996 001 Jan 31, 2007
- 1mg A077996 002 Jan 31, 2007
- 2mg A077996 003 Jan 31, 2007
- 3mg A077996 004 Jan 31, 2007

## NIRCAM

- UCB Inc 0.25mg ** N021726 001 Jan 19, 2005
- 0.5mg ** N021726 002 Jan 19, 2005
- 1mg ** N021726 003 Jan 19, 2005
- 2mg ** N021726 004 Jan 19, 2005

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>TABLET, CHEWABLE; ORAL</td>
<td>ALUMINUM HYDROXIDE AND MAGNESIUM TRISILICATE</td>
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<td><strong>Foamcoat</strong></td>
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<td><strong>AMCINONIDE</strong></td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
# Approved Drug Product List

## Discontinued Drug Product List

**See List Footnote**

### Amino Acids

**Injectable, Injection**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Concentration</th>
<th>Brand Names</th>
<th>NDC Code</th>
<th>Date Approved/Withdrawn</th>
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<tbody>
<tr>
<td>Aminosyn II 10%</td>
<td>10%</td>
<td>ICU Medical Inc</td>
<td>N019438 005</td>
<td>Apr 03, 1986</td>
</tr>
<tr>
<td>Aminosyn II 3.5%</td>
<td>3.5%</td>
<td>ICU Medical Inc</td>
<td>N019438 002</td>
<td>Apr 03, 1986</td>
</tr>
<tr>
<td>Aminosyn II 8.5%</td>
<td>8.5%</td>
<td>ICU Medical Inc</td>
<td>N019438 003</td>
<td>Apr 03, 1986</td>
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<tr>
<td>Aminosyn-HBC 7%</td>
<td>7%</td>
<td>ICU Medical Inc</td>
<td>N019374 001</td>
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<td>Aminosyn-HF 8%</td>
<td>8%</td>
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<tr>
<td>Aminosyn-RF 5.2%</td>
<td>5.2%</td>
<td>Branchamin 4%</td>
<td>N018429 001</td>
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<tr>
<td>Freamine 8.5%</td>
<td>8.5%</td>
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<td>N016822 001</td>
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<td>Freamine II 8.5%</td>
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<tr>
<td>Hepatiasol 8%</td>
<td>8%</td>
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<td>A020360 001</td>
<td>Feb 05, 1993</td>
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<tr>
<td>Neopham 6.4%</td>
<td>6.4%</td>
<td>Hospira</td>
<td>N018792 001</td>
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<tr>
<td>Novamine 15%</td>
<td>15%</td>
<td>Hospira Inc</td>
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<td>15%</td>
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<td>Novamine 8.5%</td>
<td>8.5%</td>
<td>Hospira Inc</td>
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<tr>
<td>Renamin W/O electrolytes</td>
<td>6.5%</td>
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<td>N017493 006</td>
<td>Sep 12, 1988</td>
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<tr>
<td>Travasol 15% W/O electrolytes</td>
<td>15%</td>
<td>Baxter Healthcare</td>
<td>N017493 006</td>
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<td>Travasol 8.5% W/O electrolytes</td>
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<td>Sep 12, 1988</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

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**ICU Medical Inc**

- Aminosyn II 10%
- Aminosyn II 3.5%
- Aminosyn II 8.5%
- Aminosyn-HBC 7%
- Aminosyn-RF 5.2%
- Freamine 8.5%
- Freamine II 8.5%
- Hepatiasol 8%
- Neopham 6.4%
- Novamine 15%
- Novamine 15% sulfite free
- Novamine 8.5%
- Renamin W/O electrolytes
- Travasol 15% W/O electrolytes
- Travasol 8.5% W/O electrolytes

**Abbott**

- Aminosyn II 3.5%
- Aminosyn II 5%
- Aminosyn II 7%
- Aminosyn II 8.5%
- Aminosyn-HF 8%
- Aminosyn-RF 5.2%
- Freamine 8.5%
- Freamine II 8.5%
- Neopham 6.4%
- Novamine 15%
- Novamine 15% sulfite free
- Novamine 8.5%
- Renamin W/O electrolytes
- Travasol 15% W/O electrolytes
- Travasol 8.5% W/O electrolytes

**B Braun**

- Aminosyn II 3.5%
- Aminosyn II 10%
- Aminosyn II 3.5%
- Aminosyn II 5%
- Aminosyn II 7%
- Aminosyn II 8.5%
- Aminosyn-HBC 7%
- Branchamin 4%
- Branchamin 4% in plastic container

**Baxter Healthcare**

- Aminosyn II 3.5% w/ electrolytes in dextrose 25% w/ calcium in plastic container
- Aminosyn II 4.25% w/ electrolytes in dextrose 20% w/ calcium in plastic container

**Hospira**

- Aminosyn II 3.5% w/ electrolytes in dextrose 25% w/ calcium in plastic container
- Aminosyn II 4.25% w/ electrolytes in dextrose 20% w/ calcium in plastic container
**See List Footnote**

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<tr>
<th>Drug Product</th>
<th>Concentration</th>
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<th>Approval Number</th>
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<td>Aminosyn II 4.25% w/ Electrolytes in Dextrose 25% w/ Calcium in Plastic Container</td>
<td>4.25%, 36.8mg/100mL; 25mg/100mL, 51mg/100mL; 2.4mg/100mL; 261mg/100mL, 205mg/100mL</td>
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<td>Aminosyn II 5% w/ Electrolytes in Dextrose 25% w/ Calcium in Plastic Container</td>
<td>5%, 36.8mg/100mL; 25mg/100mL, 51mg/100mL; 2.4mg/100mL; 261mg/100mL, 205mg/100mL</td>
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<td>Aminosyn II 4.25% in Dextrose 10% in Plastic Container</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Product Description</th>
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<th>Strength</th>
<th>Date</th>
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<td>HOSPIRA INC</td>
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**See List Footnote**

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<tbody>
<tr>
<td>AMINOSYN 3.5% M in Plastic Container</td>
<td>ABBOTT 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML</td>
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<td>AMINOSYN 3.5% M</td>
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<td>HOSPIRA INC 8%; 61MG/100ML; 211MG/100ML; 56MG/100ML; 38; 8MG/100ML</td>
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<td>AMINOSYN II 10% W/ ELECTROLYTES</td>
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<tr>
<td>AMINOSYN II 8.5% W/ ELECTROLYTES</td>
<td>ICU MEDICAL INC 8.5%; 102MG/100ML; 45MG/100ML; 522MG/100ML; 410MG/100ML</td>
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<td>N019437 005 Apr 03, 1986 410MG/100ML</td>
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</tr>
<tr>
<td><strong>AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE</strong></td>
<td>INJECTABLE; INJECTION</td>
</tr>
<tr>
<td>TRAVASOL 3.5% Sulfite Free W/ ELECTROLYTES</td>
<td>BAXTER HLTHCARE 3.5%; 51MG/100ML; 131MG/100ML; 218MG/100ML; 35MG/100ML</td>
</tr>
<tr>
<td>N020173 001 Oct 27, 1995 35MG/100ML</td>
<td></td>
</tr>
<tr>
<td><strong>AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE</strong></td>
<td>INJECTABLE; INJECTION</td>
</tr>
<tr>
<td>TRAVASOL 5.5% Sulfite Free W/ ELECTROLYTES</td>
<td>BAXTER HLTHCARE 5.5%; 102MG/100ML; 522MG/100ML; 431MG/100ML; 224MG/100ML</td>
</tr>
<tr>
<td>N020173 002 Oct 27, 1995 224MG/100ML</td>
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<tr>
<td><strong>TRAVASOL 5.5% SULFITE FREE W/ ELECTROLYTES IN PLASTIC CONTAINER</strong></td>
<td>INJECTABLE; INJECTION</td>
</tr>
<tr>
<td>TRAVASOL 5.5% Sulfite Free W/ ELECTROLYTES</td>
<td>BAXTER HLTHCARE 5.5%; 102MG/100ML; 522MG/100ML; 431MG/100ML; 154MG/100ML</td>
</tr>
<tr>
<td>N020173 003 154MG/100ML</td>
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</tr>
<tr>
<td><strong>TRAVASOL 8.5% SULFITE FREE W/ ELECTROLYTES IN PLASTIC CONTAINER</strong></td>
<td>INJECTABLE; INJECTION</td>
</tr>
<tr>
<td>TRAVASOL 8.5% Sulfite Free W/ ELECTROLYTES</td>
<td>BAXTER HLTHCARE 8.5%; 102MG/100ML; 522MG/100ML; 594MG/100ML</td>
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<td>N020173 003 154MG/100ML 154MG/100ML</td>
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<tr>
<td><strong>TRAVASOL 8.5% W/ ELECTROLYTES IN PLASTIC CONTAINER</strong></td>
<td>INJECTABLE; INJECTION</td>
</tr>
<tr>
<td>TRAVASOL 8.5% W/ ELECTROLYTES</td>
<td>BAXTER HLTHCARE 8.5%; 102MG/100ML; 522MG/100ML; 594MG/100ML</td>
</tr>
<tr>
<td>N017493 003 154MG/100ML 154MG/100ML</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### AMINO ACIDS, MAGNESIUM CHLORIDE, POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE

**INJECTABLE; INJECTION**

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMINOSYN 7% W/ ELECTROLYTES</td>
<td>ICU MEDICAL INC</td>
<td>7%; 102MG/100ML; 522MG/100ML; 410MG/100ML</td>
<td>N017789 002</td>
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<tr>
<td>AMINOSYN 8.5% W/ ELECTROLYTES</td>
<td>ICU MEDICAL INC</td>
<td>8.5%; 102MG/100ML; 522MG/100ML; 410MG/100ML</td>
<td>N017673 005</td>
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### AMINOCAPROIC ACID

**INJECTABLE; INJECTION**

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<th>Manufacturer</th>
<th>Strength</th>
<th>NDC</th>
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</thead>
<tbody>
<tr>
<td>AMICAR</td>
<td>CLOVER PHARMS</td>
<td>250MG/ML **</td>
<td>N015229 002</td>
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**SYRUP; ORAL**

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<tbody>
<tr>
<td>AMICAR</td>
<td>CLOVER PHARMS</td>
<td>1.25GM/5ML</td>
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### AMINOGLUTETHIMIDE

**TABLET; ORAL**

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<tbody>
<tr>
<td>AMINOGLUTETHIMIDE</td>
<td>NOVARTIS</td>
<td>250MG</td>
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### AMINOHIPPURATE SODIUM

**INJECTABLE; INJECTION**

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<th>Product</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC</th>
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<tbody>
<tr>
<td>AMINOHIPPURATE SODIUM</td>
<td>MERCK</td>
<td>20%</td>
<td>N005619 001</td>
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### AMINOPHYLLINE

**ENEMA; RECTAL**

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<th>Strength</th>
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<tbody>
<tr>
<td>SOMOFHYLLIN</td>
<td>FISONS</td>
<td>300MG/5ML</td>
<td>N018232 001</td>
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**INJECTABLE; INJECTION**

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<th>Product</th>
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<th>NDC</th>
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<tbody>
<tr>
<td>AMINOPHYLLINE</td>
<td>GD SEARLE LLC</td>
<td>25MG/ML</td>
<td>A087243 001</td>
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<td></td>
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<td>25MG/ML</td>
<td>A087621 001</td>
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**AMINOPHYLLINE**

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<th>Product</th>
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<th>Strength</th>
<th>NDC</th>
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<tbody>
<tr>
<td>ABRAXIS PHARM</td>
<td>ABRAXIS PHARM</td>
<td>25MG/ML</td>
<td>A070522 001</td>
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<tr>
<td></td>
<td>BAXTER HLTHCARE</td>
<td>250MG/ML</td>
<td>A018950 001</td>
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<td>HOSPIRA</td>
<td>250MG/ML</td>
<td>A070888 001</td>
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<tr>
<td></td>
<td>ELKINS SINN</td>
<td>25MG/ML</td>
<td>A087239 001</td>
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<td>HOSPIRA</td>
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<td></td>
<td>INTL MEDICATION</td>
<td>25MG/ML</td>
<td>A087209 001</td>
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<td>KING PHARMS</td>
<td>25MG/ML</td>
<td>A088027 001</td>
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<td>LUITPOLD</td>
<td>25MG/ML</td>
<td>A087240 001</td>
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<td></td>
<td>LYPHOMED</td>
<td>25MG/ML</td>
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<td></td>
<td>PHARMA SERVE NY</td>
<td>25MG/ML</td>
<td>A087387 001</td>
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<td></td>
<td>SMITH AND NEPHEW</td>
<td>25MG/ML</td>
<td>A088429 001</td>
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<td>TEVA PARENTERAL</td>
<td>25MG/ML</td>
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**AMINOPHYLLINE IN SODIUM CHLORIDE 0.45%**

<table>
<thead>
<tr>
<th>Product</th>
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</tr>
</thead>
<tbody>
<tr>
<td>ABRAXIS PHARM</td>
<td>ABRAXIS PHARM</td>
<td>100MG/100ML</td>
<td>A088147 002</td>
</tr>
<tr>
<td></td>
<td>HOSPIRA</td>
<td>200MG/100ML</td>
<td>A088147 003</td>
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</table>

**AMINOPHYLLINE IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER**

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABRAXIS PHARM</td>
<td>ABRAXIS PHARM</td>
<td>100MG/100ML</td>
<td>N018924 001</td>
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<tr>
<td></td>
<td>HOSPIRA</td>
<td>200MG/100ML</td>
<td>N018924 002</td>
</tr>
<tr>
<td></td>
<td>400MG/100ML</td>
<td>N018924 003</td>
<td></td>
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<tr>
<td></td>
<td>500MG/100ML</td>
<td>N018924 004</td>
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**SOLUTION; ORAL**

<table>
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<tbody>
<tr>
<td>AMINOPHYLLINE</td>
<td>MORTON GROVE</td>
<td>105MG/5ML</td>
<td>A088156 001</td>
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</tbody>
</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
AMINOPHYLLINE

SOLUTION; ORAL

AMINOPHYLLINE

ROXANE

105MG/5ML

A088126 001 Aug 19, 1983

AMINOPHYLLINE DYE FREE

ACTAVIS MID ATLANTIC

105MG/5ML

A087727 001 Apr 16, 1982

SOMOPHYLLIN

FISON'S

105MG/5ML

A086466 001

SOMOPHYLLIN-DF

FISON'S

105MG/5ML

A087045 001

SUPPOSITORY; RECTAL

TRUPHYLLINE

G AND W LABS

250MG

A085498 001 Mar 23, 1983

500MG

A085498 002 Jan 03, 1983

TABLET; ORAL

AMINOPHYLLIN

GD SEARLE LLC

100MG

N002386 002

200MG

N002386 003

AMINOPHYLLINE

ANI PHARMS INC

100MG

A085261 004

200MG

A085261 002

ASCOT

100MG

A087522 001 Feb 12, 1982

200MG

A087523 001 Feb 12, 1982

BARR

100MG

A088297 001 Aug 19, 1983

200MG

A088298 001 Aug 19, 1983

DURAMED PHARMS BARR

100MG

A088182 001 Mar 31, 1983

HALSEY

100MG

A084674 001

HIKMA INTL PHARMS

100MG

A084540 001

200MG

A085003 001

IMPAX LABS

100MG

A084574 001

200MG

A084576 001

KV PHARM

100MG

A085284 001

200MG

A085289 001

LANNETT

100MG

A084588 001

200MG

A084598 002

PAL PAK

100MG

A084533 001

PANRAY

100MG

A084552 001

200MG

A084552 002

PUREPAC PHARM

100MG

A084699 001

200MG

A085333 001

ROXANE

100MG

A087500 001 Feb 09, 1982

200MG

A087501 001 Feb 09, 1982

VALEANT PHARM INTL

100MG

A084563 001

VANGARD

100MG

A088334 001 Oct 03, 1983

200MG

A088339 001 Oct 03, 1983

VINTAGE PHARMS

100MG

A085409 001

200MG

A085410 001

WATSON LABS

100MG

A085567 001

200MG

A085564 001

TABLET, DELAYED RELEASE; ORAL

AMINOPHYLLINE

IMPAX LABS

100MG

A084577 001

200MG

A084575 001

TABLICAPS

100MG

A084632 002

VALE

100MG

A084531 001

200MG

A084530 001

TABLET, EXTENDED RELEASE; ORAL

PHYLOCONTIN

PHARM RES ASSOC

225MG

A086760 001

AMINOSALICYLATE SODIUM

POWDER; ORAL

P.A.S. SODIUM

CENTURY PHARMS

4GM/PACKET

A080947 001

SODIUM AMINOSALICYLATE

HEXCEL

100%

A080097 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
<thead>
<tr>
<th><strong>AMINOSALICYLATE SODIUM</strong></th>
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<tbody>
<tr>
<td><strong>TABLET; ORAL</strong></td>
<td><strong>PARASAL SODIUM</strong></td>
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<tr>
<td><strong>PANRAY</strong></td>
<td><strong>500MG</strong></td>
<td><strong>1GM</strong></td>
</tr>
<tr>
<td><strong>SODIUM P.A.S.</strong></td>
<td><strong>LANNETT</strong></td>
<td><strong>500MG</strong></td>
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<tr>
<td><strong>TEEBACIN</strong></td>
<td><strong>CONSOLIDATED MIDLAND</strong></td>
<td><strong>500MG</strong></td>
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<tr>
<td><strong>AMINOSALICYLATE SODIUM; AMINOSALICYLIC ACID</strong></td>
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<td><strong>TABLET; ORAL</strong></td>
<td><strong>NEOPASALATE</strong></td>
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<td><strong>MEDPOINTE PHARM HLC</strong></td>
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<tr>
<td><strong>AMINOSALICYLIC ACID</strong></td>
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<td><strong>TABLET; ORAL</strong></td>
<td><strong>PARASAL</strong></td>
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<tr>
<td><strong>PANRAY</strong></td>
<td><strong>500MG</strong></td>
<td><strong>1GM</strong></td>
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<tr>
<td><strong>AMINOSALICYLIC ACID RESIN COMPLEX</strong></td>
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<td><strong>POWDER; ORAL</strong></td>
<td><strong>REZIPAS</strong></td>
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<td><strong>BRISTOL MYERS SQUIBB</strong></td>
<td><strong>EQ 500MG BASE/GM</strong></td>
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<tr>
<td><strong>AMIODARONE HYDROCHLORIDE</strong></td>
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</tr>
<tr>
<td><strong>INJECTABLE; INJECTION</strong></td>
<td><strong>AMIODARONE HYDROCHLORIDE</strong></td>
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<tr>
<td><strong>AKORN</strong></td>
<td><strong>50MG/ML</strong></td>
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<tr>
<td><strong>BEDFORD</strong></td>
<td><strong>50MG/ML</strong></td>
<td><strong>A076018 001</strong></td>
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<td><strong>BEDFORD LABS</strong></td>
<td><strong>50MG/ML</strong></td>
<td><strong>A076299 001</strong></td>
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<tr>
<td><strong>BEN VENUE</strong></td>
<td><strong>50MG/ML</strong></td>
<td><strong>A076088 001</strong></td>
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<td><strong>HOSPIRA</strong></td>
<td><strong>50MG/ML</strong></td>
<td><strong>A076108 001</strong></td>
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<td><strong>INTL MEDICATION SYS</strong></td>
<td><strong>50MG/ML</strong></td>
<td><strong>N021594 001</strong></td>
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<td><strong>PAR STERILE PRODUCTS</strong></td>
<td><strong>50MG/ML</strong></td>
<td><strong>A076394 001</strong></td>
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<td><strong>TEVA PHARMS USA</strong></td>
<td><strong>50MG/ML</strong></td>
<td><strong>A076163 001</strong></td>
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<tr>
<td><strong>CORDARONE</strong></td>
<td><strong>+ WYETH PHARMS INC</strong></td>
<td><strong>50MG/ML</strong> <strong>N020377 001</strong></td>
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<tr>
<td><strong>NEXTERONE</strong></td>
<td><strong>+ BAXTER HLTHCARE</strong></td>
<td><strong>50MG/ML</strong> <strong>N022325 001</strong></td>
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<tr>
<td><strong>AMIODARONE HYDROCHLORIDE</strong></td>
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<td><strong>TABLET; ORAL</strong></td>
<td><strong>MYLAN</strong></td>
<td><strong>200MG</strong></td>
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<td><strong>TEVA</strong></td>
<td><strong>200MG</strong></td>
<td><strong>A074895 001</strong></td>
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<td><strong>CORDARONE</strong></td>
<td><strong>+ WYETH PHARMS</strong></td>
<td><strong>200MG</strong> <strong>N018972 001</strong></td>
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<td><strong>AMITRIPTYLINE HYDROCHLORIDE</strong></td>
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<tr>
<td><strong>CONCENTRATE; ORAL</strong></td>
<td><strong>ENDEF</strong></td>
<td><strong>40MG/ML</strong></td>
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<td><strong>ROCHE</strong></td>
<td><strong>A085749 001</strong></td>
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<tr>
<td><strong>AMITRIPTYLINE HYDROCHLORIDE</strong></td>
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</tr>
<tr>
<td><strong>WATSON LABS</strong></td>
<td><strong>10MG/ML</strong></td>
<td><strong>A085594 001</strong></td>
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<tr>
<td><strong>ELAVIL</strong></td>
<td><strong>10MG/ML</strong></td>
<td><strong>N012704 001</strong></td>
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<td><strong>ASTRAZENECA</strong></td>
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<td><strong>AMITID</strong></td>
<td><strong>BRISTOL MYERS SQUIBB</strong></td>
<td><strong>10MG</strong> <strong>A086454 001</strong></td>
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<tr>
<td><strong>WARNER CHILCOTT</strong></td>
<td><strong>25MG</strong></td>
<td><strong>A088399 001</strong></td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### AMITRIPTYLINE HYDROCHLORIDE

**TABLET; ORAL**

**AMITRIPTYLINE HYDROCHLORIDE**

<table>
<thead>
<tr>
<th>Strength</th>
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<th>Date</th>
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<tbody>
<tr>
<td>25MG</td>
<td>A088672</td>
<td>Nov 20, 1984</td>
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<td>50MG</td>
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<td>75MG</td>
<td>A088674</td>
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<tr>
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<td>A088675</td>
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<td>A085031</td>
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**NOTE:** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons.
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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| TRIAVIL 2-10                                  |
| NEW RIVER                                     |
| 10MG;2MG **                                   | N014715 004 |
| TRIAVIL 2-25                                  |
| NEW RIVER                                     |
| 25MG;2MG **                                   | N014715 002 |
| TRIAVIL 4-10                                  |
| NEW RIVER                                     |
| 10MG;4MG **                                   | N014715 003 |
| TRIAVIL 4-25                                  |
| NEW RIVER                                     |
| 25MG;4MG **                                   | N014715 005 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

**Triavil 4-50**  
**NEW RIVER**  
50MG;4MG **  
N014715 006

### AMLEXANOX

**Paste; Dental**  
**Aphtasol**  
**Uluru Topical**  
**Uluru 2MG**  
N021727 001  
Sep 29, 2004

### AMLODIPINE BESYLATE

**Tablet; Oral**  
**Amlodipine Besylate**  
**Amneal Pharms NY**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**GenPharm**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**Mylan Pharms Inc**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**Puracap Pharm**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**Sovereign Pharms**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**Sun Pharm Industries**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**Sunshine Lake**  
EQ 2.5MG BASE  
EQ 5MG BASE  
**Synthion Pharms**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**Yaopharma Co Ltd**  
EQ 2.5MG BASE  
EQ 5MG BASE  
EQ 10MG BASE  
**Tablet, orally disintegrating; Oral**  
**Amlodipine Besylate**  
**Synthion Pharms**  
EQ 2.5MG BASE  
N022026 001  
Sep 27, 2007

### AMLODIPINE MALEATE

**Tablet; Oral**  
**Amvaz**  
**Dr Reddys Labs Inc**  
2.5MG  
5MG  
10MG  
N021435 001  
Oct 31, 2003

### AMMONIA N-13

**Injectable; Intravenous**  
**Ammonia N 13**  
**Central Radiopharm**  
3.75-260mCi/ML  
A204539 001  
Jun 23, 2015

### AMMONIUM CHLORIDE

**Injectable; Injection**  
**Abbott**  
5MEQ/ML  
A083130 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Ammonium Chloride

### Injectable; Injection

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Ammonium Chloride 0.9% in Normal Saline | Mcgaw | 900mg/100ml | N006580 001 | Aug 29, 1996
| Ammonium Chloride 2.14% | B Braun | 40meq/100ml | A085734 001 | Apr 24, 1985

## Ammonium Lactate

### Cream; Topical

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Lac-Hydrin | Sun Pharm Inds Inc | Eq 12% Base ** | N020508 001 | Jun 28, 1991
| Lac-Hydrin + Sun Pharm Inds Inc | Eq 12% Base ** | N019155 001 | May 11, 1989

## Amodiaquine Hydrochloride

### Tablet; Oral

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Amodiaquine Hydrochloride | Parke Davis | Eq 200mg Base | N006441 001 | Mar 20, 1992

## Amoxapine

### Tablet; Oral

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Amoxapine | Upsher Smith Labs | 25mg | A072943 001 | Dec 22, 1992
| | 50mg | A072944 001 | May 11, 1991
| | 100mg | A072878 001 | May 11, 1991
| | 150mg | A072879 001 | May 11, 1991
| Watson Pharms Teva | 25mg | A072418 001 | Dec 22, 1992
| | 50mg | A072419 001 | May 11, 1991
| | 100mg | A072420 001 | May 11, 1991
| | 150mg | A072421 001 | May 11, 1991

## Asendin

### Lederle

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Asendin | 25mg | N018021 001 | Dec 22, 1992
| | 50mg | N018021 002 | May 11, 1991
| | 100mg | N018021 003 | May 11, 1991
| | 150mg | N018021 004 | May 11, 1991

## Amoxicillin

### Capsule; Oral

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Amoxicillin | Labs Atral | 250mg | A062528 001 | Aug 07, 1985
| | 500mg | A062528 002 | Aug 07, 1985
| | 500mg | A062067 001 | Aug 07, 1985
| | 500mg | A062067 002 | Aug 07, 1985
| Sun Pharm Inds Ltd | 250mg | A065016 001 | Aug 07, 1985
| | 500mg | A065015 002 | Aug 07, 1985
| TEVA | 250mg | A062853 001 | Aug 07, 1985
| | 250mg | A063030 001 | Aug 07, 1985
| | 500mg | A062854 001 | Aug 07, 1985
| | 500mg | A063031 001 | Aug 07, 1985

## Amoxil

### + Glaxosmithkline

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Amoxil + Glaxosmithkline | 250mg ** | N050459 001 | Aug 07, 1985
| | 500mg ** | N050459 002 | Aug 07, 1985

## Trimox

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Trimox | 250mg | A061885 001 | Aug 07, 1985
| | 250mg | A062098 001 | Aug 07, 1985
| | 250mg | A062152 001 | Aug 07, 1985
| | 250mg | A063099 001 | Aug 07, 1985
| | 500mg | A061885 002 | Aug 07, 1985
| | 500mg | A062098 002 | Aug 07, 1985
| | 500mg | A062152 002 | Aug 07, 1985
| | 500mg | A063099 002 | Aug 07, 1985

## Utimox

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Utimox | 250mg | A062107 001 | Aug 07, 1985
| | 500mg | A062107 002 | Aug 07, 1985

## Wyimox

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Wyimox | 250mg | A062120 001 | Aug 07, 1985
| | 500mg | A062120 002 | Aug 07, 1985

## For Suspension; Oral

| Product Description | Manufacturer | Formulation | NDC Number | Date
|---------------------|--------------|-------------|------------|-----
| Azithromycin | Am Antibiots | 125mg/5ml | A062059 001 | Aug 07, 1985

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<th>AMOXICILLIN</th>
<th>FOR SUSPENSION; ORAL</th>
<th>AMOXICILLIN</th>
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<th>A062059 002</th>
<th>125MG/5ML</th>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Amoxicillin

**Tablet, for Suspension; Oral**

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<th>Company</th>
<th>Strength</th>
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<th>Date</th>
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<td>Aurobindo Pharma Ltd</td>
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<td>Ranbaxy Labs Ltd</td>
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<td>600 mg</td>
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## Amoxicillin; Clarithromycin; Lansoprazole

**Capsule, Capsule, Delayed Rel Pellets; Tablet; Oral**

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## Amoxicillin; Clavulanate Potassium

**Capsule, for Suspension; Oral**

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<td>200 mg/5 mL; EQ 28.5 mg Base/5 mL</td>
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## Amphetamine Adipate; Amphetamine Sulfate; Dextroamphetamine Adipate; Dextroamphetamine Sulfate

**Capsule; Oral**

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**Tablet; Oral**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

### Discontinued Drug Product List

#### Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate

**Tablet; Oral**

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<td>2.5mg; 2.5mg; 2.5mg; 2.5mg</td>
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<td>Adderall 12.5</td>
<td>3.125mg; 3.125mg; 3.125mg; 3.125mg</td>
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<td>Adderall 15</td>
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<td>Adderall 7.5</td>
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**Tablet; Oral**

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#### Amphetamine Resin Complex, Dextroamphetamine Resin Complex

**Capsule, Extended Release; Oral**

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<td>Sep 30, 2003</td>
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<tr>
<td>UCB Inc</td>
<td>7.5mg; 7.5mg; 7.5mg; 7.5mg</td>
<td>A040472 004</td>
<td>Sep 30, 2003</td>
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</table>

#### Amphetamine Sulfate

**Tablet; Oral**

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<tr>
<th>Product</th>
<th>Strengths</th>
<th>NDC Numbers</th>
<th>Date Discontinued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lannett</td>
<td>5mg</td>
<td>A083901 001</td>
<td>Aug 31, 1984</td>
</tr>
<tr>
<td>Lannett</td>
<td>10mg</td>
<td>A083901 002</td>
<td>Aug 31, 1984</td>
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#### Amphotericin B

**Cream; Topical**

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<tr>
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<th>NDC Numbers</th>
<th>Date Discontinued</th>
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<tbody>
<tr>
<td>Apothecon</td>
<td>3%</td>
<td>N050314 001</td>
<td>Aug 31, 1984</td>
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**Injectable; Injection**

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<th>Date Discontinued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>50mg/vial</td>
<td>A064141 001</td>
<td>Dec 23, 1996</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>50mg/vial</td>
<td>A062728 001</td>
<td>Apr 13, 1987</td>
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<tr>
<td>Teva Parenteral</td>
<td>50mg/vial</td>
<td>A064062 001</td>
<td>Mar 31, 1995</td>
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**Injectable, Lipid Complex; Injection**

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</thead>
<tbody>
<tr>
<td>Alkopharma USA</td>
<td>50mg/vial</td>
<td>N050729 001</td>
<td>Nov 22, 1996</td>
</tr>
<tr>
<td>Alkopharma USA</td>
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<td>N050729 002</td>
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**Lotion; Topical**

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**Ointment; Topical**

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**Suspension; Oral**

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<tr>
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<td>100mg/ml</td>
<td>N050341 003</td>
<td>Nov 22, 1996</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## AMPICILLIN SODIUM

**INJECTABLE; INJECTION**

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<tr>
<td>ACS DOBFAR SPA</td>
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<td>500MG BASE/VIAL</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
AMPICILLIN SODIUM
Injectable; Injection
TOTACILLIN-N
EQ 2GM BASE/VIAL A060677 005
EQ 2GM BASE/VIAL A062727 002 Dec 19, 1986
EQ 10GM BASE/VIAL A060677 006

AMPICILLIN SODIUM; SULBACTAM SODIUM
Injectable; Injection
UNASYN
PFIZER EQ 500MG BASE/VIAL; EQ 250MG BASE/VIAL N050608 003 Dec 31, 1986

AMPICILLIN/AMPICILLIN TRIHYDRATE
Capsule; Oral
AMCILL
PARKE DAVIS EQ 250MG BASE A062041 001
EQ 500MG BASE A062041 002

AMPICILLIN TRIHYDRATE
AM ANTIBIOTICS
IVAX SUB TEVA PHARMS
LEDERLE
MYLAN
PURPAC PHARM
TEVA
VITARINE
EQ 250MG BASE A061602 001
EQ 500MG BASE A061602 002
EQ 250MG BASE A060765 001
EQ 500MG BASE A060765 002
EQ 250MG BASE A062208 001
EQ 500MG BASE A062208 002
EQ 250MG BASE A061755 001
EQ 500MG BASE A061755 002
EQ 250MG BASE A061853 001
EQ 500MG BASE A061853 002
EQ 250MG BASE A061502 001
EQ 500MG BASE A061502 002
EQ 250MG BASE A061387 001
EQ 500MG BASE A061387 003

OMNIPEN (AMPICILLIN)
WYETH AYERST 250MG A060624 001
500MG A060624 002

PENBRITIN
WYETH AYERST EQ 250MG BASE A060908 001
EQ 500MG BASE A060908 002

PFIZER PEN-A
PFIZER
EQ 250MG BASE A062050 001
EQ 500MG BASE A062050 002

POLYCILLIN
BRISTOL
EQ 250MG BASE N050310 001
EQ 500MG BASE N050310 002

PRINCIPEN
APOTHECON
BRISTOL MYERS SQUIBB
EQ 250MG BASE A062888 001 Mar 04, 1988
EQ 500MG BASE A062888 002 Mar 04, 1988
EQ 250MG BASE A061392 001
EQ 500MG BASE A061392 002

PRINCIPEN '250'
APOTHECON
EQ 250MG BASE A062157 002
EQ 250MG BASE N050056 001

PRINCIPEN '500'
APOTHECON
EQ 500MG BASE A062157 001
EQ 500MG BASE N050056 002

TOTACILLIN
GLAXOsmithkline
EQ 250MG BASE A060060 001
EQ 250MG BASE A062212 001
EQ 500MG BASE A060060 002
EQ 500MG BASE A062212 002

FOR SUSPENSION; Oral
AMCILL
PARKE DAVIS EQ 125MG BASE/5ML A062030 001
EQ 250MG BASE/5ML A062030 002

AMPICILLIN TRIHYDRATE
AM ANTIBIOTICS
MYLAN
PUREPAC PHARM
EQ 125MG BASE/5ML A061601 001
EQ 250MG BASE/5ML A061601 002
EQ 125MG BASE/5ML A061829 002
EQ 250MG BASE/5ML A061829 001
EQ 125MG BASE/5ML A061980 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficaciy reasons**
<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Strengths</th>
<th>Generic Code</th>
<th>NDC Codes</th>
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<td><strong>AMPCILLIN/AMPCILLIN TRIHYDRATE</strong></td>
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<td>Ampicillin Trihydrate</td>
<td>TEVA</td>
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<td>A061980</td>
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<td>Omnipeg (ampicillin)</td>
<td>Wyeth Ayerst</td>
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<td>Amgenavir</td>
<td>GlaxoSmithKline</td>
<td>50Mg</td>
<td>N021007</td>
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<td>150Mg</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ANAGRELIDE HYDROCHLORIDE  
CAPSULE;ORAL  
AGRYLIN  
* SHIRE LLC  
EQ 1MG BASE **  
N020333 002  
Mar 14, 1997  
ANAGRELIDE HYDROCHLORIDE  
MYLAN PHARMS INC  
EQ 0.5MG BASE  
A076811 001  
Apr 18, 2005  
EQ 0.5MG BASE  
A077613 001  
Jun 27, 2006  
EQ 1MG BASE  
A076811 002  
Apr 18, 2005  
EQ 1MG BASE  
A077613 002  
Jun 27, 2006  
ROXANE  
EQ 0.5MG BASE  
A076489 001  
Apr 18, 2005  
EQ 1MG BASE  
A076489 002  
Apr 18, 2005  
UPSHER SMITH LABS  
EQ 0.5MG BASE  
A076683 001  
Apr 18, 2005  
EQ 1MG BASE  
A076683 002  
Apr 18, 2005  
WATSON LABS  
EQ 0.5MG BASE  
A076417 001  
Apr 18, 2005  
EQ 1MG BASE  
A076417 002  
Apr 18, 2005  
ANASTROZOLE  
TABLET;ORAL  
ANASTROZOLE  
IMPAX LABS INC  
1MG  
A091242 001  
May 31, 2012  
LANNETT CO INC  
1MG  
A091331 001  
Jan 05, 2011  
SANDOZ  
1MG  
A079007 001  
Jun 28, 2010  
SUN PHARM INDS LTD  
1MG  
A091177 001  
Jul 15, 2011  
SYNTHON PHARMS  
1MG  
A078322 001  
Jun 26, 2010  
WATSON LABS TEVA  
1MG  
A078994 001  
Jun 28, 2010  
ANGIOTENSIN II ACETATE  
SOLUTION;INTRAVENOUS  
GIAPREZA  
* LA JOLLA PHARMA  
EQ 5MG BASE/2ML (EQ 2.5MG BASE/ML)  
N209360 002  
Dec 21, 2017  
ANILERIDINE HYDROCHLORIDE  
TABLET;ORAL  
LERITINE  
MERCK  
EQ 25MG BASE  
N010585 002  
ANILERIDINE PHOSPHATE  
INJECTABLE;INJECTION  
LERITINE  
MERCK  
25MG/ML  
N010520 003  
ANISINDIONE  
TABLET;ORAL  
MIRADON  
SCHERING  
50MG  
N010909 003  
ANISOTROPINE METHYLBROMIDE  
TABLET;ORAL  
ANISOTROPINE METHYLBROMIDE  
WATSON LABS  
50MG  
A086046 001  
ENDO PHARMS  
50MG  
N013428 001  
ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE  
SOLUTION/DROPS;OPHTHALMIC  
VASOCON-A  
NOVARTIS  
0.5%;0.05%  
N018746 002  
Jul 11, 1994  
APOMORPHINE HYDROCHLORIDE  
INJECTABLE;SUBCUTANEOUS  
APOKYN  
US WORLDMEDS  
20MG/2ML (10MG/ML)  
N021264 001  
Apr 20, 2004  
APROTININ  
INJECTABLE;INJECTION  
TRASYLOL  
BAYER HLTHCARE  
10,000KIU/ML  
N020304 001  
Dec 29, 1993  
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<tr>
<th>Drug Name</th>
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<tr>
<td>ARBUTAMINE HYDROCHLORIDE</td>
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<td>GENESA</td>
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<td>NORMIFLO</td>
<td>5,000 UNITS/0.5ML **</td>
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<td>10,000 UNITS/0.5ML **</td>
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<td>ARGATROBAN</td>
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<td>SANDOX</td>
<td>125MG/125ML (1MG/ML)</td>
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<td>ARIPIPRAZOLE</td>
<td>INJECTABLE; INTRAMUSCULAR</td>
<td>OTSUKA</td>
<td>9.75MG/1.3ML (7.5MG/ML)</td>
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<td>SOLUTION; ORAL</td>
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<td>1MG/ML **</td>
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<td>TABLET; ORAL</td>
<td>MYLAN PHARMS INC</td>
<td>2MG</td>
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<td>5MG</td>
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<td>10MG</td>
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<td>15MG</td>
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<td>30MG</td>
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<td>OTSUKA</td>
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<td>30MG **</td>
<td>Jun 07, 2006</td>
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<td>ARMODAFINIL</td>
<td>TABLET; ORAL</td>
<td>WATSON LABS INC</td>
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<td>NUVEGIL</td>
<td>CEPHALON</td>
<td>100MG **</td>
<td>Mar 26, 2009</td>
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<td>ARSENIC TRIOXIDE</td>
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<td>TRISENOX</td>
<td>1MG/ML</td>
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<tr>
<td>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN B-6 PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN E</td>
<td>INJECTABLE; INJECTION</td>
<td>BEROCCA PN</td>
<td>50MG/ML; 0.03MG/ML; 0.0025MG/ML; 7.5MG/ML</td>
<td>Oct 10, 1985</td>
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<td>IU/ML; 0.2MG/ML; 20MG/ML; 2MG/ML; 1.8MG/ML</td>
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<td>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN B-6 PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN E</td>
<td>INJECTABLE; INJECTION</td>
<td>M.V.C. 9+3</td>
<td>10MG/ML; 0.006MG/ML; 0.5MCG/ML; 1.5MG/ML</td>
<td>Aug 08, 1985</td>
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<td>M.V.1.-12 ADULT HOSPIRA</td>
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<td>IU/ML; 0.04MG/ML; 4MG/ML; 0.4MG/ML; 0.36MG/</td>
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<td>20MG/ML; 0.006MG/ML; 0.5MCG/ML; 1.5MG/ML</td>
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<td>0.0005MG/ML; 0.04MG/ML; 4MG/ML; 0.6MG/ML</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<tr>
<th>Name and Formulation</th>
<th>Manufacturer/Code</th>
<th>Date</th>
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<td><strong>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E</strong></td>
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<td>Injectable; Injection</td>
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<td>M.V.I.-1.2 ADULT</td>
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<td>MVC PLUS</td>
<td>WATSON LABS</td>
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<td>0.36MG/ML; 0.6MG/ML; 0.1MG/ML; 1MG/ML</td>
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<td>M.V.I.-1.2 ADULT</td>
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<td>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE; VITAMIN A PALMITATE; VITAMIN E</td>
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<td>TELIGENT PHARMA INC</td>
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<td>VIAL; 3.6MG/VIAL; 3MG/VIAL; 1MG/VIAL</td>
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<td>NOVEL LABS INC</td>
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<td>4.7GM; 100GM; 1.015GM; 5.9GM; 2.691GM; 7.5GM</td>
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<td>ASPRIN; TABLET; ORAL</td>
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<td>MEASURIN</td>
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<td>SAVAGE LABS</td>
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<td>650MG; 50MG</td>
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<td>NOSTROM LABS INC</td>
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<td>WATSON LABS</td>
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<td>325MG; 50MG; 40MG</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### ASPIRIN; BUTFALBITAL; CAFFEINE
**TABLET; ORAL**

<table>
<thead>
<tr>
<th>Brand</th>
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<th>NDC Numbers</th>
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<tr>
<td>+ ALLERGAN SALES LLC</td>
<td>325MG;50MG;40MG **</td>
<td>N017534 003</td>
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<td>LANNETT</td>
<td>325MG;50MG;40MG</td>
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### ASPIRIN; BUTFALBITAL; CAFFEINE; CODEINE PHOSPHATE
**CAPSULE; ORAL**

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<th>Brand</th>
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<th>NDC Numbers</th>
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<tr>
<td>BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE</td>
<td>325MG;50MG;40MG;30MG</td>
<td>A075351 001</td>
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<td>WATSON LABS</td>
<td>325MG;50MG;40MG;30MG</td>
<td>A074359 001</td>
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### ASPIRIN; CAFFEINE; DINHYDROCODEINE BITARTRATE
**CAPSULE; ORAL**

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<td>SYNALGOS-DC</td>
<td>356.4MG;30MG;16MG</td>
<td>N011483 004</td>
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### ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE
**TABLET; ORAL**

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<td>INVASIC</td>
<td>385MG;30MG;25MG</td>
<td>A074817 001</td>
<td>Nov 27, 1996</td>
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<tr>
<td>INVASIC FORTE</td>
<td>770MG;60MG;50MG</td>
<td>A074817 002</td>
<td>Nov 27, 1996</td>
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<td>NORGESIC</td>
<td>385MG;30MG;25MG **</td>
<td>N013416 003</td>
<td>Oct 27, 1982</td>
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<tr>
<td>NORGESIC FORTE</td>
<td>770MG;60MG;50MG **</td>
<td>N013416 004</td>
<td>Oct 27, 1982</td>
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<td>ORPHENADRINE CITRATE, ASPIRIN, AND CAFFEINE</td>
<td>385MG;30MG;25MG</td>
<td>A074988 001</td>
<td>Apr 30, 1999</td>
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<td>STEVENS J</td>
<td>770MG;60MG;50MG</td>
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<td>Apr 30, 1999</td>
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<td>ORPHENGESIC</td>
<td>385MG;30MG;25MG</td>
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<td>May 29, 1998</td>
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<tr>
<td>ORPHENGESIC FORTE</td>
<td>770MG;60MG;50MG</td>
<td>A075141 002</td>
<td>May 29, 1998</td>
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### ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE
**CAPSULE; ORAL**

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<th>Brand</th>
<th>Strengths</th>
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<td>ALRA</td>
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<td>DARVON COMPOUND</td>
<td>389MG;32.4MG;32MG</td>
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<td>DARVON COMPOUND-65</td>
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<td>SANDOX</td>
<td>389MG;32.4MG;65MG</td>
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<td>TEVA</td>
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<td>PROPOXYPHENE HYDROCHLORIDE W/ ASPIRIN AND CAFFEINE</td>
<td>389MG;32.4MG;65MG</td>
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### ASPIRIN; CARISOPRODOL
**TABLET; ORAL**

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<th>NDC Numbers</th>
<th>Date Discontinued</th>
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<tr>
<td>CARISOPRODOL AND ASPIRIN</td>
<td>325MG;200MG</td>
<td>A040252 001</td>
<td>Dec 10, 1997</td>
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<tr>
<td>CARISOPRODOL COMPOUND</td>
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<td>A088809 001</td>
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<td>SOMA COMPOUND</td>
<td>325MG;200MG **</td>
<td>N012365 005</td>
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### ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE
**TABLET; ORAL**

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<th>NDC Numbers</th>
<th>Date Discontinued</th>
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<td>CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE</td>
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<td>SOMA COMPOUND W/ CODEINE</td>
<td>325MG;200MG;16MG **</td>
<td>N012366 002</td>
<td>Jul 11, 1983</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ASPIRIN; HYDROCODONE BITARTRATE
TABLET; ORAL
AZDONE
SCHWARZ PHARMA 500MG; 5MG **
A089420 001 Jan 25, 1988
VICOFRIN
ABBOTT 500MG; 5MG
A086333 001 Sep 14, 1983

ASPIRIN; MEPROBAMATE
TABLET; ORAL
EQUAGESIC
SUN PHARM INDUSTRIES 325MG; 200MG
N011702 003 Dec 29, 1983
MEPRA-ASPIRIN
SANDOZ 325MG; 200MG
A089127 001 Mar 02, 1987
MEPROBAMATE AND ASPIRIN
PAR PHARM 325MG; 200MG
A089126 001 Aug 19, 1986
MICRAFIN
MEDPOINTE PHARM HLC 325MG; 200MG
A084978 001
Q-GESIC
QUANTUM PHARMICS 325MG; 200MG
A088740 001 Jun 01, 1984

ASPIRIN; METHOCARBAMOL
TABLET; ORAL
METHOCARBAMOL AND ASPIRIN
IVAX SUB TEVA PHARMS 325MG; 400MG
A087211 001 Dec 22, 1982
MCNEIL 325MG; 400MG
A089193 001 Feb 12, 1986
PAR PHARM 325MG; 400MG
A089657 001 Nov 04, 1988
ROBAXISAL
ROBINS AH 325MG; 400MG
N012281 001

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE
TABLET; ORAL
CODOXY
HALSEY 325MG; 4.5MG; 0.38MG
A087464 001 Jul 01, 1982
OXYCODONE AND ASPIRIN
SUN PHARM INDUSTRIES 325MG; 4.5MG; 0.38MG
A040260 001 Jul 17, 1998
325MG; 4.5MG; 0.38MG
A087794 001 May 26, 1982
325MG; 4.5MG; 0.38MG
A040255 001 Feb 27, 1998
OXOCDONE AND ASPIRIN (HALF-STRENGTH)
ROXANE 325MG; 2.25MG; 0.19MG
A087742 001 Jun 04, 1982
PERCODAN
ENDO PHARMS 325MG; 4.5MG; 0.38MG **
N007337 006
PERCODAN-DEMI
ENDO PHARMS 325MG; 2.25MG; 0.19MG **
N007337 005
ROXIPRIN
ROXANE 325MG; 4.5MG; 0.38MG
A087743 001 Jun 04, 1982

ASPIRIN; PENTAZOCINE HYDROCHLORIDE
TABLET; ORAL
TALWIN COMPOUND
SANOFI AVENTIS US + 325MG; EQ 12.5MG BASE **
N016891 001

ASPIRIN; PRAVASTATIN SODIUM
TABLET, TABLET; ORAL
PRAVIGARD PAC (COPACKAGED)
BRISTOL MYERS SQUIBB 325MG, N/A; N/A, 80MG
N021387 006 Jun 24, 2003
TABLET, TABLET, TABLET; ORAL
PRAVIGARD PAC (COPACKAGED)
BRISTOL MYERS SQUIBB 81MG, N/A; N/A, 20MG
N021387 001 Jun 24, 2003
81MG, N/A; N/A, 40MG
N021387 002 Jun 24, 2003
81MG, N/A; N/A, 80MG
N021387 003 Jun 24, 2003
325MG, N/A; N/A, 20MG
N021387 004 Jun 24, 2003
325MG, N/A; N/A, 40MG
N021387 005 Jun 24, 2003

ASPIRIN; PROPOXYPHENE HYDROCHLORIDE
CAPSULE; ORAL
DARVON W/ ASA
XANODYNE PHARM 325MG; 65MG
N010996 005

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Formulation</th>
<th>Manufacturer</th>
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<tr>
<td>Aspirin; Propoxyphene Napsylate</td>
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<td>AAI Pharma LLC</td>
<td>325MG;100MG</td>
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<td>Atazanavir Sulfate</td>
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<td>REYATAZ</td>
<td>25MG</td>
<td>N021567 001 Jun 20, 2003</td>
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<td>Atenolol</td>
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<td>TENORMIN</td>
<td>0.5MG/ML</td>
<td>N019058 001 Sep 13, 1989</td>
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<td>50MG</td>
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<td>Atenolol</td>
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<td>WATSON LABS</td>
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<td>Atenolol; Chlorothalidone</td>
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<td>Atomoxetine Hydrochloride</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### ATORVASTATIN CALCIUM

**TABLET; ORAL**

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<tr>
<th>Brand Name</th>
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<td>A078773 001</td>
<td>10MG BASE 20MG BASE</td>
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<td>20MG BASE 40MG BASE</td>
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<td>A078773 003</td>
<td>40MG BASE 80MG BASE</td>
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<td>A078773 004</td>
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**ATORVASTATIN CALCIUM; EZETIMIBE**

**TABLET; ORAL**

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<td>10MG BASE 10MG BASE</td>
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**ATOVAQUONE**

**TABLET; ORAL**

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**ATRACURIUM BESYLATE**

**INJECTABLE; INJECTION**

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<tr>
<td>BAXTER HLTHCARE</td>
<td>10MG/ML</td>
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<td>BAXTER HLTHCARE CORP</td>
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<td>HOSPIRA</td>
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<td>TEVA PARENTERAL</td>
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<td>WATSON PHARMS TEVA</td>
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**ATROPINE**

**INJECTABLE; INJECTION**

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<tr>
<td>ABBVIE</td>
<td>EQ 2MG SULFATE/0.7ML</td>
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**ATROPINE SULFATE**

**AEROSOL, METERED; INHALATION**

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<td>US ARMY</td>
<td>EQ 0.36MG BASE/INH</td>
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**ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE**

**TABLET; ORAL**

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<td>SEBELA IRELAND LTD</td>
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**ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE**

**CAPSULE; ORAL**

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<td>SCHERER RP</td>
<td>0.025MG; 2.5MG</td>
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**COLONIAID**

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<td>MEDPOINTE PHARM HLC</td>
<td>0.025MG/5ML; 2.5MG/5ML</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### ATROPINE SULFATE; DIPhenOXylATE HYDROCHLORIDE

**SOLUTION; ORAL**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| LOMANATE ALPHARMA US PHARMS | 0.025MG/5ML; 2.5MG/5ML | A085746 | Nov 27, 2000
| LOMOTIL GD SÉARLE LLC | 0.025MG/5ML; 2.5MG/5ML | N012699 | Nov 27, 2000
| MEDPOINTE PHARM HLC | 0.025MG; 2.5MG | A085737 | Nov 27, 2000
| MD PHARM | 0.025MG; 2.5MG | A085266 | Nov 27, 2000

**DIPhenOXylATE HYDROCHLORIDE AND ATROPINE SULFATE**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| ASCOT | 0.025MG; 2.5MG | A087934 | Jul 19, 1983
| FOSUN PHARMA | 0.025MG; 2.5MG | A086173 | Mar 15, 1982
| HEATHER | 0.025MG; 2.5MG | A086798 | Mar 15, 1982
| HIKMA PHARMS | 0.025MG; 2.5MG | A087765 | Mar 15, 1982
| INWOOD LABS | 0.025MG; 2.5MG | A085509 | Mar 15, 1982
| KV PHARM | 0.025MG; 2.5MG | A085659 | Mar 15, 1982
| LEBELE | 0.025MG; 2.5MG | A086950 | Mar 15, 1982
| PARKE DAVIS | 0.025MG/2.5MG | A087131 | Mar 15, 1982
| PVT FORM | 0.025MG/2.5MG | A085766 | Mar 15, 1982
| R AND S PHARMA | 0.025MG/2.5MG | A085035 | Mar 15, 1982
| ROXANE | 0.025MG/2.5MG | A086057 | Mar 15, 1982
| SUN PHARM INDUSTRIES | 0.025MG/2.5MG | A085506 | Mar 15, 1982
| USL PHARMA | 0.025MG/2.5MG | A087842 | Mar 15, 1982
| VALEANT PHARM INTL | 0.025MG/2.5MG | A087195 | Mar 15, 1982
| WATSON LABS | 0.025MG/2.5MG | A085876 | Mar 15, 1982

**INJECTABLE; INJECTION**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| ENLON-PLUS MYLAN INSTITUTIONAL | 0.14MG/ML; 10MG/ML | N019677 | Nov 06, 1991
| + 0.14MG/ML; 10MG/ML | N019678 | Nov 06, 1991

### ATROPINE SULFATE; EDROPHONIUM CHLORIDE

**INJECTABLE; INJECTION**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| MYLAN INSTITUTIONAL | 0.4MG/ML; 50MG/ML | A087853 | Nov 26, 1982
| 0.4MG/ML; 75MG/ML | A087847 | Nov 26, 1982
| 0.4MG/ML; 100MG/ML | A087848 | Nov 26, 1982

### ATROPINE SULFATE; MEPERIDINE HYDROCHLORIDE

**INJECTABLE; INJECTION**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| ABBVIE | 0.4MG/ML; 50MG/ML | A087853 | Nov 26, 1982
| 0.4MG/ML; 75MG/ML | A087847 | Nov 26, 1982
| 0.4MG/ML; 100MG/ML | A087848 | Nov 26, 1982

### ATROPINE; PRALIDOxIME CHLORIDE

**INJECTABLE; INTRAMUSCULAR**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| US ARMY | 2.1MG/0.7ML; 600MG/2ML | N021175 | Jan 17, 2002

### AVOBENZONE; OCTINOXATE; OXYBENZONE

**LOTION; TOPICAL**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| SHADE UVAGUARD BAYER HEALTHCARE LLC | 3%; 7.5%; 3% | N020045 | Dec 07, 1992

### AZATADINE MALEATE

**TABLET; ORAL**

| Brand Name | Strength | NDC Code | Date
|------------|----------|----------|------
| SCHERING | 1MG | N017601 | Dec 07, 1992

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<td>Tablet, Extended Release; Oral</td>
<td>Schering</td>
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<td>Tablet; Oral</td>
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<td>Optivar</td>
<td>N021127</td>
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<td>Mylan Specialty LP</td>
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<td>Apotex Inc</td>
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<td>Sandox</td>
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<td>Azithromycin</td>
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<td>Azithromycin Dihydrate; Trovafloxacin Mesylate</td>
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<td>Trovan/Zithromax Compliance Pak</td>
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<td>Azlocillin Sodium</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
| **AZTREONAM** | **INJECTABLE; INJECTION** | **AZACTAM** | **INJECTABLE; INJECTION** |
| **BRISTOL MYERS SQUIBB** | **500MG/VIAL** | **AZACTAM IN PLASTIC CONTAINER** | **BRISTOL MYERS SQUIBB** |
| **10MG/ML** | **AZTREONAM** | **WEST-WARD PHARMS INT** |
| **1GM/VIAL** | **2GM/VIAL** | **** See List Footnote **|

| **BACAMPICILLIN HYDROCHLORIDE** | **FOR SUSPENSION; ORAL** | **SPECTROBID** | **TABLET; ORAL** |
| **PFIZER** | **125MG/5ML** | **PFIZER** | **400MG** |
| **1200MG/5ML** | **800MG** | **5000MG/5ML** | **5000MG/5ML** |

| **BACITRACIN** | **INJECTABLE; INJECTION** | **BACITRACIN** | **INJECTABLE; INJECTION** |
| **MYLAN ASI** | **50,000 UNITS/VIAL** | **PFIZER** | **50,000 UNITS/VIAL** |
| **PFIZER** | **50,000 UNITS/VIAL** | **PHARMACIA AND UPJOHN** | **10,000 UNITS/VIAL** |
| **PHARMADERM** | **500 UNITS/GM** | **PHARMAFAIR** | **500 UNITS/GM** |
| **PHARMAFAIR** | **400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 10,000 UNITS/VIAL** |

| **BACITRACIN** | **OINTMENT; OPHTHALMIC** | **BACIGUENT** | **OINTMENT; TOPICAL** |
| **PHARMACIA AND UPJOHN** | **500 UNITS/GM** | **BACITRACIN** | **BACITRACIN** |
| **LILLY** | **500 UNITS/GM** | **COMBE** | **500 UNITS/GM** |
| **PHARMADERM** | **500 UNITS/GM** | **NASKA** | **500 UNITS/GM** |
| **PHARMAFAIR** | **500 UNITS/GM** | **POWDER; FOR RX COMPOUNDING** | **BAC-RX** |
| **ZIBA-RX** | **X GEN PHARMS** | **5,000,000 UNITS/BOT** | **5,000,000 UNITS/BOT** |
| **X GEN PHARMS** | **5,000,000 UNITS/BOT** | **PADDOCK LLC** | **5,000,000 UNITS/BOT** |

| **BACITRACIN ZINC** | **OINTMENT; OPHTHALMIC** | **CORTISPORIN** | **OINTMENT; TOPICAL** |
| **CASPHER PHARMA LLC** | **400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 10,000 UNITS/VIAL** | **ZINC BACITRACIN, NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE** | **NEOMYCIN & POLYMYXIN B SULFATES & BACITRACIN ZINC & HYDROCORTISONE** |
| **PHARMAFAIR** | **400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 10,000 UNITS/VIAL** | **PHARMAFAIR** | **400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; 5,000 UNITS/VIAL** |

| **BACITRACIN ZINC; LIDOCAINE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE** | **OINTMENT; TOPICAL** | **LANABOTIC** | **COMBE** |
| **400 UNITS/GM; 40MG/GM; EQ 5MG BASE/GM; 5,000 UNITS/GM** | **A062499 001** | **A062499 001** | **A062499 001** |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
Barium Sulfate
For Suspension; Oral
E-Z-Cat Dry
+ Bracco 40% (9gm/ pou奇) N208036 003 Jan 03, 2017

Beclozaéthasone Dipropionate
Aerosol, Metered; Inhalation
Beclomévent
GlaxoSmithKline 0.042mg/inh N018153 001
Qvar 40
+ Teva Branded Pharm 0.04mg/inh N020911 002 Sep 15, 2000
Qvar 80
+ Teva Branded Pharm 0.08mg/inh N020911 001 Sep 15, 2000
Vanceril
Scheriing 0.042mg/inh N017573 001
Vanceril Double Strength
Schering 0.084mg/inh N020486 001 Dec 24, 1996
Aerosol, Metered; Nasal
Beconase
GlaxoSmithKline 0.042mg/inh N018584 001
Vancenase
Schering 0.042mg/inh N018521 001

Beclozaéthasone Dipropionate Monohydrate
Spray, Metered; Nasal
Vancenase AQ
Schering Eq 0.042mg diprop/spray N019589 001 Dec 23, 1987
Eq 0.084mg diprop/spray N020469 001 Jun 26, 1996

Benazepril Hydrochloride
Tablet; Oral
Benazepril Hydrochloride
Actavis Labs FL Inc 5mg A076267 001 Feb 11, 2004
10mg A076267 002 Feb 11, 2004
20mg A076267 003 Feb 11, 2004
40mg A076267 004 Feb 11, 2004
Genpharm 5mg A076476 001 Feb 11, 2004
10mg A076476 002 Feb 11, 2004
20mg A076476 003 Feb 11, 2004
40mg A076476 004 Feb 11, 2004

Benazepril Hydrochloride; Hydrochlorothiazide
Tablet; Oral
Benazepril Hydrochloride and Hydrochlorothiazide
Actavis Labs FL Inc 5mg; 6.25mg A076342 001 Feb 11, 2004
10mg; 12.5mg A076342 002 Feb 11, 2004
20mg; 12.5mg A076342 003 Feb 11, 2004
20mg; 25mg A076342 004 Feb 11, 2004
IVAX Sub Teva Pharm 5mg; 6.25mg A076348 001 Feb 11, 2004
10mg; 12.5mg A076348 002 Feb 11, 2004
20mg; 12.5mg A076348 003 Feb 11, 2004
20mg; 25mg A076348 004 Feb 11, 2004
Mylan Pharm Inc 5mg; 6.25mg A076612 001 Feb 11, 2004
10mg; 12.5mg A076612 002 Feb 11, 2004
20mg; 12.5mg A076612 003 Feb 11, 2004
20mg; 25mg A076612 004 Feb 11, 2004
SUN Pharm Inds Ltd 5mg; 6.25mg A077483 001 Sep 08, 2005
10mg; 12.5mg A077483 002 Sep 08, 2005
20mg; 12.5mg A077483 003 Sep 08, 2005
20mg; 25mg A077483 004 Sep 08, 2005
Lotensin HCT
+ US Pharm Holdings I 5mg; 6.25mg ** N020033 001 May 19, 1992

Bendamustine Hydrochloride
Solution; IV (Infusion)
Trezanda
+ Cephalon 45mg/ 0.5ml (90mg/ml) N022249 003 Sep 13, 2013
+ 180mg/ 2ml (90mg/ml) N022249 004 Sep 13, 2013

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
** See List Footnote

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<th><strong>BENDROFLUMETHIAZIDE</strong></th>
<th><strong>Tablet; Oral</strong></th>
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<th><strong>10mg</strong></th>
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<td><strong>Tablet; Oral</strong></td>
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<td><strong>2.5mg</strong></td>
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<th><strong>BENOXINATE HYDROCHLORIDE</strong></th>
<th><strong>Solution; Drops; Ophthalmic</strong></th>
<th><strong>Benoxinate Hydrochloride</strong></th>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
BENZTROPINE MESYLATE
TABLET; ORAL
BENZTROPINE MESYLATE
CHARTWELL RX
1MG
2MG
LANNETT CO INC
0.5MG **
1MG **
2MG **
OXFORD PHARMS
2MG
QUANTUM PHARMICS
0.5MG
1MG
2MG
USL PHARMA
0.5MG
1MG
2MG
COGENTIN
+ MERCK
0.5MG **
1MG **
2MG **

BENZYL BENZOATE
EMULSION; TOPICAL
BENZYL BENZOATE
LANNETT
50%

BEPRIDIL HYDROCHLORIDE
TABLET; ORAL
BEPADIN
MEDPOINTE PHARM HLC
200MG
300MG
400MG
VASCOR
JOHNSON AND JOHNSON
200MG
300MG
400MG

BETA CAROTENE
CAPSULE; ORAL
SOLATENE
ROCHE
30MG

BETAMETHASONE
CREAM; TOPICAL
CELESTONE
SCHERING
0.2%

SYRUP; ORAL
CELESTONE
MERCK SHARP DOHME
0.6MG/5ML

TABLET; ORAL
CELESTONE
SCHERING
0.6MG

BETAMETHASONE BENZOATE
CREAM; TOPICAL
UTICORT
PARKE DAVIS
0.025%

GEL; TOPICAL
UTICORT
PARKE DAVIS
0.025%

LOTION; TOPICAL
UTICORT
PARKE DAVIS
0.025%

OINTMENT; TOPICAL
UTICORT
PARKE DAVIS
0.025%

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL
ALPHATREX
Savage Labs
EQ 0.05% BASE
N019138 001 Jun 26, 1984
Perrigo New York
EQ 0.05% BASE
A072536 001 Jan 31, 1990
G and W Labs Inc
EQ 0.05% BASE
A074579 001 Nov 26, 1997
Pharmaderm
EQ 0.05% BASE
N019136 001 Jun 26, 1984
Taro
EQ 0.05% BASE
A071143 001 Jun 17, 1987
Teva
EQ 0.05% BASE
A071476 001 Aug 18, 1987
Diproson
Schering
EQ 0.05% BASE
N017536 001

Creme, Augmented; Topical
Diprolene
Schering
EQ 0.05% BASE
N019408 001 Jan 31, 1986

Diprosone
Schering
EQ 0.1% BASE
N017829 001

Gel, Augmented; Topical
Diprolene
Schering
EQ 0.05% BASE
N019408 002 Nov 22, 1991

Lotion; Topical
Alphatrex
Savage Labs
EQ 0.05% BASE
A070273 001 Aug 12, 1985
Pharmaderm
EQ 0.05% BASE
A071085 001 Feb 03, 1987
Taro
EQ 0.05% BASE
A071182 001 Jun 06, 1988
Teva
EQ 0.05% BASE
A070274 001 Aug 12, 1985
A072276 001 Aug 24, 1988
A074272 001 Sep 30, 1994

Diproson + Schering
EQ 0.05% BASE **
N017781 001

Lotion, Augmented; Topical
Diprolene + Merck Sharp Dohme
EQ 0.05% BASE
N019716 001 Aug 01, 1988

Ointment; Topical
Alphatrex
Savage Labs
EQ 0.05% BASE
N019143 001 Sep 04, 1984
Pharmaderm
EQ 0.05% BASE
A072526 001 Jan 31, 1990
Teva
EQ 0.05% BASE
A071140 001 Sep 04, 1984
A071477 001 Aug 18, 1987

Diproson + Schering
EQ 0.05% BASE
N017691 001

BETAMETHASONE SODIUM PHOSPHATE

Injectable; Injection
BETAMETHASONE SODIUM PHOSPHATE
Watson Labs
EQ 3MG BASE/ML
A085738 001
Celestone + Schering
EQ 3MG BASE/ML **
N017561 001

BETAMETHASONE VALERATE

Cream; Topical
Betaderm
Roaco
EQ 0.1% BASE
N018839 001 Jun 30, 1983
Betamethasone Valerate
Perrigo New York
EQ 0.1% BASE
A070053 001 Jun 10, 1986
Pharmaderm
EQ 0.1% BASE
N018860 002 Aug 31, 1983
Pharmafair
EQ 0.1% BASE
A070485 001 May 29, 1987
Taro
EQ 0.1% BASE
A070062 001 May 14, 1985
Betatrex
Savage Labs
EQ 0.1% BASE
N018862 001 Aug 31, 1983
Valisone
Schering
EQ 0.01% BASE
N016322 002
EQ 0.1% BASE
N016322 001

Lotion; Topical
Beta-Val
G and W Labs Inc
EQ 0.1% BASE
A070072 001 Jun 27, 1985

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
BETAMETHASONE VALERATE
LOTION;TOPICAL
BETAMETHASONE VALERATE
PHARMADERM EQ 0.1% BASE N018870 001 Aug 31, 1983
PHARMAFAIR EQ 0.1% BASE A070484 001 May 29, 1987
TEVA PHARMS EQ 0.1% BASE A071883 001 Apr 22, 1988
BETATREX SAVAGE LABS EQ 0.1% BASE N018867 001 Aug 31, 1983
VALISONE SCHERING EQ 0.1% BASE N016932 001

BETAMETHASONE VALERATE
OINTMENT;TOPICAL
BETAMETHASONE VALERATE
PERRIGO NEW YORK EQ 0.1% BASE A071478 001 Dec 23, 1987
PHARMADERM EQ 0.1% BASE N018864 001 Aug 31, 1983
PHARMAFAIR EQ 0.1% BASE A070486 001 May 29, 1987
BETATREX SAVAGE LABS EQ 0.1% BASE N018863 001 Aug 31, 1983
VALISONE SCHERING EQ 0.1% BASE N016740 001

BETAXOLOL HYDROCHLORIDE
SOLUTION/DROPS;OPHTHALMIC
BETAXOLOL HYDROCHLORIDE
APOTEX INC EQ 0.5% BASE A075446 001 Sep 28, 2000
TABLET;ORAL
SANOFI AVENTIS US 10MG N019507 001 Oct 27, 1989
20MG N019507 002 Oct 27, 1989

BETAXOLOL HYDROCHLORIDE; CHLORTHALIDONE
TABLET;ORAL
KERLEDEX
SANOFI AVENTIS US 5MG;12.5MG N019807 001 Oct 30, 1992
10MG;12.5MG N019807 002 Oct 30, 1992

BETAXOLOL HYDROCHLORIDE; PILOCARPINE HYDROCHLORIDE
SUSPENSION/DROPS;OPHTHALMIC
BETOPTIC PILO
ALCON EQ 0.25% BASE;1.75% N020619 001 Apr 17, 1997

BETAZOLE HYDROCHLORIDE
INJECTABLE;INJECTION
HISTALOG LILLY 50MG/ML N009344 001

BETHANECHOL CHLORIDE
INJECTABLE;INJECTION
URECHOLINE + ODYSSEY PHARMS 5MG/ML ** N006536 001
TABLET;ORAL
BETHANECHOL CHLORIDE
ABLE 5MG A040492 001 Jul 27, 2004
10MG A040483 001 Jul 27, 2004
25MG A040485 001 Jul 27, 2004
50MG A040509 001 Jul 27, 2004
ACTAVIS ELIZABETH 5MG A040552 001 Oct 28, 2004
10MG A040553 001 Oct 28, 2004
25MG A040554 001 Oct 28, 2004
50MG A040551 001 Oct 28, 2004
ASCOT 10MG A088288 001 Jun 08, 1983
25MG A088289 001 Jun 08, 1983
IMPAK LABS 5MG A040721 001 Nov 01, 2006
10MG A040721 002 Nov 01, 2006
25MG A040721 003 Nov 01, 2016
50MG A040721 004 Nov 01, 2006
IVAX SUB TEVA PHARMS 25MG A084689 001
LANNETT 5MG A084702 001
10MG A084712 001
25MG A084074 001
SANDOZ 5MG A084353 001
10MG A084378 001
10MG A084379 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Drug Name</th>
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<td>A084188 004</td>
<td>Apr 22, 2009</td>
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<tr>
<td>URECHOLINE</td>
<td>+ ODYSSEY PHARMS</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>+</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>BETHANIDINE SULFATE</td>
<td>TABLET; ORAL</td>
<td>TENATHAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ROBINS AH</td>
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<tr>
<td>BICALUTAMIDE</td>
<td>TABLET; ORAL</td>
<td>KUDCO IRELAND</td>
<td>A077996 001</td>
<td>Jul 06, 2009</td>
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<td></td>
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<td>ROXANE</td>
<td>A078285 001</td>
<td>Mar 24, 2011</td>
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<tr>
<td>BIMATOPROST</td>
<td>SOLUTION/DROPS; OPHTHALMIC</td>
<td>LUMIGAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>+ ALLERGAN</td>
<td>0.03%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BIPERIDEN HYDROCHLORIDE</td>
<td>TABLET; ORAL</td>
<td>AHBBVIE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BIPERIDEN LACTATE</td>
<td>INJECTABLE; INJECTION</td>
<td>AHBBVIE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BISACODYL; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE</td>
<td>FOR SOLUTION, TABLET, DELAYED RELEASE; ORAL</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Manufacturer</th>
<th>NDC Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BISMUTH SUBSALICYLATE; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE</td>
<td>TABLET, CHEWABLE, TABLET, CAPSULE; ORAL</td>
<td>Hелидак + Casper Pharma LLC</td>
<td>N050719 001</td>
<td>Aug 15, 1996</td>
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<tr>
<td>BISOPROLOL FUMARATE</td>
<td>TABLET; ORAL</td>
<td>ANDA Repository</td>
<td>A075474 001</td>
<td>Oct 25, 2002</td>
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<td>Zebeta</td>
<td>A075474 002</td>
<td>Oct 25, 2002</td>
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<tr>
<td>BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE</td>
<td>TABLET; ORAL</td>
<td>ACTAVIS ELIZABETH</td>
<td>A075672 001</td>
<td>Sep 25, 2000</td>
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<td>Apothecon</td>
<td>A075672 002</td>
<td>Sep 25, 2000</td>
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<td>Ivax Sub Teva Pharma</td>
<td>A075632 001</td>
<td>Sep 27, 2000</td>
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<td>Sandoz</td>
<td>A075527 001</td>
<td>Sep 25, 2000</td>
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<td>Teva</td>
<td>A075686 001</td>
<td>Jan 19, 2001</td>
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<td></td>
<td>Watson Labs Teva</td>
<td>A075469 001</td>
<td>Sep 25, 2000</td>
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<td>BITOLTEROL MESYLATE</td>
<td>AEROSOL, METERED; INHALATION</td>
<td>Sanofi Aventis US</td>
<td>N018770 001</td>
<td>Dec 28, 1984</td>
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<tr>
<td>BLEOMYCIN SULFATE</td>
<td>INJECTABLE; INJECTION</td>
<td>Sanofi Aventis US</td>
<td>N019548 001</td>
<td>Feb 19, 1992</td>
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<td>BOCETREVIR</td>
<td>CAPSULE; ORAL</td>
<td>Merck Sharp Dohme</td>
<td>N202258 001</td>
<td>May 13, 2011</td>
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<tr>
<td>BORTEZOORB</td>
<td>POWDER; INTRAVENOUS, SUBCUTANEOUS</td>
<td>Hospira Inc</td>
<td>N209191 001</td>
<td>Jul 12, 2018</td>
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<tr>
<td>BRETYLIUM TOSYLATE</td>
<td>INJECTABLE; INJECTION</td>
<td>Abraxis Pharm</td>
<td>A070134 001</td>
<td>Apr 29, 1986</td>
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<tr>
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<td></td>
<td>AstraZeneca</td>
<td>A071298 001</td>
<td>Feb 13, 1987</td>
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<tr>
<td></td>
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<td>AstraZeneca</td>
<td>A071151 001</td>
<td>Aug 10, 1987</td>
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<tr>
<td></td>
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<td>AstraZeneca</td>
<td>A071152 001</td>
<td>Aug 10, 1987</td>
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<td>AstraZeneca</td>
<td>A071153 001</td>
<td>Aug 10, 1987</td>
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BRETYLIUM TOSYLATE
INJECTABLE; INJECTION
BRETYLIUM TOSYLATE
EUROHLTH INTL SARL 50MG/ML A070546 001 May 14, 1986
+ HOSPIRA 50MG/ML ** N019030 001 Apr 29, 1986
50MG/ML N019033 001 Apr 29, 1986
INTL MEDICATION 50MG/ML A070119 001 Apr 29, 1986
LUITPOLD 50MG/ML A070891 001 Jul 26, 1998
WEST-WARD PHARMS INT 50MG/ML A070545 001 May 14, 1986
BRETYLIUM TOSYLATE IN DEXTROSE 5%
ABBOTT 200MG/100ML N019005 002 Apr 29, 1986
400MG/100ML N019005 003 Apr 29, 1986
800MG/100ML N019005 001 Apr 29, 1986
HOSPIRA INC
BRETYLOL
HOSPIRA 50MG/ML N017954 001

BRIMONIDINE TARTRATE
SOLUTION/DROPS; OPHTHALMIC
ALPHAGAN
+ ALLERGAN 0.2% ** N020613 001 Sep 06, 1996
0.5% N020490 001 Mar 13, 1997
BRIMONIDINE TARTRATE
TEVA PARENTERAL 0.2% A076372 001 Sep 10, 2004

BROMFENAC SODIUM
SOLUTION/DROPS; OPHTHALMIC
BROMDAY
+ BAUSCH AND LOMB INC EQ 0.09% ACID ** N021664 002 Oct 16, 2010
BROMFENAC SODIUM
AMRING PHARMS EQ 0.09% ACID A202030 001 Jan 09, 2013
APOTEX INC EQ 0.09% ACID A202435 001 Jun 19, 2014
EQ 0.09% ACID A202620 001 Jun 23, 2014
COASTAL PHARMS EQ 0.09% ACID A201211 001 May 11, 2011
PADDock LLC EQ 0.09% ACID A201941 001 Feb 10, 2015
XIBROM
+ BAUSCH AND LOMB INC EQ 0.09% ACID ** N021664 001 Mar 24, 2005

BROMOCRIPTINE MESYLATE
CAPSULE; ORAL
BROMOCRIPTINE MESYLATE
LEK PHARM EQ 5MG BASE A075100 001 Dec 10, 1998

BROMODIPHENHYDRAMINE HYDROCHLORIDE
CAPSULE; ORAL
AMBODRYL
PARKE DAVIS 25MG N007984 001

BROMPHENIRAMINE MALEATE
ELIXIR; ORAL
BROMPHENIRAMINE MALEATE
ALPHARMA US PHARMS 2MG/5ML A086936 001
KV PHARM 2MG/5ML A085466 001
PHARM ASSOC 2MG/5ML A085717 001
USL PHARMA 2MG/5ML A087964 001 Jan 25, 1983

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### BROMPHENIRAMINE MALEATE

**Injectable; Injection**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watson Labs</td>
<td>10mg/ml</td>
<td>A083821 001</td>
</tr>
<tr>
<td></td>
<td>100mg/ml</td>
<td>A083820 001</td>
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</table>

**Dimetane-Ten**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wyeth Ayerst</td>
<td>10mg/ml</td>
<td>N011418 002</td>
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</table>

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watson Labs</td>
<td>4mg</td>
<td>A084468 001</td>
</tr>
<tr>
<td>Ivax Sub Teva Pharms</td>
<td>4mg</td>
<td>A084351 001</td>
</tr>
<tr>
<td>Newtron Pharms</td>
<td>4mg</td>
<td>A086987 001</td>
</tr>
<tr>
<td>Nexgen Pharma Inc</td>
<td>4mg</td>
<td>A086187 001</td>
</tr>
<tr>
<td>Par Pharm</td>
<td>4mg</td>
<td>A087009 001</td>
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<tr>
<td>Pioneer Pharms</td>
<td>4mg</td>
<td>A088604 001</td>
</tr>
<tr>
<td>Upsher Smith Labs</td>
<td>4mg</td>
<td>A083215 001</td>
</tr>
<tr>
<td>Vitarine</td>
<td>4mg</td>
<td>A083123 001</td>
</tr>
<tr>
<td>Watson Labs</td>
<td>4mg</td>
<td>A085769 001</td>
</tr>
<tr>
<td></td>
<td>12mg</td>
<td>N010799 003</td>
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**Dimetane; Tablet, Extended Release; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wyeth Cons</td>
<td>4mg</td>
<td>A083216 001</td>
</tr>
<tr>
<td>Wyeth Cons</td>
<td>8mg</td>
<td>N010799 010</td>
</tr>
<tr>
<td></td>
<td>12mg</td>
<td>N010799 011</td>
</tr>
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</table>

### BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

**Syrup; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpharma US Pharms</td>
<td>2mg/5ml; 10mg/5ml; 30mg/5ml</td>
<td>A088722 001</td>
</tr>
<tr>
<td>Broomate DM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bromfed-DM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wockhardt</td>
<td>2mg/5ml; 10mg/5ml; 30mg/5ml</td>
<td>A089681 001</td>
</tr>
<tr>
<td>Dimetane-DX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ Robin's AH</td>
<td>2mg/5ml; 10mg/5ml; 30mg/5ml</td>
<td>N019279 001</td>
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</table>

**Tablet, Extended Release; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efidac 24 Pseudoephedrine Hydrochloride/Brompheniramine Maleate Alza</td>
<td>16mg;240mg</td>
<td>N019672 001</td>
</tr>
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</table>

### BUCLIZINE HYDROCHLORIDE

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bucladin-S</td>
<td>50mg</td>
<td>N010911 006</td>
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</table>

### Budesonide

**Aerosol, Metered; Nasal**

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<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td>0.032mg/inh</td>
<td>N020233 001</td>
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<tr>
<td>Powder, Metered; Inhilation</td>
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<tr>
<td>Pulmicort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>0.16mg/inh</td>
<td>N020441 002</td>
</tr>
<tr>
<td></td>
<td>0.32mg/inh</td>
<td>N020441 003</td>
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</table>

### Bumetanide

**Injectable; Injection**

<table>
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<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Athenex Inc</td>
<td>0.25mg/ml</td>
<td>A074441 001</td>
</tr>
<tr>
<td>Hospira</td>
<td>0.25mg/ml</td>
<td>A074160 001</td>
</tr>
<tr>
<td>Teva Parenteral</td>
<td>0.25mg/ml</td>
<td>A074613 001</td>
</tr>
<tr>
<td>Bumex + Validus Pharms</td>
<td>0.25mg/ml</td>
<td>N018226 001</td>
</tr>
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</table>

### Bupivacaine Hydrochloride

**Injectable; Injection**

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<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospira</td>
<td>0.75%</td>
<td>A070587 001</td>
</tr>
<tr>
<td>Bupivacaine Hydrochloride Kit</td>
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<tr>
<td>Hospira</td>
<td>0.075%</td>
<td>N019978 001</td>
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<tr>
<td></td>
<td>0.114%</td>
<td>N019978 002</td>
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<tr>
<td></td>
<td>0.23%</td>
<td>N019978 003</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

<table>
<thead>
<tr>
<th><strong>BUPIVACAINE HYDROCHLORIDE</strong></th>
<th><strong>INJECTABLE; INJECTION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>BUPIVACAINE HYDROCHLORIDE PRESERVATIVE FREE</td>
<td>INTEL MEDICATED</td>
</tr>
<tr>
<td>0.25%</td>
<td>A076012 001 Jan 09, 2002</td>
</tr>
<tr>
<td>0.5%</td>
<td>A076012 002 Jan 09, 2002</td>
</tr>
<tr>
<td>0.75%</td>
<td>A076012 003 Jan 09, 2002</td>
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<tr>
<td>BUPIVACAINE HYDROCHLORIDE</td>
<td>INJECTABLE; SPINAL</td>
</tr>
<tr>
<td>FRESENIUS KABI USA</td>
<td>0.75% A071202 001 Apr 15, 1987</td>
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**BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE**

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<tbody>
<tr>
<td>BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE</td>
</tr>
<tr>
<td>0.25%; 0.005MG/ML</td>
</tr>
<tr>
<td>0.5%; 0.005MG/ML</td>
</tr>
<tr>
<td>0.75%; 0.005MG/ML</td>
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**BUPIVACAINE HYDROCHLORIDE; LIDOCAINE HYDROCHLORIDE**

<table>
<thead>
<tr>
<th><strong>INJECTABLE; INJECTION</strong></th>
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</thead>
<tbody>
<tr>
<td>DUOCaine</td>
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<tr>
<td>AMPHASTAR PHARMS INC</td>
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**BUPRENORPHINE HYDROCHLORIDE**

<table>
<thead>
<tr>
<th><strong>TABLET; SUBLINGUAL</strong></th>
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</thead>
<tbody>
<tr>
<td>SUBUTEX</td>
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<tr>
<td>+ INDIVIOR INC</td>
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<td>+</td>
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**BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE**

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<th><strong>TABLET; SUBLINGUAL</strong></th>
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<tbody>
<tr>
<td>SUBOXONE</td>
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<tr>
<td>+ INDIVIOR INC</td>
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**BUPROPION HYDROCHLORIDE**

<table>
<thead>
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<th><strong>TABLET; ORAL</strong></th>
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</thead>
<tbody>
<tr>
<td>BUPROPION HYDROCHLORIDE</td>
</tr>
<tr>
<td>SANDOZ</td>
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<tr>
<td>75MG</td>
</tr>
<tr>
<td>100MG</td>
</tr>
<tr>
<td>TEVA</td>
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<tr>
<td>75MG</td>
</tr>
<tr>
<td>100MG</td>
</tr>
<tr>
<td>WELLBUTRIN</td>
</tr>
<tr>
<td>+ GLAXOSMITHKLINE</td>
</tr>
<tr>
<td>+</td>
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<tr>
<td>TABLET, EXTENDED RELEASE; ORAL</td>
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<tr>
<td>BUPROPION HYDROCHLORIDE</td>
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<tr>
<td>ACTAVIS LABS PL INC</td>
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<tr>
<td>IMPAX LABS</td>
</tr>
<tr>
<td>SANDOZ</td>
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<tr>
<td>150MG</td>
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<tr>
<td>150MG</td>
</tr>
<tr>
<td>WOCKHARDT LTD</td>
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<tr>
<td>150MG</td>
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<tr>
<td>200MG</td>
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<tr>
<td>WELLBUTRIN SR</td>
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<td>GLAXOSMITHKLINE</td>
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<td>ZYBAN</td>
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<td>GLAXOSMITHKLINE</td>
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**BUSPIRONE HYDROCHLORIDE**

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<tr>
<td>BUSPAR</td>
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<tr>
<td>BRISTOL MYERS SQUIBB</td>
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<td>7.5MG</td>
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<td>10MG</td>
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<tr>
<td>15MG</td>
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<tr>
<td>TABLET; ORAL</td>
</tr>
<tr>
<td>BUSPAR</td>
</tr>
<tr>
<td>+ BRISTOL MYERS SQUIBB</td>
</tr>
<tr>
<td>+</td>
</tr>
</tbody>
</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
BUTABARBITAL SODIUM
TABLET; ORAL
SARISOL NO. 1
HALSEY 15MG A084719 001
SARISOL NO. 2
HALSEY 30MG A084719 002
SODIUM BUTABARBITAL
HIKMA PHARMS 15MG A085418 001
30MG A085432 001
IVAX SUB TEVA PHARMS 15MG A083484 001
30MG A084040 001
LANNETT 15MG A085849 001
30MG A085866 001
100MG A085881 001
MARSHALL PHARMA 16.2MG A083524 001
32.4MG A083858 001

BUTENAFINE HYDROCHLORIDE
CREAM; TOPICAL
MENTAX-TC
MYLAN 1% N021408 001 Oct 17, 2002

BUTOCONAZOLE NITRATE
CREAM; VAGINAL
BUTOCONAZOLE NITRATE
PERRIGO PHARMA INTL 2% N019881 001 Feb 07, 1997
FEMSTAT ROCHE PALO 2% N019215 001 Nov 25, 1985
FEMSTAT 3 + BAYER 2% N020421 001 Dec 21, 1995
SUPPOSITORY; VAGINAL
FEMSTAT ROCHE PALO 100MG N019359 001 Nov 25, 1985

BUTORPHANOL TARTRATE
INJECTABLE; INJECTION
BUTORPHANOL TARTRATE
BAXTER HLTHCARE CORP 2MG/ML A075697 001 Oct 23, 2001
HIKMA FARMACEUTICA 2MG/ML A078247 001 Apr 29, 2009
HOSPIRA 1MG/ML A075342 001 Nov 04, 1999
1MG/ML A075559 001 Mar 20, 2000
2MG/ML A075342 002 Nov 04, 1999
2MG/ML A075559 002 Mar 20, 2000
BUTORPHANOL TARTRATE PRESERVATIVE FREE
BAXTER HLTHCARE CORP 1MG/ML A075695 001 Oct 23, 2001
2MG/ML A075695 002 Oct 23, 2001
HOSPIRA 1MG/ML A074620 001 Jan 22, 1997
1MG/ML A075170 001 Sep 28, 1998
2MG/ML A074620 002 Jan 22, 1997
2MG/ML A075170 002 Sep 28, 1998
STADOL + APOTHECON 2MG/ML ** N017857 004
STADOL PRESERVATIVE FREE + APOTHECON 1MG/ML ** N017857 001
+ 2MG/ML ** N017857 002
SPRAY, METERED; NASAL
STADOL BRISTOL MYERS SQUIBB 1MG/SPRAY ** N019890 001 Dec 12, 1991

CABERGOLINE
TABLET; ORAL
CABERGOLINE
APOTEX CORP 0.5MG A201503 001 Mar 08, 2013
IMPAX LABS INC 0.5MG A077843 001 Jul 03, 2007
DOSTINEX + PHARMACIA AND UPJOHN 0.5MG ** N020664 001 Dec 23, 1996

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

CALCIUM ACETATE
CAPSULE; ORAL
FRESENIUS MEDCL 333.5MG N021160 001 Apr 02, 2001
667MG N021160 002 Apr 02, 2001

TABLET; ORAL
CALCIUM ACETATE
WEST-WARD PHARMS INT 667MG A077693 001 Jan 30, 2008
ELIPHOS 667MG A078502 001 Nov 25, 2008
PHOSLO 667MG ** N019976 001 Dec 10, 1990

CALCIUM CARBONATE; RISEDRONATE SODIUM
TABLET, TABLET; ORAL
ACTONEL WITH CALCIUM (COPACKAGED)

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE**

**INJECTABLE; INJECTION**

**ISOLYTE R IN DEXTROSE 5% IN PLASTIC CONTAINER**
- **B Braun**
  - 37MG/100ML; 5GM/100ML; 31MG/100ML; 120MG/100ML; 88MG/100ML
  - N019864 001
  - Jun 10, 1993

**ISOLYTE R W/ DEXTROSE 5% IN PLASTIC CONTAINER**
- **B Braun**
  - 37MG/100ML; 5GM/100ML; 31MG/100ML; 120MG/100ML; 88MG/100ML
  - N018271 001
  - Jun 10, 1993

**ISOLYTE E IN DEXTROSE 5% IN PLASTIC CONTAINER**
- **B Braun**
  - 35MG/100ML; 5GM/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML
  - N019867 001
  - Dec 20, 1993

**ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER**
- **B Braun**
  - 35MG/100ML; 5GM/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML
  - N018269 002
  - Jan 17, 1983

**ISOLYTE LM AND DEXTROSE 5% IN PLASTIC CONTAINER**
- **Fresenius Medcl**
  - 25.9MG/100ML; 1.5GM/100ML; 51MG/100ML; 7.5MG/100ML; 567MG/100ML; 392MG/100ML
  - N017390 001
  - Aug 26, 1983

**ISOLYTE W/ DEXTROSE 1.5% IN PLASTIC CONTAINER**
- **B Braun**
  - 29MG/100ML; 1.5GM/100ML; 15MG/100ML; 610MG/100ML
  - N018460 001
  - Jan 29, 1986

**ISOLYTE W/ DEXTROSE 4.25% IN PLASTIC CONTAINER**
- **B Braun**
  - 29MG/100ML; 4.25GM/100ML; 15MG/100ML; 610MG/100ML
  - N018460 003
  - Jan 29, 1986

**ISOLYTE W/ DEXTROSE 3% IN PLASTIC CONTAINER**
- **B Braun**
  - 25.7MG/100ML; 3.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 448MG/100ML
  - N018379 002
  - Jun 24, 1988

**ISOLYTE W/ DEXTROSE 1.5% IN PLASTIC CONTAINER**
- **B Braun**
  - 25.7MG/100ML; 1.5GM/100ML; 567MG/100ML; 392MG/100ML
  - N018379 001
  - Jul 07, 1982

**ISOLYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER**
- **B Braun**
  - 25.7MG/100ML; 2.5GM/100ML; 567MG/100ML; 448MG/100ML
  - N018379 005
  - Jul 07, 1982

**ISOLYTE W/ DEXTROSE 3.5% IN PLASTIC CONTAINER**
- **B Braun**
  - 25.7MG/100ML; 3.5GM/100ML; 567MG/100ML; 448MG/100ML
  - N018379 008
  - Jun 24, 1988

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Concentration</th>
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<td><strong>Intraperitoneal Solution</strong></td>
<td><strong>DELFLUX™ LIM w/ DEXTROSE 4.25%</strong></td>
<td>FRESENIUS MEDICAL</td>
<td>25.7MG/100ML, 4.25GM/100ML, 5.08MG/100ML, 538MG/100ML, 448MG/100ML</td>
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<td><strong>INPERSOL™ LC/LM w/ DEXTROSE 1.5%</strong></td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote
**DISCONTINUED DRUG PRODUCT LIST**

**CAPTOPRIL**

**TABLET; ORAL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>WARNER CHILCOTT</td>
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<tr>
<td><strong>TERIL</strong></td>
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<td>TARO</td>
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<tr>
<td><strong>CARBAMAZEPINE</strong></td>
<td><strong>TABLET, CHEWABLE; ORAL</strong></td>
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<tr>
<td>JUBILANT CADISTA</td>
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<td>100MG</td>
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<tr>
<td><strong>ROERIG</strong></td>
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<tr>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### CARBOPLATIN

**INJECTABLE; INJECTION**

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**DISCONTINUED DRUG PRODUCT LIST**

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**INJECTABLE; IV (INFUSION)**

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<td>FRESENIUS KABI USA</td>
<td>50MG/5ML (10MG/ML)</td>
<td>A077247 001</td>
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<td>50MG/5ML (10MG/ML)</td>
<td>A077266 001</td>
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<td>MYLAN LABS LTD</td>
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<td>PHARMACHEMIE BV</td>
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**PARAPLATIN**

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<tr>
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<td>50MG/5ML (10MG/ML)**</td>
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### CARISOPRODOL

**CAPSULE; ORAL**

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**TABLET; ORAL**

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<td>A040421 001</td>
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<td>EPIC PHARMA LLC</td>
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<td>OXFORD PHARMS</td>
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<td>PIONEER PHARMS</td>
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<td>WATSON LABS TEVA</td>
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**CARPHENAZINE MALEATE**

**CONCENTRATE; ORAL**

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**TABLET; ORAL**

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<td>WYETH AYERST</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### CARPROFEN
**Tablet; Oral**
- **Rimadyl**
  - **Roche**
    - 100mg
    - 150mg
      - N018550 002 Dec 31, 1987
      - N018550 003 Dec 31, 1987

### CARTEOLOL HYDROCHLORIDE
**Solution/Drops; Ophthalmic**
- **Carteolol Hydrochloride**
  - **Apotex Inc**
    - 1%
    - A076097 001 Feb 06, 2002
  - **Ocupress**
    - + Novartis 1%**
    - N019972 001 May 23, 1990
  - **Cartrol**
    - **AbbVie**
      - 2.5mg
      - 5mg
      - 10mg
      - N019204 001 Dec 28, 1988
      - N019204 002 Dec 28, 1988
      - N019204 003 Dec 28, 1988

### CARVEDILOL
**Tablet; Oral**
- **Carvedilol**
  - **Hikma**
    - 3.125mg
    - 6.25mg
    - 12.5mg
    - 25mg
    - A077887 001 Sep 07, 2007
    - A077887 002 Sep 07, 2007
    - A077887 003 Sep 07, 2007
  - **Pliva Hrvatska Doo**
    - 3.125mg
    - 6.25mg
    - 12.5mg
    - 25mg
    - A078240 001 Oct 30, 2007
    - A078240 002 Oct 30, 2007
    - A078240 003 Oct 30, 2007
  - **Wockhardt Ltd**
    - 3.125mg
    - 6.25mg
    - 12.5mg
    - 25mg
    - A078786 001 Dec 22, 2009
    - A078786 002 Dec 22, 2009
    - A078786 003 Dec 22, 2009

### CEFACLOR
**Capsule; Oral**
- **Cefaclor**
  - + Lilly
    - EQ 250mg Base **
    - N050522 001
  - EQ 500mg Base **
    - N050522 002

### CEFACLOR
**Suspension; Oral**
- **Cefaclor**
  - + Lilly
    - EQ 125mg Base/5ml **
    - N050522 001
  - EQ 250mg Base/5ml **
    - N050522 002

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

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**Note:** The content of the document is a list of drug products approved or discontinued, along with their manufacturers, formulations, and withdrawal dates. The list includes specific information about each product, such as dosage forms and withdrawal dates, and notes the withdrawal for safety or efficacy reasons in some cases.
**See List Footnote**

## CEFACLOR

**FOR SUSPENSION; ORAL**

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## CEFADROXIL

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**TABLET; ORAL**

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**ULTRACEF**

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**Ultraflox/CEFADROXIL HEMIHYDRATE**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### CEFAZOLIN SODIUM
**INJECTABLE; INJECTION**

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### CEFDINIR
**CAPSULE; ORAL**

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### CEFDITOREN PIVOXIL
**TABLET; ORAL**

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### CEFEPIME HYDROCHLORIDE
**INJECTABLE; INJECTION**

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**FOR SUSPENSION; ORAL**

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**INJECTABLE; INJECTION**

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### CEFONICID SODIUM
**INJECTABLE; INJECTION**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Substitute Name</th>
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<td><strong>CEFIBID</strong></td>
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<td><strong>CEFOTAXIME SODIUM</strong></td>
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<td>Fresenius Kabi USA</td>
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<td>Teligent Pharma Inc.</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Cefotiam Hydrochloride

**Injectable; Injection**

**Ceradon**

Takeda

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<th>Brand Name</th>
<th>Manufacturer</th>
<th>NDC</th>
<th>Date Discontinued</th>
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**See List Footnote**

### Cefoxitin Sodium

**Injectable; Injection**

**Cefoxitin**

ACS Dobfar Spa

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<th>Brand Name</th>
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Fresenius Kabi USA

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**Mefoxin**

Mylan Institutional

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**Mefoxin in Dextrose 5% in Plastic Container**

+ Merck

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**Mefoxin in Sodium Chloride 0.9% in Plastic Container**

+ Merck

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### Cefpiramide Sodium

**Injectable; Injection**

**Cefpiramide Sodium**

Wyeth Ayerst

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### Cefpodoxime Proxetil

**For Suspension; Oral**

**Banan**

Sankyo

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<th>Brand Name</th>
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Cepodoxime Proxetil

Sun Pharm Inds Ltd

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Vantin

+ Pharmacia and Upjohn

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**Tablet; Oral**

**Banan**

Sankyo

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Cepodoxime Proxetil

Sun Pharm Inds Ltd

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Vantin

+ Pharmacia and Upjohn

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### Cefprozil

**For Suspension; Oral**

**Cefprozil**

Ranbaxy Labs Ltd

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**Cefzil**

+ Corden Pharma

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**Tablet; Oral**

**Cefprozil**

Ranbaxy Labs Ltd

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**Cefzil**

+ Corden Pharma

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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## Ceftriaxone Sodium

**Injectable; Injection**

### Hospira Inc
- **EQ 1GM BASE/VIAL**: A065231 001 Aug 02, 2005
- **EQ 1GM BASE/VIAL**: A20563 002 Aug 20, 2012
- **EQ 2GM BASE/VIAL**: A065231 002 Aug 02, 2005
- **EQ 2GM BASE/VIAL**: A20563 002 Aug 20, 2012

### Lupin
- **EQ 10GM BASE/VIAL**: A065263 001 Sep 12, 2006

### Teva
- **EQ 10GM BASE/VIAL**: A065274 001 May 01, 2006

### Rocephin
- **Hoffmann La Roche**:
  - **EQ 250MG BASE/VIAL**: A06339 001 Aug 13, 1993
  - **EQ 500MG BASE/VIAL**: A062654 001 Apr 30, 1987
  - **EQ 500MG BASE/VIAL**: A062654 002 Apr 30, 1987
  - **EQ 1GM BASE/VIAL**: A062654 003 Aug 13, 1993
  - **EQ 2GM BASE/VIAL**: A062654 003 Apr 30, 1987

### Ceftriaxone Sodium; Lidocaine

**Injectable; Injection**

### Hospira Inc
- **EQ 1GM BASE/VIAL**: A065231 001 Aug 02, 2005
- **EQ 1GM BASE/VIAL**: A20563 002 Aug 20, 2012

### Teva
- **EQ 10GM BASE/VIAL**: A065274 001 May 01, 2006

### Rocephin
- **Hoffmann La Roche**:
  - **EQ 500MG BASE/VIAL**: N050585 002 Dec 21, 1984
  - **EQ 1GM BASE/VIAL**: N050585 003 Dec 21, 1984
  - **EQ 2GM BASE/VIAL**: N050585 004 Dec 21, 1984

### Rocephin Kit
- **Hoffmann La Roche**:
  - **EQ 10MG BASE/ML**: N050624 001 Feb 11, 1987
  - **EQ 20MG BASE/ML**: N050624 002 Feb 11, 1987
  - **EQ 40MG BASE/ML**: N050624 003 Feb 11, 1987

### Cefuroxime Axetil

**For Suspension; Oral**

### Cefixin
- **GlaxoSmithKline**:
  - **EQ 125MG BASE/5ML**: N050672 001 Jun 30, 1994
  - **EQ 250MG BASE/5ML**: N050672 002 Apr 29, 1997

### Cefuroxime Axetil

**For Suspension; Oral**

### Sun Pharm Inds Ltd
- **EQ 125MG BASE/5ML**: A06523 001 Feb 05, 2008
- **EQ 250MG BASE/5ML**: A06523 002 Feb 05, 2008

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**DISCONTINUED DRUG PRODUCT LIST**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CETIRIZINE HYDROCHLORIDE
SYRUP; ORAL

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### CHLORAMPHENICOL; PREDNISOLONE

**OINTMENT; OPHTHALMIC**

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### CHLORDIAZEPoxide

**CAPSULE, EXTENDED RELEASE; ORAL LIBRELEASE**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### CHLORDIAZEPoxide Hydrochloride

**Capsule; Oral**

<table>
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<tr>
<th>Brand</th>
<th>Strength</th>
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<th>Date Approved</th>
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<tbody>
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**Injectable; Injection**

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**Chlordiazepoxide; Estrogens, Esterified**

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**Chlorhexidine Gluconate**

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<td>BAJAJ</td>
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<td>MICRODERM</td>
<td>4%</td>
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<td>MATRIX MEDCL</td>
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<td>KENDALL IL</td>
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<td>E-Z SCRUB</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CHLORMERODRIN HG-197
INJECTABLE; INJECTION
CHLORMERODRIN HG 197
BRACCO 0.6-1.4mCi/ML N017269 001

CHLORMEZANONE
TABLET; ORAL
TRANCOPAL
SANOFI AVENTIS US 100MG N011467 003
200MG N011467 005

CHLOROPROCAINE HYDROCHLORIDE
INJECTABLE; INJECTION
NESACAINE-MPF
FRESENIUS KABI USA 2% N0009435 003
3% N0009435 004

CHLOROQUINE HYDROCHLORIDE
INJECTABLE; INJECTION
ARALEN HYDROCHLORIDE
SANOFI AVENTIS US EQ 40MG BASE/ML N006002 002

CHLOROQUINE PHOSPHATE
TABLET; ORAL
ARALEN
+ SANOFI AVENTIS US EQ 300MG BASE N006002 001
CHLOROQUINE PHOSPHATE
IMPA F LABS EQ 150MG BASE A080880 001
MD PHARM EQ 300MG BASE A040516 001 Aug 29, 2003
PUREPAC PHARM EQ 150MG BASE A080886 001
TEVA EQ 150MG BASE A087504 001 Jan 13, 1982
WATSON LABS EQ 150MG BASE A087979 001 Dec 21, 1982
EQ 300MG BASE A088030 001 Dec 21, 1982

CHLOROQUINE PHOSPHATE; PRIMAQUINE PHOSPHATE
TABLET; ORAL
ARALEN PHOSPHATE W/ PRIMAQUINE PHOSPHATE
SANOFI AVENTIS US EQ 300MG BASE; EQ 45MG BASE N014860 002

CHLOROTHIAZIDE
TABLET; ORAL
CHLOROTHIAZIDE
ABC HOLDING 250MG A085569 001
HIKMA INTL PHARMS 250MG A086028 001 Jul 14, 1982
500MG A087736 001 Jul 14, 1982
LED ERLE 250MG A086940 001
500MG A086938 001
SANDOZ 250MG A085485 001
WATSON LABS 250MG A085165 001
250MG A085173 001
250MG A086795 001 Aug 15, 1983
500MG A084026 001 Sep 01, 1982
500MG A086796 001 Aug 15, 1983
DIURIL
+ OAK PHARMS AKORN 250MG ** N011145 004
+ 500MG ** N011145 002

CHLOROTHIAZIDE; METHYLDOPA
TABLET; ORAL
ALDOCLOR-150
MERCK 150MG; 250MG N016016 001
ALDOCLOR-250
MERCK 250MG; 250MG N016016 002
METHYLDOPA AND CHLOROTHIAZIDE
P AR PHARM 150MG; 250MG A070783 001 Nov 06, 1987
250MG; 250MG A070654 001 Nov 06, 1987

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Manufacturer</th>
<th>API Dosage</th>
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<td>MYLAN</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

---

**DISCONTINUED DRUG PRODUCT LIST**

---

**CHLOROTHIAZIDE AND RESERPINE**

- **TABLET; ORAL**
  - HIKMA PHARMS: 250MG; 0.125MG (A088557 001 Dec 22, 1983), 500MG; 0.125MG (A088365 001 Dec 22, 1983)
  - WATSON LABS: 250MG; 0.125MG (A084853 001), 500MG; 0.125MG (A088151 001 Jun 09, 1983)
  - MYLAN: 250MG; 0.125MG (A087744 001 May 06, 1982), 500MG; 0.125MG (A088745 001 May 06, 1982)
  - MERCK: 250MG; 0.125MG (N011635 003 Aug 26, 1987), 500MG; 0.125MG (N011635 006 Aug 26, 1987)
  - Other manufacturers and NDC codes listed.

---

**CHLOROTHIAZIDE AND RESERPINE**

- **TABLET; ORAL**
  - WATSON LABS: 250MG; 0.125MG (A084853 001), 500MG; 0.125MG (A088151 001)
  - MYLAN: 250MG; 0.125MG (A087744 001), 500MG; 0.125MG (A088745 001)
  - MERCK: 250MG; 0.125MG (N011635 003), 500MG; 0.125MG (N011635 006)
  - Other manufacturers and NDC codes listed.

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**CHLOROTRIANISENE**

- **CAPSULE; ORAL**
  - BANNER PHARMACAPS: 12MG (A084652 001)
  - TACE: 12MG (N008102 004), 25MG (N011444 001), 72MG (N016235 001)

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**CHLOROXINE**

- **SHAMPOO; TOPICAL**
  - CAPITROL: 2% (N017594 001)

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**CHLORPHENESIN CARBAMATE**

- **TABLET; ORAL**
  - MAOLATE: 400MG (N014217 002)

---

**CHLORPHENIRAMINE MALEATE**

- **CAPSULE, EXTENDED RELEASE; ORAL**
  - AUROLIFE PHARMA LLC: 12MG (A070797 001 Aug 12, 1988)
  - TELDRIN: 8MG (N017369 001), 12MG (N017369 002)

---

**INJECTABLE; INJECTION**

- **CHLOR-TRIMETON**
  - SCHERING PLOUGH: 10MG/ML (N008826 001), 100MG/ML (N008794 001)
  - BEL MAR: 10MG/ML (A080821 001)
  - ELKINS SINN: 10MG/ML (A080797 001)
  - WATSON LABS: 10MG/ML (A083593 001), 100MG/ML (A086096 001), 100MG/ML (A086095 001)
  - IVAX SUB TEVA PHARMS: 4MG (A083078 001)

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**PYRIDAMAL 100**

- **Syrup; Oral**
  - CHLOR-TRIMETON: 100MG/ML (A083733 001)

---

**TABLET; ORAL**

- **ANTAGONATE**
  - BAYER PHARMAS: 4MG (A083381 001)
  - CHLOR-TRIMETON: 4MG (N006921 002)
  - SCHERING: 4MG (N006921 002)
  - CHLORPHENIRAMINE MALEATE: 4MG (A083078 001), 4MG (A080961 001), 4MG (A083062 001), 4MG (A080938 001), 4MG (A080809 001), 4MG (A080779 001)

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**CHLORPHENIRAMINE MALEATE**

- **Syrup; Oral**
  - CHLOR-TRIMETON: 2MG/5ML (N006921 006)
  - SCHERING PHARM ASSOC: 2MG/5ML (A087520 001 Feb 10, 1982)
  - BEL MAR: 10MG/ML (A083733 001)

---

**CHLORPHENIRAMINE MALEATE**

- **Syrup; Oral**
  - IVAX SUB TEVA PHARMS: 4MG (A083078 001), 4MG (A080961 001), 4MG (A083062 001), 4MG (A080938 001), 4MG (A080809 001), 4MG (A080779 001)
**CHLORPHENIRAMINE MALEATE**

**TABLET; ORAL**

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<td>LEBERLE</td>
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<td>NEWTRON PHARMS</td>
<td>4MG</td>
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<td>PANRAY</td>
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<td>PHARMERAL</td>
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**NEWTRON PHARMS 4MG A086519 001**

**PHARMERAL 4MG A083753 001**

**PIONEER PHARMS 4MG A088556 001**

**ROXANE 4MG A080626 001**

**SUN PHARM INDUSTRIES 4MG A080700 001**

**WATSON LABS 4MG A080696 001**

**WEST WARD 4MG A080791 001**

**HALSEY 4MG A083629 001**

**PHENERON 4MG A080846 001**

**TABLET, EXTENDED RELEASE; ORAL**

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**CHLORPHENIRAMINE MALEATE; HYDROCODEONE BITARTRATE**

**SOLUTION; ORAL**

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<td>TRIS PHARMA INC</td>
<td>4MG/5ML;5MG/5ML</td>
<td>A206438 001</td>
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**CHLORPHENIRAMINE MALEATE; HYDROCODEONE BITARTRATE, PSEUODOEPHEDRINE HYDROCHLORIDE**

**SOLUTION; ORAL**

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<th>Company</th>
<th>NDC Number</th>
<th>Lot Number</th>
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<td>TRIS PHARMA INC</td>
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**CHLORPHENIRAMINE MALEATE; PSEUODOEPHEDRINE HYDROCHLORIDE**

**CAPSULE, EXTENDED RELEASE; ORAL**

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<th>Lot Number</th>
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<tbody>
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<td>COLD CAPSULE IV</td>
<td>12MG;75MG</td>
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<tr>
<td>COLD CAPSULE V</td>
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**TABLET, EXTENDED RELEASE; ORAL**

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**CHLORPHENIRAMINE MALEATE; PSEUODOEPHEDRINE SULFATE**

**TABLET, EXTENDED RELEASE; ORAL**

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<td>N018935 001</td>
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<tr>
<td>ISOCOLOR</td>
<td>8MG;120MG</td>
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**PSEUODOEPHEDRINE HYDROCHLORIDE AND CHLORPHENIRAMINE MALEATE**

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**CHLORPHENIRAMINE MALEATE; PSEUODOEPHEDRINE SULFATE**

**TABLET, EXTENDED RELEASE; ORAL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
# 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

## DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

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** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### CHLORTHALIDONE

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### CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE

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<tr>
<td>DEMI-REGROTON</td>
<td>25MG;0.125MG</td>
<td>A05103</td>
<td>002</td>
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<td>REGROTON</td>
<td>50MG;0.25MG</td>
<td>A05103</td>
<td>001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**CHLORZOXAZONE**

**TABLET; ORAL**

<table>
<thead>
<tr>
<th>Chlorzoxazone</th>
<th>Tablet</th>
<th>Oral</th>
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</thead>
<tbody>
<tr>
<td>Actavis Elizabeth</td>
<td>250MG</td>
<td>A088928 001 May 08, 1987</td>
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<td></td>
<td>500MG</td>
<td>A040113 001 Sep 29, 1995</td>
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<tr>
<td>Aurolife Pharma LLC</td>
<td>250MG</td>
<td>A089852 001 May 04, 1988</td>
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<td>500MG</td>
<td>A089853 001 May 04, 1988</td>
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<td>Barr</td>
<td>500MG</td>
<td>A089895 001 May 04, 1988</td>
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<td>Ohm Labs</td>
<td>250MG</td>
<td>A081298 001 Dec 29, 1993</td>
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<td>500MG</td>
<td>A081299 001 Dec 29, 1993</td>
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<td>Par Pharm</td>
<td>250MG</td>
<td>A087981 001 Sep 20, 1983</td>
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<td>Pioneer Pharmas</td>
<td>250MG</td>
<td>A089592 001 Jan 06, 1989</td>
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<td>500MG</td>
<td>A089948 001 Jan 06, 1989</td>
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<tr>
<td>Sun Pharm Industries</td>
<td>500MG</td>
<td>A089970 001 Sep 27, 1990</td>
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<td>Watson Labs</td>
<td>250MG</td>
<td>A086901 001 Aug 09, 1982</td>
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<td>250MG</td>
<td>A086948 001 Aug 09, 1996</td>
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<td>500MG</td>
<td>A081019 001 Jul 29, 1991</td>
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<td>500MG</td>
<td>A081040 001 Aug 22, 1989</td>
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<tr>
<td>Paraflex</td>
<td>+ Ortho McNeil Pharm 250MG **</td>
<td>N011300 003</td>
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<tr>
<td>Parafon Forte DSC</td>
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<tr>
<td>+ Janssen R and D 500MG **</td>
<td>N011529 002 Jun 15, 1987</td>
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<tr>
<td>Strifon Forte DSC</td>
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<td>Ferndale Labs</td>
<td>500MG</td>
<td>A081008 001 Dec 23, 1988</td>
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**CHOLESTYRAMINE**

**BAR, CHEWABLE; ORAL**

<table>
<thead>
<tr>
<th>Cholestyramine</th>
<th>Bar, Chewable</th>
<th>Oral</th>
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</thead>
<tbody>
<tr>
<td>Parke Davis</td>
<td>EQ 4GM RESIN/BAR</td>
<td>A071621 001 May 26, 1988</td>
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<td>EQ 4GM RESIN/BAR</td>
<td>A071739 001 May 26, 1988</td>
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**POWDER; ORAL**

<table>
<thead>
<tr>
<th>Cholestyramine</th>
<th>Powder</th>
<th>Oral</th>
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<tr>
<td>Ivax Sub Teva Pharmas</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074771 001 Jul 09, 1997</td>
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<tr>
<td>Teva</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074347 001 May 28, 1998</td>
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<td>Cholestyramine Light</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074347 002 May 28, 1998</td>
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<td>Teva</td>
<td>EQ 4GM RESIN/PACKET</td>
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<td>Teva Pharmas</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074555 001 Sep 30, 1998</td>
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<td>EQ 4GM RESIN/PACKET</td>
<td>A074555 002 Sep 30, 1998</td>
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<tr>
<td>Locholest</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074561 001 Aug 15, 1996</td>
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<tr>
<td>Sandoz</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074561 002 Aug 15, 1996</td>
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<td>Locholest Light</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074562 001 Aug 15, 1996</td>
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<td>Sandoz</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074562 002 Aug 15, 1996</td>
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<tr>
<td>Questran</td>
<td>EQ 4GM RESIN/PACKET</td>
<td>A074560 001 Aug 15, 1996</td>
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<tr>
<td>+ Bristol Myers</td>
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<td>Questran Light</td>
<td>EQ 4GM RESIN/PACKET **</td>
<td>N019669 001 Dec 05, 1988</td>
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<td>+ Bristol Myers</td>
<td>EQ 4GM RESIN/PACKET **</td>
<td>N019669 003 Dec 05, 1988</td>
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<td>TABLET; ORAL</td>
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<tr>
<td>Questran</td>
<td>APOTHECON</td>
<td>EQ 800MG RESIN</td>
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<td>A073403 002 Dec 27, 1999</td>
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<tr>
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<td>EQ 1GM RESIN</td>
<td>A073403 001 Apr 28, 1994</td>
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**CHORIOGONADOTROPIN ALFA**

**INJECTABLE; INJECTION**

<table>
<thead>
<tr>
<th>Chorionic Gondotropin Alpha</th>
<th>Injectable</th>
<th>Injection</th>
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<tbody>
<tr>
<td>Ovidrel</td>
<td>EMD Serono</td>
<td>0.25MG/VIAL</td>
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**CHROMIC CHLORIDE**

**INJECTABLE; INJECTION**

<table>
<thead>
<tr>
<th>Chromic Chloride</th>
<th>Injectable</th>
<th>Injection</th>
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<tbody>
<tr>
<td>Abraxis Pharm</td>
<td>EQ 0.004MG CHROMIUM/ML</td>
<td>N019271 001 May 05, 1987</td>
</tr>
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</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CHROMIC PHOSPHATE P-32
INJECTABLE; INJECTION
PHOSPHOCOL P32
MALLINKRODT NUCLEAR 5mCi/ML
N017084 001

CHYMOPAPAIN
INJECTABLE; INJECTION
CHYMODIACTIN
CHART MEDCL 4,000 UNITS/VIAL
+ 10,000 UNITS/VIAL **
DISCASE
ABBOTT 12,500 UNITS/VIAL
N018633 002 Aug 21, 1984
N018633 001 Nov 10, 1982

CHYMOTRYPSIN
FOR SOLUTION; OPTHALMIC
ALPHA CHYMAR
SOLA BARNES HIND 750 UNITS/VIAL
N011837 001
CATARASE
CIBA 300 UNITS/VIAL
N016938 001
NOVARTIS 150 UNITS/VIAL
N018121 001
ZOLYSE
ALCON 750 UNITS/VIAL
N011903 001

CICLOPIROX
SOLUTION; TOPICAL
CICLOPIROX
MYLAN PHARMS INC 8%
A078567 001 Sep 18, 2007
TEVA PHARMS 8%
A078079 001 Sep 18, 2007

CIDOPORIN
INJECTABLE; INJECTION
VISTIDE
+ GILEAD SCIENCES INC EQ 75MG BASE/ML **
N020638 001 Jun 26, 1996

CILASTATIN SODIUM; IMIPENEM
INJECTABLE; INJECTION
PRIMAXIN
MERCK EQ 250MG BASE/VIAL; 250MG/VIAL
A062756 001 Jan 08, 1987
EQ 500MG BASE/VIAL; 500MG/VIAL
A062756 002 Jan 08, 1987
POWDER; INTRAMUSCULAR
PRIMAXIN
MERCK EQ 500MG BASE/VIAL; 500MG/VIAL
N050630 001 Dec 14, 1990
EQ 750MG BASE/VIAL; 750MG/VIAL
N050630 002 Dec 14, 1990
POWDER; INTRAVENOUS
IMIPENEM AND CILASTATIN
HOSPIRA INC EQ 250MG BASE/VIAL; 250MG/VIAL
A090825 001 Nov 16, 2011
PRIMAXIN
+ MERCK EQ 250MG BASE/VIAL; 250MG/VIAL
N050587 001 Nov 26, 1985

CILOSTAZOL
TABLET; ORAL
CILOSTAZOL
ACTAVIS ELIZABETH 100MG
A077028 002 Nov 26, 2004
EPIC PHARMA LLC 50MG
A077150 001 Mar 11, 2005
100MG
A077022 001 Nov 23, 2004
IVAX SUB TEVA PHARMS 100MG
A077020 002 Mar 01, 2005
MYLAN 50MG
A077323 002 Apr 20, 2006
100MG
A077323 001 Apr 20, 2006
MYLAN PHARMS INC 50MG
A077019 001 Nov 23, 2004
100MG
A077019 002 Nov 23, 2004
PLIVA HRVATSKA DOO 50MG
A077898 001 Oct 29, 2007
100MG
A077898 002 Oct 29, 2007
PLETAL
+ OTSUKA 50MG **
N020863 001 Jan 15, 1999
+ 100MG **
N020863 002 Jan 15, 1999

CIMETIDINE
SUSPENSION; ORAL
TAGAMET HB 200
GLAXOSMITHKLINE 200MG/20ML
N020951 001 Jul 09, 1999

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote
CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HYDROCHLORIDE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
HOSPIRA

| EQ | BASE/ML | A074269 | 001 | Dec 27, 1994 |
| EQ | 6MG | 90MG/100ML | A074468 | 005 | Dec 29, 1994 |
| EQ | 120MG/100ML | A074468 | 006 | Dec 29, 1994 |
| EQ | 180MG/100ML | A074468 | 003 | Dec 29, 1994 |
| EQ | 240MG/100ML | A074468 | 004 | Dec 29, 1994 |
| EQ | 360MG/100ML | A074468 | 001 | Dec 29, 1994 |
| EQ | 480MG/100ML | A074468 | 002 | Dec 29, 1994 |

TAGAMET

GLAXOSMITHKLINE

| EQ | BASE/2ML | N017939 | 002 |

TAGAMET HYDROCHLORIDE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| + | GLAXOSMITHKLINE | EQ | BASE/ML | N019434 | 001 | Oct 31, 1985 |

SOLUTION; ORAL
CIMETIDINE HYDROCHLORIDE

ANI PHARMS INC

| EQ | BASE/5ML | A074859 | 001 | Jul 09, 1998 |
| EQ | 300MG | 300MG/5ML | A075110 | 001 | Jun 18, 1998 |
| G AND W LABS INC | 300MG/5ML | A074541 | 001 | Aug 05, 1997 |
| LANNETT CO INC | 300MG/5ML | A074251 | 001 | Dec 22, 1994 |

CYCLE PHARMS LTD

| EQ | BASE/5ML | A074176 | 001 | Jun 01, 1994 |

CIPROFLOXACIN

INJECTABLE; INJECTION
CIPRO

| + | BAYER HLTHCARE | 400MG/40ML (10MG/ML) | N019847 | 001 | Dec 26, 1990 |
| + | BAYER HLTHCARE | 200MG/20ML (10MG/ML) | N019847 | 002 | Dec 26, 1990 |
| | 1200MG/120ML (10MG/ML) | N019847 | 003 | Dec 26, 1990 |

CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINER

| + | BAYER HLTHCARE | 200MG/100ML | N019857 | 001 | Dec 26, 1990 |
| + | BAYER HLTHCARE | 400MG/200ML | N019857 | 002 | Dec 26, 1990 |

CIPRO IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

BAYER PHARMS

| 200MG/100ML | A078558 | 001 | Dec 26, 1990 |

CIPROFLOXACIN

BEDFORD LABS

| 200MG/20ML (10MG/ML) | A076992 | 001 | Aug 28, 2006 |
| 400MG/40ML (10MG/ML) | A076992 | 002 | Aug 28, 2006 |
| 1200MG/120ML (10MG/ML) | A076993 | 001 | Aug 28, 2006 |
| FRESENIUS KABI USA | 200MG/20ML (10MG/ML) | A076484 | 001 | Aug 28, 2006 |
| 400MG/40ML (10MG/ML) | A076484 | 002 | Aug 28, 2006 |
| TEVA PHARMS USA | 200MG/20ML (10MG/ML) | A077782 | 001 | Aug 28, 2006 |
| 400MG/40ML (10MG/ML) | A077782 | 002 | Aug 28, 2006 |

CIPROFLOXACIN IN DEXTROSE 5%

HIKMA FARMACEUTICA

| 200MG/100ML | A076757 | 001 | Apr 21, 2008 |

CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

BAXTER HLTHCARE

| 200MG/100ML | A077888 | 001 | Mar 18, 2008 |
| 400MG/200ML | A077888 | 002 | Mar 18, 2008 |
| BEDFORD | 200MG/100ML | A078114 | 001 | Mar 18, 2008 |
| 400MG/200ML | A078114 | 002 | Mar 18, 2008 |
| TEVA PHARMS | 200MG/100ML | A077138 | 001 | Mar 18, 2008 |
| 400MG/200ML | A077138 | 002 | Mar 18, 2008 |

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION; DROPS; OPHTHALMIC

AMRING PHARMS

| EQ | BASE | A078598 | 001 | Jan 16, 2008 |

APOTEX INC

| EQ | BASE | A075928 | 001 | Jun 09, 2004 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CIPROFLOXACIN HYDROCHLORIDE
TABLET; ORAL

CIPRO
* BAYER HLTHCARE
  EQ 100MG BASE
  N019537 001 Apr 08, 1996
+ EQ 750MG BASE
  N019537 004 Oct 22, 1987

CIPROFLOXACIN HYDROCHLORIDE
ANI PHARMS INC
EQ 100MG BASE
A075399 001 Mar 03, 2005
EQ 250MG BASE
A075399 002 Jun 09, 2004
EQ 500MG BASE
A075399 003 Jun 09, 2004
EQ 750MG BASE
A075399 004 Jun 09, 2004

BARR
EQ 250MG BASE
A074124 001 Jun 09, 2004
EQ 500MG BASE
A074124 002 Jun 09, 2004
EQ 750MG BASE
A074124 003 Jun 09, 2004

FOSUN PHARMA
EQ 250MG BASE
A076593 002 Jun 09, 2004
EQ 500MG BASE
A076593 003 Jun 09, 2004

MYLAN
EQ 100MG BASE
A075817 001 Jun 25, 2007
EQ 250MG BASE
A075817 002 Jun 09, 2004
EQ 500MG BASE
A075817 003 Jun 09, 2004
EQ 750MG BASE
A075817 004 Jun 09, 2004

NOSTRUM LABS
EQ 250MG BASE
A076136 001 Jun 09, 2004
EQ 500MG BASE
A076136 002 Jun 09, 2004

PLIVA
EQ 100MG BASE
A076426 001 Jun 15, 2005
EQ 250MG BASE
A076426 002 Jun 15, 2005
EQ 500MG BASE
A076426 003 Jun 15, 2005
EQ 750MG BASE
A076426 004 Jun 15, 2005

SUN PHARM INDUS LTD
EQ 250MG BASE
A075747 001 Jun 09, 2004
EQ 500MG BASE
A075747 002 Jun 09, 2004

TEVA
EQ 250MG BASE
A076136 001 Jun 09, 2004
EQ 500MG BASE
A076136 002 Jun 09, 2004
EQ 750MG BASE
A076136 003 Jun 09, 2004

TABLET, EXTENDED RELEASE; ORAL

PROQUIN XR
DEPOMED INC
EQ 500MG BASE
N021744 001 May 19, 2005

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE
TABLET, EXTENDED RELEASE; ORAL

CIPRO XR
BAYER HLTHCARE
212.6MG; EQ 287.5MG BASE **
N021473 001 Dec 13, 2002
425.2MG; EQ 574.9MG BASE **
N021473 002 Aug 28, 2003

CIPROFLOXACIN EXTENDED RELEASE
ACTAVIS LABS FL INC
212.6MG; EQ 287.5MG BASE
A077417 001 Nov 30, 2010
425.2MG; EQ 574.9MG BASE
A077809 001 Nov 30, 2010

DR REDDYS LABS LTD
212.6MG; EQ 287.5MG BASE
A077701 002 Oct 31, 2007

FOSUN PHARMA
212.6MG; EQ 287.5MG BASE
A078712 001 Dec 11, 2007

CISAPRIDE MONOHYDRATE
SUSPENSION; ORAL

PROPEL
JANSSEN PHARMAS
EQ 1MG BASE/ML
N020398 001 Sep 15, 1995

TABLET; ORAL

PROPEL
JANSSEN PHARMS
EQ 10MG BASE
N020210 001 Jul 29, 1993
EQ 20MG BASE
N020210 002 Dec 23, 1993

TABLET, ORALLY DISINTEGRATING; ORAL

PROPEL QUICKSOLVE
JANSSEN PHARMA
EQ 20MG BASE
N020767 001 Nov 07, 1997

CISATRACURUM BESYLYATE INJECTABLE; INJECTION
CISATRACURUM BESYLYATE
HOSPIRA INC
EQ 2MG BASE/ML
A203236 001 Mar 30, 2018
EQ 2MG BASE/ML
A203236 002 Mar 30, 2018
EQ 10MG BASE/ML
A203236 002 Mar 30, 2018

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CISPLATIN

INJECTABLE; INJECTION

CISPLATIN

BEDFORD

10MG/VIAL A074713 001 Nov 14, 2000

50MG/VIAL A074713 002 Nov 14, 2000

TEVA PHARMS USA

1MG/ML A074814 001 May 16, 2000

PLATINOL

+ HQ SPCLT PHARMA 10MG/VIAL N018057 001

+ 50MG/VIAL N018057 002

PLATINOL-HQ

+ HQ SPCLT PHARMA 0.5MG/ML N018057 003 Jul 18, 1984

CITALOPRAM HYDROBROMIDE

CAPSULE; ORAL

CITALOPRAM HYDROBROMIDE

MYLAN PHARMS INC

EQ 10MG BASE A077668 001 Feb 28, 2007

EQ 20MG BASE A077668 002 Feb 28, 2007

EQ 40MG BASE A077668 003 Feb 28, 2007

SOLUTION; ORAL

CELEXA

+ FOREST LABS Eq 10MG BASE/5ML ** N021046 001 Dec 22, 1999

CITALOPRAM HYDROBROMIDE

APOTEX INC Eq 10MG BASE/5ML A077601 001 Nov 15, 2005

TABLET; ORAL

CELEXA

ALLERGAN SALES LLC Eq 60MG BASE N020822 004 Jul 17, 1998

CITALOPRAM HYDROBROMIDE

ACTAVIS ELIZABETH

EQ 10MG BASE A077033 001 Oct 28, 2004

EQ 20MG BASE A077033 002 Oct 28, 2004

EQ 40MG BASE A077033 003 Oct 28, 2004

EPIC PHARMA LLC

EQ 10MG BASE A077036 001 Oct 28, 2004

EQ 20MG BASE A077036 002 Oct 28, 2004

EQ 40MG BASE A077036 003 Oct 28, 2004

FOSUN PHARMA

EQ 10MG BASE A077035 001 Oct 28, 2004

EQ 10MG BASE A077040 001 Aug 17, 2005

EQ 20MG BASE A077035 002 Oct 28, 2004

EQ 20MG BASE A077040 002 Aug 17, 2005

EQ 40MG BASE A077035 003 Oct 28, 2004

EQ 40MG BASE A077040 003 Aug 17, 2005

MYLAN

EQ 10MG BASE A077039 001 Feb 03, 2005

EQ 20MG BASE A077039 002 Feb 03, 2005

EQ 40MG BASE A077039 003 Feb 03, 2005

MYLAN PHARMS INC

EQ 10MG BASE A077037 001 Nov 05, 2004

EQ 20MG BASE A077037 002 Nov 05, 2004

EQ 40MG BASE A077037 003 Nov 05, 2004

NATCO PHARMA LTD

EQ 20MG BASE A077141 002 Apr 10, 2008

EQ 40MG BASE A077141 002 Apr 10, 2008

ROXANE

EQ 10MG BASE A077041 001 Nov 23, 2004

EQ 20MG BASE A077041 002 Nov 23, 2004

EQ 40MG BASE A077041 003 Nov 23, 2004

SUN PHARM INDUSTRIES

EQ 10MG BASE A077052 001 Jul 03, 2006

EQ 20MG BASE A077052 002 Jul 03, 2006

EQ 40MG BASE A077052 003 Jul 03, 2006

TARO

EQ 10MG BASE A077213 001 Mar 31, 2006

EQ 20MG BASE A077213 002 Mar 31, 2006

TEVA PHARMS

EQ 10MG BASE A077213 003 Mar 31, 2006

EQ 20MG BASE A077213 003 Mar 31, 2006

EQ 40MG BASE A077213 003 Mar 31, 2006

WATSON LABS

EQ 10MG BASE A077034 001 Jun 30, 2005

EQ 20MG BASE A077034 002 Jun 30, 2005

EQ 40MG BASE A077034 003 Jun 30, 2005

TABLET, ORALLY DISINTEGRATING; ORAL

CITALOPRAM HYDROBROMIDE

BIOVAIL LABS INTL

EQ 10MG BASE N021763 001 Dec 20, 2005

EQ 20MG BASE N021763 002 Dec 20, 2005

EQ 40MG BASE N021763 003 Dec 20, 2005

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CLEVIDIPINE
EMULSION; INTRAVENOUS
CLEVIPREX
CHIESI USA INC
125MG/250ML (0.5MG/ML)
N022156 003 Nov 08, 2013

CLIDINIUM BROMIDE
CAPSULE; ORAL
ROCHE
2.5MG
N010355 001
5MG
N010355 002

CLINDAMYCIN HYDROCHLORIDE
CAPSULE; ORAL
CLEOCIN
PHARMACIA AND UPJOHN
EQ 75MG BASE
A061809 001
EQ 150MG BASE
A061809 002

CLINDAMYCIN HYDROCHLORIDE
FOR SOLUTION; ORAL
CLEOCIN
ABRAXIS PHARM
EQ 75MG BASE/ML
A061827 001

CLINDAMYCIN HYDROCHLORIDE
INJECTABLE; INJECTION
CLEOCIN
PHARMACIA AND UPJOHN
EQ 75MG BASE/5ML
A061827 001

CLINDAMYCIN PALMITATE HYDROCHLORIDE
CREAM; VAGINAL
CLEOCIN
PHARMACIA AND UPJOHN
EQ 2% BASE
N050680 001 Aug 11, 1992

CLINDAMYCIN PHOSPHATE
CREAM; VAGINAL
CLEOCIN
PHARMACIA AND UPJOHN
EQ 2% BASE
N050680 001 Aug 11, 1992

CLINDAMYCIN PHOSPHATE
FOR SOLUTION; ORAL
CLEOCIN
PHARMACIA AND UPJOHN
EQ 75MG BASE/5ML
A061827 001

CLINDAMYCIN PHOSPHATE
INJECTABLE; INJECTION
CLEOCIN
PHARMACIA AND UPJOHN
EQ 150MG BASE/ML
A061839 001

CLINDAMYCIN PHOSPHATE
IN DEXTROSE 5%
CLEOCIN T
PHARMACIA AND UPJOHN
EQ 1% BASE
A062363 001 Feb 08, 1982

CLINDAMYCIN PHOSPHATE
IN DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABS
EQ 6MG BASE/ML
N050636 001 Dec 22, 1989
EQ 12MG BASE/ML
N050636 002 Dec 22, 1989

BAXTER HLTHCARE
EQ 18MG BASE/ML
N050648 001 Dec 29, 1989
EQ 12MG BASE/ML
N050648 002 Dec 29, 1989

NOVAST LABS
EQ 6MG BASE/ML
N050648 001 Dec 29, 1989
EQ 12MG BASE/ML
N050648 002 Dec 29, 1989

WOCKHARDT BIO AG
EQ 900MG BASE/100ML
N050648 003 Dec 29, 1989

SOLUTION; TOPICAL
CLEOCIN T
PHARMACIA AND UPJOHN
EQ 1% BASE
A062363 001 Feb 08, 1982

CLINDAMYCIN PHOSPHATE
ABRAXIS PHARM
EQ 12MG BASE/ML
A050636 001 Dec 22, 1989

CLINDAMYCIN PHOSPHATE IN DEXTROSE 5%
ABBOTT LABS
EQ 6MG BASE/ML
N050636 001 Dec 22, 1989
EQ 12MG BASE/ML
N050636 002 Dec 22, 1989

BAXTER HLTHCARE
EQ 6MG BASE/ML
N050648 001 Dec 29, 1989
EQ 12MG BASE/ML
N050648 002 Dec 29, 1989

NOVAST LABS
EQ 6MG BASE/ML
N050648 001 Dec 29, 1989
EQ 12MG BASE/ML
N050648 002 Dec 29, 1989

WOCKHARDT BIO AG
EQ 900MG BASE/100ML
N050648 003 Dec 29, 1989

SOLUTION; TOPICAL
**CLIOQUINOL; NYSTATIN**
OINTMENT; TOPICAL
NYSTAFORM
BAYER PHARMS
10MG/GM; 100,000 UNITS/GM

**CLOBAZAM**
TABLET; ORAL
ONFI
LUNDBECK PHARMS LLC
5MG

**CLOBETASOL PROPIONATE**
CREAM; TOPICAL
CLOBETASOL PROPIONATE
TEVA PHARMS USA
0.05%

CLOBETASOL PROPIONATE (EMOLLIENT)
NOVAST LABS
0.05%

TEMOVATE
+ FOUGERA PHARMS
0.05% **

TEMOVATE E
+ FOUGERA PHARMS
0.05% **

GEL; TOPICAL
TEMOVATE
+ FOUGERA PHARMS
0.05% **

OINTMENT; TOPICAL
CLOBETASOL PROPIONATE
ACTAVIS MID ATLANTIC
0.05%

TEMOVATE
+ FOUGERA PHARMS
0.05% **

SOLUTION; TOPICAL
TEMOVATE
+ FOUGERA PHARMS
0.05% **

SPRAY; TOPICAL
CLOBETASOL PROPIONATE
APOTEX INC
0.05%

**CLOPAZIMINE**
CAPSULE; ORAL
LAMPRENE
+ NOVARTIS
50MG

100MG

**CLOFIBRATE**
CAPSULE; ORAL
ATROMID-S
WYETH AYERST
500MG

CLOPHEPHENE CITRATE
TABLET; ORAL
CLOMID
+ SANOFI AVENTIS US
50MG

MILOPHENE
MILEX
50MG

SEROPHENE
EMD SERONO
50MG

**CLOMIPRAMINE HYDROCHLORIDE**
CAPSULE; ORAL
CLOMIPRAMINE HYDROCHLORIDE
TEVA
25MG

50MG

75MG

WATSON LABS
25MG

25MG

50MG

75MG

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CLOMIPRAMINE HYDROCHLORIDE
CAPSULE; ORAL
CLOMIPRAMINE HYDROCHLORIDE
75MG

CLONAZEPAM
TABLET; ORAL
CLONAZEPAM
APOTEX INC
0.5MG
1MG
2MG
MYLAN PHARMS INC
0.5MG
1MG
2MG
SANDOZ
0.5MG
1MG
2MG
TEVA
0.5MG
1MG
2MG

KLONOPIN
TABLET, ORALLY DISINTEGRATING; ORAL
KLONOPIN RAPIDLY DISINTEGRATING
+ ROCHE
0.125MG **
0.25MG **

CLONIDINE
SUSPENSION, EXTENDED RELEASE; ORAL
CLONIDINE
TRIS PHARMA INC
EQ 0.09MG BASE/ML
N022499 001 Dec 03, 2009
TABLET, EXTENDED RELEASE; ORAL
CLONIDINE
TRIS PHARMA INC
EQ 0.17MG BASE
EQ 0.26MG BASE
N022500 001 Dec 03, 2009
N022500 002 Dec 03, 2009

CLONIDINE HYDROCHLORIDE
TABLET; ORAL
CLONIDINE HYDROCHLORIDE
AM THERAP
0.1MG
0.2MG
0.3MG
AUROLIFE PHARMA LLC
0.1MG
0.2MG
0.3MG
CHARTWELL MOLECULES
0.1MG
0.2MG
0.3MG
DURAMED PHARMS BARR
0.1MG
0.2MG
0.3MG
INTERPHARM
0.1MG
0.2MG
0.3MG
PAR PHARM
0.1MG
0.2MG
0.3MG
TEVA
0.1MG
0.2MG
0.3MG
WARNER CHILCOTT
0.1MG
0.2MG
0.3MG
WATSON LABS
0.1MG
0.2MG
0.3MG

** See List Footnote

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
**See List Footnote**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
# CLORAZEPATE DIPOTASSIUM

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**See List Footnote**

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** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
# DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

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| RUBRATOPE-57 KIT |
| N/A; N/A; N/A; N/A |
| N16089 001 |

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| RUBRATOPE-60 KIT |
| N/A; N/A; N/A; N/A |
| N16090 001 |

| CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL |
| PHENERGAN VC W/ CODEINE |
| + ANI PHARMS | 10MG/5ML; 5MG/5ML; 6.25MG/5ML ** |
| N008306 005 Apr 02, 1984 |

| HALSEY |
| 10MG/5ML; 5MG/5ML; 6.25MG/5ML |
| N008870 001 Mar 02, 1987 |

| PROMETHAZINE VC W/ CODEINE |
| CENCI | 10MG/5ML; 5MG/5ML; 6.25MG/5ML |
| N008816 001 Nov 22, 1985 |

| WOCKHARDT | 10MG/5ML; 5MG/5ML; 6.25MG/5ML |
| N008896 001 Jan 04, 1985 |

| CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL |
| PHENERGAN W/ CODEINE |
| + ANI PHARMS | 10MG/5ML; 6.25MG/5ML ** |
| N008306 004 Apr 02, 1984 |

| HALSEY | 10MG/5ML; 6.25MG/5ML |
| N008873 001 Dec 23, 1988 |

| PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE PHARM ASSOC | 10MG/5ML; 6.25MG/5ML |
| N008647 001 Dec 22, 1988 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE
SYRUP; ORAL
PROMETHAZINE W/ CODEINE
CENCI 10MG/5ML; 6.25MG/5ML A088814 001 Nov 22, 1985

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE
SYRUP; ORAL
ACTIFED W/ CODEINE
GLAXOSMITHKLINE 10MG/5ML; 30MG/5ML; 1.25MG/5ML N012575 003 Apr 04, 1984
TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES W/ CODEINE
CENCI 10MG/5ML; 30MG/5ML; 1.25MG/5ML A089018 001 Jul 23, 1986
TRIPROLIDINE HYDROCHLORIDE, PSEUDOEPHEDRINE HYDROCHLORIDE AND CODEINE PHOSPHATE
WOCHARDT 10MG/5ML; 30MG/5ML; 1.25MG/5ML A088833 001 Nov 16, 1984

CODEINE SULFATE
SOLUTION; ORAL
CODEINE SULFATE
WEST-WARD PHARMS INT N202245 001 Jun 30, 2011

COLCHICINE; PROBENECID
TABLET; ORAL
COLBENEMID
+ MERCK 0.5MG; 500MG ** N012383 001
PROBENECID + WATSON LABS 0.5MG; 500MG A085552 001
PROBENECID AND COLCHICINE
ANI PHARMS INC 0.5MG; 500MG A083734 001
BEECHAM 0.5MG; 500MG A084321 001
IMPAK LABS 0.5MG; 500MG A083720 002
SANDOX 0.5MG; 500MG A086130 001
PROBENECID W/ COLCHICINE
LEDERLE 0.5MG; 500MG A086954 001
WATSON LABS 0.5MG; 500MG A083221 001

COLESEVELAM HYDROCHLORIDE
CAPSULE; ORAL
WELCHOL
DAIICHI SANKYO 375MG N021141 001 May 26, 2000

COLISTIN SULFATE
SUSPENSION; ORAL
COLY-MICIN S
PARKE DAVIS EQ 25MG BASE/5ML N050355 001

CONIVAPTAN HYDROCHLORIDE
INJECTABLE; INTRAVENOUS
VAPRISOL
CUMBERLAND PHARMS 20MG/4ML (5MG/ML) N021697 001 Dec 29, 2005

COPPER
INTRAUTERINE DEVICE; INTRAUTERINE
CU-7
GD SEARLE LLC 89MG N017408 001
TATUM-T
GD SEARLE LLC N018205 001

CORTICOTROPIN
INJECTABLE; INJECTION
ACTH
PARKEDALE 25 UNITS/VIAL N008317 002
40 UNITS/VIAL N008317 004
ACTHAR
SANOFI AVENTIS US 25 UNITS/VIAL N007504 002
40 UNITS/VIAL N007504 003
CORTICOTROPIN
ORGANICS LAGRANGE 40 UNITS/ML N010831 001
80 UNITS/ML N010831 002
WATSON LABS 40 UNITS/VIAL A088772 001 Nov 21, 1984
H.P. ACTHAR GEL
MALLINCKRODT ARD 40 UNITS/ML N008372 006
PURIFIED CORTROPHIN GEL
ANI PHARMS INC 40 UNITS/ML N008975 001
80 UNITS/ML N008975 002

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CORTICOTROPIN-ZINC HYDROXIDE
INJECTABLE; INJECTION
CORTROPHIN-ZINC
ANI PHARMS INC 40 UNITS/ML N009854 001

CORTISONE ACETATE
INJECTABLE; INJECTION
CORTISONE ACETATE
PHARMACIA AND UPJOHN 25MG/ML N008126 002
WATSON LABS 25MG/ML A083147 003
25MG/ML A085677 001
50MG/ML A083147 004
50MG/ML A085677 002

CORTISONE TABLET; ORAL
CORTISONE ACETATE
BARR 25MG A083471 001
ELKINS SINN 25MG A080836 001
EVERYLIFE 25MG A084246 001
HEATHER 25MG A085736 001
IMPAK LABS 25MG N009458 001
INWOOD LABS 25MG A080731 001
IVAX SUB TEVA PHARMS 25MG A080630 001
25MG A083536 001
LANNETT 25MG A080694 001
PANRAY 5MG A008284 002
25MG N008284 002
PHARMACIA AND UPJOHN 5MG N008126 003
10MG N008126 004
25MG N008126 001
PUREPAC PHARM 25MG A080493 001
VITARINE 25MG A080333 001
WATSON LABS 25MG A085884 001
WHITENORTH TOWN PLSN 25MG A080341 001

CORTISONE + MERCK 25MG ** N007750 003

COSYNTROPIN
SOLUTION; INTRAVENOUS
COSYNTROPIN
SANDOZ INC 0.25MG/ML (0.25MG/ML) N022028 001 Feb 21, 2008

CROMOLYN SODIUM
AEROSOL, METERED; INHALATION
INTAL
KING PHARMS LLC 0.8MG/INH N018887 001 Dec 05, 1985

CAPSULE; INHALATION
INTAL
+ SANOFI AVENTIS US 20MG ** N016990 001

CAPSULE; ORAL
GASTROCROM
UCB INC 100MG N019188 001 Dec 22, 1989

CONCENTRATE; ORAL
CROMOLYN SODIUM
GENERIA PHARMS 100MG/5ML A090954 001 Dec 18, 2009

SOLUTION; INHALATION
CROMOLYN SODIUM
ACTAVIS MID ATLANTIC 10MG/ML A075067 001 Jul 19, 1999
APOTEX INC 10MG/ML A075333 001 Apr 30, 2002
BAUSCH AND LOMB 10MG/ML A075585 001 Dec 21, 2000
FERA PHARMS LLC 10MG/ML A075437 001 Apr 21, 2000
ROXANE 10MG/ML A075175 001 Sep 30, 1999
WATSON LABS 10MG/ML A076469 001 Jun 17, 2005

INTAL
+ KING PHARMS LLC 10MG/ML ** N018596 001 May 28, 1982

SOLUTION/ DROPS; OPHTHALMIC
CROMOLYN SODIUM
BAUSCH AND LOMB 4% A074443 001 Jan 30, 1995

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
CROMOLYN SODIUM
SOLUTION/DROPS;OPHTHALMIC
CROMOLYN SODIUM
   APOTEX INC  4%  A075615 001 Jan 26, 2001
CROMOPTIC
   KING PHARMS  4%  A075088 001 Apr 27, 1999
OPTICROM
   + ALLERGAN  4%  **
SPRAY, METERED;NASAL
CROMOLYN SODIUM
   ACTAVIS MID ATLANTIC 5.2MG/SPRAY  A074800 001 Jul 26, 2001
   HH AND P  5.2MG/SPRAY  A077976 001 Sep 07, 2007
NASALCROM
   + BLACKSMITH BRANDS  5.2MG/SPRAY  **
CRYPTEMAMINE ACETATES
INJECTABLE;INJECTION
MEDPOINTE PHARM HLC 260CSR UNIT/ML
   UNITENSEN  N008814 001
CRYPTEMAMINE TANNATES
TABLET;ORAL
MEDPOINTE PHARM HLC 260CSR UNIT
   UNITENSEN  N009217 001
CUPRIC SULFATE
INJECTABLE;INJECTION
CUPRIC SULFATE
   ABRAXIS PHARM  EQ 0.4MG COPPER/ML  N019350 001 May 05, 1987
CYANOCOBALAMIN
GEL, METERED;NASAL
NASCOBAL
   PAR PHARM  0.5MG/INH  N019722 001 Nov 05, 1996
INJECTABLE;INJECTION
BERUBIGEN
   PHARMACIA AND UPJOHN 1MG/ML  N006798 001
BETALIN 12
   LILLY  0.1MG/ML  A080855 001
   1MG/ML  A080855 002
COBAVITE
   WATSON LABS  0.1MG/ML  A083013 001
   1MG/ML  A083064 001
CYANOCOBALAMIN
ABRAXIS PHARM 0.03MG/ML
   0.1MG/ML  A080510 003
   1MG/ML  A080510 001
   1MG/ML  A080510 002
AKORN
   1MG/ML  A087969 001 Nov 10, 1983
DELL LABS
   0.03MG/ML  A080689 001
   0.1MG/ML  A080689 002
   1MG/ML  A080689 003
FRESENIUS KABI USA
   0.1MG/ML  A080557 002
LUITPOLD
   0.03MG/ML  A080668 001
LYPHMED
   1MG/ML  A083075 001
MYLAN INSTITUTIONAL
   1MG/ML  A080564 001 Sep 23, 2003
SANOFI AVENTIS US
   1MG/ML  A087551 001 Feb 29, 1984
SOLOPAK
   1MG/ML  N007085 002
WARNER CHILCOTT
   1MG/ML  A080554 001
WATSON LABS
   0.1MG/ML  A080573 002
   0.1MG/ML  A083120 001
   1MG/ML  A080573 001
   1MG/ML  A083120 002
   1MG/ML  A083120 002
   1MG/ML  A080554 002
WYETH AYERST
   0.1MG/ML  A080554 001
   1MG/ML  A080554 002
DODEX
   ACCORD HLTHCARE 1MG/ML  A083022 001
REDISOL
   MERCK  1MG/ML  N006668 001
RUBIVITE
   BEL MAR  0.03MG/ML  N010791 004
   0.05MG/ML  N010791 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

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### Cyclobenzaprine Hydrochloride

**Tablet; Oral**

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<th>Manufacturer</th>
<th>Strength</th>
<th>NDC</th>
<th>Date of Approval</th>
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<td>Upsher Smith Labs</td>
<td>5mg</td>
<td>A072854 002</td>
<td>Feb 03, 2006</td>
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<td>10mg</td>
<td>A072854 001</td>
<td>Nov 19, 1991</td>
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<td>Watson Labs</td>
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<td>A073143 001</td>
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**Flexeril**

+ | Janssen Res and Dev | 5mg ** | N017821 001 |
+ | | 10mg ** | N017821 002 |

### Cyclopentolate Hydrochloride

**Solution/Drops; Ophthalmic**

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<td>1%</td>
<td>A085555 001</td>
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<td>2%</td>
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### Cyclophosphamide

**Injectable; Injection**

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<td>500mg/vial</td>
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<td>1gm/vial</td>
<td>A088374 001</td>
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**Cytoxan**

+ | Baxter HealthCare | 100mg/vial ** | N012142 001 |
+ | | 200mg/vial ** | N012142 002 |

**Cytoxan (Lyophilized)**

+ | Baxter HealthCare | 500mg/vial | N012142 003 |
+ | | 500mg/vial ** | N012142 008 | Jan 04, 1984 |
+ | | 1gm/vial | N012142 004 | Aug 30, 1982 |
+ | | 1gm/vial ** | N012142 010 | Sep 24, 1985 |
+ | | 2gm/vial | N012142 005 | Aug 30, 1982 |
+ | | 2gm/vial ** | N012142 009 | Dec 10, 1985 |

**Lyophilized Cytoxan**

+ | Baxter HealthCare | 100mg/vial ** | N012142 006 | Dec 05, 1985 |
+ | | 200mg/vial ** | N012142 007 | Dec 10, 1985 |

### Neosar

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### Tablet; Oral

**Cyclophosphamide**

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**Cytoxan**

+ | Baxter HealthCare | 25mg ** | N012141 002 |
+ | | 50mg ** | N012141 001 |

### Cyclosporine

**Capsule; Oral**

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*Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons*
### CYCLOSPORINE

**SOLUTION; ORAL**

- **Cyclosporine**
  - APOTEX INC 100MG/ML
  - **SN050101 Jan 05, 2005**

### CYCLOTHIAZIDE

**TABLET; ORAL**

- **Anhydrion**
  - LILLY 2MG
    - **N013157 002**
  
### CYCROMEHYDROCHLORIDE

**TABLET; ORAL**

- **Pagitane**
  - LILLY
    - 1.25MG
      - **N008951 001**
    - 2.5MG
      - **N008951 002**

### CYPROHEPATDINE HYDROCHLORIDE

**SYRUP; ORAL**

- **Cyproheptadine Hydrochloride**
  - ACTAVIS MID ATLANTIC 2MG/5ML **
    - **A086833 001**
  - **Halsey**
    - 2MG/5ML
      - **A089199 001 Jul 03, 1986**
  - **Morton Grove**
    - 2MG/5ML
      - **A087001 001 Nov 04, 1982**
  - **Nasha**
    - 2MG/5ML
      - **A089021 001 Dec 21, 1987**
  - **Periactin**
    - + **Merck**
      - 2MG/5ML **
        - **N013220 002**

### CYSTEINE HYDROCHLORIDE

**INJECTABLE; INJECTION**

- **Cyctsteine Hydrochloride**
  - **Hospira**
    - 7.25% **
      - **N019523 001 Oct 22, 1986**

### CYTOSAR-U

**INJECTABLE; INJECTION**

- **Cytarabine**
  - + **Teva Parenteral**
    - 100MG/VIAL **
      - **N016793 001**
    - 500MG/VIAL **
      - **N016793 002**
    - 1GM/VIAL **
      - **N016793 003 Dec 21, 1987**
    - 2GM/VIAL **
      - **N016793 004 Dec 21, 1987**
  - **CytoSar-U**
    - **Teva Pharms USA**
      - 100MG/VIAL
        - **A075206 001 Dec 30, 1998**
      - 500MG/VIAL
        - **A075206 002 Dec 30, 1998**
      - 1GM/VIAL
        - **A075206 004 Dec 30, 1998**
      - 2GM/VIAL
        - **A075206 003 Dec 30, 1998**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

DACARBOSINE
INJECTABLE, INJECTION
DACARBOSINE
ABRAXIS PHARM 100MG/VIAL A070962 001 Aug 28, 1986
200MG/VIAL A070990 001 Aug 28, 1986
DTIC-DOME
+ BAYER HLTHCARE 100MG/VIAL ** N017575 001
+ 200MG/VIAL ** N017575 002

DACINOMYCIN
INJECTABLE, INJECTION
DACINOMYCIN
WEST-WARD PHARMS INT 0.5MG/VIAL A090304 001 Mar 16, 2010

DALFOPRISTIN; QUINUPRISTIN
INJECTABLE, INTRAVENOUS
SYNERCID
KING PHARMS 420MG/VIAL; 180MG/VIAL N050748 002 Aug 24, 2000

DALTEPARIN SODIUM
INJECTABLE, INJECTION
FRAGMIN
PFIZER INC 7,500 IU/0.75ML N020287 008 Apr 04, 2002

FRAGMIN
INJECTABLE, SUBCUTANEOUS
PFIZER INC 10,000IU/0.4ML (25,000IU/ML) N020287 002 May 01, 2007
95,000IU/9.5ML (10,000IU/ML) N020287 007 Apr 04, 2002

DANAPAROID SODIUM
INJECTABLE, INJECTION
ORGARAN
ASPEN GLOBAL INC 750 UNITS/0.6ML N020430 001 Dec 24, 1996

DANAZOL
CAPSULE, ORAL
DANAZOL
AM THERAP 200MG A071569 001 Dec 30, 1987
DANOCRINE
SANOFI AVENTIS US 50MG ** N017557 003
100MG ** N017557 004
200MG ** N017557 002

DAPIPRAZOLE HYDROCHLORIDE
SOLUTION/DROPS, OPHTHALMIC
DAPIPRAZOLE HYDROCHLORIDE
FERA PHARMS 0.5% ** N019849 001 Dec 31, 1990

CAPTOPRIL
POWDER, IV (INFUSION)
CUBICIN
CUBIST PHARMS LLC 250MG/VIAL N021572 001 Sep 12, 2003

DARUNAVIR ETHANOLATE
TABLET, ORAL
PREZISTA
JANSSEN PRODS EQ 300MG BASE ** N021976 001 Jun 23, 2006
EQ 400MG BASE ** N021976 003 Oct 21, 2008

DASATINIB
TABLET, ORAL
DASATINIB
APOTEX INC 20MG A202103 001 Jun 10, 2016
50MG A202103 002 Jun 10, 2016
70MG A202103 003 Jun 10, 2016
100MG A202103 004 Jun 10, 2016

DAUNORUBICIN CITRATE
INJECTABLE, LIPOSOMAL, INJECTION
DAUNOXOME
GALEN (UK) EQ 2MG BASE/ML N050704 002 Apr 08, 1996

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
DAUNORUBICIN HYDROCHLORIDE  
INJECTABLE; INJECTION  
CERUBIDINE  
SANOFI AVENTIS US  
EQ 20MG BASE/VIAL  
A061876 001  
WYETH AYERST  
EQ 20MG BASE/VIAL **  
N050484 001  
DAUNORUBICIN HYDROCHLORIDE  
TEVA PARENTERAL  
EQ 20MG BASE/VIAL  
A064212 001  
May 03, 1999  
EQ 50MG BASE/VIAL  
A064212 002  
Jun 23, 1998

DECAMETHONIUM BROMIDE  
INJECTABLE; INJECTION  
SYNCURINE  
GLAXOSMITHKLINE  
1MG/ML  
N006931 002

DEFEROXAMINE MESYLATE  
INJECTABLE; INJECTION  
WATSON LABS  
500MG/VIAL  
A076806 001  
Mar 31, 2006  
2G/M/VIAL  
A076806 002  
Mar 31, 2006

DEMECARIUM BROMIDE  
SOLUTION/DROPS; OPHTHALMIC  
HUMORSOL  
MERCK  
0.125%  
N011860 002  
0.25%  
N011860 001

DEMECLOCYCLINE HYDROCHLORIDE  
CAPSULE; ORAL  
DECLOMYCIN  
LEDERLE  
150MG  
N050262 001  
SYRUP; ORAL  
DECLOMYCIN  
LEDERLE  
75MG/5ML  
N050257 001

TABLET; ORAL  
DECLOMYCIN  
COREPHARMA  
75MG  
N050261 001  
150MG  
N050261 002  
300MG  
N050261 003

DEMECLOCYCLINE HYDROCHLORIDE  
IMPAX LABS  
150MG  
A065094 001  
Mar 22, 2004  
300MG  
A065094 002  
Mar 22, 2004

DESERPIDINE  
TABLET; ORAL  
HARMONYL  
ABBVIE  
0.1MG  
N010796 001  
0.25MG  
N010796 002

DESERPIDINE; HYDROCHLOROTHIAZIDE  
TABLET; ORAL  
ORETICYL 25  
ABBVIE  
0.125MG; 25MG  
N012148 001  
ORETICYL 50  
ABBVIE  
0.125MG; 50MG  
N012148 003  
ORETICYL FORTE  
ABBVIE  
0.25MG; 25MG  
N012148 002

DESERPIDINE; METHYCLOTHIAZIDE  
TABLET; ORAL  
ENDURONYL  
ABBOTT  
0.25MG; 5MG  
N012775 001  
ENDURONYL FORTE  
ABBOTT  
0.5MG; 5MG  
N012775 002  
METHYCLOTHIAZIDE AND DESERPIDINE  
WATSON LABS  
0.25MG; 5MG  
A088486 001  
Aug 10, 1984  
0.5MG; 5MG  
A088452 001  
Aug 10, 1984

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Brand Name</th>
<th>Manufacturer</th>
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<th>Approval Date</th>
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<td>Desipramine Hydrochloride</td>
<td>Capsule; Oral</td>
<td>PERTOFRANE</td>
<td>SANOFI AVENTIS US</td>
<td>N013621 001</td>
<td>May 29, 1997</td>
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<td>Desirudin Recombinant</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DESOCIMETASONE
GEL;TOPICAL
TOPICORT
+ TARO PHARM INDS LTD 0.05% ** N018586 001 Mar 29, 1982
OINTMENT;TOPICAL
DESOCIMETASONE
ALTANA 0.25% A073440 001 Apr 01, 1998
TOPICORT
+ TARO PHARM INDS LTD 0.25% ** N018763 001 Sep 30, 1983

DESOCORTICOSTERONE ACETATE
INJECTABLE;INJECTION
DOCA
ORGANON USA INC 5MG/ML N001104 001
PELLET;IMPLANTATION
PERCORTEN
NOVARTIS 125MG N005151 001

DESOCORTICOSTERONE PIVALATE
INJECTABLE;INJECTION
PERCORTEN
NOVARTIS 25MG/ML N008822 001

DESVENLAFAXINE FUMARATE
TABLET, EXTENDED RELEASE;ORAL
DESVENLAFAXINE
+ SUN PHARMA GLOBAL EQ 50MG BASE N205583 001 Jan 28, 2014
+ EQ 100MG BASE N205583 002 Jan 28, 2014
+ TEVA PHARMS USA EQ 50MG BASE N205208 001 Oct 11, 2013
+ EQ 100MG BASE N205208 002 Oct 11, 2013

DEXAMETHASONE
AEROSOL;TOPICAL
AEROSEB-DEX
ALLERGAN HERBERT 0.01% ** A083296 002
DECAFLUOR
+ MERCK 0.04% ** N012731 002
ELIXIR;ORAL
DECADRON
MERCK 0.5MG/5ML N012376 002
DEXAMETHASONE
ALPHARMA US PHARMS 0.5MG/5ML A088997 001 Oct 10, 1986
HEXADROL
ASPEN GLOBAL INC 0.5MG/5ML N012674 001
GEL;TOPICAL
DECADERM
MERCK 0.1% N013538 001
SUSPENSION/DROPS;OPHTHALMIC
DEXAMETHASONE
WATSON LABS 0.1% A089170 001 May 09, 1989
TABLET;ORAL
DECADRON
+ MERCK 0.25MG ** N011664 001
+ 0.5MG ** N011664 001
+ 0.75MG ** N011664 003
+ 1.5MG ** N011664 005
+ 4MG ** N011664 006 Jul 30, 1982
DECAMETHASONE
ANI PHARMS INC 0.75MG A080399 001
IMPAX LABS 0.75MG A085376 001
PAR PHARM 0.25MG A088149 002 Apr 28, 1983
+ PHOENIX LABS NY 0.75MG A083806 001
PVT FORM 0.75MG A083420 001
ROXANE 0.25MG A084614 001
SUN PHARM INDUSTRIES 0.25MG A084013 001
+ 0.25MG A084764 001
+ 0.5MG A084084 001
+ 0.75MG A084081 001
+ 0.75MG A084765 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

Dexamethasone
Tablet; Oral

- 1.5mg
- 1.5mg UPSHER SMITH
- 0.75mg
- 1.5mg WATSON LABS
- 0.25mg
- 0.5mg
- 0.75mg
- 0.75mg
- 1.5mg
- 1.5mg
- 0.75mg
- 0.75mg
- 1.5mg
- 1.5mg WHITEWORTH TOWN PLSN

Dexamethasone Acetate
Injectable; Injection

- Decadron-LA + MERCK
- 8mg base/ml ** N016675 001

Dexamethasone Acetate
Watson Labs

- 8mg base/ml N012675 004
- 1.0mg topically N012675 007
- 1.5mg N012675 009
- 4mg N012675 010

Dexamethasone Sodium Phosphate
Aerosol; Nasal

- Decadron: UCB Inc
- 0.1mg phosphate/nasal N014242 001

Dexamethasone Sodium Phosphate
Cream; Topical

- Decadron: UCB Inc
- 0.1% phosphate N011983 002

Dexamethasone
Injectable; Injection

- Decadron: MERCK
- 4mg phosphate/ml ** N012071 002
- 24mg phosphate/ml ** N012071 004

Dexamethasone
Aerosol; Inhalation

- Accent: ABRAXIS PHARM
- 4mg phosphate/ml A088448 001 Jan 25, 1984

Dexamethasone Sodium Phosphate
Parenteral

- Watson Labs
- 4mg phosphate/ml A088469 001 Jan 25, 1984

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

HEXADROL

* ASPEN GLOBAL INC  EQ 4MG PHOSPHATE/ML **  N014694 002
+ EQ 10MG PHOSPHATE/ML **  N014694 003
+ EQ 20MG PHOSPHATE/ML  N014694 004

OINTMENT; OPHTHALMIC

DECADRON

MERCK  EQ 0.05% PHOSPHATE  N011977 001

DEXAIR

PHARMAFAIR  EQ 0.05% PHOSPHATE  A088071 001  Dec 28, 1982

MAXIDEX

ALCON  EQ 0.05% PHOSPHATE  A083342 001

SOLUTION/DROPS; OPHTHALMIC

DEXAIR

PHARMAFAIR  EQ 0.1% PHOSPHATE  A088433 001  Dec 15, 1983

DECADRON

SOLA BARNES HIND  EQ 0.1% PHOSPHATE  A084170 001

DECADRON

SOLUTION/DROPS; OPHTHALMIC, OTIC

MERCK  EQ 0.1% PHOSPHATE  N011984 001

SOLUTION/DROPS; OTIC

DECAMETHASONE SODIUM PHOSPHATE

AKORN  EQ 0.1% PHOSPHATE  A084855 001

DEXAMETHASONE SODIUM PHOSPHATE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

DECADRON W/ XYLOCAINE

MERCK  EQ 4MG PHOSPHATE/ML; 10MG/ML  N013334 002

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

OINTMENT; OPHTHALMIC

NEODECADRON

MERCK  EQ 0.05% PHOSPHATE; EQ 3.5MG BASE/GM  N050324 001

SOLUTION/DROPS; OPHTHALMIC

NEODECADRON

MERCK  EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML  N050322 001

NEOMYCIN SULFATE AND DEXAMETHASONE SODIUM PHOSPHATE

BAUSCH AND LOMB  EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML  A064055 001  Oct 30, 1995

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

ALCON PHARMS LTD  EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML  A062714 001  Jul 21, 1986

PHARMAFAIR  EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML  A062539 001  Jan 10, 1985

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMIXIN B SULFATE

OINTMENT; OPHTHALMIC

DEXACIDIN

NOVARTIS  0.1%; EQ 3.5MG BASE/GM; 10,000 UNITS/GM  A062566 001  Feb 22, 1985

DEXASPORIN

PHARMAFAIR  0.1%; EQ 3.5MG BASE/GM; 10,000 UNITS/GM  A062411 001  May 16, 1983

SUSPENSION/DROPS; OPHTHALMIC

DEXACIDIN

NOVARTIS  0.1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML  A062544 001  Oct 29, 1984

DEXASPORIN

PHARMAFAIR  0.1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML  A062428 001  May 18, 1983

NEOMYCIN AND POLYMIXIN B SULFATES AND DEXAMETHASONE

ALCON PHARMS LTD  0.1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML  A062721 001  Nov 17, 1986

DEXEROMPHENIRAMINE MALEATE

SYRUP; ORAL

DISOMER

SCHERING  2MG/5ML  N011814 002

TABLET; ORAL

DISOMER

SCHERING  2MG  N011814 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Approved Drug Product List

**DISCONTINUED DRUG PRODUCT LIST**

![Image](image.png)

**See List Footnote**

<table>
<thead>
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<th>Brand Name</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC</th>
<th>Date Discontinued</th>
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<td>AVANTI INC</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

#### DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Manufacturer</th>
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<th>Date Discontinued/Withdrawn</th>
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<td>DEXTROAMPHETAMINE SULFATE TABLET; ORAL FERNDEX</td>
<td>FERNDALE LABS 5MG</td>
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<td>DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL PHERAZINE DM HALSEY</td>
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<td>Prometh W/ Dextromethphan G AND W LABS INC 15MG/5ML; 6.25MG/5ML **</td>
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<td>DEXTROSE INJECTABLE; INJECTION</td>
<td>Dextrose 10% in Plastic Container B Braun</td>
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<td>5GM/ML</td>
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<td>60GM/100ML</td>
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<td>DEXTROSE; MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE INJECTABLE; INJECTION</td>
<td>Plasma-Lyte 56 and Dextrose 5% in Plastic Container Baxter Hlthcare</td>
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<td>Isolyte P w/ Dextrose 5% in Plastic Container B Braun</td>
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<td>Ionosol B and Dextrose 5% in Plastic Container Hospira</td>
<td>5GM/100ML; 53MG/100ML; 100MG/100ML; 100MG/100ML; 180MG/100ML; 280MG/100ML; 16MG/100ML</td>
<td>N019515 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE
INJECTABLE; INJECTION
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;150MG/100ML;330MG/100ML N018268 012 Jan 18, 1986
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;220MG/100ML;330MG/100ML N018268 013 Jan 18, 1986
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.30% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;300MG/100ML;330MG/100ML N018268 014 Jan 18, 1986
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.075%
B BRAUN 5GM/100ML;75MG/100ML;450MG/100ML N018268 010
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;220MG/100ML;450MG/100ML N018268 001
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.30% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;300MG/100ML;450MG/100ML N018268 002
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;300MG/100ML;450MG/100ML N018268 003
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML;224MG/100ML;450MG/100ML N018008 003
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ (K) IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML;300MG/100ML;450MG/100ML N018008 001
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER
BAXTER HLTHCARE 5GM/100ML;74.5MG/100ML;450MG/100ML N018008 002
POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
+ ICU MEDICAL INC 5GM/100ML;74.5MG/100ML;900MG/100ML N019691 002 Mar 24, 1988
+ 5GM/100ML;149MG/100ML;900MG/100ML N019691 004 Mar 24, 1988
POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
+ ICU MEDICAL INC 5GM/100ML;224MG/100ML;450MG/100ML N018362 006 Mar 28, 1988
+ ICU MEDICAL INC 5GM/100ML;224MG/100ML;900MG/100ML N018362 001 Mar 28, 1988
POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
+ ICU MEDICAL INC 5GM/100ML;298MG/100ML;450MG/100ML N018362 007 Mar 28, 1988
+ ICU MEDICAL INC 5GM/100ML;298MG/100ML;900MG/100ML N018362 003 Mar 28, 1988
POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
+ ICU MEDICAL INC 5GM/100ML;224MG/100ML;900MG/100ML N018362 001 Oct 04, 1984
+ 5GM/100ML;298MG/100ML;900MG/100ML N018362 003 Oct 04, 1984
DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
B BRAUN 10GM/100ML;200MG/100ML N018386 001
DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
B BRAUN 10GM/100ML;450MG/100ML N018229 001
DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN 10GM/100ML;900MG/100ML N018047 001
B BRAUN 10GM/100ML;900MG/100ML N018030 005
BAXTER HLTHCARE 10GM/100ML;450MG/100ML N018030 001
HOSPIRA 10GM/100ML;450MG/100ML N018030 002
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
B BRAUN 2.5GM/100ML;450MG/100ML N018030 001
HOSPIRA 2.5GM/100ML;450MG/100ML N018096 001
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN 2.5GM/100ML;900MG/100ML N018376 001
DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT 3.3GM/100ML;300MG/100ML N018055 001
ABBOTT 3.3GM/100ML;300MG/100ML N018501 001
DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
ABBOTT 5GM/100ML;110MG/100ML N018050 001
ABBOTT 5GM/100ML;110MG/100ML N018030 005
MILES 5GM/100ML;200MG/100ML N018030 004
MILES 5GM/100ML;200MG/100ML N018399 001
DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ABBOTT 5GM/100ML;225MG/100ML N019482 001 Oct 04, 1985
DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT 5GM/100ML;300MG/100ML N019486 001 Oct 04, 1985
MILES 5GM/100ML;300MG/100ML N018501 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION
DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML; 330MG/100ML N018030 003
DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
ABBOTT 5GM/100ML; 450MG/100ML N019484 001 Oct 04, 1985
B BRAUN 5GM/100ML; 450MG/100ML N018030 002
MILES 5GM/100ML; 450MG/100ML N018400 001
DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
ABBOTT 5GM/100ML; 900MG/100ML N019483 001 Oct 04, 1985
B BRAUN 5GM/100ML; 900MG/100ML N018026 001
MILES 5GM/100ML; 900MG/100ML N018500 001

DEXTROTHYROXINE SODIUM

TABLET; ORAL
CHOLOXIN
ABBVIE 1MG N012302 005
2MG N012302 006
4MG N012302 004
6MG N012302 006

DEZOCINE

INJECTABLE; INJECTION
DALGAN
ASTRAZENECA 5MG/ML N019082 001 Dec 29, 1989
10MG/ML N019082 002 Dec 29, 1989
15MG/ML N019082 003 Dec 29, 1989

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION
ANGIOVIST 282
BAYER HLTHCARE 60% A087726 001 Sep 23, 1982
CARDIOGRAFIN 85% N011620 002
BRACCO 76% N010040 017
DIATRIZOATE MEGLUMINE-HYPAQUE-GE HEALTHCARE 30% N016403 002
60% N016403 001
RENO-60-BRACCO 60% N010040 016
RENO-DIP-BRACCO 30% N010040 012
UROVIST MEGLUMINE DIU/CT-BAYER HLTHCARE 30% A087739 001 Sep 23, 1982
SOLUTION; URETERAL
RENO-30-BRACCO 30% N010040 021
UROVIST CYSTO-BAYER HLTHCARE 30% A087729 001 Sep 23, 1982
UROVIST CYSTO PEDIATRIC-BAYER HLTHCARE 30% A087731 001 Sep 23, 1982
SOLUTION; URETHRAL
HYPAQUE-CYSTO-GE HEALTHCARE 30% N016403 003

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
ANGIOVIST 292
BAYER HLTHCARE 52%; 8% A087724 001 Sep 23, 1982
ANGIOVIST 370
BAYER HLTHCARE 66%; 10% A087723 001 Sep 23, 1982
DIATRIZOATE-60
INTL MEDICATION 52%; 8% A088166 001 Jun 17, 1983
HYPAQUE-76
GE HEALTHCARE 66%; 10% A086505 001
HYPAQUE-M, 75%
GE HEALTHCARE 50%; 25% N010220 003
HYPAQUE-M, 90%
GE HEALTHCARE 60%; 30% N010220 002

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTION; INJECTION

MD-60
MALLINCKRODT 52%; 8% A087074 001

MD-76
MALLINCKRODT 66%; 10% A087073 001

MD-76R
+ LIEBEL-FLARSHEIM 66%; 10% N019292 001 Sep 29, 1989

RENOCAL-76
BRACCO 66%; 10% A089347 001 Jun 01, 1988

RENografin-60
BRACCO 52%; 8% N010040 006

RENografin-76
+ BRACCO 66%; 10% N010040 001

RENOVIST
BRACCO 34.3%; 35% N010040 020

RENOVIST II
BRACCO 28.5%; 29.1% N010040 019

SOLUTION; ORAL, RECTAL

GASTROVIST
BAYER HLTHCARE 66%; 10% A087728 001 Sep 23, 1982

DIATRIZOATE MEGLUMINE; IODIPAMIDE MEGLUMINE

SOLUTION; INTRAUTERINE

SINOGRAFIN
+ BRACCO 52.7%; 26.8% N011324 002

DIATRIZOATE SODIUM

FOR SOLUTION; ORAL, RECTAL

HYPAQUE
GE HEALTHCARE 100% N011386 001

INJECTION; INJECTION

HYPAQUE
GE HEALTHCARE 25% N009561 003
50% N009561 001

MD-50
MALLINCKRODT 50% A087075 001

UROVIST SODIUM 300
BAYER HLTHCARE 50% A087725 001 Sep 23, 1982

SOLUTION; ORAL, RECTAL

HYPAQUE
GE HEALTHCARE 40% N011386 003

SOLUTION; URETERAL

HYPAQUE SODIUM 20%
GE HEALTHCARE 20% N009561 002

DIAZEPAM

CAPSULE, EXTENDED RELEASE; ORAL

VALRELEASE
ROCHE 15MG N018179 001

GEL; RECTAL

DIASTAT
+ VALENT PHARS NORTH 5MG/ML (5MG/ML) ** N020648 002 Jul 29, 1997
+ 10MG/2ML (5MG/ML) ** N020648 003 Jul 29, 1997
+ 15MG/3ML (5MG/ML) ** N020648 004 Jul 29, 1997
+ 20MG/4ML (5MG/ML) ** N020648 005 Jul 29, 1997

INJECTION; INJECTION

DIAZEPAM

ABRAXIS PHARM 5MG/ML A070662 001 Jun 25, 1986
HOSPIRA 5MG/ML A071584 001 Oct 13, 1987
MARGA PHARS LLC 5MG/ML A072371 001 Jan 29, 1993
PARENTA PHARS 5MG/ML A076815 001 Apr 15, 2004
US ARMY 5MG/ML ** N020124 001 Dec 05, 1990
WARNER CHILCOTT 5MG/ML A071613 001 Oct 22, 1987
5MG/ML A071614 001 Oct 22, 1987
WATSON LABS 5MG/ML A070296 001 Feb 12, 1986
5MG/ML A070911 001 Aug 28, 1986
5MG/ML A070912 001 Aug 28, 1986
5MG/ML A070930 001 Dec 01, 1986
WATSON LABS INC 5MG/ML A072370 001 Jan 29, 1993
5MG/ML A072397 001 Jan 29, 1993

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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## DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

### DIAZEPAM

#### INJECTABLE; INJECTION

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#### DIZAC

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#### TABLET; ORAL

<table>
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<th><strong>VALIUM + ROCHE</strong></th>
<th>5MG/ML **</th>
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### DIAZOXIDE

#### CAPSULE; ORAL

<table>
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<tr>
<th><strong>PROGLYCEM</strong></th>
<th>50MG</th>
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<td></td>
<td>100MG</td>
<td>N017425 002</td>
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#### INJECTABLE; INJECTION

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<tr>
<th><strong>ABRAXIS PHARM</strong></th>
<th>15MG/ML</th>
<th>A071519 001</th>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

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<tr>
<th>Drug Name</th>
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<th>Manufacturer</th>
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<tbody>
<tr>
<td>Diazoxide</td>
<td>Injectable; Injection</td>
<td>Hyperstat</td>
<td>N016996 001</td>
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<tr>
<td>Dibucaine hydrochloride</td>
<td>Injectable; Injection</td>
<td>Heavy Solution Nupercaine</td>
<td>N006203 001</td>
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<tr>
<td>Diclofenac potassium</td>
<td>Tablet; Oral</td>
<td>Daranide + Strongbridge US</td>
<td>N011366 001</td>
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<tr>
<td>Diclofenac potassium</td>
<td>Tablet; Oral</td>
<td>Cataflam</td>
<td>N020142 001</td>
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<td>Diclofenac sodium</td>
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<td>Dyloject</td>
<td>N022396 001</td>
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<td>Nuvo Pharms Inc</td>
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<td>Falcon Pharma's</td>
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<td>Diclofenac sodium</td>
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<td>Voltaren-XR</td>
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<td>Dicloxacillin sodium</td>
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<td>Wyeth Ayerst</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DICLOXACILLIN SODIUM

FOR SUSPENSION; ORAL

DICLOXACILLIN SODIUM APOTHECON EQ 62.5MG BASE/5ML A061455 001

DYNAPEN APOTHECON EQ 62.5MG BASE/5ML N050337 002

PATHOCIL WYETH AYERST EQ 62.5MG BASE/5ML N050092 001

DICUMAROL

CAPSULE; ORAL

DICUMAROL LILLY 25MG N005509 003

50MG N005509 001

TABLET; ORAL

DICUMAROL ABBVIE 25MG N005545 003

50MG N005545 004

100MG N005545 005

DICUMAROL

INJECTABLE; INJECTION

DICUMAROL WATSON LABS 10MG/ML A080614 001 Feb 11, 1986

SYRUP; ORAL

BENTYL + APTALIS PHARMA US 10MG/5ML ** N007961 002 Oct 15, 1984

DICUMAROL ALPHARMA US PHARMS 10MG/5ML A084479 001

TABLET; ORAL

DICUMAROL PIONEER PHARMS 20MG A088585 001 Aug 20, 1986

SUN PHARM INDUSTRIES 20MG A084600 001 Jul 29, 1985

WATSON LABS 20MG A084361 001 Feb 06, 1986

DICUMAROL

INJECTABLE; INJECTION

DICUMAROL WATSON LABS 10MG/ML A080614 001 Feb 11, 1986

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMINE HYDROCHLORIDE PIONEER PHARMS 10MG A089361 001 Jan 10, 1989

SUN PHARM INDUSTRIES 10MG A084505 001 Oct 21, 1986

WATSON LABS 10MG A083179 001 Feb 12, 1986

INJECTABLE; INJECTION

DICYCLOMINE HYDROCHLORIDE WATSON LABS 10MG/ML A080614 001 Feb 11, 1986

SYRUP; ORAL

BENTYL + APTALIS PHARMA US 10MG/5ML ** N007961 002 Oct 15, 1984

DICYCLOMINE HYDROCHLORIDE ALPHARMA US PHARMS 10MG/5ML A084479 001

TABLET; ORAL

DICYCLOMINE HYDROCHLORIDE PIONEER PHARMS 20MG A088585 001 Aug 20, 1986

SUN PHARM INDUSTRIES 20MG A084600 001 Jul 29, 1985

WATSON LABS 20MG A084361 001 Feb 06, 1986

DICYCLOMINE HYDROCHLORIDE

CAPSULE, DELAYED REL PELLETS; ORAL

DIDANOSINE BARR 200MG A077167 001 Dec 03, 2004

250MG A077167 002 Dec 03, 2004

400MG A077167 003 Dec 03, 2004

MYLAN PHARMS INC 125MG A090788 001 Apr 08, 2010

200MG A090788 002 Apr 08, 2010

250MG A090788 003 Apr 08, 2010

400MG A090788 004 Apr 08, 2010

FOR SOLUTION; ORAL

DIDANOSINE AUROBINDO PHARMA 10MG/ML A078112 001 Mar 08, 2007

VIDEX BRISTOL MYERS SQUIBB 100MG/PACKET N020155 003 Oct 09, 1991

167MG/PACKET N020155 004 Oct 09, 1991

250MG/PACKET N020155 005 Oct 09, 1991

375MG/PACKET N020155 006 Oct 09, 1991

TABLET, CHEWABLE; ORAL

VIDEX + BRISTOL MYERS SQUIBB 25MG ** N020154 002 Oct 09, 1991

+ 50MG ** N020154 003 Oct 09, 1991

+ 100MG ** N020154 004 Oct 09, 1991

+ 150MG ** N020154 005 Oct 09, 1991

+ 200MG ** N020154 006 Oct 28, 1999

TABLET, FOR SUSPENSION; ORAL

DIDANOSINE AUROBINDO 100MG A077275 001 Aug 14, 2012

150MG A077275 002 Aug 14, 2012

200MG A077275 003 Aug 14, 2012

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

DIENE

DIENESTROL CREAM; VAGINAL

ORTHOMCNEILPHARM 0.01% N006110 005

DV SANOFI AVENTIS US 0.01% A083518 001

ESTRAGUARD SOLVAY 0.01% A084436 001

SUPPOSITORY; VAGINAL DV SANOFI AVENTIS US 0.7MG A083517 001

DIETHYL CARBAMAZINE CITRATE TABLET; ORAL

HETRAZAN LEDERLE 50MG N006459 001

DIETHYLPROPION HYDROCHLORIDE TABLET; ORAL

DIETHYLPROPION HYDROCHLORIDE CHARTWELL RX 25MG A088267 001 Aug 25, 1983

25MG A088268 001 Aug 25, 1983

EPIC PHARMA LLC 25MG A040828 001 Nov 05, 2008

SANDOZ 25MG A085916 001

TEVA 25MG A088642 001 Sep 20, 1984

UCB INC 25MG A085544 001

WATSON LABS 25MG A085741 001

TENUATE SANOFI AVENTIS US 25MG N017668 001

TEPANIL 3M 25MG N011673 001

TABLET, EXTENDED RELEASE; ORAL TENUATE

SANOFI AVENTIS US 75MG N017669 001

TEPANIL TEN-TAB 3M 75MG N017956 001

DIETHYLSTILBESTROL INJECTABLE; INJECTION

STILBESTROL BRISTOL MYERS SQUIBB 0.2MG/ML N004056 003

0.5MG/ML N004056 004

1MG/ML N004056 005

5MG/ML N004056 006

SUPPOSITORY; VAGINAL DIETHYLSTILBESTROL LILLY 0.1MG N004040 001

0.5MG N004040 002

STILBESTROL BRISTOL MYERS SQUIBB 0.1MG N004056 001

0.5MG N004056 002

TABLET; ORAL

DIETHYLSTILBESTROL LILLY 0.1MG N004041 002

0.5MG N004041 003

1MG N004041 004

5MG N004041 005

STILBESTROL TABLICAPS 0.5MG A083004 001

1MG A083002 001

5MG A083006 001

STILBETIN BRISTOL MYERS SQUIBB 0.1MG N004056 007

0.25MG N004056 017

0.5MG N004056 008

1MG N004056 009

5MG N004056 010

TABLET, DELAYED RELEASE; ORAL

DIETHYLSTILBESTROL LILLY 0.1MG N004039 002

0.25MG N004039 005

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DIETHYLSTILBESTROL DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

<table>
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<tr>
<th>DIETHYLSTILBESTROL</th>
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<td>5MG</td>
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<tr>
<th>DIETHYLSTILBESTROL DIPHOSPHATE</th>
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<td>STILPHOSTROL</td>
<td>BAYER PHARMS 250MG/5ML</td>
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<th>DIFLORASONE DIACETATE</th>
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<td>DIFLORASONE DIACETATE</td>
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<td>FLORONE</td>
<td>PHARMACIA AND UPJOHN 0.05% **</td>
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<td>FLORONE E</td>
<td>PHARMACIA AND UPJOHN 0.05%</td>
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<tr>
<td>PSORCON</td>
<td>TARO PHARMS NORTH 0.05% **</td>
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<tr>
<td>PSORCON</td>
<td>PHARMACIA AND UPJOHN 0.05%</td>
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<td>SOCORRO</td>
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<td>+ MERCK</td>
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<tbody>
<tr>
<td>CRYSOTODIGIN</td>
<td>LILLY 0.2MG/ML</td>
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<tr>
<th>DIGOXIN</th>
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<tbody>
<tr>
<td>LANOXICAPS</td>
<td>GLAXOSMITHKLINE LLC 0.05MG</td>
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<td>0.1MG</td>
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<td>0.2MG</td>
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<th>DIGOXIN</th>
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<td>ABRAXIS PHARM 0.25MG/ML</td>
<td>A083217 001</td>
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<td>HOSPIRA   0.25MG/ML</td>
<td>A040093 001 May 16, 1996</td>
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<td>0.25MG/ML</td>
<td>A040206 001 Aug 28, 1998</td>
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DIGOXIN

INJECTABLE; INJECTION

DIGOXIN

WYETH AYERST 0.25MG/ML A084386 001

DIGOXIN PEDIATRIC

HOSPIRA 0.1MG/ML A040992 001 Apr 25, 1996

TABLET; ORAL

LANOXIN

+ CONCORDIA PHARMS INC 0.1875MG N020405 003 Sep 30, 1997

0.375MG N020405 005 Sep 30, 1997

0.5MG N020405 006 Sep 30, 1997

DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

EMBOLEX

NOVARTIS 0.5MG/0.5ML; 2,500 UNITS/0.5ML; 5.33MG/0.5ML

0.5MG/0.7ML; 5,000 UNITS/0.7ML; 7.46MG/0.7ML

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM SR

+ BIOVAIL 60MG ** N019471 001 Jan 23, 1989

+ 90MG ** N019471 002 Jan 23, 1989

+ 120MG ** N019471 003 Jan 23, 1989

+ 180MG ** N019471 004 Jan 23, 1989

DILACOR XR

+ ALLERGAN SALES LLC 120MG ** N020092 001 May 29, 1992

+ 180MG ** N020092 002 May 29, 1992

+ 240MG ** N020092 003 May 29, 1992

DILT-CD

APOTEX 120MG A076151 001 May 20, 2004

180MG A076151 002 May 20, 2004

240MG A076151 003 May 20, 2004

300MG A076151 004 May 20, 2004

DILTIAZEM HYDROCHLORIDE

ACTAVIS LABS FL INC 120MG A074852 001 Oct 10, 1997

180MG A074852 002 Oct 10, 1997

240MG A074852 003 Oct 10, 1997

BIOVAIL 60MG A074845 001 Sep 15, 1999

90MG A074845 002 Sep 15, 1999

120MG A074845 003 Sep 15, 1999

120MG N020939 001 Jan 28, 2000

180MG N020939 002 Jan 28, 2000

240MG N020939 003 Jan 28, 2000

300MG N020939 004 Jan 28, 2000

360MG N020939 005 Jan 28, 2000

420MG N020939 006 Jan 28, 2000

NESHER PHARMS 120MG A076563 002 Sep 12, 2006

180MG A076563 003 Sep 12, 2006

240MG A076563 004 Sep 12, 2006

300MG A076563 005 Sep 12, 2006

360MG A076563 006 Sep 12, 2006

420MG A076563 001 Sep 12, 2006

TEVA 60MG A074079 001 Nov 30, 1993

90MG A074079 002 Nov 30, 1993

120MG A074079 003 Nov 30, 1993

INJECTABLE; INJECTION

CARDIZEM

BIOVAIL 100MG/VIAL ** N020792 001 Sep 05, 1997

+ BIOVAIL LABS INTL 5MG/ML ** N02027 001 Oct 24, 1991

+ 25MG/VIAL ** N02027 003 Aug 18, 1995

DILTIAZEM HYDROCHLORIDE

HOSPIRA 5MG/ML A075004 001 Feb 16, 2000

5MG/ML A075106 001 Apr 29, 1999

MYLAN LABS LTD 5MG/ML A075375 001 Sep 30, 1999

TEVA PHARMS USA 5MG/ML A074894 001 Aug 26, 1997

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
# DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

## DILTIAZEM HYDROCHLORIDE

<table>
<thead>
<tr>
<th>Tablet; Oral</th>
<th>Company/Manufacturer</th>
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<tbody>
<tr>
<td>Diltiazem Hydrochloride</td>
<td>Apotecn</td>
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<tr>
<td>Diltiazem Hydrochloride</td>
<td>Chartwell Molecules</td>
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<tr>
<td>Diltiazem Hydrochloride</td>
<td>IVAX Sub Teva Pharms</td>
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<td>Diltiazem Hydrochloride</td>
<td>Teva</td>
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<td>Diltiazem Hydrochloride</td>
<td>Teva Pharms</td>
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## DILTIAZEM MALATE

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<th>Tablet, Extended Release; Oral</th>
<th>Company/Manufacturer</th>
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<tbody>
<tr>
<td>Diltiazem Malate; Tiamate</td>
<td>Merck</td>
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<td>Diltiazem Malate; Enalapril Maleate</td>
<td>Teczem</td>
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## DIMENHYDRINATE

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<td>Baxter Hlthcare</td>
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<td>Dimenhydrinate</td>
<td>Watson Labs</td>
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<td>Dimenhydrinate</td>
<td>Watson Labs Teva</td>
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<td>Dimenhydrinate</td>
<td>Wyeth Ayerst</td>
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<td>Dimenhydrinate</td>
<td>Alra</td>
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<td>Dimenhydrinate</td>
<td>Heather</td>
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<td>Dimenhydrinate</td>
<td>Nexgen Pharma Inc</td>
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<td>Dimenhydrinate</td>
<td>Watson Labs</td>
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## DIMYRISTOYL LECITHIN; PERFLEXANE

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<th>Injectable; Intravenous</th>
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<tr>
<td>Dimyristoyl Lecithin; Perflexane</td>
<td>Vesselon SPV LLC</td>
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## DINOPOROST TROMETHAMINE

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<td>Dinoport Tromethamine</td>
<td>Prostin F2 Alpha</td>
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## DIPHENHYDRAMINE HYDROCHLORIDE

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<th>Capsule; Oral</th>
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<td>Diphendryamine Hydrochloride</td>
<td>McNeil Cons</td>
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<tr>
<td>Diphendryamine Hydrochloride</td>
<td>Alra</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

#### DIPHENHYDRAMINE HYDROCHLORIDE

**CAPSULE; ORAL**

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<td>50MG</td>
</tr>
<tr>
<td>ELKINS SNN</td>
<td>25MG, 50MG</td>
</tr>
<tr>
<td>FOSUN PHARMA</td>
<td>25MG, 50MG</td>
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<tr>
<td>HALSEY</td>
<td>25MG, 50MG</td>
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<tr>
<td>HIKMA INTL PHARMS</td>
<td>50MG</td>
</tr>
<tr>
<td>IMPAX LABS</td>
<td>25MG, 50MG</td>
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<tr>
<td>IVAX SUB TEVA PHARMS</td>
<td>25MG, 50MG</td>
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<tr>
<td>LANNETT</td>
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<td>LIDERLE</td>
<td>25MG, 50MG</td>
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<td>LNK</td>
<td>25MG</td>
</tr>
<tr>
<td>MK LABS</td>
<td>25MG, 50MG</td>
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<td>MUTUAL PHARM</td>
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<td>NEWTRON PHARMS</td>
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<td>NEXGEN PHARMA INC</td>
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<td>PERRIGO</td>
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<td>PIONEER PHARMS</td>
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**ELIXIR; ORAL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**DISCONTINUED DRUG PRODUCT LIST**

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**See List Footnote**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DISULFIRAM
TABLET; ORAL

WATSON LABS
250MG
A086889 001
250MG
A087973 001 Aug 05, 1983
500MG
A087974 001 Aug 05, 1983

WATSON LABS TEVA
500MG
A086890 001

DIVALPROEX SODIUM
TABLET, DELAYED RELEASE; ORAL

DEPAXOTE CP
ABBOTT
EQ 250MG BASE
N019794 001 Jul 11, 1990
EQ 500MG BASE
N019794 002 Jul 11, 1990

DIVALPROEX SODIUM
MYLAN
EQ 125MG VALPROIC ACID
A077254 001 Jul 29, 2008
EQ 250MG VALPROIC ACID
A077254 002 Jul 29, 2008
EQ 500MG VALPROIC ACID
A077254 003 Jul 29, 2008

DIVALPROEX SODIUM
G AND W LABS INC
EQ 500MG VALPROIC ACID
A078700 001 Aug 03, 2009

DOBUTAMINE HYDROCHLORIDE
INJECTABLE; INJECTION

DOBUTAMINE HYDROCHLORIDE
BAXTER HLTHCARE
EQ 12.5MG BASE/ML
A074381 001 Sep 26, 1996
HOSPIRA
EQ 1.25GM BASE/100ML
A074634 001 Sep 27, 1996
LUITPOLD
EQ 12.5MG BASE/ML
A074545 001 Jun 25, 1998
TEILIGENT PHARMA INC
EQ 12.5MG BASE/ML
A074098 001 Feb 21, 1995
TEVA PARENTERAL
EQ 12.5MG BASE/ML
A074114 001 Nov 30, 1993
WATSON LABS
EQ 12.5MG BASE/ML
A074279 001 Feb 18, 1998

A074297 001 Feb 18, 1998
WATSON LABS INC
EQ 12.5MG BASE/ML
A074995 001 Mar 31, 1998

DOBUTAMINE HYDROCHLORIDE IN DEXTROSE 5%
HOSPIRA
EQ 50MG BASE/100ML
N020269 001 Oct 19, 1993
EQ 100MG BASE/100ML
N020269 002 Oct 19, 1993
EQ 200MG BASE/100ML
N020269 003 Oct 19, 1993

DOBUTAXEL
+ LILLY
EQ 12.5MG BASE/ML
N017820 002

DOCETAXEL
INJECTABLE; INJECTION

DOCEFREZ
+ SUN PHARMA GLOBAL
20MG/VIAL
N022534 001 May 03, 2011
80MG/VIAL
N022534 002 May 03, 2011

+ ACCORD HLTHCARE
20MG/0.5ML (40MG/ML)
N201195 001 Jun 08, 2011
80MG/2ML (40MG/ML)
N201195 002 Jun 08, 2011

+ APOTEX INC
20MG/0.5ML (40MG/ML)
N202312 001 Jan 11, 2012
80MG/2ML (40MG/ML)
N202312 002 Jan 11, 2012

+ HOSPIRA INC
120MG/6ML (20MG/ML)
N202356 006 Mar 13, 2014
PFIZER LABS
20MG/2ML (10MG/ML)
N202356 001 Mar 13, 2014
80MG/8ML (10MG/ML)
N202356 002 Mar 13, 2014
130MG/13ML (10MG/ML)
N202356 003 Mar 13, 2014
200MG/20ML (10MG/ML)
N202356 004 Mar 13, 2014

TAXOTERE
+ SANOFI AVENTIS US
40MG/ML **
N020449 001 May 14, 1996

DOLASETRON MESYLATE
INJECTABLE; INJECTION

ANZEMET
+ US PHARM HOLDINGS
12.5MG/0.625ML (20MG/ML)
N020624 002 Sep 11, 1997
100MG/5ML (20MG/ML)
N020624 001 Sep 11, 1997
500MG/25ML (20MG/ML)
N020624 003 Dec 11, 2001

TABLET; ORAL
ANZEMET
+ US PHARM HOLDINGS
50MG
N020623 001 Sep 11, 1997
100MG
N020623 002 Sep 11, 1997

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### Donepezil Hydrochloride

**Solution; Oral**
- **ARICEPT**
  - **Eisai Inc** 5mg/5ml N021719 001 Oct 18, 2004

**Tablet; Oral**
- **Donepezil Hydrochloride**
  - **Accord Healthcare**
    - 5mg A201335 001 Aug 29, 2011
    - 10mg A201335 002 Aug 29, 2011
  - **Apotex**
    - 5mg A078841 001 Jun 02, 2011
    - 10mg A078841 002 Jun 02, 2011
  - **Hikma Pharms**
    - 5mg A090247 001 May 31, 2011
    - 10mg A090247 002 May 31, 2011
  - **Sun Pharm Inds Ltd**
    - 5mg A076786 001 Nov 26, 2010
    - 10mg A076786 002 Nov 26, 2010

**Tablet, Orally Disintegrating; Oral**
- **ARICEPT ODT**
  - **Eisai Inc**
    - 5mg N021720 001 Oct 18, 2004
    - 10mg N021720 002 Oct 18, 2004
  - **Donepezil Hydrochloride**
    - **Barr**
      - 5mg A078388 001 Nov 26, 2010
      - 10mg A078388 002 Nov 26, 2010
    - **SUN PHARM INDUSTRIES**
      - 5mg A077975 001 Dec 11, 2009
      - 10mg A077975 002 Dec 11, 2009
    - **ZYDUS PHARMS USA INC**
      - 5mg A090175 001 May 10, 2011
      - 10mg A090175 002 May 10, 2011

**Donepezil Hydrochloride; Memantine Hydrochloride**
- **Capsule, Extended Release; Oral**
  - **MEMANTINE HYDROCHLORIDE AND DONEPEZIL HYDROCHLORIDE**
    - **Amneal Pharms**
      - 10mg; 14mg A208328 001 Jan 27, 2017
      - 10mg; 28mg A208328 002 Jan 27, 2017

### Dopamine Hydrochloride

**Injectable; Injection**
- **Dopamine Hydrochloride**
  - **Abbott**
    - 40mg/ml A070656 001 Jan 24, 1989
    - 80mg/ml A070657 001 Jan 24, 1989
  - **Abraxis Pharm**
    - 40mg/ml A070012 001 Jun 12, 1985
    - 40mg/ml A070058 001 Mar 20, 1985
    - 80mg/ml A070013 001 Jun 12, 1985
    - 80mg/ml A070059 001 Mar 20, 1985
    - 160mg/ml A070364 001 Dec 04, 1985
  - **Baxter HealthCare**
    - 40mg/ml N018398 001
    - 80mg/ml N018398 002 May 23, 1996
  - **Hospira**
    - 40mg/ml A07q403 001 May 23, 1996
    - 80mg/ml A070007 001 Oct 23, 1985
    - 80mg/ml A070039 001 Oct 23, 1985
    - 80mg/ml A070090 001 Oct 23, 1985
    - 80mg/ml A070091 001 Oct 23, 1985
    - 160mg/ml A070092 001 Oct 23, 1985
    - 160mg/ml A070093 001 Oct 23, 1985
    - 160mg/ml A070094 001 Oct 23, 1985
  - **Intl Medication**
    - 40mg/ml N018014 001
  - **Luitpold**
    - 160mg/ml A07q826 001 Feb 11, 1987
  - **Lymphomed**
    - 40mg/ml A078549 001 Mar 23, 1983
  - **Smith and Nephew**
    - 40mg/ml A070011 001 Aug 29, 1985
    - 40mg/ml A070046 001 Aug 29, 1985
    - 80mg/ml A070047 001 Aug 29, 1985
  - **Teligen**
    - 40mg/ml N018656 001 Jun 23, 1983
  - **Teva Parenteral**
    - 40mg/ml A072999 001 Oct 23, 1991
    - 80mg/ml A073000 001 Oct 23, 1991
  - **Warner Chilcott**
    - 40mg/ml A070558 001 Sep 20, 1985
    - 40mg/ml N018138 001
    - 80mg/ml A070559 001 Sep 20, 1985

**Dopamine Hydrochloride in Dextrose 5%**
- **Hospira**
  - 1.6mg/ml N020542 001 Aug 30, 1995

**Intropin**
- **Hospira**
  - 40mg/ml N017395 001
  - 80mg/ml N017395 002
  - 160mg/ml N017395 003

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
DORIPENEM
INJECTABLE; INTRAVENOUS
DORISAX
+ SHIONOGI INC 250MG/VIAL N022106 002 Oct 05, 2010
+ 500MG/VIAL N022106 001 Oct 12, 2007

DORZOLAMIDE HYDROCHLORIDE
SOLUTION/DROPS; OPHTHALMIC
DORZOLAMIDE HYDROCHLORIDE
APOTEX INC EQ 2% BASE A078395 001 Oct 28, 2008
TEVA PHARMS EQ 2% BASE A078756 001 Dec 04, 2008
WATSON LABS INC EQ 2% BASE A202053 001 Sep 11, 2014
ZAMBON SPA EQ 2% BASE A091034 001 Dec 04, 2013

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE
SOLUTION/DROPS; OPHTHALMIC
DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE
APOTEX INC EQ 2% BASE; EQ 0.5% BASE A078201 001 Oct 28, 2008
LANNETT CO INC EQ 2% BASE; EQ 0.5% BASE A201998 001 Dec 17, 2014
WATSON LABS INC EQ 2% BASE; EQ 0.5% BASE A202054 001 Sep 03, 2014
ZAMBON SPA EQ 2% BASE; EQ 0.5% BASE A091180 001 Dec 04, 2013

DOXACURIUM CHLORIDE
INJECTABLE; INJECTION
NUROMAX ABBVIE
DOXAPRAM HYDROCHLORIDE
INJECTABLE; INJECTION
DOXAPRAM HYDROCHLORIDE
WATSON LABS

DOXAZOSIN MESYLATE
TABLET; ORAL
DOXAZOSIN MESYLATE
ACTAVIS ELIZABETH EQ 1MG BASE A075574 001 Oct 18, 2000
EQ 2MG BASE A075574 002 Oct 18, 2000
EQ 4MG BASE A075574 003 Oct 18, 2000
EQ 8MG BASE A075574 004 Oct 18, 2000
GENPHARM EQ 1MG BASE A075466 001 Oct 18, 2000
EQ 2MG BASE A075466 002 Oct 18, 2000
EQ 4MG BASE A075466 003 Oct 18, 2000
EQ 8MG BASE A075466 004 Oct 18, 2000
IVAX SUB TEVA PHARMS EQ 1MG BASE A075453 001 Oct 18, 2000
EQ 2MG BASE A075453 002 Oct 18, 2000
EQ 4MG BASE A075453 003 Oct 18, 2000
EQ 8MG BASE A075453 004 Oct 18, 2000
NESHER PHARMS EQ 1MG BASE A075609 001 Oct 18, 2000
EQ 2MG BASE A075609 002 Oct 18, 2000
EQ 4MG BASE A075609 003 Oct 18, 2000
EQ 8MG BASE A075609 004 Oct 18, 2000
TEVA EQ 1MG BASE A075353 001 Jan 12, 2001
EQ 2MG BASE A075353 002 Jan 12, 2001
EQ 4MG BASE A075353 003 Jan 12, 2001
EQ 8MG BASE A075353 004 Jan 12, 2001
WATSON LABS INC EQ 1MG BASE A075426 001 Oct 18, 2000
EQ 2MG BASE A075426 002 Oct 18, 2000
EQ 4MG BASE A075426 003 Oct 18, 2000
EQ 8MG BASE A075426 004 Oct 18, 2000
YAOPHARMA CO LTD EQ 1MG BASE A075646 001 Oct 18, 2000
EQ 2MG BASE A075646 002 Oct 18, 2000
EQ 4MG BASE A075646 003 Oct 18, 2000
EQ 8MG BASE A075646 004 Oct 18, 2000

DOXEPIN HYDROCHLORIDE
CAPSULE; ORAL
DOXEPIN HYDROCHLORIDE
DAVA PHARMS INC EQ 10MG BASE A071685 001 Jan 05, 1988
EQ 25MG BASE A071686 001 Jan 05, 1988
EQ 50MG BASE A071673 001 Jan 05, 1988
EQ 75MG BASE A071674 001 Jan 05, 1988
EQ 100MG BASE A071675 001 Jan 05, 1988

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DISCONTINUED DRUG PRODUCT LIST

#### DOXEPIN HYDROCHLORIDE

**Capsule; Oral**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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| PHARMACIA AND UPJOHN     | 10MG/VIAL         | N050467  | 001 May 28, 1985 |
|                          | 20MG/VIAL         | N050467  | 003 May 28, 1985 |
|                          | 50MG/VIAL         | N050467  | 002 May 28, 1985 |
|                          | 150MG/VIAL        | N050467  | 004 Jul 22, 1987 |
| SANDOX INC               | 2MG/ML            | A200146  | 001 Jul 18, 2012 |
| **RUBEX**                |                   |          |            |
| BRISTOL MYERS SQUIBS     | 10MG/VIAL         | A062926  | 001 Apr 13, 1989 |
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Drug Product</th>
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<td>Doxylamine Succinate; Pyridoxine Hydrochloride</td>
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** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**DISCONTINUED DRUG PRODUCT LIST**

**See List Footnote**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

**ENALAPRIL MALEATE**

**TABLET; ORAL**

**ENALAPRIL MALEATE**

APOTHECON

- 2.5MG A075583 001 Aug 22, 2000
- 5MG A075583 002 Aug 22, 2000
- 10MG A075583 003 Aug 22, 2000
- 20MG A075583 004 Aug 22, 2000

IVAX SUB TEVA PHARMS

- 2.5MG A075482 001 Aug 22, 2000
- 5MG A075482 002 Aug 22, 2000
- 10MG A075482 003 Aug 22, 2000
- 20MG A075482 004 Aug 22, 2000

KRKA DD NOVO MESTO

- 2.5MG A075370 001 Aug 22, 2000
- 5MG A075370 002 Aug 22, 2000
- 10MG A075369 001 Aug 22, 2000
- 20MG A075369 002 Aug 22, 2000

MYLAN

- 2.5MG A075472 001 Aug 22, 2000
- 5MG A075472 002 Aug 22, 2000
- 10MG A075472 003 Aug 22, 2000
- 20MG A075472 004 Aug 22, 2000

SANDOZ

- 2.5MG A075048 001 Aug 22, 2000
- 5MG A075048 002 Aug 22, 2000
- 10MG A075048 003 Aug 22, 2000
- 20MG A075048 004 Aug 22, 2000

SANDOZ INC

- 2.5MG A075621 001 Aug 22, 2000
- 5MG A075621 002 Aug 22, 2000
- 10MG A075621 003 Aug 22, 2000
- 20MG A075621 004 Aug 22, 2000

SUN PHARM INDS LTD

- 2.5MG A075556 001 Aug 22, 2000
- 5MG A075556 002 Aug 22, 2000
- 10MG A075556 003 Aug 22, 2000
- 20MG A075556 004 Aug 22, 2000

WATSON LABS

- 2.5MG A075501 001 Aug 22, 2000
- 5MG A075501 002 Aug 22, 2000
- 10MG A075501 003 Aug 22, 2000
- 20MG A075501 004 Aug 22, 2000

**ENALAPRIL MALEATE; FELODIPINE**

**TABLET, EXTENDED RELEASE; ORAL**

LEXCEL

ASTRAZENECA

- 5MG; 2.5MG A076668 002 Oct 28, 1998
- 5MG; 5MG A076668 001 Dec 27, 1996

**ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE**

**TABLET; ORAL**

IVAX SUB TEVA PHARMS

- 5MG; 12.5MG A075736 001 Mar 25, 2003
- 10MG; 25MG A075736 002 Mar 25, 2003

UPSHER SMITH LABS

- 5MG; 12.5MG A076116 001 Sep 19, 2001
- 10MG; 25MG A076116 002 Sep 19, 2001

**ENALAPRILAT**

**INJECTABLE; INJECTION**

HOSPIRA

- 1.25MG/ML A075456 001 Aug 22, 2000
- 1.25MG/ML A075457 001 Aug 22, 2000

VASOTEC

- + BIVAIL LABS INTL 1.25MG/ML ** N019309 001 Feb 09, 1988

**ENFLURANE**

**LIQUID; INHALATION**

ABBOTT

- 99.9% A070803 001 Sep 08, 1987

PIRAMAL CRITICAL

- 99.9% A074396 001 Jul 29, 1994

BAXTER HLTHCARE

- 99.9% N017087 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Enoxacin
- **Tablet; Oral**
  - Penetrex
  - Sanofi Aventis US
  - 200mg
  - 400mg
  - N019616 004 Dec 31, 1991
  - N019616 005 Dec 31, 1991

### Enoxaparin Sodium
- **Injectable; Subcutaneous**
  - Lovenox (Preservative Free)
  - Sanofi Aventis US
  - 90mg/0.6ml (150mg/ml) **
  - N020164 006 Jun 02, 2000

### Entacapone
- **Tablet; Oral**
  - Entacapone
  - Mylan Pharms Inc
  - 200mg
  - A202394 001 May 13, 2013

### Epinephrine
- **Aerosol, Metered; Inhalation**
  - Bronakaid Mist
    - Sterling
    - 0.25mg/Inh
    - N016803 001
  - Epinephrine
    - Armstrong Pharms
    - 0.2mg/Inh
    - A087907 001 May 23, 1984
  - Primatene Mist
    - Wyeth Cons
    - 0.2mg/Inh
    - N016126 001
  - Injectable; Injection
    - Sus-Phrine Sulfite Free
      - Forest Labs
      - 1.5mg/amp
      - 5mg/ml
      - N007942 003 Feb 05, 1999
      - N007942 001
  - Injectable; Intramuscular
    - Epi E Z Pen Jr
      - Mylan Speciality LP
      - 0.15mg/delivery
      - N019430 004 Aug 03, 1995
    - Epipen E Z Pen
      - Mylan Speciality LP
      - 0.3mg/delivery
      - N019430 003 Aug 03, 1995
  - Injectable; Intramuscular, Subcutaneous
    - Twinject 0.15
      - Impax
      - Eq 0.15mg/delivery
      - N020800 002 May 28, 2004
    - twinject 0.3
      - Impax
      - Eq 0.3mg/delivery
      - N020800 001 May 30, 2003

### Epinephrine Bitartrate
- **Aerosol, Metered; Inhalation**
  - Bronitin Mist
    - Wyeth Cons
    - 0.3mg/Inh
    - N016126 002
  - Mediraler-Epi 3m
    - 0.3mg/Inh
    - N010374 003

### Epinephrine Bitartrate; Etidocaine Hydrochloride
- **Injectable; Injection**
  - DuraNeast
    - + AstraZeneca
      - 0.005mg/ml; 1% **
      - N017751 006
    - + AstraZeneca
      - 0.005mg/ml; 1.5% **
      - N017751 007
    - + Dentsply Pharm
      - 0.005mg/ml; 1.5% **
      - N021384 001

### Epinephrine Bitartrate; Prilocaine Hydrochloride
- **Injectable; Injection**
  - Citanest Forte
    - AstraZeneca
    - 0.005mg/ml; 4%
    - N014763 008

### Epinephrine; Etidocaine Hydrochloride
- **Injectable; Injection**
  - DuraNeast
    - + AstraZeneca
    - 0.005mg/ml; 0.5% **
    - N017751 004

### Epinephrine; Lidocaine Hydrochloride
- **Injectable; Injection**
  - Alphacaine Hydrochloride W/ Epinephrine
    - Carlisle
    - 0.01mg/ml; 2%
    - A084720 001
    - 0.02mg/ml; 2%
    - A084732 001
  - Lidocaine Hydrochloride and Epinephrine
    - Belmora LLC
    - 0.01mg/ml; 2%
    - A080504 004 Oct 19, 1983
    - 0.02mg/ml; 2%
    - A080504 005 Oct 19, 1983
    - Eastman Kodak
    - 0.01mg/ml; 2%
    - A040057 002 Feb 26, 1993
    - 0.02mg/ml; 2%
    - A040057 001 Feb 26, 1993

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**EPINEPHRINE; LIDOCAINE HYDROCHLORIDE**

**INJECTABLE; INJECTION**

- **LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE**
  - **HOSPIRA**
    - 0.005MG/ML; 1%
    - 0.005MG/ML; 1.5%
    - 0.01MG/ML; 2%
    - 0.02MG/ML; 2%
  - **WEST-WARD PHARMS INT**
    - 0.01MG/ML; 1%
    - 0.01MG/ML; 2%

- **LIDOCAINE HYDROCHLORIDE W/ EPINEPHRINE**
  - **ABBOTT**
    - 0.01MG/ML; 1%
    - 0.01MG/ML; 2%
  - **BEL MAR**
    - 0.01MG/ML; 1%
    - 0.01MG/ML; 2%
  - **DELL LABS**
    - 0.01MG/ML; 1%
    - 0.01MG/ML; 2%
  - **INTL MEDICATION**
    - 0.01MG/ML; 1%
    - 0.01MG/ML; 1%
  - **WATSON LABS**
    - 0.01MG/ML; 1%
    - 0.01MG/ML; 2%

**LIDOCAIN**

- **PHARMATON**
  - 0.01MG/ML; 1%
  - 0.02MG/ML; 2%

**OCTOCAINE**

- **SEPTODONT**
  - 0.01MG/ML; 2%
  - 0.02MG/ML; 2%

**XYLOCAINE DENTAL WITH EPINEPHRINE**

- **DENTSPLY PHARM**
  - 0.01MG/ML; 2%
  - 0.02MG/ML; 2%

**XYLOCAINE W/ EPINEPHRINE**

- **ASTRAZENECA**
  - 0.005MG/ML; 1%
  - 0.005MG/ML; 1.5%
  - 0.005MG/ML; 2%
- **FRESENIUS KABI USA**
  - 0.01MG/ML; 2%

**PATCH; IONTOPHORESIS, TOPICAL**

- **LIDOSITE TOPICAL SYSTEM KIT**
  - **VYTERIS**
    - 1.05MG/PATCH; 100MG/PATCH

**SOLUTION; IONTOPHORESIS**

- **IONTOCAINE**
  - **IONMED**
    - 0.01MG/ML; 2%

**SOLUTION; IONTOPHORESIS, TOPICAL**

- **LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE**
  - **EMPI**
    - 0.01MG/ML; 2%

**EPINEPHRINE; PROCAINE HYDROCHLORIDE**

**INJECTABLE; INJECTION**

- **PROCAINE HYDROCHLORIDE W/ EPINEPHRINE**
  - **BEL MAR**
    - 0.02MG/ML; 1%
    - 0.02MG/ML; 2%

**EPIRUBICIN HYDROCHLORIDE**

**INJECTABLE; INJECTION**

- **EPIRUBICIN HYDROCHLORIDE**
  - **EBEWE PHARMA**
    - 50MG/25ML (2MG/ML)
    - 200MG/100ML (2MG/ML)
  - **HOSPIRA**
    - 50MG/25ML (2MG/ML)
    - 200MG/100ML (2MG/ML)
  - **MUSTAPA NEVSAT**
    - 50MG/25ML (2MG/ML)
    - 200MG/100ML (2MG/ML)
  - **MYLAN INSTITUTIONAL**
    - 50MG/25ML (2MG/ML)
    - 200MG/100ML (2MG/ML)
  - **POWDER; INTRAVENOUS**
    - **EPIRUBICIN HYDROCHLORIDE**
      - **HOSPIRA**
        - 50MG/VIAL
        - 200MG/VIAL

**EPILERENONE**

- **TABLET; ORAL**
  - **INSPIRA**
    - 100MG

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Eprosartan Mesylate

**Tablet, Oral**
- Teveten
  - ABBVIE EQ 300MG BASE N020738 004 Dec 22, 1997
  - EQ 400MG BASE N020738 005 Dec 22, 1997
  - EQ 600MG BASE N020738 006 May 27, 1999

**Tablet, Oral; Hydrochlorothiazide**
- Teveten HCT
  - ABBVIE 600MG;12.5MG N021268 001 Nov 01, 2001
  - 600MG;25MG N021268 002 Nov 01, 2001

### Eptifibatide

**Injectable, Injection**
- Teva Pharms USA 75MG/100ML A091555 001 Jun 05, 2015

### Ergocalciferol

**Capsule, Oral**
- Deltalin
  - Lilly 50,000 IU A080884 001
  - Vitamin D
    - Chase Chem 50,000 IU A080747 001
    - EveryLife 50,000 IU A080955 001
    - Impax Labs 50,000 IU A080951 001
    - Lannett 50,000 IU A080825 001
    - Vitarine 50,000 IU A084053 001
    - West Ward 50,000 IU A083102 001

### Ergoloid Mesylates

**Capsule, Oral**
- Hydergine LC
  - Novartis 1MG N018706 001 Jan 18, 1983

**Solution, Oral**
- Hydergine
  - Novartis 1MG/ML N018418 001

**Tablet, Oral**
- Ergoloid Mesylates
  - Mutual Pharm 1MG A088891 001 Nov 01, 1985
  - Watson Labs 1MG A086433 001 May 27, 1982
  - 1MG A087244 001 Aug 16, 1982

**Tablet, Sublingual**
- Alkergot
  - Sandoz 0.5MG A085153 001
  - 1MG A085417 001

**Circanol**
- 3M 0.5MG A084868 001
  - 1MG A085809 001

**Deapril-St**
- Bristol Myers Squibb 1MG A085020 002

**Ergoloid Mesylates**
- Kv Pharm
  - 0.5MG A085899 001
  - 1MG A086265 001
  - 1MG A085900 001
  - 1MG A086264 001

**Lederle**
- 0.5MG A086984 001
  - 1MG A086985 001

**Sun Pharm Industries**
- 0.5MG A087407 001
  - 1MG A087552 001

**Superpharm**
- 0.5MG A089233 001 Sep 23, 1986
  - 1MG A089234 001 Sep 23, 1986

**Vanguard**
- 0.5MG A088013 001 Sep 20, 1982
  - 1MG A088014 001 Sep 20, 1982

**Watson Labs**
- 0.5MG A084930 001
  - 0.5MG A087233 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>SYOSSET</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ERYTHROMYCIN

SOLUTION; TOPICAL

C-SOLVE-2

FOUGERA PHARMS 2% A062468 001 Jul 03, 1985
ERYDERM

ARBOR PHARMS INC 2% A062299 001
ERYMAX

MERZ PHARMS 2% A062508 002 Jul 11, 1985
ERYTHRA-DERM

ANDA REPOSITORY 2% A062687 001 Feb 05, 1988
ERYTHRO-STATIN

HI TECH PHARMA 2% A064101 001 Oct 22, 1996
ERYTHROMYCIN

ALPHARMA US PHARMS 1.5% A062328 001 Apr 19, 1982

2% A062326 001 Apr 19, 1982

2% A062327 001 Apr 19, 1982

2% A062342 001 Feb 25, 1982

2% A062957 001 Jul 21, 1988

BAUSCH AND LOMB 2% A064039 001 Jan 27, 1994

FOUGERA PHARMS 2% A064187 001 Sep 30, 1997
LILLY 2% N050532 001

PHARMAFAIR 1.5% ** A062485 001 Jul 11, 1984

2% A062616 001 Jul 25, 1985

RENAISSANCE PHARMA 2% A064127 001 Feb 14, 1997
SANSAC

DOW PHARM 2% A062522 001 Jan 24, 1985
STATICIN + WESTWOOD SQUIBB 1.5% ** N050526 001
T-STAT

WESTWOOD SQUIBB 2% ** A062436 001 Mar 09, 1983
SWAB; TOPICAL

C-SOLVE-2

IVAX SUB TEVA PHARMS 2% A062751 001 Jul 30, 1993
ERYCETTE + JOHNSON AND JOHNSON 2% ** N050594 001 Feb 15, 1985
ERYTHROMYCIN

FOUGERA PHARMS 2% A065320 001 Jul 25, 2006
MYLAN PHARMS INC 2% A064128 001 Jul 25, 1985
T-STAT

WESTWOOD SQUIBB 2% A062748 001 Jul 23, 1987
TABLET, COATED PARTICLES; ORAL

PCE

+ ARBOR PHARMS LLC 333MG N050611 001 Sep 09, 1986
+ 500MG N050611 002 Aug 22, 1990
TABLET, DELAYED RELEASE; ORAL

E-BASE

BARR 333MG A063028 001 May 15, 1990
333MG A063086 001 May 15, 1990
500MG A062999 001 Nov 25, 1990
E-MYCIN

ARBOR PHARMS INC 250MG A060272 001
333MG A060272 002
ILOTYCIN

DISTA 250MG A061910 001
R-P MYCIN

SOLVAY 250MG A061659 001
ROBIMYCIN

ROBINS AH 250MG A061633 001
ERYTHROMYCIN ESTOLATE

CAPSULE; ORAL

ERYTHROMYCIN ESTOLATE

BARR EQ 125MG BASE A062162 001
EQ 250MG BASE A062162 002
IVAX SUB TEVA PHARMS EQ 250MG BASE A062237 001
WATSON LABS EQ 250MG BASE A062087 001
ILOSONE

LILLY EQ 125MG BASE A061897 001
EQ 250MG BASE A061897 002

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ERYTHROMYCIN ESTOLATE
FOR SUSPENSION; ORAL
ILOSONE
DISTA
EQ 125MG BASE/5ML A061893 001
SUSPENSION; ORAL
ERYTHROMYCIN ESTOLATE
ALPHARMA US PHARMS
EQ 125MG BASE/5ML A062353 001 Nov 18, 1982
EQ 250MG BASE/5ML A062409 001 Dec 16, 1982
G AND W LABS INC
EQ 125MG BASE/5ML A062169 001 Oct 17, 1990
EQ 250MG BASE/5ML A062169 002 Oct 17, 1990
LIFE LABS
EQ 250MG BASE/5ML A062362 001 Dec 17, 1982
ILOSONE
LILLY
EQ 125MG BASE/5ML A061894 001
EQ 125MG BASE/5ML N050010 001
EQ 250MG BASE/5ML A061894 002
EQ 250MG BASE/5ML N050010 002
SUSPENSION/DROPS; ORAL
ILOSONE
LILLY
EQ 100MG BASE/ML A061894 003
TABLET; ORAL
ILOSONE
LILLY
EQ 500MG BASE A061896 001
TABLET, CHEWABLE; ORAL
ILOSONE
DISTA
EQ 125MG BASE A061895 001
EQ 250MG BASE A061895 002
ERYTHROMYCIN ESTOLATE; SULFISOXAZOLE ACETYL
SUSPENSION; ORAL
ILOSONE SULFA
LILLY
EQ 125MG BASE/5ML, EQ 600MG BASE/5ML N050599 001 Sep 29, 1989
ERYTHROMYCIN ETHYLSUCCINATE
GRANULE; ORAL
PEDIAMYCIN
ROSS LABS
EQ 200MG BASE/5ML A062305 001
SUSPENSION; ORAL
E-MYCIN E
PHARMACIA AND UPJOHN
EQ 200MG BASE/5ML A062198 001
EQ 400MG BASE/5ML A062198 002
E.E.S. 200
ARBOR PHARMS LLC
EQ 200MG BASE/5ML ** A061639 001
E.E.S. 400
ARBOR PHARMS LLC
EQ 400MG BASE/5ML ** A061639 002
ERYTHROMYCIN ETHYLSUCCINATE
ALPHARMA US PHARMS
EQ 200MG BASE/5ML A062200 001
EQ 400MG BASE/5ML A062200 002
DISTA
EQ 200MG BASE/5ML A062177 001
EQ 400MG BASE/5ML A062177 002
NASKA
EQ 400MG BASE/5ML A062674 001 Mar 10, 1987
PARKE DAVIS
EQ 200MG BASE/5ML A062231 001
EQ 400MG BASE/5ML A062231 002
PHARMAFAIR
EQ 200MG BASE/5ML A062559 001 Mar 15, 1985
EQ 400MG BASE/5ML A062558 001 Mar 15, 1985
PEDIAMYCIN
ARBOR PHARMS LLC
EQ 200MG BASE/5ML A062304 001
PEDIAMYCIN 400
ARBOR PHARMS LLC
EQ 400MG BASE/5ML A062304 002
WYAMYCIN E
WYETH AYERST
EQ 200MG BASE/5ML A062123 002
EQ 400MG BASE/5ML A062123 001
SUSPENSION/DROPS; ORAL
PEDIAMYCIN
ROSS LABS
EQ 100MG BASE/2.5ML A062305 002
TABLET; ORAL
E.E.S. 400
ARBOR PHARMS LLC
EQ 400MG BASE A061905 001
ERYTHROMYCIN ETHYLSUCCINATE
BARR
EQ 400MG BASE A062256 001
MYLAN
EQ 400MG BASE A062847 001 Sep 14, 1988

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### ERYTHROMYCIN ETHYL SUCCINATE

**Tablet, Chewable, Oral**

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<td>PEDIAMycin</td>
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**ERYTHROMYCIN ETHYL SUCCINATE, SULFISOXAZOLE ACETYL**

**Granule, Oral**

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**ERYTHROMYCIN GLUCESCINATE**

**Injectable, Injection**

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**ERYTHROMYCIN LACTOBIONATE**

**Injectable, Injection**

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**ERYTHROMYCIN STEARATE**

**Tablet, Oral**

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**ERYTHROMYCIN STEARATE**

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**ETHRIL 250**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### ERYTHROMYCIN STEARATE

**Tablet; Oral**

- **ETHRIL 500**
  - **BRISTOL MYERS SQUIBB** EQ 500MG BASE A061605 002
  - **PFIZER-E** EQ 250MG BASE A061791 001
  - **Pfizer** EQ 500MG BASE A061791 002
  - **Wyamycin S** EQ 250MG BASE A061675 001
  - **Wyeth Ayerst** EQ 500MG BASE A061675 002

### ESCITALOPRAM OXALATE

**Capsule; Oral**

- **ESCITALOPRAM OXALATE**
  - **Mylan Pharms Inc** EQ 5MG BASE A077660 001
  - **ESCITALOPRAM OXALATE** EQ 10MG BASE A077660 002
  - **ESCITALOPRAM OXALATE** EQ 20MG BASE A077660 003

**Tablet; Oral**

- **ESCITALOPRAM OXALATE**
  - **Mylan Pharms Inc** EQ 5MG BASE A077550 001
  - **ESCITALOPRAM OXALATE** EQ 10MG BASE A077550 002
  - **ESCITALOPRAM OXALATE** EQ 20MG BASE A077550 003

### ESMOLOL HYDROCHLORIDE

**Injectable; Injection**

- **BREVILOC**
  - **BAXTER HLTHCARE** 10MG/ML N019386 003
  - **BAXTER HLTHCARE** 20MG/ML N019386 007

### ESOPEPRAZOLE SODIUM

**Injectable; Intravenous**

- **ESOPEPRAZOLE SODIUM**
  - **Aurobindo Pharma Ltd** EQ 20MG BASE/VIAL A204657 001
  - **ESOPEPRAZOLE SODIUM** EQ 20MG BASE/VIAL A202686 001
  - **ESOPEPRAZOLE SODIUM** EQ 20MG BASE/VIAL A200882 001

### ESOPEPRAZOLE STRONTIUM

**Capsule, Delayed Release; Oral**

- **ESOPEPRAZOLE STRONTIUM**
  - **R2 Pharma LLC** 24.65MG N202342 001

### ESTAZOLAM

**Tablet; Oral**

- **PROSOM**
  - **ABBOTT** 1MG ** N019080 001
  - **ABBOTT** 2MG ** N019080 002

### ESTRADIOL

**Film, Extended Release; Transdermal**

- **ESCLIM**
  - **WOMEN FIRST HLTHCARE** 0.025MG/24HR N020847 001
  - **WOMEN FIRST HLTHCARE** 0.0375MG/24HR N020847 002
  - **WOMEN FIRST HLTHCARE** 0.05MG/24HR N020847 003
  - **WOMEN FIRST HLTHCARE** 0.075MG/24HR N020847 004
  - **WOMEN FIRST HLTHCARE** 0.1MG/24HR N020847 005

- **ESTRADERM**
  - **NOVARTIS** 0.05MG/24HR N019081 002
  - **NOVARTIS** 0.1MG/24HR N019081 003

- **ESTRADIOL**
  - **ORTHO MCNEIL PHARM** 0.05MG/24HR N021048 001
  - **ORTHO MCNEIL PHARM** 0.075MG/24HR N021048 002
  - **ORTHO MCNEIL PHARM** 0.1MG/24HR N021048 003

- **FEMPATCH**
  - **PARKE DAVIS** 0.025MG/24HR N020417 001

- **VIVELLE**
  - **NOVARTIS** 0.025MG/24HR N020323 005
  - **NOVARTIS** 0.0375MG/24HR N020323 006
  - **NOVARTIS** 0.05MG/24HR N020323 007
  - **NOVARTIS** 0.075MG/24HR N020323 008
  - **NOVARTIS** 0.1MG/24HR N020323 009

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

| Product | Formulation | Manufacturer/Brand | Strength | NDC Code | Date
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| Estrone Esterified Tablet; Oral | Estratab | Roche Palo | 2.5mg | A083857 001 |
| | Evex | | 0.625mg | A084215 001 |
| | | | 1.25mg | A083376 002 |
| | Femogen | PVT Form | 0.625mg | A085076 001 |
| | | | 1.25mg | A085008 001 |
| | | | 2.5mg | A085007 001 |
| Estrone Injectable; Injection | Estrogenic Substance WYETH AYERST | | 2mg/ml | A083488 001 |
| | Watson Labs | | 2mg/ml | A083397 001 |
| | Watson Labs Teva | | 5mg/ml | A085239 001 |
| | Natural Estrogenic Substance-Estrone Watson Labs | | 2mg/ml | A085237 001 Nov 23, 1982 |
| Theelin | Parkedale | | 1mg/ml | N003977 001 |
| | | | 2mg/ml | N003977 002 |
| | | | 5mg/ml | N003977 003 |
| Estropipate Cream; Vaginal | Ogen | Pharmacia And Upjohn | 1.5mg/gm | A084710 001 |
| | | | 0.75mg | A040135 001 Nov 27, 1996 |
| | | | | A040135 002 Nov 27, 1996 |
| | | | | A040135 003 Nov 27, 1996 |
| | | | | A040135 004 Nov 27, 1996 |
| | | | | A040296 001 Nov 01, 1999 |
| | | | | A040296 002 Nov 01, 1999 |
| | | | | A040296 003 Nov 01, 1999 |
| | | | | A040359 001 Aug 26, 1999 |
| | | | | A081213 001 Sep 23, 1993 |
| | | | | A081214 001 Sep 23, 1993 |
| | | | | A081216 001 Sep 23, 1993 |
| | Watson Labs Teva | | 3mg | A081215 001 Sep 23, 1993 |
| | | | | A081215 002 Sep 23, 1993 |
| | | | | A081215 003 Sep 23, 1993 |
| | | | | A081215 004 Sep 23, 1993 |
| | | | | A089567 001 Feb 27, 1991 |
| | | | | A089582 001 Jul 17, 1991 |
| Eszopiclone Tablet; Oral | Eszopiclone Wockhardt Ltd | | 1mg | A091165 001 Jul 14, 2011 |
| | | | | A091165 002 Jul 14, 2011 |
| | | | | A091165 003 Jul 14, 2011 |
| Ethacrynic Acid Tablet; Oral | Edecrin Aton | | 50mg | N016092 002 |
| Ethambutol Hydrochloride Tablet; Oral | Myambutol STI Pharma LLC | | 200mg | N016320 002 |
| | | | | N016320 004 |
| | | | | N016320 007 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>PORTIA-21</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Ethinyl Estradiol; Norethindrone

**Tablet; Oral-21**

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**Tablet; Oral-28**

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**Tablet; Oral-21**

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<td>Norlestrin 21 1/50</td>
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**Tablet; Oral-28**

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### Ethinyl Estradiol; Norgestimate

**Tablet; Oral-21**

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<td>Ortho Tri-Cyclen</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>ETHYLESTRENOL</td>
<td>Elixir; Oral</td>
<td>MAXIBOLIN</td>
<td>N014006 002</td>
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<td>Organon USA Inc</td>
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<td>2MG/5ML</td>
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<td>MAXIBOLIN</td>
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<td>TABLET; Oral</td>
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<td>ETHYNODIOL Diacetate; Mestranol Tablet; Oral</td>
<td>20</td>
<td>1MG, 0.1MG</td>
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<td>OVULEN</td>
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<td>N016029 003</td>
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<td>GD Searle LLC</td>
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<td>1MG, 0.1MG</td>
<td>N016705 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

ETIDOCAINE HYDROCHLORIDE
INJECTABLE; INJECTION
DURANEST
+ ASTRazeneca
  0.5% ** N017751 003
+ 1% ** N017751 005

ETIDRONATE DISODIUM
INJECTABLE; INJECTION
DIDRONEL
MGi PHARMA INC 50MG/ML N019545 001 Apr 20, 1987
TABLET; ORAL
DIDRONEL
+ APIL
  200MG ** N017831 001
+ 400MG ** N017831 002

ETODOLAC
CAPSULE; ORAL
ETODOLAC
ANI PHARMS INC
  200MG A074840 001 Aug 29, 1997
  200MG A074899 001 Jul 08, 1997
  300MG A074840 002 Aug 29, 1997
  300MG A074899 002 Jul 08, 1997
CHARTWELL MOLECULES
  200MG A074842 001 Jul 17, 1997
  300MG A074842 002 Jul 17, 1997
ECI PHARMS LLC
  300MG A074929 001 Jan 30, 1998
MYLAN
  200MG A074932 001 May 16, 1997
  200MG A075071 001 Sep 30, 1998
  300MG A074932 002 May 16, 1997
  300MG A075071 002 Sep 30, 1998
SANDOZ
  300MG A074942 001 Sep 30, 1997
  300MG A074942 002 Sep 30, 1997
WATSON LABS
  200MG A074844 001 Dec 23, 1997
  300MG A074844 002 Dec 23, 1997
LODINE
+ WYETH PHARMS INC
  200MG ** N018922 002 Jan 31, 1991
  300MG N018922 003 Jan 31, 1991
TABLET; ORAL
ETODOLAC
CHARTWELL MOLECULES
  400MG A074841 001 Jun 27, 1997
ECI PHARMS LLC
  400MG A074927 001 Oct 30, 1997
IVAX SUB TEVA PHARMS
  500MG A074883 001 Feb 28, 1997
MYLAN
  400MG A074883 002 Nov 20, 1998
  500MG A075012 001 Sep 30, 1998
  500MG A075012 002 Sep 30, 1998
MYLAN PHARMS INC
  400MG A075104 001 Feb 06, 1998
  500MG A075104 002 Nov 20, 1998
OXFORD PHARMS
  400MG A074819 001 Feb 28, 1997
  500MG A074819 002 Apr 28, 1998
RANBAXY LABS LTD
  500MG A075226 001 Nov 24, 1998
SANDOZ
  400MG A074839 001 Jul 11, 1997
  400MG A074846 001 Feb 28, 1997
TEVA
  400MG A074847 001 Apr 23, 1999
  500MG A074847 002 Apr 23, 1999
WATSON LABS
  400MG A074892 001 Apr 16, 1997
  400MG A075069 001 Apr 16, 1998
  500MG A074892 002 Oct 29, 1998
LODINE
+ WYETH PHARMS INC
  400MG ** N018922 004 Jul 29, 1993
  500MG ** N018922 005 Jun 28, 1996
TABLET, EXTENDED RELEASE; ORAL
ETODOLAC
ACTAVIS ELIZABETH
  400MG A075696 001 Jul 31, 2000
ANI PHARMS INC
  400MG A075943 001 Jul 26, 2002
  500MG A075943 002 Jul 26, 2002
  600MG A075943 003 Jul 26, 2002
WATSON LABS FLORIDA
  400MG A075829 001 Nov 30, 2001
  500MG A075829 002 Nov 30, 2001
LODINE XL
WYETH PHARMS INC
  400MG ** N020584 001 Oct 25, 1996

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

| **ETODOLAC** | **TABLET, EXTENDED RELEASE; ORAL** |
| LODINE XL | 500MG ** N020584 003 Jan 20, 1998 |
| + 600MG ** N020584 002 Oct 25, 1996 |

| **ETONOGESTREL** | **IMPLANT; IMPLANTATION** |
| IMPLANON | 68MG/IMPLANT N021529 001 Jul 17, 2006 |

| **ETOPOSIDE** | **CAPSULE; ORAL** |
| VEPESID | 50MG N019557 001 Dec 30, 1986 |
| + DAVA PHARMS INC 100MG N019557 002 Dec 30, 1986 |

| **ETOPOSIDE** | **INJECTABLE; INJECTION** |
| **ETOPOSIDE** | HOSPIRA 20MG/ML A074320 001 Aug 30, 1995 |
| + PHARMACHEMIE BV 20MG/ML A074227 001 Feb 22, 1996 |
| + PIERRE FABRE 20MG/ML A074813 001 Jul 09, 1997 |
| + TEVA PARENTERAL 20MG/ML A074510 001 Jun 29, 1995 |
| + TEVA PHARMS USA 20MG/ML A074284 001 Feb 10, 1994 |
| + WATSON LABS 20MG/ML A074228 001 Oct 15, 1996 |
| + WATSON LABS INC 20MG/ML A074968 001 Jan 09, 1998 |
| TOPOSAR | TEVA PARENTERAL 20MG/ML A074166 001 Feb 27, 1995 |
| VEPESID | + CORDEN PHARMA 20MG/ML ** N018768 001 Nov 10, 1983 |

| **ETOPOSIDE PHOSPHATE** | **INJECTABLE; INJECTION** |
| ETOPOPHOS PRESERVATIVE FREE | BRISTOL MYERS SQUIBB EQ 500MG BASE/VIAL N020906 001 Feb 27, 1998 |
| + EQ 1GM BASE/VIAL N020906 002 Feb 27, 1998 |

| **ETRITINATE** | **CAPSULE; ORAL** |
| TEGISON | ROCHE 10MG N019369 001 Sep 30, 1986 |
| + 25MG N019369 002 Sep 30, 1986 |

| **EVANS BLUE** | **INJECTABLE; INJECTION** |
| EVANS BLUE | PARKE DAVIS 0.5% ** N008041 001 |

| **EZOGABINE** | **TABLET; ORAL** |
| POTIGA | + GLAXOSMITHKLINE 50MG N022345 001 Jun 10, 2011 |
| + 200MG N022345 002 Jun 10, 2011 |
| + 300MG N022345 003 Jun 10, 2011 |
| + 400MG N022345 004 Jun 10, 2011 |

| **FAMCICLOVIR** | **TABLET; ORAL** |
| FAMVIR | + NOVARTIS 125MG ** N020363 003 Dec 11, 1995 |
| + 250MG ** N020363 001 Apr 26, 1996 |
| + 500MG ** N020363 002 Jun 29, 1994 |

| **FAMOTIDINE** | **INJECTABLE; INJECTION** |
| FAMOTIDINE | APOTEX INC 10MG/ML A075942 001 Aug 02, 2002 |
| + APOTHECON 10MG/ML A075707 001 Apr 16, 2001 |
| + HOSPIRA 10MG/ML A075705 001 Apr 16, 2001 |
| + 10MG/ML A075870 001 Nov 23, 2001 |
| + 10MG/ML A075905 001 Nov 23, 2001 |
| + WEST-WARD PHARMS INT 10MG/ML A075799 001 Apr 30, 2002 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## FAMOTIDINE

**INJECTABLE; INJECTION**

**FAMOTIDINE PRESERVATIVE FREE**

<table>
<thead>
<tr>
<th>Company</th>
<th>Strength</th>
<th>NDC Number</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>APOTEX INC</td>
<td>10MG/ML</td>
<td>A076324</td>
<td>Nov 27, 2002</td>
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<td>APOTHECON</td>
<td>10MG/ML</td>
<td>A075708</td>
<td>Apr 16, 2001</td>
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<td>HOSPIRA</td>
<td>10MG/ML</td>
<td>A075669</td>
<td>Apr 16, 2001</td>
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<td>WEST-WARD PHARMS INT</td>
<td>10MG/ML</td>
<td>A075789</td>
<td>Apr 30, 2002</td>
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**FAMOTIDINE PRESERVATIVE FREE (PHARMACY BULK)**

<table>
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<th>Company</th>
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<tbody>
<tr>
<td>APOTEX INC</td>
<td>10MG/ML</td>
<td>A076322</td>
<td>Nov 27, 2002</td>
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**FAMOTIDINE PRESERVATIVE FREE IN PLASTIC CONTAINER**

<table>
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<th>Company</th>
<th>Strength</th>
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<th>Date</th>
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<tbody>
<tr>
<td>PEPCID</td>
<td>0.4MG/ML</td>
<td>A075729</td>
<td>Dec 17, 2001</td>
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**PEPCID PRESERVATIVE FREE**

<table>
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<tr>
<th>Company</th>
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<th>Date</th>
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<tr>
<td>ABBVIE</td>
<td>10MG/ML</td>
<td>N019510</td>
<td>Nov 04, 1986</td>
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**PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER**

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<th>Company</th>
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<tr>
<td>ABBVIE</td>
<td>0.4MG/ML</td>
<td>N020249</td>
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**TABLET; ORAL**

**FAMOTIDINE**

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<th>Company</th>
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<tr>
<td>ACTAVIS ELIZABETH</td>
<td>20MG</td>
<td>A075650</td>
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<td>APOTEX</td>
<td>10MG</td>
<td>A075610</td>
<td>Mar 12, 2002</td>
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<td>MYLAN PHARMS INC</td>
<td>20MG</td>
<td>A075457</td>
<td>Apr 18, 2001</td>
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<td>40MG</td>
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<td>PLD ACQUISITIONS</td>
<td>20MG</td>
<td>A075302</td>
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<td>Sandoz</td>
<td>10MG</td>
<td>A076101</td>
<td>Oct 21, 2002</td>
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<td>20MG</td>
<td>A075607</td>
<td>May 10, 2001</td>
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<td>20MG</td>
<td>A075793</td>
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<td>40MG</td>
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<td>WATSON LABS</td>
<td>10MG</td>
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<td>Nov 28, 2001</td>
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<td>20MG</td>
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**PEPCID AC**

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<tr>
<td>+ J AND J CONSUMER INC</td>
<td>10MG</td>
<td>N020801</td>
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**TABLET, ORALLY DISINTEGRATING; ORAL**

**FLUIDIC**

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<tr>
<td>UCB INC</td>
<td>20MG</td>
<td>N021712</td>
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<td>40MG</td>
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**PEPCID RPD**

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<tr>
<td>MERCK</td>
<td>20MG</td>
<td>N020752</td>
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## FELODIPINE

**TABLET, EXTENDED RELEASE; ORAL**

**FELODIPINE**

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<tr>
<td>WOCKHARDT LTD</td>
<td>2.5MG</td>
<td>A091484</td>
<td>Aug 15, 2012</td>
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<td>5MG</td>
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**PLENDIL**

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<tr>
<td>+ ASTRAZENECA</td>
<td>2.5MG</td>
<td>N019834</td>
<td>Sep 22, 1994</td>
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<td>+ 5MG</td>
<td>N019834</td>
<td>Jul 25, 1991</td>
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<td>+ 10MG</td>
<td>N019834</td>
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## FENOFIBRATE

**CAPSULE; ORAL**

**ANTARA (MICRONIZED)**

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<td>LUPIN ATLANTIS</td>
<td>87MG</td>
<td>N021695</td>
<td>Nov 30, 2004</td>
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**LIPIDIL**

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<td>ABBVIE</td>
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<td>N019304</td>
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**LIPOFEN**

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<td>CIPHER PHARMS INC</td>
<td>100MG</td>
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**TRICOR (MICRONIZED)**

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<td>+ ABBVIE</td>
<td>67MG</td>
<td>N019304</td>
<td>Feb 09, 1998</td>
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<td>+ 134MG</td>
<td>N019304</td>
<td>Jun 30, 1999</td>
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<td>+ 200MG</td>
<td>N019304</td>
<td>Jun 30, 1999</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
FENOFIBRATE

TABLET; ORAL

FENOFIBRATE
MYLAN
107MG
A076520 002 Dec 29, 2005

TRICOR
+ ABBVIE INC
54MG **
N021203 001 Sep 04, 2001
+
160MG **
N021203 003 Sep 04, 2001

TRIGLIDE
SKYEPHARMA AG
50MG
N021350 001 May 07, 2005

FENOLOPAM MESYLATE

INJECTABLE; INJECTION

FENOLOPAM MESYLATE

LUITPOLD EQ
10MG BASE/ML
A076656 001 Dec 01, 2003

TEVA PARENTERAL EQ
10MG BASE/ML
A077826 001 Mar 07, 2007

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

AM THERAP
EQ 200MG BASE
A072307 001 Aug 22, 1988
EQ 300MG BASE
A072308 001 Aug 22, 1988

AUROLIFE PHARMA LLC
EQ 200MG BASE
A072394 001 Oct 17, 1988
EQ 300MG BASE
A072395 001 Oct 17, 1988

HALSEY
EQ 200MG BASE
A072355 001 Aug 17, 1988
EQ 300MG BASE
A072356 001 Aug 17, 1988

PAR PHARM
EQ 200MG BASE
A072437 001 Aug 22, 1988
EQ 300MG BASE
A072438 001 Aug 22, 1988

QUANTUM PHARMICS
EQ 200MG BASE
A072214 001 Aug 17, 1988
EQ 300MG BASE
A071739 001 Aug 17, 1988

WARNER CHILCOTT
EQ 200MG BASE
A072946 001 Apr 30, 1991
EQ 300MG BASE
A072472 001 Apr 30, 1991

WATSON LABS
EQ 200MG BASE
A072294 001 Aug 17, 1988
EQ 200MG BASE
A072981 001 Aug 19, 1991
EQ 300MG BASE
A072293 001 Aug 17, 1988
EQ 300MG BASE
A072982 001 Aug 19, 1991

NALFON
XSPIRE PHARMA
EQ 300MG BASE
N017604 002

TABLET; ORAL

FENOPROFEN CALCIUM

ACTAVIS ELIZABETH
EQ 600MG BASE
A072274 001 May 02, 1988

AM THERAP
EQ 600MG BASE
A072309 001 Aug 17, 1988

AUROLIFE PHARMA LLC
EQ 600MG BASE
A072396 001 Oct 17, 1988

DAVA PHARMS INC
EQ 600MG BASE
A072326 001 Aug 17, 1988

HALSEY
EQ 600MG BASE
A072357 001 Aug 17, 1988

IVAX SUB TEVA PHARMS
EQ 600MG BASE
A072537 001 Aug 29, 1988

PAR PHARM
EQ 600MG BASE
A072429 001 Aug 17, 1988

QUANTUM PHARMICS
EQ 600MG BASE
A072194 001 Aug 17, 1988

SUN PHARM INDUSTRIES
EQ 600MG BASE
A072902 001 Dec 21, 1990

USL PHARMA
EQ 600MG BASE
A072362 001 Aug 17, 1988

WATSON LABS
EQ 600MG BASE
A072165 001 Aug 17, 1988
EQ 600MG BASE
A072602 001 Oct 11, 1988

WATSON LABS TEVA
EQ 600MG BASE
A072407 001 Aug 17, 1988

NALFON
DISTA
EQ 600MG BASE
N017710 001

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

FENTANYL-100
ACTAVIS LABS UT INC
100MCG/HR
A076709 004 Aug 20, 2007
NOVEN
100MCG/HR
A077775 004 Oct 16, 2009

FENTANYL-25
ACTAVIS LABS UT INC
25MCG/HR
A076709 001 Aug 20, 2007
NOVEN
25MCG/HR
A077775 001 Oct 16, 2009

FENTANYL-50
ACTAVIS LABS UT INC
50MCG/HR
A076709 002 Aug 20, 2007
NOVEN
50MCG/HR
A077775 002 Oct 16, 2009

FENTANYL-75
ACTAVIS LABS UT INC
75MCG/HR
A076709 003 Aug 20, 2007
NOVEN
75MCG/HR
A077775 003 Oct 16, 2009

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
FENTANYL CITRATE

FILM; BUCAL
ONSOLIS
BDSI
EQ 0.2MG BASE N022266 001 Jul 16, 2009
EQ 0.4MG BASE N022266 002 Jul 16, 2009
EQ 0.6MG BASE N022266 003 Jul 16, 2009
EQ 0.8MG BASE N022266 004 Jul 16, 2009
EQ 1.2MG BASE N022266 005 Jul 16, 2009

INJECTABLE; INJECTION
FENTANYL CITRATE
ABBOTT
EQ 0.05MG BASE/ML A070636 001 Apr 30, 1990
EQ 0.05MG BASE/ML A070637 001 Apr 30, 1990
WATSON LABS
EQ 0.05MG BASE/ML A073488 001 Jun 30, 1992

FENTANYL CITRATE PRESERVATIVE FREE
WATSON LABS INC
EQ 0.05MG BASE/ML A074917 001 Feb 03, 1998

TABLET; BUCAL, SUBLINGUAL
FENTANYL CITRATE
WATSON LABS
EQ 0.1MG BASE A079075 001 Jan 07, 2011
EQ 0.2MG BASE A079075 002 Jan 07, 2011
EQ 0.4MG BASE A079075 003 Jan 07, 2011
EQ 0.6MG BASE A079075 004 Jan 07, 2011
EQ 0.8MG BASE A079075 005 Jan 07, 2011

FENTORA
+ CEPHALON
EQ 0.3MG BASE ** N021947 006 Mar 02, 2007

TROCHE/LOZENGE; ORAL
FENTANYL
CEPHALON
EQ 0.1MG BASE N020195 007 Oct 30, 1995
EQ 0.2MG BASE N020195 001 Oct 04, 1993
EQ 0.3MG BASE N020195 002 Oct 04, 1993
EQ 0.4MG BASE N020195 003 Oct 04, 1993

TROCHE/LOZENGE; TRANSMUCOSAL
FENTANYL CITRATE
PAR PHARM
EQ 0.2MG BASE A077312 001 Oct 30, 2009
EQ 0.4MG BASE A077312 002 Oct 30, 2009
EQ 0.6MG BASE A077312 003 Oct 30, 2009
EQ 0.8MG BASE A077312 004 Oct 30, 2009
EQ 1.2MG BASE A077312 005 Oct 30, 2009
EQ 1.6MG BASE A077312 006 Oct 30, 2009

FENTANYL HYDROCHLORIDE
SYSTEM; IONTOPORESIS, TRANSDERMAL
IONSYS
+ THE MEDICINES CO
EQ 40MCG BASE/ACTIVATION N021338 001 May 22, 2006

FERRIC AMMONIUM CITRATE
FOR SOLUTION; ORAL
FERRISELTZ
OTSUKA
600MG/PACKET N020292 001 Oct 14, 1997

FERRIC PYROPHOSPHATE CITRATE
SOLUTION; INTRAVENOUS
TRIFERIC
+ ROCKWELL MEDICAL INC 272MG IRON/50ML (5.44MG IRON/ML) N206317 002 Sep 04, 2015

FERROUS CITRATE, Fe-59
INJECTABLE; INJECTION
FERROUS CITRATE FE 59
MALLINCKRODT 25uCi/ML N016729 001

FERROUS SULFATE; FOLIC ACID
CAPSULE; ORAL
FOLVRON
LEDERLE 182MG; 0.33MG ND06012 003

FERUMOXIDES
INJECTABLE; INJECTION
FERIDEX I.V.
AMAG PHARMS INC EQ 11.2MG IRON/ML ND20416 001 Aug 30, 1996

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
FERUMOXIL
SUSPENSION; ORAL
GASTROMARK
AMAG PHARMS INC
EQ 0.175MG IRON/ML
N020410 001 Dec 06, 1996

FESOTERODINE FUMARATE
TABLET, EXTENDED RELEASE; ORAL
FESOTERODINE FUMARATE
ALKEM LABS LTD
4MG
A204827 001 Dec 10, 2015
8MG
A204827 002 Dec 10, 2015

FEXOFENADINE HYDROCHLORIDE
CAPSULE; ORAL
ALLEGRA
SANOFI AVENTIS US
60MG **
N020625 001 Jul 25, 1996
FEXOFENADINE HYDROCHLORIDE
BARR
60MG
A076169 001 Jul 13, 2005

FEXOFENADINE HYDROCHLORIDE
SUSPENSION; ORAL
ALLEGRA
SANOFI AVENTIS US
30MG/5ML
N021963 001 Oct 16, 2006
CHILDREN'S ALLEGRA IVES
+ SANOFI AVENTIS US
30MG/5ML
N201373 002 Jan 24, 2011
CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY
TARO PHARM
30MG/5ML
A208123 001 Nov 09, 2017
CHILDREN'S FEXOFENADINE HYDROCHLORIDE IVES
TARO PHARM
30MG/5ML
A208123 002 Nov 09, 2017
FEXOFENADINE HYDROCHLORIDE
ACTAVIS MID ATLANTIC
30MG/5ML
A201311 001 Jul 25, 2012

FEXOFENADINE HYDROCHLORIDE
TABLET; ORAL
ALLEGRA IVES
+ SANOFI AVENTIS US
60MG
N020872 008 Jan 24, 2011
+ 180MG
N020872 009 Jan 24, 2011
CHILDREN'S ALLEGRA ALLERGY
+ SANOFI AVENTIS US
30MG
N020872 005 Jan 24, 2011
CHILDREN'S ALLEGRA IVES
+ SANOFI AVENTIS US
30MG
N020872 006 Jan 24, 2011
TABLET, ORALLY DISINTEGRATING; ORAL
CHILDREN'S ALLEGRA ALLERGY
+ SANOFI AVENTIS US
30MG
N021909 002 Jan 24, 2011
CHILDREN'S ALLEGRA IVES
+ SANOFI AVENTIS US
30MG
N021909 003 Jan 24, 2011
CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY
DR REDDYS LABS LTD
30MG
A202978 001 Jan 18, 2013
CHILDREN'S FEXOFENADINE HYDROCHLORIDE IVES
DR REDDYS LABS LTD
30MG
A202978 002 Jan 18, 2013

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE
TABLET, EXTENDED RELEASE; ORAL
FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE
BARR
60MG;120MG
A076236 001 Apr 14, 2005
IMPAX PHARMS
60MG;120MG
A076298 001 Nov 12, 2010

FIBRINOGEN, I-125
INJECTABLE; INJECTION
IBRIN
GE HEALTHCARE
154uCi/VIAL
N017879 001
RADIONUCLIDE-LABELED (I-125) FIBRINOGEN (HUMAN) SENSOR
ABBOTT
140uCi/ML
N017787 001

FINASTERIDE
TABLET; ORAL
FINASTERIDE
GEDEON RICHTER USA
5MG
A077251 001 Dec 22, 2006
IVAX SUB TEVA PHARMS
5MG
A076340 001 Jun 19, 2006
MYLAN PHARMS INC
1MG
A078161 001 Nov 05, 2013

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### FLAVOXATE HYDROCHLORIDE

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLAVOXATE HYDROCHLORIDE IMPAX PHARMS</td>
<td>100MG</td>
<td>A076234</td>
<td>Aug 28, 2003</td>
</tr>
<tr>
<td>ORTHO MCNEIL JANSSEN</td>
<td>100MG</td>
<td>N016769</td>
<td>Aug 28, 2003</td>
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</table>

**See List Footnote**

### FLECAINIDE ACETATE

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLECAINIDE ACETATE ANI PHARMS INC</td>
<td>50MG</td>
<td>A076030</td>
<td>Oct 28, 2002</td>
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<tr>
<td></td>
<td>100MG</td>
<td>A076030</td>
<td>Oct 28, 2002</td>
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<tr>
<td></td>
<td>150MG</td>
<td>A076030</td>
<td>Oct 28, 2002</td>
</tr>
<tr>
<td>APOTEX INC</td>
<td>50MG</td>
<td>A079164</td>
<td>Jul 09, 2009</td>
</tr>
<tr>
<td></td>
<td>100MG</td>
<td>A079164</td>
<td>Jul 09, 2009</td>
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<tr>
<td></td>
<td>150MG</td>
<td>A079164</td>
<td>Jul 09, 2009</td>
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<tr>
<td>TAMBOCOR CNTY LINE PHARMS</td>
<td>200MG</td>
<td>N018830</td>
<td>Oct 31, 1985</td>
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</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

### FLORBETAPIR F-18 SOLUTION; INTRAVENOUS

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>AMYVID AVID RADIOPHARMS INC</td>
<td>10ML (13.5-51mCi/ML)</td>
<td>N202008</td>
<td>Apr 06, 2012</td>
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### FLURURIDINE

**Injectable; Injection**

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<th>Strength</th>
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<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>FUDR + HOSPIRA</td>
<td>500MG/VIAL</td>
<td>N016929</td>
<td>Jul 09, 2009</td>
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</table>

### FLUCONAZOLE

**For Suspension; Oral**

<table>
<thead>
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<th>Product Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUN PHARM INDS LTD</td>
<td>50MG/5ML</td>
<td>A076332</td>
<td>Jan 13, 1990</td>
</tr>
<tr>
<td></td>
<td>200MG/5ML</td>
<td>A076332</td>
<td>Jan 13, 1990</td>
</tr>
<tr>
<td>TARO PHARM INDS</td>
<td>50MG/5ML</td>
<td>A076918</td>
<td>Dec 18, 2006</td>
</tr>
<tr>
<td></td>
<td>200MG/5ML</td>
<td>A076918</td>
<td>Dec 18, 2006</td>
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</table>

**Injectable; Injection**

<table>
<thead>
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<th>Product Name</th>
<th>Strength</th>
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<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>DIFLUCAN IN DEXTROSE 5% IN PLASTIC CONTAINER + PFIZER</td>
<td>200MG/100ML (2MG/ML)</td>
<td>N019950</td>
<td>Sep 29, 1992</td>
</tr>
<tr>
<td></td>
<td>400MG/200ML (2MG/ML)</td>
<td>N019950</td>
<td>Jul 08, 1994</td>
</tr>
<tr>
<td>DIFLUCAN IN SODIUM CHLORIDE 0.9% + PFIZER</td>
<td>200MG/100ML (2MG/ML)</td>
<td>N019950</td>
<td>Jan 29, 1990</td>
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<tr>
<td></td>
<td>400MG/200ML (2MG/ML)</td>
<td>N019950</td>
<td>Jul 08, 1994</td>
</tr>
<tr>
<td>DIFLUCAN IN SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER + PFIZER</td>
<td>200MG/100ML (2MG/ML)</td>
<td>N019950</td>
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<td>400MG/200ML (2MG/ML)</td>
<td>N019950</td>
<td>Jan 29, 1990</td>
</tr>
<tr>
<td>DIFLUCAN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER MYLAN LABS LTD</td>
<td>200MG/100ML (2MG/ML)</td>
<td>A076888</td>
<td>Mar 25, 2005</td>
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<td>400MG/200ML (2MG/ML)</td>
<td>A076888</td>
<td>Mar 25, 2005</td>
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<tr>
<td>DIFLUCAN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER TEVA PHARMS USA</td>
<td>200MG/100ML (2MG/ML)</td>
<td>A076653</td>
<td>Jul 29, 2004</td>
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<td>400MG/200ML (2MG/ML)</td>
<td>A076653</td>
<td>Jul 29, 2004</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

### TABLET; ORAL

<table>
<thead>
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<th>NDC Code</th>
<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>ANI PHARMS INC</td>
<td>50MG</td>
<td>A076086</td>
<td>Jul 29, 2004</td>
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<tr>
<td></td>
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<td>150MG</td>
<td>A076086</td>
<td>Jul 29, 2004</td>
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<td>200MG</td>
<td>A076086</td>
<td>Jul 29, 2004</td>
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<td>GEDEON RICHTER USA</td>
<td>50MG</td>
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<td>100MG</td>
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<td>150MG</td>
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<tr>
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<td>200MG</td>
<td>A076432</td>
<td>Jul 29, 2004</td>
</tr>
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<td>MYLAN PHARMS INC</td>
<td>50MG</td>
<td>A076042</td>
<td>Jul 29, 2004</td>
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<td>100MG</td>
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<td>Jul 29, 2004</td>
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### FLUCONAZOLE

<table>
<thead>
<tr>
<th>Strength</th>
<th>Brand</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>150mg</td>
<td>PLIVA</td>
<td>Jul 29, 2004</td>
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<tr>
<td>200mg</td>
<td>PLIVA</td>
<td>Jul 29, 2004</td>
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<tr>
<td>50mg</td>
<td>RANBAXY LABS LTD</td>
<td>Jul 29, 2004</td>
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<tr>
<td>100mg</td>
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<td>150mg</td>
<td>RANBAXY LABS LTD</td>
<td>Jul 29, 2004</td>
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<tr>
<td>200mg</td>
<td>RANBAXY LABS LTD</td>
<td>Jul 29, 2004</td>
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<tr>
<td>50mg</td>
<td>ROXANE</td>
<td>Jul 29, 2004</td>
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<tr>
<td>100mg</td>
<td>ROXANE</td>
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<td>150mg</td>
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<tr>
<td>200mg</td>
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### FLUDARABINE PHOSPHATE

<table>
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<tr>
<th>Strength</th>
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<tbody>
<tr>
<td>50mg</td>
<td>GENZYME CORP</td>
<td>Apr 18, 1991</td>
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<tr>
<td>4-40mCi/ML</td>
<td>DOWNSTATE CLINCL</td>
<td>Aug 19, 1994</td>
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<td>4-90mCi/ML</td>
<td>DOWNSTATE CLINCL</td>
<td>Sep 25, 2001</td>
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<tr>
<td>20-200mCi/ML</td>
<td>FEINSTEIN</td>
<td>Aug 19, 2005</td>
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<tr>
<td>10-100mCi/ML</td>
<td>FEINSTEIN</td>
<td>Aug 05, 2004</td>
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<tr>
<td>1mg/10ml</td>
<td>HOFFMANN LA ROCHE</td>
<td>Dec 20, 1991</td>
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<td>0.5mg/5ml</td>
<td>HOFFMANN LA ROCHE</td>
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### FLUDEOXYGLUCOSE F-18

<table>
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<th>Strength</th>
<th>Brand</th>
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<tr>
<td>0.03%</td>
<td>NOVARTIS</td>
<td>001</td>
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### FLUMAZENIL

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<tr>
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<th>Brand</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>0.5mg/5ml</td>
<td>BAXTER HLTHCARE CORP</td>
<td>Oct 12, 2004</td>
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<tr>
<td>0.1mg/ML</td>
<td>BAXTER HLTHCARE CORP</td>
<td>Oct 12, 2004</td>
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<tr>
<td>0.5mg/5ml</td>
<td>TEVA PHARMS USA</td>
<td>Oct 12, 2004</td>
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<tr>
<td>0.1mg/ML</td>
<td>TEVA PHARMS USA</td>
<td>Oct 12, 2004</td>
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<tr>
<td>1mg/10ml</td>
<td>ROMAZICON</td>
<td>Oct 12, 2004</td>
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<tr>
<td>0.029mg/SPRAY</td>
<td>APOTEX INC</td>
<td>Aug 09, 2007</td>
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<tr>
<td>0.025mg/SPRAY</td>
<td>IVAX RES</td>
<td>Aug 17, 1984</td>
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<tr>
<td>0.025mg/SPRAY</td>
<td>IVAX RES</td>
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### FLUMETHASONE PIVALATE

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<td>001</td>
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### FLUNISOLIDE

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<tr>
<th>Strength</th>
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<tbody>
<tr>
<td>0.25mg/INH</td>
<td>ROCHE PALO</td>
<td>Aug 17, 1984</td>
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<td>0.025mg/SPRAY</td>
<td>APOTEX INC</td>
<td>Aug 09, 2007</td>
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<td>0.025mg/SPRAY</td>
<td>IVAX RES</td>
<td>Aug 17, 1984</td>
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<tr>
<td>0.025mg/SPRAY</td>
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<td>Aug 17, 1984</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
FLUCINOLONE ACETONIDE

CREAM; TOPICAL

FLUOCET
ALPHARMA US PHARMS 0.025% A088360 001 Jan 16, 1984

FLUCINOLONE ACETONIDE

ALPHARMA US PHARMS 0.01% A088361 001 Jan 16, 1984
G AND W LABS 0.025% A089525 001 Jul 26, 1988
PERRIGO NEW YORK 0.01% A086810 001 Mar 04, 1982
0.025% A086811 001 Mar 04, 1982
PHARMADERM 0.01% A088047 001 Dec 16, 1982
0.025% A088045 001 Dec 16, 1982
PHARMAFAIR 0.01% A088499 001 Aug 02, 1984
0.025% A088506 001 Aug 02, 1984
TARO 0.01% A040035 001 Oct 31, 1994
0.01% A087102 001 Apr 27, 1982
0.025% A040042 001 Oct 31, 1994
USL PHARMA 0.01% A088757 001 Feb 11, 1985
0.025% A088756 001 Mar 28, 1985

FLUONID

ALLERGAN HERBERT 0.025% A087156 002 Sep 06, 1984

FLUOTREX

SAVAGE LABS 0.01% A088174 001 May 06, 1983
0.025% A088173 001 Mar 09, 1983

SYNALAR-HP

GEL; TOPICAL

MEDIMETRIKS PHARMS 0.2% N016161 002

FLUONID

ALLERGAN HERBERT 0.025% A087300 001 May 27, 1982

OINTMENT; TOPICAL

FLUCINOLONE ACETONIDE

PHARMADERM 0.025% A088046 001 Dec 16, 1982
PHARMAFAIR 0.025% A088507 001 Feb 27, 1984
USL PHARMA 0.025% A088742 001 Feb 08, 1985

FLUONID

ALLERGAN HERBERT 0.025% A087157 001 Sep 06, 1984

FLUOTREX

SAVAGE LABS 0.025% A088172 001 Mar 09, 1983

SOLUTION; TOPICAL

FLUCINOLONE ACETONIDE

ALPHARMA US PHARMS 0.01% A087159 001 Jun 16, 1982
BAUSCH AND LOMB 0.01% A040059 001 Dec 20, 1993
G AND W LABS INC 0.01% A207441 001 Sep 28, 2016
GLASSHOUSE PHARMS 0.01% A209596 001 Dec 26, 2017
MORTON GROVE 0.01% A088312 001 Jan 27, 1984
PHARMADERM 0.01% A088408 001 Dec 16, 1982
PHARMAFAIR 0.01% A088449 001 Feb 08, 1984

FLUONID

ALLERGAN HERBERT 0.01% A087158 001 Mar 17, 1983

FLUOTREX

SAVAGE LABS 0.01% A088171 001 Mar 09, 1983

FLUCINONIDE

CREAM; TOPICAL

FLUCINONIDE

PERRIGO NEW YORK 0.05% A071790 001 Jul 13, 1988

LIDEX + CNTRY LINE PHARMS 0.05% N016908 002

SOLUTION; TOPICAL

FLUCINONIDE

TARO 0.05% A072857 001 Aug 02, 1989
TEVA PHARMS 0.05% A072522 001 Sep 28, 1990

FLUORESCIN SODIUM

INJECTABLE; INJECTION

FUNDUSCEIN-25 + NOVARTIS 25% ** N017869 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date</th>
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<tbody>
<tr>
<td>Flutaveline Hydrochloride</td>
<td>Capsule; Oral</td>
<td>Wockhardt Ltd</td>
<td>Eq 20mg Base</td>
<td>A075807 002</td>
<td>Jan 29, 2002</td>
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<td>Eq 10mg Base</td>
<td>A077469 002</td>
<td>Nov 17, 2008</td>
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<td>Eq 40mg Base</td>
<td>A078143 003</td>
<td>Jan 16, 2008</td>
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<tr>
<td>Prozac</td>
<td>Capsule; Oral</td>
<td>Eli Lilly and Co</td>
<td>Eq 60mg Base</td>
<td>N018936 004</td>
<td>Jun 15, 1999</td>
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<td>Eq 10mg Base</td>
<td>N018936 007</td>
<td>Jul 06, 2000</td>
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<td>Eq 20mg Base</td>
<td>N018936 008</td>
<td>Jul 06, 2000</td>
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<tr>
<td>Flutaveline Hydrochloride</td>
<td>Solution; Oral</td>
<td>Actavis Mid Atlantic</td>
<td>Eq 20mg Base/5ml</td>
<td>A075690 001</td>
<td>Jan 31, 2002</td>
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<td>Eq 20mg Base/5ml</td>
<td>A075525 001</td>
<td>Jun 27, 2002</td>
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<td>Lannett Co Inc</td>
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<td>N020101 001</td>
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<td>Flutaveline Hydrochloride</td>
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<td>Eq 10mg Base</td>
<td>A075810 001</td>
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<td>A076024 001</td>
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<td>Flutaveline Decanoate</td>
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<td>Hospira</td>
<td>25mg/ML</td>
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<td>25mg/ML</td>
<td>A074795 001</td>
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<td>Concentrate; Oral</td>
<td>ANI Pharmaceuticals Inc</td>
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<td>Schering</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

FLUPHENAZINE HYDROCHLORIDE
ELIXIR; ORAL
FLUPHENAZINE HYDROCHLORIDE
ANI PHARMS INC
2.5MG/5ML
A081310 001 Apr 29, 1993
PROLIXIN
+ APOTHECON
2.5MG/5ML **
N012145 003
INJECTABLE; INJECTION
FLUPHENAZINE HYDROCHLORIDE
APOTHECON
2.5MG/ML **
N011751 005
TABLET; ORAL
FLUPHENAZINE HYDROCHLORIDE
WATSON LABS
1MG
A088555 001 Dec 18, 1987
2.5MG
A088544 001 Dec 18, 1987
5MG
A088527 001 Dec 18, 1987
10MG
A088550 001 Dec 18, 1987
PERMITIL
SCHERING
0.25MG
N012034 001
2.5MG
N012034 004
5MG
N012034 005
10MG
N012034 006
PROLIXIN
+ APOTHECON
1MG **
N011751 004
+ 2.5MG **
N011751 001
+ 5MG **
N011751 003
+ 10MG **
N011751 002
TABLET, EXTENDED RELEASE; ORAL
PERMITIL
SCHERING
1MG
N012419 004
FLUPREDNISOLONE
TABLET; ORAL
ALPHADROL
PHARMACIA AND UPJOHN
1.5MG
N012259 002
FLURANDRENOLIDE
LOTION; TOPICAL
FLURANDRENOLIDE
ALPHARMA US PHARMS
0.05%
A087203 001 Apr 29, 1982
OINTMENT; TOPICAL
CORDRAN
+ AQUA PHARMS
0.025% **
N012806 004
FLURANDRENOLIDE; NEOMYCIN SULFATE
CREAM; TOPICAL
CORDRAN N
LILLY
0.05%; EQ 3.5MG BASE/GM
N050346 001
OINTMENT; TOPICAL
CORDRAN N
LILLY
0.05%; EQ 3.5MG BASE/GM
N050345 001
FLURAZEPAM HYDROCHLORIDE
CAPSULE; ORAL
DALMANE
VALEANT PHARM INTL
15MG **
N016721 001
30MG **
N016721 002
FLURAZEPAM HYDROCHLORIDE
AUROLIFE PHARMA LLC
15MG
A071717 002 Jul 31, 1991
30MG
A071717 001 Jul 31, 1991
HALSEY
15MG
A071809 001 Jan 07, 1988
30MG
A071809 001 Jan 07, 1988
HIKMA INTL PHARMS
15MG
A071107 001 Dec 08, 1986
HIKMA PHARMS
30MG
A071108 001 Dec 08, 1986
PAR PHARM
15MG
A070444 001 Mar 20, 1986
30MG
A070445 001 Mar 20, 1986
PUREPAC PHARM
15MG
A071927 001 Sep 09, 1987
30MG
A071551 001 Sep 09, 1987
SUN PHARM INDUSTRIES
15MG
A070454 001 Aug 04, 1986
30MG
A070455 001 Aug 04, 1986
SUPERPHARM
15MG
A071639 001 Aug 04, 1988
30MG
A071660 001 Aug 04, 1988
USL PHARMA
15MG
A070562 001 Jul 09, 1987
** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
FLURAZEPAM HYDROCHLORIDE
CAPSULE; ORAL
FLURAZEPAM HYDROCHLORIDE

30MG  A070563  001  Jul 09, 1987
WARNER CHILCOTT
15MG  A071767  001  Dec 04, 1987
30MG  A071768  001  Dec 04, 1987
WATSON LABS
15MG  A071205  001  Nov 25, 1986
15MG  A072368  001  Mar 30, 1989
30MG  A071068  001  Nov 25, 1986
30MG  A072369  001  Mar 30, 1989

FLURBIPROFEN
TABLET; ORAL
ANSAID

PHARMACIA AND UPJOHN
50MG  N018766  002  Oct 31, 1988
100MG  N018766  003  Oct 31, 1988

FLURBIPROFEN
AUROLIFE PHARMA LLC
50MG  A074447  001  Jul 28, 1995
100MG  A074448  002  Jul 28, 1995
IVAX SUB TEVA PHARMS
50MG  A074411  001  May 31, 1995
100MG  A074412  002  May 31, 1995
PLIVA
50MG  A074647  001  Apr 01, 1997
100MG  A074648  002  Apr 01, 1997
TEVA
50MG  A074405  002  May 24, 1995
100MG  A074406  001  May 24, 1995
THERAGEN
100MG  A074560  002  May 16, 1997

FLUTAMIDE
CAPSULE; ORAL
EULEXIN
+SCHERING
125MG  N018554  001  Jan 27, 1989
FLUTAMIDE
MYLAN
125MG  A076224  001  May 09, 2003
YAOPHARMA CO LTD
125MG  A075818  001  Sep 18, 2001

FLUTEMETAMOL F-18
INJECTABLE; INTRAVENOUS
VIZAMYL
+ GE HEALTHCARE
40.5mCi/10ML (4.05mCi/ML)  N203137  001  Oct 25, 2013

FLUTICASONE PROPIONATE
AEROSOL, METERED; INHALATION
FLOVENT

GLAXOSMITHKLINE
0.044MG/INH  N020548  001  Mar 27, 1996
0.11MG/INH  N020548  002  Mar 27, 1996
0.22MG/INH  N020548  003  Mar 27, 1996

CREAM; TOPICAL
CUTIVATE
+Fougera Pharms
0.05% **  N019958  001  Dec 18, 1990
FLUTICASONE PROPIONATE
NESHER PHARMS
0.05%  A076865  001  Sep 10, 2004

OINTMENT; TOPICAL
CUTIVATE
+Fougera Pharms
0.005%  N019957  001  Dec 14, 1990
FLUTICASONE PROPIONATE
Fougera Pharms
0.005%  A076300  001  May 14, 2004
TARO PHARM INDS
0.005%  A077145  001  Jun 14, 2005

POWDER; INHALATION
FLOVENT

GLAXOSMITHKLINE
0.044MG/INH  N020549  001  Nov 07, 1997
0.088MG/INH  N020549  002  Nov 07, 1997
0.22MG/INH  N020549  003  Nov 07, 1997

SPRAY, METERED; NASAL
FLONASE
+ GLAXOSMITHKLINE
0.05MG/SPRAY **  N020121  001  Oct 19, 1994

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**FLUVASTATIN SODIUM**
CAPSULE; ORAL
LESCOL
+ NOVARTIS
  EQ 20MG BASE ** N020261 001 Dec 31, 1993
+ EQ 40MG BASE ** N020261 002 Dec 31, 1993

**FLUVOXAMINE MALEATE**
CAPSULE, EXTENDED RELEASE; ORAL
LUVOX CR
+ JAZZ PHARMS 100MG ** N022033 001 Feb 28, 2008
  150MG ** N022033 002 Feb 28, 2008
TABLET; ORAL
FLUVOXAMINE MALEATE
  ACTAVIS ELIZABETH 25MG A075901 001 Dec 28, 2000
  50MG A075901 002 Dec 28, 2000
  100MG A075901 003 Dec 28, 2000
  ANI PHARMS INC 25MG A075898 001 Mar 12, 2001
  50MG A075898 002 Mar 12, 2001
  100MG A075898 003 Mar 12, 2001
  ECI PHARMS LLC 25MG A075900 001 Feb 23, 2006
  50MG A075900 002 Feb 23, 2006
  100MG A075900 003 Feb 23, 2006
  MYLAN 50MG A076125 001 Oct 15, 2001
  100MG A076125 002 Oct 15, 2001
  SUN PHARM INDUSTRIES 25MG A075900 001 Dec 28, 2000
  50MG A075900 002 Dec 28, 2000
  100MG A075900 003 Dec 28, 2000
  SYNTHON PHARMS 25MG A075899 001 Jan 17, 2001
  50MG A075899 002 Jan 17, 2001
  100MG A075899 003 Jan 17, 2001
  UPSHER SMITH LABS 25MG A075887 001 Jan 05, 2001
  50MG A075887 002 Jan 05, 2001
  100MG A075887 003 Jan 05, 2001
  WATSON LABS 25MG A075894 001 Apr 18, 2001
  50MG A075894 002 Apr 18, 2001
  100MG A075894 003 Apr 18, 2001
LUVOX
+ SOLVAY 25MG ** N020243 001 Oct 05, 1994
  50MG ** N020243 002 Oct 05, 1994
  100MG ** N020243 003 Oct 05, 1994
  150MG ** N020243 004 Oct 05, 1994

**FOLIC ACID**
INJECTABLE; INJECTION
FOLIC ACID
BEN VENUE 5MG/ML A081066 001 Dec 29, 1993
FOLVITE
WYETH PHARMS INC 5MG/ML N005897 008
TABLET; ORAL
FOLIC ACID
BARR 1MG A089177 001 Jan 08, 1986
  CONTRACT PHARMACAL 1MG A085061 001
  EVERYLIFE 1MG A080755 001
  HALSEY 1MG A083598 001
  IMPAX LABS 1MG A080686 001
  IVAX SUB TEVA PHARMS 1MG A083000 001
  JUBILANT CADISTA 1MG A040514 001 Jun 14, 2005
  LANNETT 1MG A080816 001
  LILLY 1MG N006135 003
  MK LABS 1MG A083526 001
  NEXGEN PHARMA INC 1MG A084915 001
  PHARMERAL 1MG A084158 001
  PIONEER PHARMS 1MG A088849 001 Sep 13, 1985
  PUREPAC PHARM 1MG A080784 001
  SANDOX 1MG A084472 001
  SUN PHARM INDUSTRIES 1MG A040582 001 Jul 18, 2005
  TABLICAPS 1MG A083133 002
  UDL 1MG A088199 001 Mar 29, 1983
  USL PHARMA 1MG A087828 001 May 13, 1982
  VALENT PHARM INTL 1MG A080903 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Folic Acid Table; Oral

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<tr>
<td>VANGARD</td>
<td>1mg</td>
<td>A088730 001</td>
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<td>VINTAGE PHARMS</td>
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<td>A086296 001</td>
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<td>WATSON LABS</td>
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<td>WHITWEORTH TOWN PLSN</td>
<td>1mg</td>
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<td>MISSION PHARMA</td>
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<td>WYETH PHARMS INC</td>
<td>1mg</td>
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### Follitropin Alfa/Beta Injection; Intramuscular, Subcutaneous

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<tr>
<td>ORGANON USA INC</td>
<td>75 IU/vial</td>
<td>N020582 001</td>
<td>Sep 29, 1997</td>
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<td>ORGANON USA INC</td>
<td>150 IU/vial</td>
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<td>ORGANON USA INC</td>
<td>75 IU/0.5 ML</td>
<td>N021273 001</td>
<td>Aug 26, 2005</td>
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<td>ORGANON USA INC</td>
<td>150 IU/0.18 ML</td>
<td>N021211 003</td>
<td>Feb 11, 2004</td>
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<tr>
<td>ORGANON USA INC</td>
<td>150 IU/0.5 ML</td>
<td>N021273 002</td>
<td>Aug 26, 2005</td>
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<td>EMD SERONO</td>
<td>37.5 IU/vial</td>
<td>N020378 003</td>
<td>May 25, 2000</td>
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<td>EMD SERONO</td>
<td>37.5 IU/vial</td>
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### Fovepizole Injection; Injection

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<tr>
<td>MYLAN INSTITUTIONAL</td>
<td>1.5 GM/1.5 ML (1 GM/ML)</td>
<td>A079033 001</td>
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### Fomiviren Sodiuin Injection; Injexion

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<td>NOVARTIS</td>
<td>6.6 MG/ML</td>
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### Formoterol Fumarate Powder; Inhalation

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<tr>
<td>FORADIL</td>
<td>0.012 MG/INH</td>
<td>N020831 001</td>
<td>Feb 16, 2001</td>
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<td>FORADIL CERTIHALER</td>
<td>0.0085 MG/INH</td>
<td>N021592 001</td>
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### Fosaprepitant Dimethylamine Powder; Intravenous

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<tr>
<td>MERCK AND CO INC</td>
<td>EQ 115 MG BASE/VIAL **</td>
<td>N022023 001</td>
<td>Jan 25, 2008</td>
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### Foscarnet Sodium Injection; Injexion

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<td>HOEPIRA</td>
<td>2.4 GM/100 ML</td>
<td>A077174 001</td>
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### Fosinopril Sodium Tablet; Oral

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<td>ACTAVIS LABS FL INC</td>
<td>10 MG</td>
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<td>Oct 15, 2004</td>
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<td>ACTAVIS LABS FL INC</td>
<td>20 MG</td>
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<td>Oct 15, 2004</td>
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<tr>
<td>ACTAVIS LABS FL INC</td>
<td>40 MG</td>
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<td>RANBAXY LABS LTD</td>
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<td>UPSHER SMITH LABS</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

<table>
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<tr>
<th>FOSINOPRIL SODIUM</th>
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<td>ACTAVIS LABS FL INC 10MG; 12.5MG A076608 001 Dec 03, 2004</td>
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<td>TEVA 10MG; 12.5MG A076945 001 Jul 05, 2006</td>
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<td>{+} BRISTOL MYERS SQUIBB 10MG; 12.5MG ** N020286 002 Nov 30, 1994</td>
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<table>
<thead>
<tr>
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<th>INJECTABLE; INJECTION</th>
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<tr>
<td>FOSPHENYTOIN SODIUM</td>
<td>APOTEX INC EQ 50MG PHENYTOIN NA/ML A078126 001 Aug 06, 2007</td>
</tr>
<tr>
<td>HOSPIRA EQ 50MG PHENYTOIN NA/ML N020286 001 Aug 06, 2007</td>
<td></td>
</tr>
<tr>
<td>TEVA PHARMS USA EQ 50MG PHENYTOIN NA/ML A076886 001 Aug 06, 2007</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOSPROPONOL DISODIUM</th>
<th>SOLUTION; INTRAVENOUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUSEDRA EISAI INC 1050MG/30ML (35MG/ML) N022244 001 Dec 12, 2008</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FURAZOLIDONE</th>
<th>SUSPENSION; ORAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHIRE 50MG/15ML N011323 002</td>
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</table>

<table>
<thead>
<tr>
<th>FUROSEMIDE</th>
<th>INJECTABLE; INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABRAXIS PHARM 10MG/ML</td>
<td>N018025 001 Sep 30, 1982</td>
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<tr>
<td>10MG/ML</td>
<td>N019036 001 Sep 30, 1984</td>
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<tr>
<td>10MG/ML A070017 001 Dec 15, 1986</td>
<td></td>
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<tr>
<td>ACCORD HLTHCARE 10MG/ML</td>
<td>A070014 001 Sep 9, 1985</td>
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<tr>
<td>A070015 001 Sep 9, 1985</td>
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<tr>
<td>ASTRazeneca 10MG/ML</td>
<td>A070578 001 Aug 13, 1987</td>
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<tr>
<td>10MG/ML</td>
<td>A072058 001 Oct 31, 1994</td>
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<tr>
<td>HOSPIRA 10MG/ML</td>
<td>A074337 001 Oct 31, 1994</td>
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<tr>
<td>IGI LABS INC 10MG/ML</td>
<td>A070985 001 Nov 30, 1994</td>
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<tr>
<td>10MG/ML</td>
<td>A070986 001 Nov 30, 1994</td>
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<tr>
<td>INTL MEDICATION 10MG/ML</td>
<td>A070025 001 Nov 30, 1994</td>
</tr>
<tr>
<td>LUITPOLD 10MG/ML ** N018579 001 Jun 30, 1983</td>
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<tr>
<td>MARGAM PHARMS LLC 10MG/ML</td>
<td>A074017 001 Jun 30, 1983</td>
</tr>
<tr>
<td>SMITH AND NEPHEW 10MG/ML</td>
<td>A070023 001 Feb 05, 1986</td>
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<tr>
<td>10MG/ML</td>
<td>A070024 001 Feb 05, 1986</td>
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<tr>
<td>WARNER CHILCOTT 10MG/ML</td>
<td>N018420 001 Feb 26, 1986</td>
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<tr>
<td>WATSON LABS 10MG/ML</td>
<td>A070708 001 Feb 26, 1986</td>
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<tr>
<td>WEST-WARD PHARMS INT 10MG/ML</td>
<td>A071439 001 Feb 26, 1986</td>
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<tr>
<td>10MG/ML</td>
<td>N018267 001 Jul 20, 1982</td>
</tr>
<tr>
<td>WYETH AYERST 10MG/ML</td>
<td>N018670 001 Jul 20, 1982</td>
</tr>
</tbody>
</table>

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### FUROSEMIDE

- **Injectable; Injection**
  - Lasix
    - Sanofi Aventis US
      - Solution; Oral
        - Lasix
        - Sanofi Aventis US
          - Tablet; Oral

### GABAPENTIN

- **Capsule; Oral**
  - Gabapentin
  - CSPC Ouyi Pharm Co
    - 100mg
      - N016363 001
    - 300mg
      - N017688 001
  - Hikma
    - 100mg
      - N018415 001 July 27, 1982
    - 400mg
      - N018415 002 July 27, 1982
  - Sandoz
    - 100mg
      - N018750 001 July 30, 1984
    - 400mg
      - N018750 002 April 01, 2014
  - Sun Pharm Industries Inc
    - 20mg
      - A091258 001 April 01, 2014
    - 40mg
      - A091258 002 April 01, 2014
  - Warner Chilcott
    - 40mg
      - A018790 001 November 29, 1983
      - A018790 002 November 29, 1983

### Footnote

**See List Footnote**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulation</th>
<th>Company</th>
<th>Strength</th>
<th>National Drug Code</th>
<th>Date Discontinued</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GABAPENTIN</strong></td>
<td>Tablet; Oral</td>
<td><strong>Teva</strong></td>
<td>800mg</td>
<td>A076120 002</td>
<td>Jan 27, 2006</td>
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<td></td>
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<td>800mg</td>
<td>A076877 002</td>
<td>Jul 06, 2006</td>
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<tr>
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<td></td>
<td><strong>TEVA</strong></td>
<td>600mg</td>
<td>A075827 001</td>
<td>Dec 15, 2004</td>
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<td></td>
<td></td>
<td></td>
<td>800mg</td>
<td>A075827 002</td>
<td>Dec 15, 2004</td>
</tr>
<tr>
<td><strong>GADODIAMIDE</strong></td>
<td>Injectable; Injection</td>
<td><strong>Omniscan</strong></td>
<td>14.35gm/50ml (287mg/ml)</td>
<td>N022066 001</td>
<td>Sep 05, 2007</td>
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<tr>
<td><strong>GADOFOVESET TRISODIUM</strong></td>
<td>Solution; Intravenous</td>
<td><strong>Ablavar</strong></td>
<td>2440mg/10ml (244mg/ml)</td>
<td>N021711 001</td>
<td>Dec 22, 2008</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>3660mg/15ml (244mg/ml)</td>
<td>N021711 002</td>
<td>Dec 22, 2008</td>
</tr>
<tr>
<td><strong>GADOVERSETAMIDE</strong></td>
<td>Injectable; Injection</td>
<td><strong>Optimark</strong></td>
<td>1654.5mg/5ml (330.9mg/ml)</td>
<td>N020937 001</td>
<td>Dec 08, 1999</td>
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<td></td>
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<td>3309mg/10ml (330.9mg/ml)</td>
<td>N020937 002</td>
<td>Dec 08, 1999</td>
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<tr>
<td></td>
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<td>4963.5mg/15ml (330.9mg/ml)</td>
<td>N020937 003</td>
<td>Dec 08, 1999</td>
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<td></td>
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<td>6618mg/20ml (330.9mg/ml)</td>
<td>N020937 004</td>
<td>Dec 08, 1999</td>
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<td></td>
<td>16.545gm/50ml (330.9mg/ml)</td>
<td>N020975 001</td>
<td>Dec 08, 1999</td>
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<td></td>
<td>Injectable; Injection</td>
<td><strong>Optimark in Plastic Container</strong></td>
<td>3309mg/10ml (330.9mg/ml)</td>
<td>N020976 002</td>
<td>Dec 08, 1999</td>
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<td>4963.5mg/15ml (330.9mg/ml)</td>
<td>N020976 003</td>
<td>Dec 08, 1999</td>
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<td>6618mg/20ml (330.9mg/ml)</td>
<td>N020976 004</td>
<td>Dec 08, 1999</td>
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<td>927mg/30ml (330mg/ml)</td>
<td>N020976 001</td>
<td>Dec 08, 1999</td>
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<tr>
<td><strong>GALANTAMINE HYDROBROMIDE</strong></td>
<td>Capsule, Extended Release; Oral</td>
<td><strong>GALANTAMINE HYDROBROMIDE</strong></td>
<td>EQ 8mg Base</td>
<td>A078484 001</td>
<td>May 27, 2009</td>
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<td>IMPAX LABS</td>
<td>EQ 16mg Base</td>
<td>A078484 002</td>
<td>May 27, 2009</td>
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<td>EQ 24mg Base</td>
<td>A078484 003</td>
<td>May 27, 2009</td>
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<td>MYLAN</td>
<td>EQ 8mg Base</td>
<td>A090900 001</td>
<td>Jan 24, 2011</td>
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<td>EQ 16mg Base</td>
<td>A090900 002</td>
<td>Jan 24, 2011</td>
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<td>EQ 24mg Base</td>
<td>A090900 003</td>
<td>Jan 24, 2011</td>
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<tr>
<td><strong>SOLUTION; ORAL</strong></td>
<td><strong>Razadyne</strong></td>
<td><strong>Janssen Pharms</strong></td>
<td>4mg/ml **</td>
<td>N021224 001</td>
<td>Jun 22, 2001</td>
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<tr>
<td><strong>GALLAMINE TRIETHIODIDE</strong></td>
<td>Injectable; Injection</td>
<td><strong>Flaxedil</strong></td>
<td>20mg/ml</td>
<td>N007842 001</td>
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<td>100mg/ml</td>
<td>N007842 002</td>
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<tr>
<td><strong>GALLIUM CITRATE GA-67</strong></td>
<td>Injectable; Injection</td>
<td><strong>Gallium Citrate GA 67</strong></td>
<td>1mcCi/ml</td>
<td>N017700 001</td>
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<td>GE HEALTHCARE</td>
<td>2mcCi/ml</td>
<td>N017655 001</td>
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</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** Discontinued Drug Product List **

** GALIUM NITRATE **
INJECTABLE; INJECTION

GANEITE

CHAPTER 7 TRUSTEE 25MG/ML ** N019961 002 Jan 17, 1991

** GANCICLOVIR **
CAPSULE; ORAL

CYTOVENE
+ ROCHE PALO
250MG ** N020460 001 Dec 22, 1994
500MG ** N020460 002 Dec 12, 1997

GANCICLOVIR
KANBAXY LABS LTD 250MG A076457 001 Jun 27, 2003
500MG A076457 002 Jun 27, 2003

IMPLANT; IMPLANTATION

VITRASERT
BAUSCH AND LOMB 4.5MG N020569 001 Mar 04, 1996

** GANCICLOVIR SODIUM **
INJECTABLE; INJECTION

GANCICLOVIR SODIUM
WEST-WARD PHARMS INT EQ 500MG BASE/VIAL A076222 001 Jul 16, 2003

** GATIFLOXACIN **
SOLUTION/DROPS; OPHTHALMIC

GATIFLOXACIN
APOTEX INC 0.3% A079084 001 Aug 19, 2011

** GEFTINIB **
TABLET; ORAL

IRESSA
ASTRAZENECA 250MG N021399 001 May 05, 2003

** GEMCITABINE HYDROCHLORIDE **
INJECTABLE; INJECTION

GEMCITABINE HYDROCHLORIDE
HAMELN RDS GMBH EQ 200MG BASE/VIAL A090663 001 Sep 10, 2012
EQ 1GM BASE/VIAL A090663 002 Sep 10, 2012
SAGENT PHARMS EQ 200MG BASE/VIAL A091597 001 May 07, 2013
EQ 1GM BASE/VIAL A091597 002 May 07, 2013

** GEMFIBROZIL **
CAPSULE; ORAL

GEMFIBROZIL
MYLAN 300MG A073466 001 Jan 25, 1993
PUREPAC PHARM 300MG A072929 001 Jan 29, 1993
LOPID
PFIZER PHARMS 200MG N018422 001
300MG N018422 002

TABLET; ORAL

GEMFIBROZIL
MYLAN 600MG A074452 001 Feb 16, 1995
PUREPAC PHARM 600MG A074360 001 Aug 31, 1994
WATSON LABS 600MG A074156 001 Oct 24, 1994
600MG A074442 001 Apr 28, 1995
YAOPHARMA CO LTD 600MG A074615 001 Sep 29, 1995

** GEMTUCUMAB OZOGAMICIN **
INJECTABLE; INJECTION

MILOTARG
WYETH PHARMS INC 5MG/VIAL N021174 001 May 17, 2000

** GENTAMICIN SULFATE **
CREAM; TOPICAL

GARANGIN
SCHERING EQ 0.1% BASE ** A060462 001

GENTAFAIR
PHARMAFAIR EQ 0.1% BASE A062458 001 Sep 01, 1983

GENTAMICIN SULFATE
ALPHARMA US PHARMS EQ 0.1% BASE A062471 001 Sep 27, 1983
FOUGERA PHARMS INC EQ 0.1% BASE A062531 001 Jul 05, 1984
PHARMADERM EQ 1MG BASE/0M A062530 001 Jul 05, 1984
TARO EQ 0.1% BASE A062427 001 May 26, 1983

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
GENTAMICIN SULFATE

INJECTABLE; INJECTION

** See List Footnote

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
GENTAMICIN SULFATE
INJECTABLE; INJECTION
GENTAMICIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
EQ 60MG BASE/100ML A062414 006 Aug 15, 1983
EQ 60MG BASE/100ML A062588 006 Jan 06, 1986
EQ 70MG BASE/100ML A062414 007 Aug 15, 1983
EQ 70MG BASE/100ML A062588 007 Jan 06, 1986
EQ 80MG BASE/100ML A062588 008 Jan 06, 1986
EQ 90MG BASE/100ML A062414 009 Aug 15, 1983
EQ 90MG BASE/100ML A062588 009 Jan 06, 1986
EQ 100MG BASE/100ML A062588 010 Jan 06, 1986

U-GENCIN
PHARMACIA AND UPJOHN
EQ 10MG BASE/ML A062248 001
EQ 40MG BASE/ML A062248 002

INJECTABLE; INTRATHecal
GARAMYCIN
+ SCHERING
EQ 2MG BASE/ML ** N050505 001

OINTMENT; OPHTHALMIC
GARAMYCIN
GARAMYCIN
EQ 0.3% BASE N050425 001
GENTACIDIN
NOVARTIS
EQ 0.3% BASE A062501 001 Jul 26, 1984
GENTAFAIR
PHARMAFAIR
EQ 3MG BASE/ML A062443 001 May 26, 1983

OINTMENT; TOPICAL
GARAMYCIN
SCHERING
EQ 0.1% BASE ** A060463 001
GENTAFAIR
PHARMAFAIR
EQ 0.1% BASE A062444 001 May 26, 1983
GENTAMICIN SULFATE
ALPHARMA US PHARMS
EQ 0.1% BASE A062496 001 Mar 14, 1984
PHARMADERM
EQ 0.1% BASE A062534 001 Oct 10, 1984

SOLUTION/DROPS; OPHTHALMIC
GARAMYCIN
+ SCHERING
EQ 0.3% BASE ** N050039 002
GENTACIDIN
NOVARTIS
EQ 0.3% BASE A062480 001 Mar 30, 1984
GENTAFAIR
PHARMAFAIR
EQ 0.3% BASE A062440 001 May 03, 1983
GENTAMICIN SULFATE
ALCON PHARMS LTD
EQ 0.3% BASE A062523 001 Nov 25, 1985
PACO
EQ 3MG BASE/ML A062932 001 Nov 07, 1988

GENTIAN VIOLET
SUPPOSITORY; VAGINAL
GVS
SAVAGE LABS
0.4% A083513 001
TAMPON; VAGINAL
GENAPAX
KEY PHARMS
5MG A085017 001

GLATIRAMER ACETATE
FOR SOLUTION; SUBCUTANEOUS
COPAXONE
TEVA PHARMS USA
20MG/VIAL N020622 001 Dec 20, 1996

GLIMEPIRIDE
TABLET; ORAL
GLIMEPIRIDE
ACTAVIS LABS FL INC
1MG A076995 001 Apr 27, 2010
2MG A076995 002 Apr 27, 2010
4MG A076995 003 Apr 27, 2010
EPIC PHARMA LLC
1MG A077274 001 Oct 06, 2005
2MG A077274 002 Oct 06, 2005
4MG A077274 003 Oct 06, 2005
HIKMA PHARMS
1MG A078952 001 Aug 01, 2013
2MG A078952 002 Aug 01, 2013
4MG A078952 003 Aug 01, 2013
MYLAN
1MG A077486 001 Feb 10, 2006
2MG A077486 002 Feb 10, 2006
4MG A077486 003 Feb 10, 2006

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE
RANBAXY
3MG A077366 001 Oct 06, 2005
6MG A077366 002 Oct 06, 2005
RANBAXY LABS LTD
1MG A076875 001 Oct 06, 2005
2MG A076875 002 Oct 06, 2005
4MG A076875 003 Oct 06, 2005
8MG A076875 004 Oct 06, 2005
WATSON LABS
1MG A077280 001 Feb 03, 2006
2MG A077280 002 Feb 03, 2006
4MG A077280 003 Feb 03, 2006

GLIMEPIRIDE; ROSIGLITAZONE MALEATE

TABLET; ORAL

AVANDARYL
+ SB PHARMCO
1MG; 4MG ** N021700 001 Nov 23, 2005
2MG; 4MG ** N021700 002 Nov 23, 2005
2MG; 8MG ** N021700 004 Mar 30, 2007
4MG; 4MG ** N021700 003 Nov 23, 2005
4MG; 8MG ** N021700 005 Mar 30, 2007

ROSIGLITAZONE MALEATE AND GLIMEPIRIDE
TEVA PHARMS USA
1MG; 4MG A078709 001 Apr 01, 2016
2MG; 4MG A078709 002 Apr 01, 2016
2MG; 8MG A078709 004 Apr 01, 2016
4MG; 4MG A078709 003 Apr 01, 2016
4MG; 8MG A078709 005 Apr 01, 2016

GLIPIZIDE

TABLET; ORAL

GLIPIZIDE
ANI PHARMS INC
5MG A074387 001 Mar 04, 1996
10MG A074387 002 Mar 04, 1996
BARR LABS INC
5MG A074619 001 Apr 04, 1997
10MG A074619 002 Apr 04, 1997
MYLAN
5MG A074438 001 Jun 20, 1995
10MG A074438 002 Jun 20, 1995
OXFORD PHARMS
5MG A074378 001 Nov 28, 1994
10MG A074378 002 Nov 28, 1994
SANDOZ
5MG A074542 001 Jun 20, 1995
10MG A074542 002 Jun 20, 1995
WATSON LABS
5MG A074370 001 Nov 22, 1994
10MG A074370 002 Nov 22, 1994
GLUCOTROL
PFIZER
2.5MG N017783 003 May 11, 1993

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

METAGLIP
+ BRISTOL MYERS SQUIBB
2.5MG; 250MG ** N021460 001 Oct 21, 2002
2.5MG; 500MG ** N021460 002 Oct 21, 2002
5MG; 500MG ** N021460 003 Oct 21, 2002

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION

GLUCAGON
+ LILLY
EQ 1MG BASE/VIAL ** N012122 001
EQ 10MG BASE/VIAL ** N012122 002

GLUTETHIMIDE

CAPSULE; ORAL
DORIDEN
SANOFI AVENTIS US
500MG N009519 008

TABLET; ORAL
DORIDEN
SANOFI AVENTIS US
250MG N009519 002
500MG N009519 005
GLUTETHIMIDE
HALSEY
250MG A089458 001 Oct 10, 1986
500MG A089459 001 Oct 10, 1986
LANNETT
250MG A083475 001
500MG A085571 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**GLYCOPHYRROLATE**

**TABLET; ORAL**

ROBINUL FORTE 2MG
* CASPER PHARMA LLC N012827 002

**GONADORELIN ACETATE**

**INJECTABLE; INJECTION**

LU'TREPULSE KIT 0.8MG/VIAL N019687 001 Oct 10, 1989
3.2MG/VIAL N019687 002 Oct 10, 1989

**GONADORELIN HYDROCHLORIDE**

**INJECTABLE; INJECTION**

FACTREL EQ 0.1MG BASE/VIAL N018123 001 Sep 30, 1982
EQ 0.2MG BASE/VIAL N018123 002 Sep 30, 1982
EQ 0.5MG BASE/VIAL N018123 003 Sep 30, 1982

**GONADOTROPIN, CHORIONIC**

**INJECTABLE; INJECTION**

A.P.L. FERRING 5,000 UNITS/VIAL N017055 001
10,000 UNITS/VIAL N017055 002
20,000 UNITS/VIAL N017055 003

CHORIONIC GONADOTROPIN BELL MAR 5,000 UNITS/VIAL N017054 001
10,000 UNITS/VIAL N017054 002
2,000 UNITS/VIAL N017016 009 Dec 27, 1984
2,000 UNITS/VIAL N017016 011 Feb 16, 1990
15,000 UNITS/VIAL N017016 010 Feb 15, 1985
20,000 UNITS/VIAL N017016 004

FRESENIUS KABI USA 5,000 UNITS/VIAL N017067 001
10,000 UNITS/VIAL N017067 004

**FOLLUTEIN**

BRISTOL Myers SQUIBB 10,000 UNITS/VIAL N017056 001

**GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE**

**SOLUTION/DROPS; OPHTHALMIC**

NEO-POLYCN DOW PHARM 0.025MG/ML; EQ 1.75MG BASE/ML; 10,000 UNITS/ML A060427 001

NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN

IPHARM 0.025MG/ML; EQ 1.75MG BASE/ML; 10,000 UNITS/ML A062818 001 Oct 11, 1988

WATSON LABS 0.025MG/ML; EQ 1.75MG BASE/ML; 10,000 UNITS/ML A062788 001 Jun 11, 1987

NEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN

PHARMAFAIR 0.025MG/ML; EQ 1.75MG BASE/ML; 10,000 UNITS/ML A062383 001 Aug 31, 1982

**GRANISETRON HYDROCHLORIDE**

**INJECTABLE; INJECTION**

GRANISETRON HYDROCHLORIDE

BAXTER HEALTHCARE CORP EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) A078197 001 Dec 31, 2007
EQ 1MG BASE/ML (EQ 1MG BASE/ML) A078198 001 Jun 30, 2008
EQ 4MG BASE/4ML (EQ 1MG BASE/ML) A078198 002 Jun 30, 2008

SANDOZ INC EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) A078808 001 Apr 29, 2008
EQ 1MG BASE/ML (EQ 1MG BASE/ML) A077963 001 Jan 03, 2008

GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE

TEVA PHARMS USA EQ 1MG BASE/ML (EQ 1MG BASE/ML) A077165 001 Dec 31, 2007

KYTRIL + ROCHE EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) ** N020239 003 Sep 17, 2004
+ EQ 1MG BASE/ML (EQ 1MG BASE/ML) ** N020239 004 Mar 11, 1994
+ EQ 3MG BASE/ML ** N020239 001 Dec 29, 1993
+ EQ 4MG BASE/4ML (EQ 1MG BASE/ML) ** N020239 002 Mar 11, 1994

**SOLUTION; ORAL**

GRANISOL

PEDIATRX EQ 2MG BASE/10ML A078334 001 Feb 28, 2008

KYTRIL + ROCHE EQ 2MG BASE/10ML ** N021238 001 Jun 27, 2001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

### Guaifenesin; Hydrocodone Bitartrate; Pseudoephedrine Hydrochloride
Solution; Oral

- HYCOFENIX + BK PHARMS 200mg/5mL; 2.5mg/5mL; 30mg/5mL N022279 001 May 14, 2015

### Guanabenz Acetate
Tablet; Oral

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Tablet; Oral

- HYLOREL

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Cream; Topical

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<td>HALOG-E</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

#### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

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<td>GLAXOSMITHKLINE 250MG N020250 001 Jul 24, 1992</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### HALOPERIDOL

**Tablet; Oral**

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### HALOPERIDOL DECANOATE

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**Concentrate; Oral**

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**Injectable; Injection**

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**Solutions; Oral**

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### HALOPROGIN

**Cream; Topical**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

### HALOTHANE

**LIQUID; INHALATION**

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<tr>
<td>Wyeth Ayerst</td>
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<td>N011338 001</td>
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<td>BH</td>
<td>99.99%</td>
<td>A084977 001</td>
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<td>Halocarbon</td>
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### HEPARIN CALCUM

**INJECTABLE; INJECTION**

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<tbody>
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### HEPARIN SODIUM

**INJECTABLE; INJECTION**

**HEPARIN LOCK FLUSH**

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<td>Luitpold</td>
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<tr>
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<td>Smith and Nephew</td>
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**HEPARIN SODIUM**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 25,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER

<table>
<thead>
<tr>
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<th>Concentration</th>
<th>NDC Code</th>
<th>Date</th>
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<tbody>
<tr>
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<tr>
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<td>5,000 UNITS/100ML</td>
<td>N018911 009</td>
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HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5%

<table>
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<th>Company</th>
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<tbody>
<tr>
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HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

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<tr>
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HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

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HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9%

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HEPARIN SODIUM 5,000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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HEPARIN SODIUM 5,000 UNITS IN DEXTROSE 5%

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HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.45%

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HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.9%

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HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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HEPARIN SODIUM PRESERVATIVE FREE

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<tbody>
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LIPO-HEPIN

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LIQUAEMIN LOCK FLUSH

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LIQUAEMIN SODIUM

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SODIUM HEPARIN

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

#### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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HISTAMINE PHOSPHATE
LILLY
EQ 0.1MG BASE/ML  N000734 003
EQ 0.2MG BASE/ML  N000734 002
EQ 1MG BASE/ML   N000734 001

HISTRELIN ACETATE
INJECTABLE; INJECTION
SUPPRELIN
SHIRE
EQ 0.2MG BASE/ML  N019836 001 Dec 24, 1991
EQ 0.5MG BASE/ML  N019836 002 Dec 24, 1991
EQ 1MG BASE/ML   N019836 003 Dec 24, 1991

HOMATROPINE METHYLBROMIDE
TABLET; ORAL
HOMAPIN-10
MISSION PHARMA 10MG A086308 001
HOMAPIN-5
MISSION PHARMA 5MG A086309 001
TABLET, CHEWABLE; ORAL
EQUIPIN
MISSION PHARMA 3MG A086310 001

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE
SYRUP; ORAL
HYCODAN
+ GENUS LIFESCIENCES 1.5MG/5ML; 5MG/5ML ** N005213 002 Jul 26, 1988
HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE
BIO-PHARM INC 1.5MG/5ML; 5MG/5ML A204765 001 Mar 06, 2017
IVAX SUB TEVA PHARMS 1.5MG/5ML; 5MG/5ML A040285 001 Jul 19, 1999
HYDROPANE
HALSEY 1.5MG/5ML; 5MG/5ML A088066 001 Jun 28, 1985

TABLET; ORAL
HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE
ACTAVIS ELIZABETH 1.5MG; 5MG A040295 001 Dec 01, 2000
HYCODAN
+ GENUS LIFESCIENCES 1.5MG; 5MG ** N005213 001 Jul 26, 1988

HYALURONIDASE
INJECTABLE; INJECTION
HYDASE
AKORN INC 150 UNITS/ML N021716 001 Oct 25, 2005
VITRASE
BAUSCH AND LOMB 6,200 UNITS/VIAL N021640 001 May 05, 2004
VITRASE
Baxter Hlthcare 150 UNITS/ML ** N006343 002
150 UNITS/VIAL ** N006343 006
1,500 UNITS/VIAL ** N006343 005

HYDRAZINE HYDROCHLORIDE
INJECTABLE; INJECTION
APRESOLINE
+ NOVARTIS 20MG/ML ** N008303 003
HYDRAZINE HYDROCHLORIDE
ABRAxis PHARM 20MG/ML A089532 001 Aug 11, 1987
SMITH AND NEPHEW 20MG/ML A088518 001 Apr 20, 1984
SOLOPAK 20MG/ML A088517 001 Aug 22, 1985
TEVA PARENTERAL 20MG/ML A040373 001 Feb 23, 2000

TABLET; ORAL
APRESOLINE
+ NOVARTIS 10MG ** N008303 004
+ 25MG ** N008303 001
+ 50MG ** N008303 002
+ 100MG ** N008303 005
DRALZINE
TEVA 25MG A084301 001

HYDRAZINE HYDROCHLORIDE
ACTAVIS ELIZABETH 25MG A088560 001 Oct 04, 1984
50MG A088649 001 Oct 18, 1984
ACTAVIS GRP PTC 10MG A091679 001 Mar 04, 2013
25MG A091679 002 Mar 04, 2013

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### HYDRALAZINE HYDROCHLORIDE

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
HYDRAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### HYDROCHLOROTHIAZIDE

**SOLUTION; ORAL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**TABLET; ORAL**

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  - 12.5MG; 75MG ** | N020758 001 | Sep 30, 1997 |
  - 25MG; 300MG ** | N020758 004 | Mar 15, 2005 |

**IRBESARTAN AND HYDROCHLOROTHIAZIDE**

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**HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE**
**TABLET; ORAL**

**NORMOZIDE**

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**TRANDATE HCT**

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**HYDROCHLOROTHIAZIDE; LISINOPRIL**
**TABLET; ORAL**

**LISINOPRIL AND HYDROCHLOROTHIAZIDE**

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<tr>
<th><strong>APOTEX INC</strong></th>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
HYDROCHLOROTHIAZIDE; LISINOPRIL
TABLET; ORAL
LISINOPRIL AND HYDROCHLOROTHIAZIDE
25MG; 20MG
PRINZIDE
+ MERCK
12.5MG; 10MG **
N019778 003 Nov 18, 1993
+ 12.5MG; 20MG **
N019778 001 Feb 16, 1989
+ 25MG; 20MG **
N019778 002 Feb 16, 1989

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM
TABLET; ORAL
HYZAAAR
+ MERCK SHARP DOHME
12.5MG; 50MG
N020387 001 Apr 28, 1995
+ 25MG; 100MG
N020387 002 Nov 10, 1998

LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE
APOTEX
12.5MG; 50MG
A090150 001 Oct 06, 2010
12.5MG; 100MG
A090150 002 Aug 11, 2010
25MG; 100MG
A090150 003 Oct 06, 2010

WATSON LABS
12.5MG; 50MG
A200180 001 Jan 12, 2011
12.5MG; 100MG
A200180 002 Jan 12, 2011
25MG; 100MG
A200180 003 Jan 12, 2011

HYDROCHLOROTHIAZIDE; METHYLDOPA
TABLET; ORAL
ALDORIL 15
MERCK
15MG; 250MG
N013402 001
ALDORIL 25
MERCK
25MG; 250MG
N013402 002
ALDORIL D30
MERCK
30MG; 500MG
N013402 003
ALDORIL D50
MERCK
50MG; 500MG
N013402 004

METHYLDOPA AND HYDROCHLOROTHIAZIDE
DAVA PHARMS INC
15MG; 250MG
A072507 001 Jun 02, 1989
25MG; 250MG
A072508 001 Jun 02, 1989
30MG; 500MG
A072509 001 Jun 02, 1989
50MG; 500MG
A072510 001 Jun 02, 1989
IVAX SUB TEVA PHARMS
15MG; 250MG
A071458 001 Mar 08, 1988
25MG; 250MG
A071459 001 Mar 08, 1988
30MG; 500MG
A071460 001 Mar 08, 1988
50MG; 500MG
A071461 001 Mar 08, 1988
PAR PHARM
15MG; 250MG
A070616 001 Feb 02, 1987
25MG; 250MG
A070612 001 Feb 02, 1987
30MG; 500MG
A070613 001 Feb 02, 1987
50MG; 500MG
A070614 001 Feb 02, 1987
PARKE DAVIS
15MG; 250MG
A071897 001 Nov 23, 1987
25MG; 250MG
A071898 001 Nov 23, 1987
30MG; 500MG
A071899 001 Nov 23, 1987
50MG; 500MG
A071900 001 Nov 23, 1987
PUREPAC PHARM
15MG; 250MG
A070853 001 Oct 08, 1986
25MG; 250MG
A070688 001 Apr 24, 1986
30MG; 500MG
A070854 001 Oct 08, 1986
50MG; 500MG
A070689 001 Apr 24, 1986
SANDOZ
15MG; 250MG
A070829 001 Mar 09, 1987
25MG; 250MG
A070830 001 Mar 09, 1987
TEVA
15MG; 250MG
A071819 001 Apr 08, 1988
25MG; 250MG
A071820 001 Apr 08, 1988
30MG; 500MG
A071821 001 Apr 08, 1988
50MG; 500MG
A071822 001 Apr 08, 1988
WATSON LABS
15MG; 250MG
A070365 001 Mar 19, 1986
25MG; 250MG
A070958 001 Feb 06, 1989
30MG; 500MG
A071920 001 Aug 29, 1988
25MG; 250MG
A070366 001 Apr 16, 1986
30MG; 500MG
A070959 001 Jan 19, 1989
25MG; 250MG
A071921 001 Aug 29, 1988
30MG; 500MG
A070367 001 Mar 19, 1986
50MG; 500MG
A071069 001 Jan 19, 1989
30MG; 500MG
A071922 001 Aug 29, 1988
50MG; 500MG
A070368 001 Apr 16, 1986
50MG; 500MG
A070960 001 Feb 06, 1989

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Date</th>
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<tr>
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<td>Tablet/Oral</td>
<td>Yaopharma Co Ltd</td>
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<td>A070544 001</td>
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<td>Hydrochlorothiazide; Metoprolol Tartrate</td>
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<td>50mg;100mg</td>
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<td>Hydrochlorothiazide; Moexipril Hydrochloride</td>
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<td>Hydrochlorothiazide; Propranolol Hydrochloride</td>
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<td>Hydrochlorothiazide; Quinapril Hydrochloride</td>
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<td>Sun Pharm Inds Ltd</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## HYDROCHLOROTHIAZIDE; RESERPINE

**TABLET; ORAL**

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<td>A085338 001</td>
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<td>ABC HOLDING</td>
<td>50MG; 0.125MG</td>
<td>A084714 002 Jun 29, 1982</td>
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<td>SANDOX</td>
<td>25MG; 0.125MG</td>
<td>A084827 001</td>
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<td>SANDOX</td>
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**HYDROCHLOROTHIAZIDE W/ RESERPINE**

| IVAX SUB TEVA PHARMS      | 25MG; 0.1MG      | A083572 001      |
|                           | 25MG; 0.125MG    | A083571 001      |
|                           | 50MG; 0.1MG      | A083568 001      |
|                           | 50MG; 0.125MG    | A083573 001      |
| PHARMERAL                 | 25MG; 0.125MG    | A085421 001      |
|                           | 50MG; 0.125MG    | A085420 001      |
| ROXANE                    | 50MG; 0.125MG    | A084603 001      |
| WATSON LABS               | 25MG; 0.125MG    | A084466 001      |
|                           | 25MG; 0.125MG    | A085317 001      |
|                           | 25MG; 0.125MG    | A086330 002      |
|                           | 50MG; 0.125MG    | A083666 001      |
|                           | 50MG; 0.125MG    | A084467 001      |
|                           | 50MG; 0.125MG    | A086331 001      |

**HYDROPRES 25**

| MERCK                    | 25MG; 0.125MG    | N011958 002      |

**HYDROPRES 50**

| MERCK                    | 50MG; 0.125MG    | N011958 003      |

**RESERPINE AND HYDROCHLOROTHIAZIDE**

| BARR                     | 25MG; 0.125MG    | A084580 001      |
|                         | 50MG; 0.125MG    | A084579 001      |
| SANDOX                  | 50MG; 0.125MG    | A088200 001 Jan 31, 1984 |

**RESERPINE AND HYDROCHLOROTHIAZIDE-50**

| WEST WARD               | 50MG; 0.125MG    | A088189 001 May 10, 1984 |

**SERPASIL-ESIDRIX #1**

| NOVARTIS               | 25MG; 0.1MG      | N011878 003      |

**SERPASIL-ESIDRIX #2**

| NOVARTIS               | 50MG; 0.1MG      | N011878 005      |

## HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

**TABLET; ORAL**

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<tr>
<td>ASCOT</td>
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<td>MUTUAL PHARM</td>
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<td>PUREPAC PHARM</td>
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<td>SUPERPHARM</td>
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<tr>
<td>WATSON LABS</td>
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<td>YAOPHARMA CO LTD</td>
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**SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE**

| IVAX PHARMS  | 25MG; 25MG        | A087004 002 May 24, 1982 |
| Lederle      | 25MG; 25MG        | A087511 001             |
| PARKER DAVIS | 25MG; 25MG        | A087948 001 Feb 22, 1983 |
| PUREPAC PHARM | 25MG; 25MG      | A088054 001 Aug 18, 1983 |
| UPSHER SMITH | 25MG; 25MG        | A087553 001             |
| USL PHARMA   | 25MG; 25MG        | A087651 001             |
| VANGARD      | 25MG; 25MG        | A087650 001             |
| WATSON LABS  | 25MG; 25MG        | A085974 001             |
|               | 25MG; 25MG        | A086026 001             |

## HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE

**TABLET; ORAL**

**TIMOLIDE 1-25**

| MERCK                  | 25MG; 10MG        | N018061 001      |

## HYDROCHLOROTHIAZIDE; TRIAMTERENE

**CAPSULE; ORAL**

**DYAZIDE**

| GLAXOSMITHKLINE LLC | 25MG; 50MG        | N016042 002      |

**TRIAMTERENE AND HYDROCHLOROTHIAZIDE**

| ANI PHARMS INC | 25MG; 37.5MG | A074970 001 Jan 06, 1998 |
|               | 25MG; 37.5MG | A074857 001 Sep 09, 1997 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## HYDROCHLOROTHIAZIDE; TRIAMTERENE

**Capsule, Oral**

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<td>Triamterene and Hydrochlorothiazide Vitarine</td>
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**Tablet, Oral**

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<td>Triamterene and Hydrochlorothiazide Am Therap</td>
<td>50MG; 75MG</td>
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<td>Apr 17, 1988</td>
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<td>Quantum Pharmics</td>
<td>50MG; 75MG</td>
<td>A071980 001</td>
<td>Apr 17, 1988</td>
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<td>Watson Labs</td>
<td>50MG; 75MG</td>
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## HYDROCHLOROTHIAZIDE; VALSARTAN

**Tablet, Oral**

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<td>Valsartan and Hydrochlorothiazide Apotex Inc</td>
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<td>A203026 002</td>
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<tr>
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<td></td>
<td>12.5MG; 320MG</td>
<td>A203026 003</td>
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<td></td>
<td>25MG; 160MG</td>
<td>A203026 004</td>
</tr>
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<td></td>
<td>25MG; 320MG</td>
<td>A203026 005</td>
</tr>
<tr>
<td>Watson Labs Teva</td>
<td>12.5MG; 80MG</td>
<td>A091519 001</td>
<td>Mar 21, 2013</td>
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<tr>
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<td>12.5MG; 160MG</td>
<td>A091519 002</td>
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<td>12.5MG; 320MG</td>
<td>A091519 003</td>
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<td></td>
<td>25MG; 160MG</td>
<td>A091519 004</td>
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<td></td>
<td></td>
<td>25MG; 320MG</td>
<td>A091519 005</td>
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## HYDROCODONE BITARTRATE

**Tablet, Extended Release, Oral**

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<thead>
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<th>Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vantrela ER + Teva Branded Pharm</td>
<td>15MG</td>
<td>N207975 001</td>
<td>Jan 17, 2017</td>
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<td></td>
<td></td>
<td>30MG</td>
<td>N207975 002</td>
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<td></td>
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<td>45MG</td>
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<td>90MG</td>
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## HYDROCODONE BITARTRATE; IBUPROFEN

**Tablet, Oral**

<table>
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<th>Product Name</th>
<th>Company</th>
<th>Code</th>
<th>Date</th>
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<tbody>
<tr>
<td>Hydrocodone Bitartrate and Ibuprofen Actavis Labs Fl Inc</td>
<td>5MG; 200MG</td>
<td>A077454 001</td>
<td>Jun 23, 2010</td>
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<tr>
<td>Vicoprofen + ABBVIE</td>
<td>7.5MG; 200MG</td>
<td>N020716 001</td>
<td>Sep 23, 1997</td>
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## HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

**Syrup, Oral**

<table>
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<tr>
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<th>Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codamine Alpharma US Pharms</td>
<td>5MG/5ML; 25MG/5ML</td>
<td>A075103 001</td>
<td>Sep 29, 2000</td>
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## HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE

**Solution, Oral**

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<th>Code</th>
<th>Date</th>
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<tbody>
<tr>
<td>Hydrocodone Bitartrate and Pseudoephedrine Hydrochloride Tris Pharma Inc</td>
<td>5MG/5ML; 60MG/5ML</td>
<td>A203839 001</td>
<td>Oct 28, 2014</td>
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## HYDROCORTAMATE HYDROCHLORIDE

**Ointment, Topical**

<table>
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<th>Product Name</th>
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<th>Date</th>
</tr>
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<tbody>
<tr>
<td>Magnacort Pfizer</td>
<td>0.5%</td>
<td>N010554 001</td>
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## HYDROCORTISONE

**Aerosol, Topical**

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<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerozole-Hc Allergan Herbert</td>
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**Cream, Topical**

<table>
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<th>Product Name</th>
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<th>Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corted-Mome Bayer Pharms</td>
<td>0.5%</td>
<td>N009585 003</td>
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<tr>
<td></td>
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<tr>
<td>Dermacort Monarch Pharms</td>
<td>1%</td>
<td>A083011 002</td>
<td></td>
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<tr>
<td>Eldecort Valeant Pharm Intl</td>
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<td>A080459 001</td>
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<td></td>
<td>2.5%</td>
<td>A084055 001</td>
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<td>Flexicort Westwood Squibb</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## HYDROCORTISONE

### CREAM; TOPICAL

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<th>NDC</th>
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<tbody>
<tr>
<td><strong>HC #1</strong></td>
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<td>PHARM ASSOC</td>
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<tr>
<td><strong>HC #4</strong></td>
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<td>BAYER PHARMS</td>
<td>A080438 002</td>
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<tr>
<td><strong>HC (HYDROCORTISONE)</strong></td>
<td>0.5%</td>
<td>C AND M PHARMA</td>
<td>A080482 003</td>
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<tr>
<td></td>
<td>1%</td>
<td>C AND M PHARMA</td>
<td>A080482 004</td>
</tr>
<tr>
<td><strong>HI-COR</strong></td>
<td>2.5%</td>
<td>C AND M PHARMA</td>
<td>A080483 001</td>
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### HYDROCORTISONE

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Company</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALPHARMA US PHARMS</strong></td>
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<td><strong>ALTANA</strong></td>
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<td></td>
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<tr>
<td><strong>G AND W LABS</strong></td>
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<td>A080456 001</td>
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<td><strong>TOPIDERM</strong></td>
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<tr>
<td><strong>WHITWORTH TOWN PLCN</strong></td>
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### HYTONE

<table>
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<tr>
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### NOGENIC HC

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<td><strong>IVAX PHARMS</strong></td>
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### NUTRACORT

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<tr>
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### PENECORT

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### PROCTOCORT

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<td><strong>MONARCH PHARMS</strong></td>
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### SYNACORT

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### GEL; TOPICAL

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<tbody>
<tr>
<td><strong>NUTRACORT</strong></td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**HYDROCORTISONE**

**LOTION; TOPICAL**

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<td>CROWN LABS</td>
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<td>BALNEOL-HC</td>
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<td>SOLVAY</td>
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<td>H-CORT</td>
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<td>PHARM ASSOC</td>
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<td>TARO</td>
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**OINTMENT; TOPICAL**

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<tbody>
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<tr>
<td>PFIZER GLOBAL</td>
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<td>C AND M PHARMA</td>
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</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
HYDROCORTISONE

POWDER; FOR RX COMPOUNDING
H-CORT
TORCH 100% A087834 001 Mar 29, 1982
X GEN PHARMS 100% A085982 001
HYDROCORTISONE
PADDock LLC 100% A088082 001 Apr 08, 1983

SOLUTION; TOPICAL
PENECORT
ALLERGAN HERBERT 1% A088214 001 Jun 06, 1984
TEXACORT
MISSION PHARMA 1% A080425 001

TABLET; ORAL
CORTIL
PFIZER 10MG N009127 005
20MG N009127 003

HYDROCORTISONE
BARR 20MG A083999 001
ELKINS SINN 20MG A080624 001
FERRANTE 10MG A080568 001
20MG A080568 002
IMPAX LABS 20MG A080781 001
INWOOD LABS 20MG A080732 001
LANNETT 20MG A085070 001
NEXGEN PHARMA INC 20MG A083140 001
PANRAY 10MG N009659 001
20MG N009659 002
PARKE DAVIS 20MG A084243 001
PUREPAC PHARM 10MG A084247 003 Aug 31, 1982
20MG A080395 001
20MG A084247 002
ROXANE 10MG A088539 001 Mar 21, 1984
20MG A080642 002
30MG A080355 001
WATSON LABS 20MG A080344 001
WHITWORTH TOWN PLSN 10MG A080344 002
20MG

HYDROCORTISONE ACETATE
MERCK 10MG N008506 007
20MG N008506 001

TABLET; VAGINAL
CORTIL
PFIPHARMECS 10MG N009796 001

HYDROCORTISONE ACETATE
CREAM; TOPICAL
HEMSOL-HC
ABLE 1% A081274 001 Jun 19, 1992
HYDROCORTISONE ACETATE
CENCI 1% A080419 001 Jan 25, 1982
FERNDALE LABS 2.5% A040259 001 Jul 29, 1999
PARKE DAVIS 1% A089914 001 Jan 03, 1989
PUREPAC PHARM 0.5% A086050 001
2% A086052 001

MICORT-HC
SEBELA IRELAND LTD 2% A040398 001 Mar 29, 2002

INJECTABLE; INJECTION
CORTEF ACETATE
PHARMACIA AND UPJOHN 50MG/ML N009378 002
CORTIL
PFIZER 25MG/ML N009164 001
HYDROCORTISONE ACETATE
AKORN 25MG/ML N009637 001
BEL MAR 25MG/ML N009637 002
50MG/ML A083739 002
WATSON LABS 25MG/ML A083128 001
25MG/ML A083759 001
50MG/ML A083759 002
50MG/ML A085214 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**HYDROCORTISONE ACETATE**

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Composition</th>
<th>Batch Numbers</th>
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<tbody>
<tr>
<td>INJECTABLE; INJECTION</td>
<td>HYDROCORTONE MERCK</td>
<td>N008228 001, 004</td>
</tr>
<tr>
<td>LOTION; TOPICAL</td>
<td>INGRAM PHARM 0.5%</td>
<td>A086207 001</td>
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<tr>
<td>OINTMENT; OPHTHALMIC</td>
<td>HYDROCORTISONE ACETATE FERA PHARMS 0.5%</td>
<td>A080828 001</td>
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<tr>
<td>OINTMENT; OPHTHALMIC</td>
<td>HYDROCORTONE MERCK 1.5%</td>
<td>N009018 003</td>
</tr>
<tr>
<td>CORTEF ACETATE Paste; TOPICAL</td>
<td>PHARMACIA AND UPJOHN 1% **</td>
<td>N008917 002</td>
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<tr>
<td>ORABASE HCA POWDER; FOR RX COMPOUNDING</td>
<td>COLGATE 0.5%</td>
<td>A083205 001</td>
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<td>HYDROCORTISONE ACETATE; NEOMYCIN SULFATE CREAM; TOPICAL</td>
<td>NEOCORTEF 1%; EQ 3.5MG BASE/GM</td>
<td>A061049 001, 002</td>
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<tr>
<td>OINTMENT; OPHTHALMIC</td>
<td>NEOCORTEF 0.5%; EQ 3.5MG BASE/GM</td>
<td>A060610 001</td>
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<tr>
<td>OINTMENT; TOPICAL</td>
<td>NEOCORTEF 0.5%; EQ 3.5MG BASE/GM</td>
<td>A060610 001, 002</td>
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<tr>
<td>Suspension/Drops; OPHTHALMIC</td>
<td>COR-OTICIN 1.5%; EQ 3.5MG BASE/ML</td>
<td>A060188 001</td>
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<td>HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE Suspension; OPHTHALMIC</td>
<td>TERRA-CORTIR 1.5%; EQ 5MG BASE/ML</td>
<td>A061016 001</td>
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<td>HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE Aerosol, Metered; Topical</td>
<td>GENUS LIFESCIENTES 1%; 1%</td>
<td>A089440 001 May 17, 1988</td>
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<tr>
<td>LOtion; Topical</td>
<td>PRAMOSONE FERNDALE LABS 0.5%; 1%</td>
<td>A083213 002</td>
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<td>HYDROCORTISONE ACETATE; UREA CREAM; Topical</td>
<td>FOUGERA PHARMS 1%; 10%</td>
<td>A080505 001</td>
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<tr>
<td>HYDROCORTISONE BUTYRATE CREAM; Topical</td>
<td>YAMANOUCHI 0.1%</td>
<td>N018795 001 Jan 07, 1983</td>
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<td>OINTMENT; Topical</td>
<td>YAMANOUCHI 0.1%</td>
<td>N019106 001 Jul 03, 1984</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
HYDROCORTISONE BUTYRATE
SOLUTION; TOPICAL
LOCOID
YAMANOUCHI 0.1% N019819 001 Sep 15, 1988

HYDROCORTISONE CYPROilate
SUSPENSION; ORAL
CORTEF
PHARMACIA AND UPJOHN EQ 10MG BASE/5ML N009900 001

HYDROCORTISONE SODIUM PHOSPHATE
INJECTABLE; INJECTION
HYDROCORTONE
MERCK EQ 50MG BASE/ML N012052 001

HYDROCORTISONE SODIUM SUCCINATE
INJECTABLE; INJECTION
A-HYDROCORT
ABBOTT EQ 100MG BASE/VIAL A085928 001
EQ 100MG BASE/VIAL A089577 001 Apr 11, 1989
EQ 250MG BASE/VIAL A089578 001 Apr 11, 1989
EQ 500MG BASE/VIAL A089579 001 Apr 11, 1989
EQ 1GM BASE/VIAL A089580 001 Apr 11, 1989
HOSPIRA EQ 100MG BASE/VIAL A040666 001 Apr 06, 2006
EQ 100MG BASE/VIAL A085929 001
EQ 250MG BASE/VIAL A085930 001
EQ 500MG BASE/VIAL A085931 001
EQ 1GM BASE/VIAL A085932 001

HYDROCORTISONE SODIUM SUCCINATE
ABRAXIS PHARM EQ 100MG BASE/VIAL A088667 001 Jun 08, 1984
EQ 100MG BASE/VIAL A088712 001 Jun 08, 1984
EQ 250MG BASE/VIAL A088668 001 Jun 08, 1984
EQ 500MG BASE/VIAL A088669 001 Jun 08, 1984
EQ 1GM BASE/VIAL A088670 001 Jun 08, 1984
BAXTER HLTHCARE EQ 100MG BASE/VIAL A086619 001
EQ 250MG BASE/VIAL A087567 001
EQ 500MG BASE/VIAL A087568 001
EQ 1GM BASE/VIAL A087569 001
INTL MEDICATION EQ 100MG BASE/VIAL A087532 001 Mar 19, 1982
WATSON LABS EQ 100MG BASE/VIAL A084737 002
EQ 250MG BASE/VIAL A083738 001
EQ 500MG BASE/VIAL A084737 001
EQ 1GM BASE/VIAL A084747 001

HYDROCORTISONE VALERATE
CREAM; TOPICAL
HYDROCORTISONE VALERATE
G AND W LABS INC 0.2% A074489 001 Aug 12, 1998
WESTCORT
+ SUN PHARM INDS INC 0.2% ** N017950 001

OINTMENT; TOPICAL
HYDROCORTISONE VALERATE
FOUGERA PHARMS 0.2% A075085 001 Jul 31, 2001
WESTCORT
+ SUN PHARM INDS INC 0.2% ** N018726 001 Aug 08, 1983

HYDROCORTISONE; NEOMYCIN SULFATE
CREAM; TOPICAL
NEO-CORT-DOME
BAYER PHARMS 0.5%; EQ 3.5MG BASE/GM N050237 006 Jun 05, 1994
1%; EQ 3.5MG BASE/GM N050237 005 Jun 05, 1994

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMXYIN B SULFATE
SOLUTION/DROPS; OTIC
CORTISPORIN
+ MONARCH PHARMS 1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML N050479 001
NEOMYCIN AND POLYMXYIN B SULFATES AND HYDROCORTISONE
AMRING PHARMS 1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML A065216 001 Oct 31, 2005
NEOMYCIN SULFATE-POLYMXYIN B SULFATE-HYDROCORTISONE
PHARMAFAIR 1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML A062394 001 Sep 29, 1982

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

**HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE**

**SOLUTION/DRYPS; OTIC**

- OTOCORT: 1%; Eq 3.5 mg base/ml; 10,000 units/ml
  - Watson Labs: A060730 002

**SUSPENSION/DRYPS; OPHTHALMIC**

- CORTISPORIN: 1%; Eq 3.5 mg base/ml; 10,000 units/ml
  - Neomycin Sulfate-Polyoxin B Sulfate-Hydrocortisone: A062623 001 Sep 24, 1985

**OTICAIR**

- Neomycin Sulfate, Polyoxin B Sulfate & Hydrocortisone: A062617 001 Sep 18, 1985

- OtoBionene

- PediOtic: 1%; Eq 3.5 mg base/ml; 10,000 units/ml
  - Monarch Pharms: A062822 001 Sep 29, 1987

**HYDROCORTISONE; POLYMYXIN B SULFATE**

**SOLUTION/DRYPS; OTIC**

- OTOBiotic: 5 mg/ml; Eq 10,000 units base/ml
  - Schering: A062302 001

- Pyocidin

- OTOBIOTIC

**HYDROCORTISONE; TETRACYCLINE HYDROCHLORIDE**

**OINTMENT; OPHTHALMIC**

- Achromycin: 1.5%; 1%
  - Lederle: N050272 001

**HYDROCORTISONE; UREA**

**CREAM; TOPICAL**

- Alphaderm

- Calmurid HC

- Pharmacia and Ufjohn: 1%; 10%
  - Bio-Glan: A086008 001
  - A083947 001

**HYDROFLUMETHIAZIDE**

**TABLET; ORAL**

- DIUCARDIN: 50 mg
  - Wyeth Ayerst: A088383 001

**HYDROFLUMETHIAZIDE AND RESERPINE**

- Reserpine

- Usl Pharma: 50 mg; 0.125 mg
  - Watson Labs: 25 mg; 0.125 mg
  - A088195 001 Oct 26, 1983

**HYDROMORPHONE HYDROCHLORIDE**

**CAPSULE, EXTENDED RELEASE; ORAL**

- Palladone: 12 mg
  - Purdue Pharma LP: N021044 001 Sep 24, 2004
  - 16 mg
  - 24 mg
  - 32 mg
  - N021044 002 Sep 24, 2004

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## HYDROMORPHONE HYDROCHLORIDE

**INJECTABLE; INJECTION**

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<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>DILAUDID + FRESENIUS KABI USA</td>
<td>4MG/ML</td>
<td>N019034 005</td>
<td>Apr 30, 2009</td>
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<tr>
<td>DILAUDID-HP + FRESENIUS KABI USA</td>
<td>10MG/ML</td>
<td>N019034 001</td>
<td>Jan 11, 1984</td>
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<tr>
<td>HYDROMORPHONE HYDROCHLORIDE</td>
<td>250MG/VIAL</td>
<td>N019034 002</td>
<td>Aug 04, 1994</td>
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<tr>
<td>HOSPIRA</td>
<td>10MG/ML</td>
<td>A074598 001</td>
<td>Jun 19, 1997</td>
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<tr>
<td>WATSON LABS</td>
<td>10MG/ML</td>
<td>A074317 001</td>
<td>Aug 23, 1995</td>
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**TABLET; ORAL**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Strength</th>
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<tr>
<td>HYDROMORPHONE HYDROCHLORIDE</td>
<td>2MG</td>
<td>A077311 001</td>
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<tr>
<td>NESHER PHARMS</td>
<td>4MG</td>
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<td>8MG</td>
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**TABLET, EXTENDED RELEASE; ORAL**

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<th>Date Approved</th>
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<tbody>
<tr>
<td>ACTAVIS LABS FL INC</td>
<td>8MG</td>
<td>A202144 001</td>
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<td></td>
<td>12MG</td>
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<td></td>
<td>16MG</td>
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<td></td>
<td>32MG</td>
<td>A202144 004</td>
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## HYDROXOCOBALAMIN

**INJECTABLE; INJECTION**

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<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>ALPHAREDISOL</td>
<td>1MG/ML</td>
<td>A080778 001</td>
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<tr>
<td>CYANOKIT</td>
<td>2.5GM/VIAL</td>
<td>N022041 002</td>
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**HYDROXYAMPHETAMINE HYDROBROMIDE**

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<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>PHAREDRINE PHARMICS</td>
<td>1%</td>
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**HYDROXYCHLOROQUINE SULFATE**

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<th>Strength</th>
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<tbody>
<tr>
<td>SANDOX</td>
<td>200MG</td>
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**HYDROXYPROGESTERONE CAPROATE**

**INJECTABLE; INJECTION**

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<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>AKORN</td>
<td>125MG/ML</td>
<td>N018004 001</td>
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<tr>
<td>ALLERGAN SALES LLC</td>
<td>125MG/ML</td>
<td>N017439 001</td>
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<tr>
<td></td>
<td>250MG/ML</td>
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**SOLUTION; INTRAMUSCULAR**

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<th>Strength</th>
<th>NDC Code</th>
<th>Date Approved</th>
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</thead>
<tbody>
<tr>
<td>DELALUTIN</td>
<td>125MG/ML (125MG/ML) **</td>
<td>N010347 004</td>
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<tr>
<td></td>
<td>125MG/ML (125MG/ML) **</td>
<td>N016911 001</td>
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<tr>
<td></td>
<td>250MG/ML (250MG/ML) **</td>
<td>N010347 002</td>
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<td></td>
<td>250MG/ML (250MG/ML) **</td>
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**HYDROXYSTILBAMIDINE ISETHIONATE**

**INJECTABLE; INJECTION**

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<th>Date Approved</th>
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<tbody>
<tr>
<td>SANOFI AVENTIS US</td>
<td>225MG/AMP</td>
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**HYDROXYUREA**

**CAPSULE; ORAL**

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<th>Strength</th>
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<th>Date Approved</th>
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<tr>
<td>BARR</td>
<td>250MG</td>
<td>A075143 002</td>
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<tr>
<td>BARR LABS INC</td>
<td>250MG</td>
<td>A075020 002</td>
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<td>500MG</td>
<td>A075020 001</td>
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<td>ROXANE</td>
<td>500MG</td>
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**TABLET; ORAL**

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</thead>
<tbody>
<tr>
<td>BARR</td>
<td>1GM</td>
<td>A075734 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DISCONTINUED DRUG PRODUCT LIST

**HYDROXYZINE HYDROCHLORIDE**

**TABLET; ORAL**

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<td>50MG</td>
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<td>100MG</td>
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<td>10MG</td>
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<tr>
<td>25MG</td>
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<td>50MG</td>
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<tr>
<td>10MG</td>
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<td>25MG</td>
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**HYDROXYZINE PAMOATE**

**CAPSULE; ORAL**

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<th>Strength</th>
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<tbody>
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**TEVA**

**HYDROXYZINE PAMOATE**

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<tbody>
<tr>
<td>EQ 25MG HYDROCHLORIDE</td>
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**DURAMED PHARMS BARR**

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<td>A088593</td>
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**IVAX SUB TEVA PHARMS**

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**PAR PHARM**

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**SANDOX**

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**SUPERPHARM**

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**VANGARD**

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**WATSON LABS**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Hydroxyzine Pamoate

**Capsule; Oral**

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**Vistaril**

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**Ibandronate Sodium**

**Tablet; Oral**

- **BONIVA**
  - Hoffmann La Roche: 2.5mg Base ** N021455 001 May 16, 2003
- **Mylan Pharms Inc**
  - EQ 150mg Base: A078995 001 Mar 19, 2012

**Ibuprofen**

**Capsule; Oral**

- **Contract Pharmacal**
  - 200mg: A074782 001 Jul 06, 1998
- **Bayer**
  - 200mg **: A070626 001 Sep 02, 1987
  - 200mg **: A071002 001 Sep 02, 1987

**Suspension; Intravenous**

- **Cumberland Pharms**
  - 400mg/4ml (100mg/ml): N022348 001 Jun 11, 2009

**Suspension; Oral**

- **Children's Advil**
  - Wyeth Cons: 100mg/5ml N019833 002 Sep 19, 1989
- **Abbott**
  - 100mg/5ml N019784 001 Dec 18, 1989
- **MOTRIN**
  - MCNEIL CONSUMER: 100mg/5ml ** N019842 001 Sep 19, 1989

**Suspension; Drops; Oral**

- **MOTRIN**
  - MCNEIL: 40mg/ml N020476 001 May 25, 1995

**Tablet; Oral**

- **ACHES-N-PAIN**
  - Lederle: 200mg A071065 001 May 28, 1987
- **CAP-PROFEN**
  - Perrigo: 200mg A072097 001 Dec 08, 1987
- **IBU**
  - BASF: 400mg A070083 001 Feb 22, 1985
  - 400mg: N018197 001
  - 600mg A070088 001 Feb 08, 1985
  - 600mg A070099 001 Mar 29, 1985
  - 800mg A070745 001 Jul 23, 1986
- **IBU-TAB**
  - ALRA: 800mg A071965 001 Aug 11, 1988
- **IBUPRIN**
  - PLIVA: 200mg A071773 001 Jul 16, 1987
- **IBUPROFEN**
  - ABBOTT: 600mg A070556 001 Jun 14, 1985
  - 800mg A071264 001 Jul 25, 1986
- **ANI PHARMS INC**
  - 200mg A071144 001 Jan 20, 1987
  - 200mg A072901 001 Dec 19, 1991
  - 200mg A072903 001 Dec 19, 1991
- **AUROLIFE PHARMA LLC**
  - 300mg A070736 002 Jun 12, 1986
  - 400mg A070736 003 Jun 12, 1986
  - 600mg A070736 001 Jun 12, 1986
  - 800mg A071938 001 Jan 14, 1988
- **Contract Pharmacal**
  - 200mg A071265 001 Oct 15, 1986
  - 200mg A071265 002 Sep 10, 1987
  - 200mg A071735 001 Sep 10, 1987

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## IBUPROFEN

**Tablet; Oral**

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**See List Footnote**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### IBUPROFEN

**TABLET; ORAL**

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**MOTORIN**

+ MCNEIL CONSUMER

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**MOTRIN MIGRAINE PAIN**

J AND J CONSUMER INC

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CHILDREN'S MOTRIN

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**IBUPROFEN**

**PERRIGO**

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**JUNIOR STRENGTH MOTRIN**

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**IBUPROFEN; OXYCODONE HYDROCHLORIDE**

**TABLET; ORAL**

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**OXYCODONE HYDROCHLORIDE AND IBUPROFEN**

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**IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE**

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**IBUTILIDE FUMARATE**

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**IDARUBICIN HYDROCHLORIDE**

**INJECTABLE; INJECTION**

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**IDARUBICIN HYDROCHLORIDE**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>EQ 100MG BASE **</td>
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<td><strong>IMIPRAMINE HYDROCHLORIDE</strong></td>
<td>Concentrate; Oral</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Discontinued Drug Product List

**See List Footnote**

#### Imipramine Hydrochloride

**Tablet; Oral**

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<tr>
<th>Strength</th>
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<td>50mg</td>
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**Janimine**

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#### Imipramine Pamoate

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**Tofranil-Pm**

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#### Imiquimod

**Cream; Topical**

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#### Inamrinone Lactate

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#### Indapamide

**Tablet; Oral**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>LILLY</td>
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<td>EQ 75MG BASE</td>
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**See List Footnote**

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<table>
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<td>TEVA</td>
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<tr>
<td>+ IROKO PHARMS LLC</td>
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<tr>
<td>+</td>
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<td>INDOMETHACIN</td>
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<td>HALSEY</td>
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<td>MUTUAL PHARM</td>
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<td>MYLAN</td>
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<td>PARKE DAVIS</td>
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<td>PIONEER PHARMS</td>
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<td>PLIVA</td>
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<td>TEVA</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
INDOMETHACIN
CAPSULE, EXTENDED RELEASE; ORAL
INDOCIN SR
+ IROKO PHARMS
INDOMETHACIN
ABLE
INDOCIN SR
INWOOD LABS
INDOMETHACIN
WATSON LABS INC
SUPPOSITORY, RECTAL
INDOCIN
+ IROKO PHARMS
INDOMETHACIN
SUSPENSION; ORAL
CYCLE PHARMS LTD
** See List Footnote

INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT
INJECTABLE; SUBCUTANEOUS
NOVOLOG MIX 50/50
NOVO NORDISK INC
50 UNITS/ML; 50 UNITS/ML
NOVOLOG MIX 70/30 PENFILL
NOVO NORDISK INC
210 UNITS/3ML; 90 UNITS/3ML (70 UNITS/ML; 30 UNITS/ML)
210 UNITS/3ML; 90 UNITS/3ML (70 UNITS/ML; 30 UNITS/ML)

INSULIN ASPART RECOMBINANT
INJECTABLE; SUBCUTANEOUS
NOVOLOG FLEXTOUCH
+ NOVO NORDISK INC
300 UNITS/3ML (100 UNITS/ML)
NOVOLOG INNOLET
NOVO NORDISK INC
300 UNITS/3ML (100 UNITS/ML)

INSULIN DETEMIR RECOMBINANT
INJECTABLE; SUBCUTANEOUS
LEVEMIR FLEXPEN
NOVO NORDISK INC
300 UNITS/3ML (100 UNITS/ML)
LEVEMIR INNOLET
NOVO NORDISK INC
300 UNITS/3ML (100 UNITS/ML)
LEVEMIR PENFILL
NOVO NORDISK INC
300 UNITS/3ML (100 UNITS/ML)

INSULIN GLULISINE RECOMBINANT
INJECTABLE; INTRAVENOUS, SUBCUTANEOUS
APIDRA
+ SANOFI AVENTIS US
300 UNITS/3ML (100 UNITS/ML)

INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT
INJECTABLE; INJECTION
HUMALOG MIX 50/50 PEN
LILLY
50 UNITS/ML; 50 UNITS/ML
HUMALOG MIX 75/25 PEN
LILLY
75 UNITS/ML; 25 UNITS/ML

INSULIN LISPRO RECOMBINANT
INJECTABLE; INJECTION
HUMALOG PEN
LILLY
100 UNITS/ML

INSULIN PORK
INJECTABLE; INJECTION
ILETIN I
LILLY
500 UNITS/ML
INSULIN
NOVO NORDISK INC
40 UNITS/ML
REGULAR INSULIN
NOVO NORDISK INC
100 UNITS/ML

INSULIN PURIFIED BEEF
INJECTABLE; INJECTION
REGULAR ILETIN II
LILLY
100 UNITS/ML

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
INSULIN PURIFIED PORK
INJECTABLE; INJECTION
ILETIN II
LILLY 500 UNITS/ML N018344 002
REGULAR ILETIN II (PORK)
LILLY 100 UNITS/ML N018344 001
REGULAR PURIFIED PORK INSULIN
NOVO NORDISK INC 100 UNITS/ML N018381 001
VELOSULIN
NOVO NORDISK INC 100 UNITS/ML N018193 001

INSULIN PURIFIED PORK; INSULIN SUSP ISOPHANE PURIFIED PORK
INJECTABLE; INJECTION
INSULIN NORDISK MIXTARD (PORK)
NOVO NORDISK INC 30 UNITS/ML; 70 UNITS/ML N018195 001

INSULIN RECOMBINANT HUMAN
INJECTABLE; INJECTION
HUMULIN BR
LILLY 100 UNITS/ML N019529 001 Apr 28, 1986
VELOSULIN BR
NOVO NORDISK INC 100 UNITS/ML N021028 001 Jul 19, 1999
POWDER; INHALATION
EXUBERA
PFIZER 1MG/INH N021868 001 Jan 27, 2006
3MG/INH N021868 002 Jan 27, 2006

INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN
INJECTABLE; INJECTION
HUMULIN 50/50
LILLY 50 UNITS/ML; 50 UNITS/ML N020100 001 Apr 29, 1992

INSULIN RECOMBINANT PURIFIED HUMAN
INJECTABLE; INJECTION
NOVOLIN R
NOVO NORDISK INC 100 UNITS/ML N018778 001 Aug 30, 1983
VELOSULIN BR HUMAN
NOVO NORDISK INC 100 UNITS/ML N019450 001 May 30, 1986

INSULIN RECOMBINANT PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN
INJECTABLE; INJECTION
MIXTARD HUMAN 70/30
BAYER PHARMS 30 UNITS/ML; 70 UNITS/ML N019585 001 Mar 11, 1988
NOVOLIN 70/30
NOVO NORDISK INC 30 UNITS/ML; 70 UNITS/ML N019441 001 Jul 11, 1986

INSULIN SUSP ISOPHANE BEEF
INJECTABLE; INJECTION
NPH INSULIN
NOVO NORDISK INC 40 UNITS/ML N017929 001
100 UNITS/ML N017929 003

INSULIN SUSP ISOPHANE BEEF/PORK
INJECTABLE; INJECTION
NPH ILETIN I (BEEF-PORK)
LILLY 40 UNITS/ML N017936 001
100 UNITS/ML N017936 002

INSULIN SUSP ISOPHANE PURIFIED BEEF
INJECTABLE; INJECTION
NPH ILETIN II
LILLY 100 UNITS/ML N018479 001

INSULIN SUSP ISOPHANE PURIFIED PORk
INJECTABLE; INJECTION
INSULIN INSULATARD NPH NORDISK
NOVO NORDISK INC 100 UNITS/ML N018194 001
NPH ILETIN II (PORK)
LILLY 100 UNITS/ML N018345 001
NPH PURIFIED PORK ISOPHANE INSULIN
NOVO NORDISK INC 100 UNITS/ML N018623 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Type</th>
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<th>Date of Discontinuation</th>
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<td>Insulin Susp Protamine Zinc Beef/Pork</td>
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<td>Lilly</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
INSULIN ZINC SUSP RECOMBINANT HUMAN
INJECTABLE; INJECTION
HUMULIN L LILLY 100 UNITS/ML
NOVO L NOVO NORDISK INC 100 UNITS/ML
NOVO NORDISK INC 100 UNITS/ML

INSULIN ZINC SUSP SEMISYNTHETIC PURIFIED HUMAN
INJECTABLE; INJECTION
NOVO L NOVO NORDISK INC 100 UNITS/ML
NOVO NORDISK INC 100 UNITS/ML

INULIN
INJECTABLE; INJECTION
INULIN AND SODIUM CHLORIDE ISO TEX 100MG/ML

INVERT SUGAR
INJECTABLE; INJECTION
TRAVERT 10% IN PLASTIC CONTAINER BAXTER HLTHCARE 10GM/100ML

IOBENGUANE SULFATE I-131 INJECTABLE; INJECTION
IOBENGUANE SULFATE I 131 PHARMALUCENCE 2.3mCi/ML

IODOCTAMIC ACID
TABLET; ORAL
CHOLEBRINE MALLINCKROOT 750MG

IODAMIDE MEGLUMINE
INJECTABLE; INJECTION
RENOVUE-65 BRACCO 65% N017902 001
RENOVUE-DIP BRACCO 24% N017903 001

IODIPAMIDE MEGLUMINE
INJECTABLE; INJECTION
CHOLOGRAFIN MEGLUMINE BRACCO 10.3% N009321 007
+ 52% N009321 003

IODIPAMIDE SODIUM
INJECTABLE; INJECTION
CHOLOGRAFIN SODIUM BRACCO 20% N009321 001

IODIXANOL
INJECTABLE; INJECTION
VISIPAQUE 270 GE HEALTHCARE 55% N020808 001 Aug 29, 1997

IODOHIPPURATE SODIUM I-123 INJECTABLE; INJECTION
NEPHROFLOW GE HEALTHCARE 1mCi/ML N018289 001 Dec 28, 1984

IODOHIPPURATE SODIUM I-131 INJECTABLE; INJECTION
HIPPURAN I 131 MALLINCKROOT 0.25mCi/ML N016666 001
HIPPUTOPE BRACCO 1-2mCi/VIAL N015419 002
IODOHIPPURATE SODIUM I 131 PHARMALUCENCE 0.2mCi/ML N017313 001

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
**See List Footnote**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
IOPHENDYLATE
INJECTABLE; INJECTION
PANTOQUE
ALCON 100%  N005319 001

IOPROMIDE
INJECTABLE; INJECTION
ULTRAVIST 150
  + BAYER HLTHCARE 31.2%  N020220 004 May 10, 1995
  + ULTRAVIST 300 IN PLASTIC CONTAINER 62.3%  N020220 005 Nov 18, 2008

IOTHALAMATE MEGLUMINE
INJECTABLE; INJECTION
CONRAY 30
  + LIEBEL-FLARSHEIM 30%  N016983 001

IOTHALAMATE MEGLUMINE; IOTHALAMATE SODIUM
INJECTABLE; INJECTION
VASCORAY
  MALLINCKRODT 52%;26%  N016783 001

IOTHALAMATE SODIUM
INJECTABLE; INJECTION
ANGIO-CONRAY
  MALLINCKRODT 80%  N013319 001
  CONRAY 325
    MALLINCKRODT 54.3%  N017685 001
  CONRAY 400
    MALLINCKRODT 66.8%  N014295 001

IOTROLAN
INJECTABLE; INTRAVASCULAR
OSMOVIST 190
  BAYER HLTHCARE 40.6%  N019580 001 Dec 07, 1989
OSMOVIST 240
  BAYER HLTHCARE 51.3%  N019580 002 Dec 07, 1989

IOVERSOL
INJECTABLE; INJECTION
OPTIRAY 160
  LIEBEL-FLARSHEIM 34%  N019710 003 Dec 30, 1988
OPTIRAY 240
  LIEBEL-FLARSHEIM 51%  N020923 001 May 28, 1998

IOXAGLATE MEGLUMINE; IOXAGLATE SODIUM
INJECTABLE; INJECTION
HEXABRIX
  GUERBET 39.3%;19.6%  N018905 002 Jul 26, 1985

IOXILAN
INJECTABLE; INJECTION
OXILAN-300
  GUERBET 62%  N020316 001 Dec 21, 1995
OXILAN-350
  GUERBET 73%  N020316 002 Dec 21, 1995

IPODATE CALCIUM
GRANULE; ORAL
ORAGRAFIN CALCIUM
  BRACCO 3GM/PACKET  N012968 001

IPODATE SODIUM
CAPSULE; ORAL
BILIVIST
  BAYER HLTHCARE 500MG  A087768 001 Aug 11, 1982
  ORAGRAFIN SODIUM
    BRACCO 500MG  N012967 001

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### IPRATROPIUM BROMIDE

**AEROSOL, METERED; INHALATION**

**ATROVENT**
- **BOEHRINGER INGELHEIM** 0.018MG/INH N019085 001 Dec 29, 1986

**SOLUTION; INHALATION**
- **ATROVENT**
  - **BOEHRINGER INGELHEIM** 0.02% ** N020228 001 Sep 29, 1993

**IPRATROPIUM BROMIDE**
- **ACTAVIS MID ATLANTIC** 0.02%
- **APOTEX INC** 0.02%
- **BAUSCH AND LOMB INC** 0.02%
- **MYLAN SPECIALITY LP** 0.02%
- **PHARMASCIENCE INC** 0.02%
- **ROXANE** 0.02%
- **TEVA PHARMS USA** 0.02%

**SPRAY, METERED; NASAL**
- **ATROVENT**
  - **BOEHRINGER INGELHEIM** 0.021MG/SPRAY N020393 001 Oct 20, 1995
  - 0.042MG/SPRAY N020394 001 Oct 20, 1995

**IPRATROPIUM BROMIDE**
- **APOTEX INC** 0.021MG/SPRAY A076156 001 Apr 18, 2003

### IRBESARTAN

**TABLET; ORAL**

**IRBESARTAN**
- **AJANTA PHARMA LTD** 75MG A203685 001 Dec 10, 2015
  - 150MG A203685 002 Dec 10, 2015
  - 300MG A203685 003 Dec 10, 2015
- **APOTEX INC** 75MG A200832 001 Oct 15, 2012
  - 150MG A200832 002 Oct 15, 2012
  - 300MG A200832 003 Oct 15, 2012
- **MYLAN PHARMS INC** 75MG A200461 001 Sep 27, 2012
  - 150MG A200461 002 Sep 27, 2012
  - 300MG A200461 003 Sep 27, 2012
- **WATSON LABS INC** 75MG A090720 001 Oct 12, 2012
  - 150MG A090720 002 Oct 12, 2012
  - 300MG A090720 003 Oct 12, 2012

### IRINOTECAN HYDROCHLORIDE

**INJECTABLE; INJECTION**

**IRINOTECAN HYDROCHLORIDE**
- **SANDOX** 40MG/2ML (20MG/ML) A077994 001 Feb 27, 2008
  - 100MG/5ML (20MG/ML) A077994 002 Feb 27, 2008
- **SANDOX INC** 40MG/2ML (20MG/ML) A090137 001 Nov 12, 2009
  - 100MG/5ML (20MG/ML) A090137 002 Nov 12, 2009
- **SUN PHARMA GLOBAL** 40MG/2ML (20MG/ML) A078805 001 Apr 21, 2008
  - 100MG/5ML (20MG/ML) A078805 002 Apr 21, 2008

### IRON DEXTRAN

**INJECTABLE; INJECTION**

**IRON DEXTRAN**
- **SANOFI AVENTIS US** EQ 50MG IRON/ML N010787 002

### IRON SUCCINATE

**INJECTABLE; INTRAVENOUS**

**VENOFER**
- **LUITPOLD** EQ 65MG BASE/3.25ML (EQ 20MG BASE/ML) N021135 005 Mar 29, 2013
  - EQ 75MG BASE/3.75ML (EQ 20MG BASE/ML) N021135 003 Mar 29, 2005

### ISOETHARINE HYDROCHLORIDE

**SOLUTION; INHALATION**

**BETA-2**
- **NEPHRON** 1% A086711 001
- **BRONKOSOL**
  - **SANOFI AVENTIS US** 0.25% N012339 009
  - 1% N012339 008
- **ISOETHARINE HYDROCHLORIDE**
  - **ALPHARMA US PHARMS** 1% A087101 001
  - **ASTRAZENECA**
    - 0.062% A088622 001 Nov 15, 1982
    - 0.062% A089614 001 Jun 13, 1991
    - 0.125% A087938 001 Nov 15, 1982
    - 0.125% A089615 001 Jun 13, 1991

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ISONIASID
SYRUP; ORAL
RIMIFON
ROCHE  50MG/5ML  N008420 001
TABLET; ORAL
DOW-ISONIAZID
DOW PHARM  300MG  A080330 002
HYZYD
MEDPOINTE PHARM HLC  100MG  A080134 003
500MG  A080134 004
INH
NOVARTIS  300MG  A080935 001
ISONIAZID
DURAMED PHARMS BARR  100MG  A088231 001  Mar 17, 1983
300MG  A088119 001  Mar 17, 1983
HALSEY  50MG  A083632 001
HIKMA INTL PHARMS  100MG  A080212 001
300MG  A087426 001
IMPAZ LABS  100MG  A080153 001
IVAX SUB TETRA PHARMS  100MG  A080270 001
300MG  A083610 001
LILLY  100MG  N008499 002
300MG  N008499 003
MK LABS  100MG  A080941 001
NEXGEN PHARMA INC  100MG  A084050 001
PANKAY  50MG  N008428 001
100MG  N008428 002
300MG  N008428 003
PERRIGO  100MG  A083060 001
PHARMAVITE  100MG  A085091 001
PHOENIX LABS NY  50MG  A083668 001
100MG  A083668 002
PUREPAC PHARM  50MG  A080132 003  Jul 14, 1982
100MG  A080132 004  Jul 14, 1982
SUN PHARM INDUSTRIES  100MG  A080136 001
300MG  A083633 001
WATSON LABS  50MG  A080522 001
100MG  A080401 001
150MG; 300MG  A080523 001
100MG  A085790 001
300MG  A080521 001
300MG  A083178 001
300MG  A085784 001
WHITWORTH TOWN PLCN  100MG  A080120 002
LANIAZID
LANNETT  50MG  A080140 001
100MG  A080140 002
NYDRAZID
BRISTOL MYERS SQUIBB  100MG  N008392 003
STANOZIDE
EVERYLIFE  100MG  A080126 001
300MG  A080126 002
ISONIAZID; RIFAMPIN
CAPSULE; ORAL
RIFAMPIN AND ISONIAZID
HIKMA INTL PHARMS  150MG; 300MG  A065221 001  Jul 29, 2005
ISOPROPAMIDE IODIDE
TABLET; ORAL
CARBID
GLAXOSMITHKLINE  EQ 5MG BASE  N010744 001
ISOPROTERENOL HYDROCHLORIDE
AEROSOL, METERED; INHALATION
ISOPROTERENOL HYDROCHLORIDE
3M  0.12MG/INH  N010375 004
ALPHARMA US PHARMS  0.12MG/INH  A085904 001
ISUPREL
SANOFI AVENTIS US  0.103MG/INH  N011178 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

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*Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons*
# DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

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<td>IMDUR</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
ISRADIPINE
CAPSULE; ORAL
DYNACIRC
+ SMITHKLINE BEECHAM 2.5MG N019546 001 Dec 20, 1990
+ 5MG N019546 002 Dec 20, 1990
TABLET, EXTENDED RELEASE; ORAL
DYNACIRC CR
+ GLAXOSMITHKLINE LLC 5MG ** N020336 001 Jun 01, 1994
+ 10MG ** N020336 002 Jun 01, 1994
ISRADIPINE MYLAN PHARMS INC 5MG A201067 001 Nov 27, 2015
10MG A201067 002 Nov 27, 2015
ITRACONAZOLE
INJECTABLE; INJECTION
SPORANOX JANSSEN PHARMS 10MG/ML N020966 001 Mar 30, 1999
IVERMECTIN
TABLET; ORAL
STROMECTOL MERCK SHARP DOHME 6MG N050742 001 Nov 22, 1996
KANAMYCIN SULFATE
CAPSULE; ORAL
KANTREX APOTHECON EQ 500MG BASE A060516 001
EQ 500MG BASE A061911 001
EQ 500MG BASE A062726 001 Mar 06, 1987
INJECTABLE; INJECTION
KANAMYCIN WEST-WARD PHARMS INT EQ 75MG BASE/2ML A06324 001
EQ 500MG BASE/2ML A06324 002
EQ 1GM BASE/3ML A06324 003
KANAMYCIN SULFATE ABRAXIS PHARM EQ 75MG BASE/2ML A062504 001 Apr 05, 1984
EQ 500MG BASE/2ML A062504 002 Apr 05, 1984
EQ 1GM BASE/3ML A062504 003 Apr 05, 1984
FRESENIUS KABI USA EQ 500MG BASE/2ML A065111 001 Dec 17, 2002
EQ 1GM BASE/3ML A065111 002 Dec 17, 2002
INTL MEDICATION EQ 500MG BASE/2ML A062466 001 Sep 30, 1983
EQ 1GM BASE/3ML A062466 002 Sep 30, 1983
LOCH EQ 75MG BASE/2ML A063021 001 Jul 31, 1992
EQ 500MG BASE/2ML A063022 001 Jul 31, 1992
EQ 1GM BASE/3ML A063025 001 Jul 31, 1992
PHARMAFAIR EQ 75MG BASE/2ML A062668 001 May 07, 1987
EQ 500MG BASE/2ML A062672 001 May 07, 1987
EQ 1GM BASE/3ML A062669 001 May 07, 1987
SOLOPAK EQ 75MG BASE/2ML A062605 003 Feb 26, 1986
EQ 500MG BASE/2ML A062605 001 Feb 26, 1986
EQ 1GM BASE/3ML A062605 002 Feb 26, 1986
WARNER CHILCOTT EQ 1GM BASE/3ML A063092 001 Oct 11, 1989
KLEBCIL KING PHARMS EQ 75MG BASE/2ML A062170 001
EQ 500MG BASE/2ML A062170 002
EQ 1GM BASE/3ML A062170 003

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### KETOCONAZOLE

**CREAM; TOPICAL**

- **NIZORAL**
  - JANSEN PHARMA 2% N019084 001 Dec 31, 1985

**SUSPENSION; ORAL**

- **NIZORAL**
  - JANSEN PHARMA 100MG/5ML A070767 001 Nov 07, 1986

**TABLET; ORAL**

- **KETOCONAZOLE**
  - AAIPHARMA LLC 200MG A075341 001 Jul 27, 1999
  - APOTEX 200MG A075912 001 Jan 10, 2002
  - PLIVA 200MG A075362 001 Jun 15, 1999
  - SUN PHARM INDUSTRIES 200MG A075314 001 Jun 15, 1999
  - TEVA 200MG A074971 001 Jun 15, 1999

- **NIZORAL**
  - JANSEN PHARMS 200MG A075364 001 Feb 07, 2002

### KETOPROFEN

**CAPSULE; ORAL**

- **KETOPROFEN**
  - AUROLIFE PHARMA LLC
    - 50MG A074024 001 Dec 29, 1995
    - 75MG A074024 002 Dec 29, 1995
  - MYLAN
    - 50MG A074035 002 Dec 31, 1996
    - 75MG A074035 003 Dec 31, 1996
  - TEVA
    - 25MG A073515 001 Dec 22, 1992
  - ORUDIS
    - WYETH AYERST
      - 25MG ** N018754 001 Jul 09, 1986
      - 50MG ** N018754 002 Jan 09, 1986
      - 75MG ** N018754 003 Jan 09, 1986

**CAPSULE, EXTENDED RELEASE; ORAL**

- **KETOPROFEN**
  - ACTAVIS LABS FL INC
    - 100MG A075270 001 Mar 24, 1999
    - 150MG A075270 003 Mar 24, 1999
    - 200MG A075270 002 Mar 24, 1999
  - ALKERMES GAINESVILLE
    - 200MG A074879 001 Oct 25, 1999
  - MYLAN
    - 100MG A075679 001 Feb 20, 2002
    - 150MG A075679 002 Feb 20, 2002
  - ORUVAIL
    - WYETH PHARMS INC
      - 100MG ** N018196 003 Feb 08, 1995
      - 150MG ** N018196 002 Feb 08, 1995
      - 200MG ** N018196 001 Sep 24, 1993
  - FILM; ORAL
    - NEXCEDE
      - NOVARTIS 12.5MG N022470 001 Jan 14, 2008

**TABLET; ORAL**

- **ACTRON**
  - BAYER 12.5MG N020499 001 Oct 06, 1995

**KETOROLAC TROMETHAMINE**

**INJECTABLE; INJECTION**

- **KETOROLAC TROMETHAMINE**
  - APOTEX INC
    - 30MG/ML A075626 001 Jul 24, 2001
  - APOTHECON
    - 15MG/ML A075348 002 Nov 28, 2000
  - BAXTER HLTHCARE CORP
    - 15MG/ML A075362 001 Jun 29, 2001
  - BEDFORD
    - 15MG/ML A075348 002 Nov 28, 2000
  - GLAND PHARMA LTD
    - 15MG/ML A075230 001 Oct 25, 1999
  - HOSPIRA
    - 30MG/ML A076722 002 Jul 27, 2004
  - LUITPOLD
    - 15MG/ML A078145 001 Jul 16, 2007
  - MYLAN LABS LTD
    - 15MG/ML A078299 001 Jul 16, 2007

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### LACTULOSE

**SOLUTION; ORAL**

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**LAMIVUDINE; NEVIRAPINE; ZIDOVUDINE**

**TABLET; ORAL**

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**LAMIVUDINE; Raltegravir Potassium**

**TABLET; ORAL**

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**LAMIVUDINE; Tenofovir Disoproxil Fumarate**

**TABLET; ORAL**

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**LAMIVUDINE; ZIDOVUDINE**

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**LAMOTRIGINE**

**TABLET; ORAL**

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<td>GLAXOSMITHKLINE LLC</td>
<td>50MG **</td>
<td>N020241 006 Dec 27, 1994</td>
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<td>N020241 004 Dec 27, 1994</td>
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<td>A078669 001 Apr 08, 2011</td>
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<td>200MG</td>
<td>A077428 004 Jan 27, 2009</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
| Drug Product | Formulation | Strength | Manufacturer | Code | Date
|--------------|-------------|----------|--------------|------|-------
| LAMOTRIGINE | Tablet; Oral | 25 mg | Mylan Labs Ltd | A078443 001 | Feb 11, 2009
|              |             | 100 mg | Mylan Labs Ltd | A078443 002 | Feb 11, 2009
|              |             | 150 mg | Mylan Labs Ltd | A078443 003 | Feb 11, 2009
|              |             | 200 mg | Mylan Labs Ltd | A078443 004 | Feb 11, 2009
|              |             | 25 mg | Pharmascience Inc | A078310 001 | Feb 04, 2009
|              |             | 100 mg | Pharmascience Inc | A078310 002 | Feb 04, 2009
|              |             | 150 mg | Pharmascience Inc | A078310 003 | Feb 04, 2009
|              |             | 200 mg | Pharmascience Inc | A078310 004 | Feb 04, 2009
|              |             | 25 mg | Roxane | A077392 001 | Jan 27, 2009
|              |             | 100 mg | Roxane | A077392 002 | Jan 27, 2009
|              |             | 150 mg | Roxane | A077392 003 | Jan 27, 2009
|              |             | 200 mg | Roxane | A077392 004 | Jan 27, 2009
|              |             | 25 mg | Sandoz | A078645 001 | Jan 27, 2009
|              |             | 100 mg | Sandoz | A078645 002 | Jan 27, 2009
|              |             | 150 mg | Sandoz | A078645 003 | Jan 27, 2009
|              |             | 200 mg | Sandoz | A078645 004 | Jan 27, 2009
|              |             | 25 mg | Wockhardt | A078982 001 | Jan 27, 2009
|              |             | 100 mg | Wockhardt | A078982 002 | Jan 27, 2009
|              |             | 150 mg | Wockhardt | A078982 003 | Jan 27, 2009
|              |             | 200 mg | Wockhardt | A078982 004 | Jan 27, 2009
|              | Chewable; Oral | 100 mg | GlaxosmithKline LLC | N020764 003 | Aug 24, 1998
| Lamictal CD |             | 5 mg | Mylan | A076630 001 | Jan 22, 2009
|              |             | 25 mg | Mylan | A076630 002 | Jan 22, 2009
|              |             | 5 mg | Sandoz | A078409 002 | Jan 22, 2009
|              |             | 25 mg | Sandoz | A078409 003 | Jan 22, 2009
|              | Extended Release; Oral | 25 mg | Handa Pharms LLC | A202887 001 | Jun 17, 2013
| Lamotrigine |             | 50 mg | Handa Pharms LLC | A202887 002 | Jun 17, 2013
|              |             | 15 mg | Handa Pharms LLC | A202887 003 | Jun 17, 2013
|              |             | 25 mg | Handa Pharms LLC | A202887 004 | Jun 17, 2013
| Lansoprazole | For Suspension, Delayed Release; Oral | 15 mg/packet | Takeda Pharms NA | N021281 001 | May 03, 2001
| PREVACID    |             | 30 mg/packet | Takeda Pharms NA | N021281 002 | May 03, 2001
|              | Injectable; Intravenous | 30 mg/vial | Takeda Pharms NA | N021566 001 | May 27, 2004
| PREVACID IV |             | 15 mg | Ani Pharms Inc | A078730 001 | Oct 15, 2010
|              |             | 30 mg | Ani Pharms Inc | A078730 002 | Oct 15, 2010
| Lansoprazole; Naproxen | Capsule, Delayed Rel Pellets, Tablet; Oral | 15 mg, n/a, n/a, 250 mg | Takeda Pharms NA | N021507 002 | Nov 14, 2003
| PREVACID NAPRAPAC 250 (COPACKAGED) |             | 15 mg, n/a, n/a, 375 mg | Takeda Pharms NA | N021507 003 | Nov 14, 2003
|              | PREVACID NAPRAPAC 500 (COPACKAGED) | 15 mg, n/a, n/a, 500 mg | Takeda Pharms NA | N021507 004 | Nov 14, 2003
| Lanthanum Carbonate | Tablet, Chewable; Oral | 250 mg | Shire LLC | N021468 001 | Oct 26, 2004
| Lapyrium Chloride; Undecoylium Chloride Iodine Complex | Solution; Topical | 0.5%; 1.8% | Chesebrough Ponds | N011914 001 | ** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
LATANOPROST
SOLUTION/DROPS;OPHTHALMIC
LATANOPROST
APOTEX INC
0.005%
A077697 001 Mar 22, 2011

LEFLUNOMIDE
TABLET;ORAL
LEFLUNOMIDE
FOSUN PHARMA
10MG
A077087 001 Sep 13, 2005
20MG
A077087 002 Sep 13, 2005
SANDOZ
10MG
A077085 001 Sep 13, 2005
20MG
A077085 002 Sep 13, 2005

LEPIRUDIN RECOMBINANT
INJECTABLE;INJECTION
REFLUDAN
BAYER HLTHCARE
50MG/VIAL
ND20807 001 Mar 06, 1998

LETROZOLE
TABLET;ORAL
LETOZOLE
ACTAVIS TOTOWA
2.5MG
A090292 001 Jul 13, 2011
IMFAX LABS
2.5MG
A091638 001 Jun 03, 2011
LANNETT CO INC
2.5MG
A091098 001 Jun 03, 2011
MYLAN
2.5MG
A202048 001 Oct 25, 2014
SYNTHON PHARMS
2.5MG
A091466 001 Jun 03, 2011

LEUCOVORIN CALCIUM
FOR SOLUTION;ORAL
LEUCOVORIN CALCIUM
HOSPIRA
EQ 60MG BASE/VIAL
N008107 003 Jan 30, 1987
INJECTABLE;INJECTION
LEUCOVORIN CALCIUM
ABIC
EQ 3MG BASE/ML
A089352 001 Jun 01, 1988
EQ 50MG BASE/VIAL
A089353 001 Jun 01, 1988
ABRAXIS PHARM
EQ 50MG BASE/VIAL
A088939 001 Dec 01, 1986
ELKINS SINN
EQ 50MG BASE/VIAL
A070480 001 Jan 02, 1987
EQ 100MG BASE/VIAL
A081224 001 Jun 03, 1994
HOSPIRA
EQ 3MG BASE/ML **
N008107 001
+
EQ 50MG BASE/VIAL **
N008107 002
+
EQ 100MG BASE/VIAL **
N008107 004 May 23, 1999
+
EQ 350MG BASE/VIAL **
N008107 005 Apr 05, 1999
PHARMAChemie
EQ 350MG BASE/VIAL
A040262 001 Dec 15, 1999
PHARMAChemie USA
EQ 50MG BASE/VIAL
A089628 001 Apr 17, 1997
EQ 100MG BASE/VIAL
A089915 001 Apr 17, 1997
TEVA PARENTERAL
EQ 50MG BASE/VIAL
A081278 001 Sep 28, 1993
LEUCOVORIN CALCIUM PRESERVATIVE FREE
HOSPIRA
EQ 10MG BASE/ML **
A040147 001 Jun 25, 1997
LUITPOLD
EQ 50MG BASE/VIAL
A040338 001 Jan 31, 2001
TEVA PARENTERAL
EQ 10MG BASE/ML
A040332 001 Jun 28, 1999
WELLCOVORIN
GLAXOSMITHKLINE
EQ 5MG BASE/ML
A087439 001 Oct 19, 1982
EQ 25MG BASE/VIAL
A089833 001 Jan 23, 1989
EQ 50MG BASE/VIAL
A089465 001 Jan 23, 1989
EQ 100MG BASE/VIAL
A089834 001 Jan 23, 1989
TABLET;ORAL
LEUCOVORIN CALCIUM
ANI PHARMS INC
EQ 15MG BASE
A075327 001 Mar 24, 1999
EPIC PHARMA LLC
EQ 5MG BASE
A074544 001 Aug 28, 1997
PAR PHARM
EQ 5MG BASE
A074544 002 Aug 28, 1997
PHARMAChemie
EQ 5MG BASE
A071598 001 Oct 14, 1987
XANOZYNE PHARM
EQ 5MG BASE
N018459 001 Jan 30, 1986
WELLCOVORIN
GLAXOSMITHKLINE
EQ 5MG BASE **
N018342 001 Jul 08, 1983

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
LEUCOVORIN CALCIUM
TABLET; ORAL
WELLCOVORIN
+  

**  

LEUPROLIDE ACETATE
IMPLANT; IMPLANTATION
VIADOR

ORTH MCNEIL JANSSEN


LEUPROLIDE ACETATE
GENZYME

LUPRON

+ ABBVIE ENDOCRINE INC

LUPRON DEPOT

+ ABBVIE ENDOCRINE INC

LUPRON DEPOT-PED

+ ABBVIE ENDOCRINE INC

LEVALLORPHAN TARTRATE
INJECTABLE; INJECTION
LORFAN

ROCHE


LEVAMISOLE HYDROCHLORIDE
TABLET; ORAL
ERGAMISOL

JANSSEN PHARMA


LEVETIRACETAM
SOLUTION; ORAL
LEVETIRACETAM

ACI HEALTHCARE LTD

APOTEX INC


LEVETIRACETAM
TABLET; ORAL
LEVETIRACETAM

ACTAVIS LABS FL INC

FOSUN PHARMA

MYLAN

WATSON LABS INC

TABLET, EXTENDED RELEASE; ORAL
LEVETIRACETAM

MYLAN PHARMS INC

SANDOZ

VIRTUS PHARMS

LEVOBETAXOLOL HYDROCHLORIDE
SUSPENSION/ DROPS; OPHTHALMIC
BETAXON

ALCON PHARMS LTD

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
LEVOBUNOLOL HYDROCHLORIDE
SOLUTION/DROPS;OPHTHALMIC
LEVOBUNOLOL HYDROCHLORIDE

ALCON LABS INC
0.25%
A074851 001 Oct 28, 1996
APOTEX INC
0.25%
A075473 001 Aug 03, 2000
0.5%
A075475 001 Aug 03, 2000
BAUSCH AND LOMB
0.25%
A074307 001 Mar 04, 1994

LEVOBUPIVACAINE HYDROCHLORIDE
INJECTABLE;INJECTION
CHIROCAINE

PURDUE PHARMA LP
EQ 2.5MG BASE/ML
N020997 001 Aug 05, 1999
EQ 5MG BASE/ML
N020997 002 Aug 05, 1999
EQ 7.5MG BASE/ML
N020997 003 Aug 05, 1999

LEVOCABASTINE HYDROCHLORIDE
SUSPENSION/DROPS;OPHTHALMIC
LIVOSTIN

NOVARTIS
EQ 0.05% BASE
N020219 001 Nov 10, 1993

LEVOCARNITINE
INJECTABLE;INJECTION
LEVOCARNITINE

TEVA PHARMS USA
200MG/ML
A075881 001 Mar 29, 2001

LEVCETIRIZINE DIHYDROCHLORIDE
TABLET;ORAL
LEVCETIRIZINE DIHYDROCHLORIDE

FOSUN PHARMA
5MG
A090486 001 Mar 26, 2013

LEVODOPA
CAPSULE;ORAL
BENDOPA

VALEANT PHARM INTL
100MG
N016948 003
250MG
N016948 001
500MG
N016948 002

DOPAR
SHIRE
100MG
N016913 003
250MG
N016913 001
500MG
N016913 002

LARODOPA
ROCHE
100MG
N016912 002
250MG
N016912 001
500MG
N016912 006

TABLET;ORAL
DOPAR

SHIRE
250MG
N016913 004
500MG
N016913 005

LARODOPA
ROCHE
100MG
N016912 005
250MG
N016912 003
500MG
N016912 004

LEVOFLOXACIN
INJECTABLE;INJECTION
LEVAQUIN

+ JANSSEN PHARMS
EQ 500MG/20ML (EQ 25MG/ML)
N020635 001 Dec 20, 1996
+ EQ 750MG/30ML (EQ 25MG/ML)
N020635 004 Dec 20, 1996

LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER
+ JANSSEN PHARMS
EQ 250MG/50ML (EQ 5MG/ML) **
N020635 002 Dec 20, 1996
+ EQ 500MG/100ML (EQ 5MG/ML) **
N020635 003 Dec 20, 1996
+ EQ 750MG/150ML (EQ 5MG/ML) **
N020635 005 Dec 20, 1996

LEVOFLOXACIN
AKORN
EQ 500MG/20ML (EQ 25MG/ML)
A091644 001 Jun 20, 2011
EQ 750MG/30ML (EQ 25MG/ML)
A091644 002 Jun 20, 2011

EMCURE PHARMS LTD
EQ 500MG/20ML (EQ 25MG/ML)
A202590 001 Jan 24, 2013
EQ 750MG/30ML (EQ 25MG/ML)
A202590 002 Jan 24, 2013

HOSPIRA INC
EQ 500MG/20ML (EQ 25MG/ML)
A078577 001 Aug 12, 2015
EQ 750MG/30ML (EQ 25MG/ML)
A078577 002 Aug 12, 2015

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

LEVOFLOXACIN
INJECTABLE; INJECTION
LEVOFLOXACIN
MYLAN ASI
EQ 500MG/20ML (EQ 25MG/ML)
A200560 001 Jun 20, 2011
EQ 750MG/30ML (EQ 25MG/ML)
A200560 002 Jun 20, 2011
ZYDUS PHARMS USA INC
EQ 500MG/20ML (EQ 25MG/ML)
A205968 001 Jun 01, 2017
EQ 750MG/30ML (EQ 25MG/ML)
A205968 002 Jun 01, 2017

SOLUTION; ORAL
LEVAQUIN
+ JANSSEN PHARMS
250MG/10ML
N021721 001 Oct 21, 2004

SOLUTION; DROPS, OPHTHALMIC
IQUIX
+ SANTEN
1.5% **
N021571 001 Mar 01, 2004
LEVOFLOXACIN
APOTEX INC
0.5%
A078282 001 Dec 20, 2010
QUIXIN
+ SANTEN
0.5% **
N021199 001 Aug 18, 2000

TABLET; ORAL
LEVAQUIN
+ JANSSEN PHARMS
250MG
N020634 001 Dec 20, 1996
+ 500MG
N020634 002 Dec 20, 1996
+ 750MG
N020634 003 Sep 08, 2000
LEVOFLOXACIN
MYLAN
250MG
A076276 001 Jun 20, 2011
500MG
A076276 002 Jun 20, 2011
750MG
A077097 001 Jun 20, 2011
WATSON LABS INC
250MG
A201484 001 Nov 22, 2013
500MG
A201484 002 Nov 22, 2013
750MG
A201484 003 Nov 22, 2013

LEVOLEUCOVORIN CALCIUM
SOLUTION; INTRAVENOUS
FUSILEV
+ SPECTRUM PHARMS
EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML)
**
N020140 002 Apr 29, 2011
EQ 250MG BASE/25ML (EQ 10MG BASE/ML) **
N020140 003 Apr 29, 2011

LEVOMEPROMAZINE
INJECTABLE; INJECTION
LEVOPROMEX
IMMUNEX
20MG/ML
N015865 001

LEVOMETHADYL ACETATE HYDROCHLORIDE
CONCENTRATE; ORAL
ORLAAM
+ ROXANE
10MG/ML **
N020315 001 Jul 09, 1993

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE
INJECTABLE; INJECTION
ARESTOCAINA HYDROCHLORIDE W/ LEVONORDEFRIN
SOLVAY
0.05MG/ML; 2%
A085010 001
CARBOCAINE W/ NEO-COBECFRIN
EASTMAN KODAK
0.05MG/ML; 2%
N012125 002
ISOCAINA HYDROCHLORIDE W/ LEVONORDEFRIN
SEPTODONT INC
0.05MG/ML; 2%
A084697 001
MEPIVACAINE HYDROCHLORIDE W/ LEVONORDEFRIN
BELMORA LLC
0.05MG/ML; 2%
A084850 002 Oct 21, 1983
POLOCAINE W/ LEVONORDEFRIN
DENTSPLY PHARM
0.05MG/ML; 2%
A089517 001 Apr 14, 1988

LEVONORDEFRIN; PROCAINE HYDROCHLORIDE; PROPOXYCAINE HYDROCHLORIDE
INJECTABLE; INJECTION
RAVOCAINA AND NOVOCAIN W/ NEO-COBECFRIN
EASTMAN KODAK
0.05MG/ML; 2%; 0.4%
N008592 007

LEVONORGESTREL
IMPLANT; IMPLANTATION
JADELLE
+ POPULATION COUNCIL
75MG/IMPLANT **
N020544 001 Nov 01, 1996
LEVONORGESTREL
WYETH PHARMS INC
75MG/IMPLANT
N020627 001 Aug 15, 1996

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

LEVONORGESTREL

IMPLANT; IMPLANTATION

NORPLANT

population council 36MG/IMPLANT N019897 001 Dec 10, 1990

NORPLANT SYSTEM IN PLASTIC CONTAINER 36MG/IMPLANT N020088 001 Dec 10, 1990

TABLET; ORAL

LEVONORGESTREL

FDN CONSUMER 0.75MG ** A078665 001 Aug 28, 2009

LUPIN LTD 0.75MG A091328 001 Jan 23, 2013

WATSON LABS 0.75MG A078666 001 Jun 24, 2009

PLAN B

+ FDN CONSUMER 0.75MG ** N021045 001 Jul 28, 1999

+ 0.75MG ** N021045 002 Aug 24, 2006

LEVOPROPoxyPHene NAPsylate ANHYDROUS

CAPSULE; ORAL

NOVRAD

LILLY EQ 50MG BASE N012928 006

EQ 100MG BASE N012928 004

SUSPENSION; ORAL

NOVRAD

LILLY EQ 50MG BASE/5ML N012928 002

LEVORPHANOL TARTRATE

INJECTABLE; INJECTION

LEVO-DROMORAN

VALENT PHARM INTL 2MG/ML N008719 001 Dec 19, 1991

TABLET; ORAL

LEVO-DROMORAN

+ VALENT PHARM INTL 2MG ** N008720 001 Dec 19, 1991

LEVOTHYRoxINE SODIUM

SOLUTION; ORAL

TIROSINT-SOL

+ INSTITUT BIOCHIMIQUE 13MG/ML N206977 001 Dec 15, 2016

+ 25MG/ML N206977 002 Dec 15, 2016

+ 50MG/ML N206977 003 Dec 15, 2016

+ 75MG/ML N206977 004 Dec 15, 2016

+ 88MG/ML N206977 005 Dec 15, 2016

+ 100MG/ML N206977 006 Dec 15, 2016

+ 112MG/ML N206977 007 Dec 15, 2016

+ 125MG/ML N206977 008 Dec 15, 2016

+ 137MG/ML N206977 009 Dec 15, 2016

+ 150MG/ML N206977 010 Dec 15, 2016

+ 175MG/ML N206977 011 Dec 15, 2016

+ 200MG/ML N206977 012 Dec 15, 2016

TABLET; ORAL

EUTHYROX

PROVELL 0.3MG N021292 012 May 31, 2002

LEVOTHEROXYINE SODIUM

MERCK KGAA

0.025MG A076752 001 Jun 16, 2005

0.05MG A076752 002 Jun 16, 2005

0.075MG A076752 003 Jun 16, 2005

0.088MG A076752 004 Jun 16, 2005

0.1MG A076752 005 Jun 16, 2005

0.112MG A076752 006 Jun 16, 2005

0.125MG A076752 007 Jun 16, 2005

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Levotyroxine Sodium

**Tablet; Oral**

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<td>0.3MG</td>
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**Levoxyl**

+ **KING PHARMS** 0.3MG **N021301 012 May 25, 2001**

**Thyro-Tabs**

+ **LLOYD** 0.025MG **N021116 001 Oct 24, 2002**
+ 0.05MG **N021116 002 Oct 24, 2002**
+ 0.075MG **N021116 003 Oct 24, 2002**
+ 0.088MG **N021116 010 Oct 24, 2002**
+ 0.1MG **N021116 004 Oct 24, 2002**
+ 0.112MG **N021116 011 Oct 24, 2002**
+ 0.125MG **N021116 005 Oct 24, 2002**
+ 0.137MG **N021116 012 Dec 07, 2004**
+ 0.15MG **N021116 006 Oct 24, 2002**
+ 0.175MG **N021116 007 Oct 24, 2002**
+ 0.2MG **N021116 008 Oct 24, 2002**
+ 0.3MG **N021116 009 Oct 24, 2002**

### Lidocaine

**Aerosol; Oral**

**Xylocaine**

**Film, Extended Release; Buccal**

**Dentipatch**

**Ointment; Topical**

**Alphacaine**

+ **Carlisle** 5% **A084944 001**
+ 5% **A084946 001**
+ 5% **A084947 001**

**Lidocaine**

+ **Belmora LLC** 5% **A080210 001**

**Xylocaine**

+ **AstraZeneca** 5% **N008048 001**

**Patch; Topical**

**Dentipatch**

+ **Noven** 46.1MG/PATCH **N020575 002 May 21, 1996**

**Solution; Topical**

**Xylocaine**

+ **AstraZeneca** 5% **N014127 001**

**Suppository; Rectal**

**Xylocaine**

+ **AstraZeneca** 100MG **N013077 001**

### Lidocaine Hydrochloride

**Injectable; Injection**

**Alphacaine Hydrochloride**

+ **Carlisle** 2% **A084721 001**

**Lidocaine Hydrochloride**

+ **Abbott** 10% **A087980 001 Feb 02, 1983**
+ 20% **A089362 001 May 25, 1988**
+ **Abraxis Pharm** 1% **A080420 001**
+ 1% **A086761 001**
+ 1.5% **A080420 005**
+ 2% **A080420 002**
+ 2% **A080420 004**
+ 2% **A086761 002**
+ 4% **N017508 001**
+ 20% **N017508 002**
+ 20% **N017508 004**

+ **Akorn** 1% **A085037 001**
+ 2% **A085037 002**
+ **Bel Mar** 1% **A080710 001**
+ 2% **A080760 001**
+ **Belmora LLC** 2% **A080504 001**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
LIDOCAINE HYDROCHLORIDE

INJECTABLE, INJECTION

LIDOCAINE HYDROCHLORIDE

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<td>ELKINS SINN</td>
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<td>GD SEARLE LLC</td>
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<td>HOSPIRA</td>
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<td>LUITPOLD</td>
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<td>1%</td>
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<tr>
<td>MILES</td>
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<td>A091058 001</td>
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<td>WATSON LABS</td>
<td>1%</td>
<td>A080377 001</td>
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<td>1%</td>
<td>A083627 001</td>
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<td></td>
<td>2%</td>
<td>A080377 002</td>
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<td></td>
<td>2%</td>
<td>A083627 002</td>
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<tr>
<td>WEST-WARD PHARMS INT</td>
<td>1%</td>
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<td></td>
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<td>A080407 002</td>
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<tr>
<td>WYETH AYERST</td>
<td>1%</td>
<td>A080383 001</td>
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<tr>
<td></td>
<td>2%</td>
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LIDOCAINE HYDROCHLORIDE 0.1% AND DEXTROSE 5% IN PLASTIC CONTAINER

<table>
<thead>
<tr>
<th>Brand</th>
<th>Concentration</th>
<th>Approval Number</th>
</tr>
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<tbody>
<tr>
<td>BAXTER HLTHCARE</td>
<td>100MG/100ML</td>
<td>N018461 001</td>
</tr>
<tr>
<td>B BRAUN</td>
<td>200MG/100ML</td>
<td>N018967 001</td>
</tr>
<tr>
<td>HOSPIRA</td>
<td>200MG/100ML</td>
<td>A083158 005</td>
</tr>
<tr>
<td>ABBOTT</td>
<td>200MG/100ML</td>
<td>N018954 001</td>
</tr>
<tr>
<td>HOSPIRA</td>
<td>200MG/100ML</td>
<td>N018388 001</td>
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<td>HOSPIRA</td>
<td>400MG/100ML</td>
<td>N018967 002</td>
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<tr>
<td>HOSPIRA</td>
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<tr>
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<td>400MG/100ML</td>
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<tr>
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<td>800MG/100ML</td>
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<tr>
<td>HOSPIRA</td>
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<td>HOSPIRA</td>
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<tr>
<td></td>
<td>10%</td>
<td>A088367 001</td>
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<tr>
<td></td>
<td>20%</td>
<td>A088368 001</td>
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| LIDOCAINE HYDROCHLORIDE PRESERVATIVE FREE
| INTL MEDICATION | 4% | N017702 002 |
|                | 20%          | N017702 001      |
| MYLAN LABS LTD | 2%           | A090665 001      |
| WEST-WARD PHARMS INT | 1% | A084626 001 |
|                | 2%           | A084625 002      |
| LIDOCAINE      | 2%           | A084727 001      |
| ASTRazeneca    | 1%           | N010418 005      |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** Discontinued Drug Product List

** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
LINDANE
LOTION; TOPICAL
SOLA BARNES HIND 1%
KWELL REED AND CARNRICK 1%
LINDANE WOCKHARDT 1%
SCABENE STIEFEL 1%

LINDANE WOCKHARDT 1%
SCABENE STIEFEL 1%

LINEZOLID
SOLUTION; INTRAVENOUS
ZYVOX + PHARMACIA AND UPJOHN 400MG/200ML (2MG/ML)
TABLET; ORAL
ZYVOX + PHARMACIA AND UPJOHN 400MG **

LIOTHYRONINE SODIUM
TABLET; ORAL
LIOTHYRONINE SODIUM EQ 0.025MG BASE
WATSON LABS EQ 0.05MG BASE

LIOTRIX (T4; T3)
TABLET; ORAL
EUTHROID-0.5 PARKE DAVIS 0.03MG; 0.0075MG
EUTHROID-1 PARKE DAVIS 0.06MG; 0.015MG
EUTHROID-2 PARKE DAVIS 0.12MG; 0.03MG
EUTHROID-3 PARKE DAVIS 0.18MG; 0.045MG
THYROLAR-0.25 PARKE DAVIS 0.0125MG; 0.0031MG
THYROLAR-0.5 + ALLERGAN SALES LLC 0.025MG; 0.0063MG
THYROLAR-1 + ALLERGAN SALES LLC 0.05MG; 0.0125MG
THYROLAR-2 + ALLERGAN SALES LLC 0.1MG; 0.025MG
THYROLAR-3 + ALLERGAN SALES LLC 0.15MG; 0.0375MG
THYROLAR-5 + ALLERGAN SALES LLC 0.25MG; 0.0625MG

LISINOPRIL
TABLET; ORAL
LISINOPRIL SANDOZ 2.5MG
2.5MG
5MG
10MG
10MG
20MG
20MG
30MG
30MG
40MG

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

**Lisinopril**

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>40mg</td>
<td>A075999</td>
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<tr>
<td>2.5mg</td>
<td>A075783</td>
<td>Jul 01, 2002</td>
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<tr>
<td>5mg</td>
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<td>Jul 01, 2002</td>
</tr>
<tr>
<td>10mg</td>
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<td>Jul 01, 2002</td>
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<td>A075783</td>
<td>Jul 01, 2002</td>
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<td>30mg</td>
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<td>40mg</td>
<td>A075783</td>
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**Pristivil**

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<tbody>
<tr>
<td>2.5mg</td>
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**Lithium carbonate**

**Capsule; Oral**

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<td>Eskalith</td>
<td>A016860</td>
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<td>Noven Therap</td>
<td>300mg</td>
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<tr>
<td>Able</td>
<td>300mg</td>
<td>A076833</td>
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<tr>
<td>Hikma Int'l Pharms</td>
<td>300mg</td>
<td>A078716</td>
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<tr>
<td>Pfizer</td>
<td>300mg</td>
<td>N018343</td>
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<tr>
<td>Watson Labs</td>
<td>300mg</td>
<td>A070407</td>
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**Tablet; Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Code</th>
<th>Date</th>
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<tbody>
<tr>
<td>Jds Pharms</td>
<td>450mg</td>
<td>N018152</td>
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<tr>
<td>Able</td>
<td>300mg</td>
<td>A076382</td>
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<tr>
<td>Barr</td>
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<td>A076170</td>
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<td>Hikma Int'l Pharms</td>
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<td>A076490</td>
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**Lithium citrate**

**Syrup; Oral**

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<tr>
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<th>Date</th>
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<tbody>
<tr>
<td>Solvay</td>
<td>EQ 300mg Carbonate/5ml</td>
<td>N017672</td>
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**Lomefloxacin hydrochloride**

**Tablet; Oral**

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<th>Brand</th>
<th>Code</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Maxaquin</td>
<td>EQ 400mg Base</td>
<td>N020013</td>
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**Lomustine**

**Capsule; Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Code</th>
<th>Date</th>
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<tbody>
<tr>
<td>Gleostine</td>
<td>5mg</td>
<td>N017588</td>
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**Loperamide hydrochloride**

**Capsule; Oral**

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<tr>
<th>Brand</th>
<th>Code</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>J &amp; J Consumer Inc</td>
<td>2mg</td>
<td>N017690</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Loperamide Hydrochloride

#### Solution; Oral

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC  Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>JANSSEN PHARMS</td>
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<td>ALLIED</td>
<td>1mg/5ml</td>
<td>A073079</td>
<td>04 30, 1992</td>
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<tr>
<td>ALPHARMA US PHARMS</td>
<td>1mg/5ml</td>
<td>A073187</td>
<td>09 15, 1992</td>
</tr>
<tr>
<td>DURAMED PHARMS BARR</td>
<td>1mg/5ml</td>
<td>A074991</td>
<td>12 29, 1997</td>
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<tr>
<td>TEVA</td>
<td>1mg/5ml</td>
<td>A073478</td>
<td>06 23, 1995</td>
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<tr>
<td>WATSON LABS</td>
<td>1mg/5ml</td>
<td>A073062</td>
<td>05 28, 1993</td>
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#### Tablet; Oral

<table>
<thead>
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<th>Strength</th>
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<th>Date</th>
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<tbody>
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<td>ABLE</td>
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<td>A073528</td>
<td>11 30, 1993</td>
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<tr>
<td>CONTRACT PHARMACAL</td>
<td>2mg</td>
<td>A073254</td>
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<td>PERRIGO</td>
<td>2mg</td>
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<td>10 30, 1992</td>
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#### Tablet, Chewable; Oral

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<th>NDC  Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMODIUM A-D EZ CHEWS</td>
<td>133.3mg;33.3mg</td>
<td>N020448</td>
<td>07 24, 1997</td>
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<tr>
<td>J AND J CONSUMER INC</td>
<td>2mg</td>
<td>N020448</td>
<td>07 24, 1997</td>
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#### Loperamide Hydrochloride; Simethicone

#### Tablet, Chewable; Oral

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<th>NDC  Code</th>
<th>Date</th>
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<tbody>
<tr>
<td>IMODIUM MULTI–SYMPTOM RELIEF</td>
<td>2mg;125mg</td>
<td>N020606</td>
<td>06 26, 1996</td>
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### Lopinavir; Ritonavir

#### Capsule; Oral

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<th>Strength</th>
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<th>Date</th>
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</thead>
<tbody>
<tr>
<td>ABBVIE</td>
<td>133.3mg;33.3mg</td>
<td>N021226</td>
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### Loracarbeef

#### Capsule; Oral

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<th>Strength</th>
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<th>Date</th>
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</thead>
<tbody>
<tr>
<td>KING PHARMS</td>
<td>200mg</td>
<td>N050668</td>
<td>12 31, 1991</td>
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<td>400mg</td>
<td>N050668</td>
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#### Tablet; Oral

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<th>NDC  Code</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>KING PHARMS</td>
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<td>N050667</td>
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<tr>
<td>200mg/5ml</td>
<td>N050667</td>
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### Loratadine

#### Syrup; Oral

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<th>NDC  Code</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>CLARITIN HIVES RELIEF</td>
<td>1mg/ml</td>
<td>N020641</td>
<td>11 19, 2003</td>
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<tr>
<td>BAYER HEALTHCARE LLC</td>
<td>1mg/ml</td>
<td>N020641</td>
<td>01 03, 2003</td>
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#### Loratadine

<table>
<thead>
<tr>
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<th>Strength</th>
<th>NDC  Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>APOTEX INC</td>
<td>1mg/ml</td>
<td>A075565</td>
<td>10 05, 2004</td>
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<tr>
<td>RANDAXY LABS LTD</td>
<td>1mg/ml</td>
<td>A076529</td>
<td>08 20, 2004</td>
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#### Tablet; Oral

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<thead>
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<th>Manufacturer</th>
<th>Strength</th>
<th>NDC  Code</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>PERRIGO</td>
<td>10mg</td>
<td>N021512</td>
<td>06 24, 2004</td>
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### Loratadine; Pseudoephedrine Sulfate

#### Tablet, Extended Release; Oral

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<th>Date</th>
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</thead>
<tbody>
<tr>
<td>ACTAVIS LABS FL INC</td>
<td>5mg;120mg</td>
<td>A076208</td>
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### Lorazepam

#### Injectable; Injection

<table>
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<th>NDC  Code</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>AKORN</td>
<td>2mg/ml</td>
<td>A074974</td>
<td>07 23, 1998</td>
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<tr>
<td>BEDFORD</td>
<td>2mg/ml</td>
<td>A077076</td>
<td>07 13, 2005</td>
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<tr>
<td>DAVA PHARMS INC</td>
<td>2mg/ml</td>
<td>A074793</td>
<td>03 16, 2000</td>
</tr>
<tr>
<td>HOSPIRA</td>
<td>2mg/ml</td>
<td>A074280</td>
<td>05 27, 1994</td>
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<tr>
<td>2mg/ml</td>
<td>A074300</td>
<td>04 12, 1994</td>
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<tr>
<td>MYLAN ASI</td>
<td>2mg/ml</td>
<td>A200217</td>
<td>04 04, 2017</td>
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<tr>
<td>WATSON LABS</td>
<td>2mg/ml</td>
<td>A200542</td>
<td>04 28, 2017</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Lorazepam

**Injectable; Injection**

<table>
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<th>Brand</th>
<th>Concentration</th>
<th>Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Watson Labs Inc</td>
<td>4mg/ML</td>
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<td>1mg/0.5ml</td>
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<td>Sep 12, 1996</td>
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<td></td>
<td>2mg/ML</td>
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<tr>
<td></td>
<td>4mg/ML</td>
<td>A074551</td>
<td>Sep 12, 1996</td>
</tr>
<tr>
<td>West-Ward Pharmas Inc</td>
<td>2mg/ML</td>
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<td>Sep 28, 1998</td>
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<td></td>
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<td>Sep 28, 1998</td>
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**Lorazepam Preservative Free**

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<th>Date</th>
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<tbody>
<tr>
<td>Bedford Labs</td>
<td>2mg/ML</td>
<td>A077074</td>
<td>Jul 13, 2005</td>
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**Solution; Oral**

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<tbody>
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<td>Roxane</td>
<td>0.5mg/5ml</td>
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<td>Mar 18, 1997</td>
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**Tablet; Oral**

<table>
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<tr>
<th>Brand</th>
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<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantum Pharmics</td>
<td>0.5mg</td>
<td>A070200</td>
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<td>1mg</td>
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<td>2mg</td>
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## Losartan Potassium

**Tablet; Oral**

<table>
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</thead>
<tbody>
<tr>
<td>Cozaar</td>
<td>25mg</td>
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<td>50mg</td>
<td>N020386</td>
<td>Apr 14, 1995</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
LOTEPREDNOL ETABONATE  
SUSPENSION/DROPS;OPHTHALMIC  
LOTENAX  
P HARMOS  0.5%  
N020841 001 Mar 09, 1998  

LOVASTATIN  
TABLET;ORAL  
LOVASTATIN  
MYLAN  
10MG  
A075935 001 Dec 17, 2001  
20MG  
A075935 002 Dec 17, 2001  
40MG  
A075935 003 Dec 17, 2001  
MEVACOR  
+ MERCK  
10MG **  
N019643 002 Mar 28, 1991  
+ 20MG **  
N019643 003 Aug 31, 1987  
+ 40MG **  
N019643 004 Dec 14, 1988  
TABLET, EXTENDED RELEASE;ORAL  
ALTOPREV  
COVIS PHARMA BV  
10MG  
N021316 001 Jun 26, 2002  

LOXAPINE HYDROCHLORIDE  
CONCENTRATE;ORAL  
LOXITANE C  
ACTAVIS LABS UT INC  
EQ 25MG BASE/ML  
N017658 001  
INJECTABLE;INJECTION  
LOXITANE IM  
ACTAVIS LABS UT INC  
EQ 50MG BASE/ML  
N018039 001  

LOXAPINE SUCCINATE  
CAPSULE;ORAL  
LOXITANE  
+ ACTAVIS LABS UT INC  
EQ 5MG BASE **  
N017525 001  
+ EQ 10MG BASE **  
N017525 002  
+ EQ 25MG BASE **  
N017525 003  
+ EQ 50MG BASE **  
N017525 004  
TABLET;ORAL  
LOXITANE  
+ ACTAVIS LABS UT INC  
EQ 10MG BASE **  
N017525 006  
+ EQ 25MG BASE **  
N017525 007  
+ EQ 50MG BASE **  
N017525 008  

LUCINACTANT  
SUSPENSION;INTRATRACHEAL  
SURFAXIN  
WINDTREE THERAP  
8.5ML  
N021746 001 Mar 06, 2012  

LUTROPIN ALFA  
INJECTABLE;SUBCUTANEOUS  
LUVERIS  
EMD SERONO  
75 IU/VIAL  
N021322 001 Oct 08, 2004  

LYPRESSIN  
SOLUTION;NASAL  
DIAPID  
NOVARTIS  
0.185MG/ML  
N016755 001  

MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE  
INJECTABLE;INJECTION  
PLASMA-LYTE 56 IN PLASTIC CONTAINER  
BAXTER HLTHCARE  
32MG/100ML;128MG/100ML;234MG/100ML  
N019047 001 Jun 15, 1984  

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE  
INJECTABLE;INJECTION  
ISOLYTE S PH 7.4 IN PLASTIC CONTAINER  
B BRAUN  
30MG/100ML;37MG/100ML;0.82MG/100ML;370MG/100ML;0.185MG/100ML;530MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12MG/100ML;0.185MG/100ML;370MG/100ML;0.82MG/100ML;12MG/100ML;500MG/100ML;12ME **

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote

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<th>Manufacturer</th>
<th>NDC Number</th>
<th>Expiration Date</th>
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<td>MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; INJECTABLE; INJECTION ISOLYTE S IN PLASTIC CONTAINER</td>
<td>B BRAUN</td>
<td>N018252 001</td>
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<tr>
<td>SOLUTION; IRRIGATION</td>
<td>HOSPIRA INC</td>
<td>N018406 001</td>
<td>Jul 08, 1982</td>
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<td>PHYSIOLSOL PH 7.4 IN PLASTIC CONTAINER</td>
<td>HOSPIRA INC</td>
<td>N018406 002</td>
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<td>SYNOVALYTE IN PLASTIC CONTAINER</td>
<td>BAXTER HLTNCARE</td>
<td>N019326 001</td>
<td>Jan 25, 1985</td>
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<td>MAGNESIUM HYDROXIDE; OMEPRAZOLE; SODIUM BICARBONATE TABLET; ORAL</td>
<td>SANTARUS</td>
<td>N022456 001</td>
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<td>MAGNESIUM HYDROXIDE AND OMEPRAZOLE AND SODIUM BICARBONATE SANTARUS</td>
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<td>Dec 04, 2009</td>
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<td>SANTARUS</td>
<td>N021850 001</td>
<td>Mar 24, 2006</td>
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<td>MAGNESIUM SULFATE; POLYETHYLENE GLYCOL 335G; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM SULFATE SOLUTION; ORAL SUCLEAR + BRAINTREE LABS</td>
<td>N203595 001</td>
<td>Jan 18, 2013</td>
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<td>MALATHION LOTION; TOPICAL</td>
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<td>A078743 001</td>
<td>Mar 06, 2009</td>
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<td>MANGAFODIPIR TRISODIUM INJECTABLE; INJECTION TESLASCAN</td>
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<td>N020652 001</td>
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<td>MANGANESE CHLORIDE TETRAHYDRATE FOR SOLUTION; ORAL LUMENHANCE</td>
<td>B BRAUN</td>
<td>N020686 001</td>
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<td>MANGANESE SULFATE INJECTABLE; INJECTION MANGANESE SULFATE ABRAXIS PHARM</td>
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<td>ICU MEDICAL INC</td>
<td>N019603 002</td>
<td>Jan 08, 1987</td>
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<td>MANNITOL 10% W/ DEXTROSE 5% IN DISTILLED WATER</td>
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<td>N016080 003</td>
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<td>MANNITOL 15%</td>
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<td>N019603 003</td>
<td>Jan 08, 1990</td>
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<tr>
<td>MANNITOL 15% W/ DEXTROSE 5% IN SODIUM CHLORIDE 0.45%</td>
<td>B BRAUN</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**MANNITOL**

**INJECTABLE; INJECTION**

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<td>HOSPIRA</td>
<td>20GM/100ML N016080 004</td>
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<td>ABRAXIS PHARM</td>
<td>12.5GM/50ML A086754 001</td>
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<td>HOSPIRA</td>
<td>12.5GM/50ML N016269 005</td>
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<tr>
<td>IGI LABS INC</td>
<td>12.5GM/50ML A089239 001 May 06, 1987</td>
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<tr>
<td>MERCK</td>
<td>12.5GM/50ML N005620 001 May 06, 1987</td>
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<td>MANNITOL 5%</td>
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<td>B BRAUN</td>
<td>5GM/100ML N016080 001</td>
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<tr>
<td>HOSPIRA</td>
<td>5GM/100ML N016269 001</td>
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**MANNITOL 5% IN PLASTIC CONTAINER**

| ICU MEDICAL INC | 5GM/100ML N019603 001 Jan 08, 1987 |

**MANNITOL 5% W/ DEXTROSE 5% IN SODIUM CHLORIDE 0.12%**

| B BRAUN | 5GM/100ML N016080 007 |

**SOLUTION; IRRIGATION**

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**MANNITOL; SORBITOL**

**SOLUTION; IRRIGATION**

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**SORBITOL-MANNITOL IN PLASTIC CONTAINER**

| HOSPIRA | 540MG/100ML; 2.7GM/100ML N017636 001 |

**MAPROPTILINE HYDROCHLORIDE**

**TABLET; ORAL**

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<td>NOVARTIS</td>
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<td>50MG N017543 002</td>
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<td>75MG N017543 003 Sep 30, 1982</td>
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| AM THERAP | 25MG A072129 001 Jan 14, 1988 |
|-----------| 50MG A072130 001 Jan 14, 1988 |
|           | 75MG A072131 001 Jan 14, 1988 |

| WATSON LABS | 25MG A071943 001 Dec 30, 1987 |
|             | 50MG A071944 001 Dec 30, 1987 |
|             | 75MG A071945 001 Dec 30, 1987 |
|             | 75MG A072164 001 Jun 01, 1988 |
|             | 50MG A072162 001 Jun 01, 1988 |
|             | 50MG A072163 001 Jun 01, 1988 |

**MASOPROCOL**

**CREAM; TOPICAL**

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**MAZINDOL**

**TABLET; ORAL**

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<td>WYETH AYERST</td>
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<tr>
<td>+ HEBIX</td>
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<td>+</td>
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**MEBENDAZOLE**

**TABLET, CHEWABLE; ORAL**

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<td>+ JANSSEN PHARMS</td>
<td>100MG ** N017481 001</td>
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<td>+</td>
<td>500MG N208398 001 Oct 19, 2016</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
| **MEBUTAMATE** | TABLET; ORAL | DOMATE | MEDPOINTE PHARM HLC | 600MG | N017374 001 |
| **MECAMYLAMINE HYDROCHLORIDE** | TABLET; ORAL | INVERSEINE | + TARGACEPT | 2.5MG | N010251 001 |
| **MECASERMIN RINFABATE RECOMBINANT** | INJECTABLE; SUBCUTANEOUS | IPLEX | INSLED | 36MG/0.6ML | N021884 001 Dec 12, 2005 |
| **MECLIZINE HYDROCHLORIDE** | TABLET; ORAL | ANTIVERT | CASPER PHARMA LLC | 12.5MG | N010721 006 |
| | | | | 25MG | N010721 004 |
| | | | | 50MG | N010721 001 Jan 20, 1982 |
| **MECHLORETHAMINE HYDROCHLORIDE** | INJECTABLE; INJECTION | MUSTARGEN | + RECORDATI RARE | 10MG/VIAL | N006695 001 |
| **MECLOCYCLINE SULFOSALICYLATE** | CREAM; TOPICAL | MECLAN | JOHNSON AND JOHNSON | 1% | N050518 001 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### MECLOFENAMATE SODIUM

**Capsule; Oral**

<table>
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<td>AM Therap</td>
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<td>BARR</td>
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<td>BARR</td>
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<td>Fosun Pharma</td>
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<td>Watson Labs Teva</td>
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<td>A071641 001</td>
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<td>Parke Davis</td>
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<td>EQ 100MG BASE</td>
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### MEDROXYPROGESTERONE ACETATE

**Injectable; Injection**

*Depo-Provera*

- DePuy, Upjohn **100MG/ML** N012541 002

**Teva Pharms USA**

- 150MG/ML A076552 001 Oct 27, 2004

**Tablet; Oral**

- Amen
  - 10MG A083242 001
- Curretab
  - 10MG A085686 001
- Cyckrin
  - 2.5MG A081239 001 Oct 30, 1992
  - 5MG A081200 001 Oct 30, 1992
  - 10MG A089386 001 Sep 09, 1987

### MEDRYSONE

**Suspension; Ophthalmic**

*HMS*

- Allergan 1% N016624 003

### MEFLOQUINE HYDROCHLORIDE

**Tablet; Oral**

*Lariam*

- Roche **250MG** N019591 001 May 02, 1989

**HiKma Intl Pharmas**

- 250MG A077699 001 Apr 21, 2010
- 250MG A076175 001 Feb 20, 2002

**US Army Walter Reed**

- 250MG ** N019578 001 May 02, 1989

### MEGESTROL ACETATE

**Suspension; Oral**

*Megace*

- Bristol Myers Squibb 40MG/ML ** N020264 001 Sep 10, 1993
- Apotex Inc 40MG/ML A077404 001 Feb 16, 2006

*Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons*
### Megestrol Acetate

**Tablet; Oral**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Megace | Bristol-Myers Squibb | 20mg | N016979 001 | Feb 27, 1998
| Megace | Bristol-Myers Squibb | 40mg | N016979 002 |
| Megestrol Acetate | TEVA | 40mg | A074745 001 |
| Megestrol Acetate | USL Pharma | 20mg | A076044 001 |

*See List Footnote*

### Meloxicam

**Suspension; Oral**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Mobic | Boehringer Ingelheim | 7.5mg/5ml | N021530 001 | Jun 01, 2004

**Tablet; Oral**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Anda Repository |  | 7.5mg | A077935 001 |
| Anda Repository |  | 15mg | A077935 002 |
| CR Double Crane |  | 7.5mg | A078039 001 |
| CR Double Crane |  | 15mg | A078039 002 |
| Impax Labs Inc |  | 7.5mg | A077930 001 |
| Impax Labs Inc |  | 15mg | A077930 002 |
| Mylan |  | 7.5mg | A077923 001 |
| Mylan |  | 15mg | A077923 002 |
| Roxane |  | 7.5mg | A077925 001 |
| Roxane |  | 15mg | A077925 002 |
| Sun Pharm Inds Inc |  | 7.5mg | A077934 001 |
| Sun Pharm Inds Inc |  | 15mg | A077934 002 |
| Yabao Pharm |  | 7.5mg | A077933 001 |
| Yabao Pharm |  | 15mg | A077933 002 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

### Melphalan Hydrochloride

**Injectable; Injection**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Alkeran | Apotex Inc | EQ 50mg Base/Vial | N020207 001 | Nov 18, 1992
| Melphalan Hydrochloride | Mylan Institutional | EQ 50mg Base/Vial | A090299 001 | Oct 27, 2009

### Memantine Hydrochloride

**Solution; Oral**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Namenda | Allergan Sales LLC | 2mg/ml | N021627 001 | Apr 18, 2005

**Tablet; Oral**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Memantine Hydrochloride | Orchid Healthcare | 5mg | A090044 001 |
| Memantine Hydrochloride | Orchid Healthcare | 10mg | A090044 002 |

### Menadiol Sodium Diphosphate

**Injectable; Injection**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Rappadione | Lilly | 10mg/ml | N005725 001 |
| Synkayvite | Lilly | 5mg/ml | N003718 004 |
| Synkayvite | Lilly | 10mg/ml | N003718 006 |
| Synkayvite | Lilly | 37.5mg/ml | N003718 008 |

**Tablet; Oral**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Synkayvite | Lilly | 5mg | N003718 010 |

### Menadione

**Tablet; Oral**

| Brand | Manufacturer | Strength | NDC | Date
|-------|--------------|----------|-----|------
| Menadione | Lilly | 5mg | N002139 003 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### MENOTROPINS (FSH; LH)

#### INJECTABLE; INJECTION

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<td>75 IU/VIAL</td>
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### MEPENZOLATE BROMIDE

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### MEPERIDINE HYDROCHLORIDE PRESERVATIVE FREE

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
MEPERIDINE HYDROCHLORIDE
TABLET; ORAL
MEPERIDINE HYDROCHLORIDE 100MG
SUN PHARM INDUSTRIES 50MG
100MG
WATSON LABS 50MG
100MG
WYETH AYERST 50MG
** See List Footnote

MEPERIDINE HYDROCHLORIDE: PROMETHAZINE HYDROCHLORIDE
INJECTABLE; INJECTION
MEPERGAN
WEST-WARD PHARMS INT 25MG/ML; 25MG/ML
N01730 001

MEPHENTERMINE SULFATE
INJECTABLE; INJECTION
WYAMINE SULFATE
BAXTER HLTHCARE CORP EQ 15MG BASE/ML
EQ 30MG BASE/ML
N008248 002
N008248 001

MEPHENTOIN
TABLET; ORAL
MESANTOIN
+ NOVAPTIS 100MG **
N006008 001

MEPIVACAINE HYDROCHLORIDE
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ARESTOCaine HYDROCHLORIDE SOLVAY 3%
N004777 002 Apr 18, 1982
CARBOCaine + EASTMAN KODAK 3% **
N012125 003
ISOCAINE HYDROCHLORIDE SEPTODONT INC 3%
A080925 001
MEPIVACAINE HYDROCHLORIDE
BELMORA LLC 3%
A083559 001
HOSPIRA INC 3%
A048086 001 Apr 28, 2008
INTL MEDICATION SYS 1%
A087509 001 Oct 05, 1982
WATSON LABS 1%
A088769 001 Nov 20, 1984
2%
A088770 001 Nov 20, 1984
POLOCAINE
DENTSPLY PHARM 3%
A088653 001 Aug 21, 1984

MEPREDNISONE
TABLET; ORAL
BETAPAR
SCHERING 4MG
N016053 002

MEPROBAMATE
CAPSULE; ORAL
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WYETH AYERST 400MG
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AMOSENE
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MEPRIAM
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BARR 600MG
A084230 001
ELKINS SINN 400MG
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** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

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<td>WEST-WARD PHARMS INT 10MG/30ML</td>
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<th><strong>METHADONE HYDROCHLORIDE</strong></th>
<th><strong>TABLET; ORAL</strong></th>
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<tr>
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<td>WESTADONE</td>
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<td>SANDOX 2.5MG</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### METHADONE HYDROCHLORIDE
- **Tablet, Effervescent; Oral**
  - Westadone
    - SANDOZ
      - 5MG
      - 10MG
      - 40MG

### METHAMPHETAMINE HYDROCHLORIDE
- **Tablet; Oral**
  - Methampex
    - TEVA
      - 10MG

- **Tablet, Hydrochloride**
  - Able
    - 5MG
  - Rexar
    - 5MG
    - 10MG
  - TEVA
    - 5MG

- **Tablet, Extended Release; Oral**
  - Desoxyx
    - Recordati Rare
      - 5MG
      - 10MG
      - 15MG

### METHANTHILINE BROMIDE
- **Tablet; Oral**
  - Banthine
    - Shire
      - 50MG

### METHARBITAL
- **Tablet; Oral**
  - Gemonil
    - Abbvie
      - 100MG

### METHAZOLAMIDE
- **Tablet; Oral**
  - Methazolamide
    - Applied Anal
      - 25MG
    - SANDOZ
      - 25MG
      - 50MG
    - Neptazane
      - + Lederle
        - 25MG **
      - +
        - 50MG **

### METHDILAZINE
- **Tablet, Chewable; Oral**
  - Tacaryl
    - Westwood Squibb
      - 3.6MG

### METHDILAZINE HYDROCHLORIDE
- **Syrup; Oral**
  - Methdilazine Hydrochloride
    - Alpharma US Pharms
      - 4MG/5ML
    - Tacaryl
      - Westwood Squibb
      - 4MG/5ML
  - TABLET; ORAL
    - Tacaryl
      - Westwood Squibb
      - 8MG

### METHICILLIN SODIUM
- **Injectable; Injection**
  - Stapcillin
    - Apothecon
      - EQ 900MG BASE/VIAL
      - EQ 900MG BASE/VIAL
      - EQ 3.6GM BASE/VIAL
      - EQ 3.6GM BASE/VIAL
      - EQ 5.4GM BASE/VIAL
      - EQ 5.4GM BASE/VIAL

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

### METHIMAZOLE

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<td>+ KING PHARMS</td>
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<td>N007517</td>
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<td>+ TAPAZOLE</td>
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### METHIXENE HYDROCHLORIDE

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<td>NOVARTIS</td>
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### METHOCARBAMOL

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<td>MARSAM PHARMS LLC</td>
<td>100MG/ML</td>
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<td>WATSON LABS</td>
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### METHOCARBAMOL

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<td>DELAXIN</td>
<td>FERNDALE LABS</td>
<td>500MG</td>
<td>A085454</td>
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<td>FORBAXIN</td>
<td>FOREST LABS</td>
<td>750MG</td>
<td>A085136</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

**DISCONTINUED DRUG PRODUCT LIST**

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**METHOCARBAMOL**

**TABLET; ORAL**

- 500MG A085180 001
- 750MG A083605 002
- 750MG A085192 001

**METHOHEXITAL SODIUM**

**INJECTABLE; INJECTION**

**BREVITAL SODIUM**

PAR STERILE PRODUCTS

- 200MG/VIAL N011559 004 Dec 21, 2012
- 5GM/VIAL N011559 003

**METHOTREXATE**

**SOLUTION; SUBCUTANEOUS**

**OTREXUP**

+ ANTARES PHARMA INC 7.5MG/0.4ML (7.5MG/0.4ML) N204824 005 Nov 07, 2014

**OTREXUP PFS**

+ ANTARES PHARMA INC 10MG/0.4ML (10MG/0.4ML) N204824 009 May 31, 2017
+ 15MG/0.6ML (15MG/0.6ML) N204824 010 May 31, 2017
+ 17.5MG/0.7ML (17.5MG/0.7ML) N204824 011 May 31, 2017
+ 20MG/0.8ML (20MG/0.8ML) N204824 012 May 31, 2017
+ 22.5MG/0.9ML (22.5MG/0.9ML) N204824 013 May 31, 2017
+ 25MG/ML (25MG/ML) N204824 014 May 31, 2017

**RASUVO**

+ MEDAC PHARMA INC 27.5MG/0.55ML (27.5MG/0.55ML) N205776 009 Jul 10, 2014

**METHOTREXATE SODIUM**

**INJECTABLE; INJECTION**

**ABITREXATE**

ABIC

- EQ 25MG BASE/ML A089161 001 Mar 10, 1987
- EQ 50MG BASE/VIAL A089354 001 Jul 17, 1987
- EQ 100MG BASE/VIAL A089355 001 Jul 17, 1987
- EQ 250MG BASE/VIAL A089356 001 Jul 17, 1987

FOLEX

PHARMACIA AND UPJOHN

- EQ 25MG BASE/VIAL A087695 001 Apr 08, 1983
- EQ 50MG BASE/VIAL A087695 002 Apr 08, 1983
- EQ 100MG BASE/VIAL A087695 003 Apr 08, 1983
- EQ 250MG BASE/VIAL A088954 001 Oct 24, 1985

FOLEX PFS

PHARMACIA AND UPJOHN

- EQ 25MG BASE/ML A081242 001 Aug 23, 1991
- EQ 25MG BASE/ML A089180 001 Jan 03, 1986

**METHOTREXATE LPF**

HOSPIRA

- EQ 25MG BASE/VIAL N011719 007 Mar 31, 1982

**METHOTREXATE PRESERVATIVE FREE**

HOSPIRA

- EQ 20MG BASE/2ML (EQ 10MG BASE/ML) N011719 014 Apr 13, 2005
+ EQ 500MG BASE/20ML (EQ 25MG BASE/ML) ** N011719 013 Apr 13, 2005
+ EQ 2.5GM BASE/100ML (EQ 25MG BASE/ML) N011719 011 Apr 13, 2005

**METHOTREXATE SODIUM**

**ABRAAXIS PHARM**

- EQ 2.5MG BASE/ML A088932 001 Jun 13, 1986
- EQ 20MG BASE/VIAL A089355 001 Oct 11, 1985
- EQ 25MG BASE/VIAL A089263 001 Jun 13, 1986
- EQ 25MG BASE/VIAL A089322 001 Jun 13, 1986
- EQ 50MG BASE/VEL A088936 001 Oct 11, 1985
- EQ 100MG BASE/VIAL A088937 001 Oct 11, 1985

FRESENIUS KABI USA

- EQ 250MG BASE/10ML (EQ 25MG BASE/ML) A082063 002 Feb 26, 1999

HOSPIRA

- EQ 2.5MG BASE/ML N011719 004
- EQ 20MG BASE/VIAL N011719 001
- EQ 25MG BASE/VIAL N011719 005
- EQ 50MG BASE/VIAL N011719 003
- EQ 100MG BASE/VIAL N011719 006

NORBROOK

- EQ 25MG BASE/ML A088848 001 May 09, 1986

PHARMACHEMIE USA

- EQ 25MG BASE/ML A089158 001 Jul 08, 1988

**METHOTREXATE SODIUM PRESERVATIVE FREE**

HOSPIRA

- EQ 1GM BASE/VIAL N011719 009 Apr 07, 1988

**MEXATE**

BRISTOL

- EQ 20MG BASE/VIAL A086358 001
- EQ 50MG BASE/VIAL A086358 002
- EQ 100MG BASE/VIAL A086358 003
- EQ 250MG BASE/VIAL A086358 004

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
METHOTREXATE SODIUM
INJECTABLE; INJECTION
MEXATE-AQ
BRISTOL MYERS
EQ 25MG BASE/ML
A088760 001 Feb 14, 1985
MEXATE-AQ PRESERVED
BRISTOL MYERS SQUIBB
EQ 25MG BASE/ML
A089887 001 Apr 14, 1989
TABLET; ORAL
METHOTREXATE SODIUM
DURAMED PHARMS BARR
EQ 2.5MG BASE
A040233 001 Jun 17, 1999
METHOXAMINE HYDROCHLORIDE
INJECTABLE; INJECTION
VASOXYL
GLAXOSMITHKLINE
10MG/ML
N006772 002
20MG/ML
N006772 001
METHOXSALEN
CAPSULE; ORAL
8-MOP
+ VALEANT PHARM INTL
10MG
N009048 001
METHOXSALEN
ANI PHARMS INC
10MG
A087781 001 Jun 08, 1982
LOTION; TOPICAL
OXSORALEN
+ VALEANT PHARM INTL
1%
N009048 002
METHSCOPOLAMINE BROMIDE
TABLET; ORAL
METHSCOPOLAMINE BROMIDE
PVT FORM
PAMINE
FOUGERA PHARMS
2.5MG **
N008848 001
PAMINE FORTE
FOUGERA PHARMS
5MG **
N008848 002 Mar 25, 2003
METHSUXIMIDE
CAPSULE; ORAL
CELONTIN
+ PARKE DAVIS
150MG
N010596 007
METHYCLOTHIAZIDE
TABLET; ORAL
AQUATENSEN
MEDPOINTE PHARM HLC
5MG
N017364 001
ENDURON
+ ABBVIE
2.5MG **
N012524 001
+ 5MG **
N012524 004
METHYCLOTHIAZIDE
IVAX PHARMS
2.5MG
A087913 001 Jun 03, 1982
5MG
A087786 001 Aug 17, 1982
MYLAN
A087671 001 Aug 17, 1982
PAR PHARM
A089135 001 Feb 12, 1986
5MG
A089136 001 Feb 12, 1986
USL PHARMA
A088745 001 Mar 21, 1985
WATSON LABS
2.5MG
A085487 001 Mar 11, 1982
2.5MG
A088750 001 Sep 06, 1984
5MG
A085476 001 Mar 11, 1982
5MG
A088724 001 Sep 06, 1984
YAOPHARMA CO LTD
2.5MG
A089835 001 Aug 18, 1988
5MG
A089837 001 Aug 18, 1988
METHYCLOTHIAZIDE; PARGYLINE HYDROCHLORIDE
TABLET; ORAL
EUTRON
ABBOTT
5MG; 25MG
N016047 001
METHYCLOTHIAZIDE; RESERPINE
TABLET; ORAL
DIUTENSEN-R
MEDPOINTE PHARM HLC
2.5MG; 0.1MG
N012708 005
** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**DISCONTINUED DRUG PRODUCT LIST**

**See List Footnote**

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<th>Company Name</th>
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<td>METVIXIA</td>
<td>GALDERMA LABS LP</td>
<td>N021415 001 Jul 27, 2004</td>
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<td>METHYLDOPA SUSPENSION; ORAL ALDOMET TABLET; ORAL ALDOMET</td>
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<td>+ 250MG **</td>
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<td>Accord Healthcare 125MG</td>
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<td>Parke Davis 125MG</td>
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<td>PLIVA 125MG</td>
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<td>Purepac Pharm 125MG</td>
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<td>Watson Labs 125MG</td>
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<td>YAOpharma Co Ltd 125MG</td>
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<td>+ MERCK 50MG/ML **</td>
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<td>Hospira 50MG/ML</td>
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<td>Marsam Pharm 50MG/ML</td>
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<td>Smith and Nephew 50MG/ML</td>
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<td>Teva Parenteral 50MG/ML</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Drug Name</th>
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<th>Company/Manufacturer</th>
<th>Lot Numbers</th>
<th>Date</th>
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<td>METHYLERGONOVINE MALEATE Tablet</td>
<td>ORAL METHERGINE + EDISON THERAPS LLC</td>
<td>0.2MG **</td>
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<td>M Ethylphenidate Hydrochloride</td>
<td>Capsule, extended release; oral</td>
<td>RITALIN LA + NOVARTIS</td>
<td>60MG **</td>
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<td>M Ethylphenidate Hydrochloride</td>
<td>Tablet; oral</td>
<td>Able</td>
<td>5MG</td>
<td>Mar 29, 2001</td>
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<td>ACTAVIS ELIZABETH</td>
<td>5MG</td>
<td>Feb 05, 2002</td>
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<td>M Ethylphenidate Hydrochloride</td>
<td>Tablet, chewable; oral</td>
<td>METHYLIN + SPECZX LLC</td>
<td>2.5MG **</td>
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<td>Apr 15, 2003</td>
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<td>WATSON LABS</td>
<td>20MG</td>
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<td>RITALIN-SR + NOVARTIS</td>
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<td>M Ethylprednisolone Tablet</td>
<td>ORAL PHARMACIA AND UPJOHN</td>
<td>24MG</td>
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<td>Rectal MEDROL</td>
<td>PHARMACIA AND UPJOHN</td>
<td>40MG/BOT</td>
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<td>M Ethylprednisolone Injectable</td>
<td>Injection M-PREDROL</td>
<td>PHARMACIA AND UPJOHN</td>
<td>40MG/ML</td>
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<td>B E L M A R</td>
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<td>M Ethylprednisolone Acetate</td>
<td>Oral AKORN</td>
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*Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### METHYLPREDNISOLONE ACETATE; NEOMYCIN SULFATE

**Cream; Topical**

**NEO-MEDROL ACETATE**

Pharmacia and Upjohn 0.25%; EQ 3.5 mg base/gm A060611 002

1%; EQ 3.5 mg base/gm A060611 001

### METHYLPREDNISOLONE SODIUM SUCCINATE

**Injectable; Injection**

**A-METHAPRED**

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**Hospira**

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**Hospira Inc**

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**Elkins Sinn**

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**Organon Usa Inc**

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**Methylocenone Sodium Succinate**

**Abraxis Pharm**

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**Elkins Sinn**

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**Intl Medication**

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**Methylocenone; Neomycin Sulfate**

**Ointment; Ophthalmic**

**Neo-Medrol**

Pharmacia and Upjohn 0.1%; EQ 3.5 mg base/gm A060645 001

**Methyltestosterone**

**Capsule; Oral**

**Methyltestosterone**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### METOCLOPRAMIDE HYDROCHLORIDE

**TABLET, ORALLY DISINTEGRATING; ORAL**

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### METOCURINE IODIDE

**INJECTABLE; INJECTION**

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<td>LILLY</td>
<td>2MG/ML</td>
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### METOLAZONE

**TABLET; ORAL**

- **DIULO**
  - GD SEARLE LLC: 2.5MG N018535 001, 5MG N018535 002, 10MG N018535 003

- **ROXANE**
  - 10MG A076482 002 | Apr 29, 2004

- **TEVA**
  - 2.5MG A076600 001 | Jan 06, 2004
  - 5MG A076833 001 | Mar 01, 2004
  - 10MG A075543 003 | Dec 24, 2003

- **WATSON LABS**
  - 10MG A076891 001 | Jul 21, 2004

- **MYKROX**
  - LANNETT CO INC: 0.5MG N019532 001 | Oct 30, 1987

### METOPROLOL FUMARATE

**TABLET, EXTENDED RELEASE; ORAL**

- **LOPRESSOR**
  - NOVARTIS: EQ 100MG TARTRATE N019786 001, EQ 200MG TARTRATE N019786 002, EQ 300MG TARTRATE N019786 003, EQ 400MG TARTRATE N019786 004 | Dec 27, 1989

### METOPROLOL SUCCINATE

**TABLET, EXTENDED RELEASE; ORAL**

- **METOPROLOL SUCCINATE**
  - NESHER PHARMS: EQ 25MG TARTRATE A077779 001 | Mar 20, 2008
  - EQ 50MG TARTRATE A077116 001 | May 14, 2008
  - EQ 100MG TARTRATE A076640 002 | May 18, 2007
  - EQ 200MG TARTRATE A076640 001 | May 18, 2007

- **SANDOZ**
  - EQ 25MG TARTRATE A076960 001 | Jul 31, 2006
  - EQ 50MG TARTRATE A076960 002 | May 18, 2007
  - EQ 100MG TARTRATE A076960 003 | Mar 20, 2008
  - EQ 200MG TARTRATE A076960 004 | Mar 28, 2008

### METOPROLOL TARTRATE

**INJECTABLE; INJECTION**

- **METOPROLOL TARTRATE**
  - WATSON LABS: 1MG/ML A074032 001 | Dec 21, 1993

**TABLET; ORAL**

- **METOPROLOL TARTRATE**
  - APOTHECON: 50MG A074258 001 | Jan 27, 1994
  - 100MG A074258 002 | Jan 27, 1994
  - MYLAN: 50MG A073666 001 | Dec 21, 1993
  - 100MG A073666 002 | Dec 21, 1993
  - PUREPAC PHARM: 50MG A074380 001 | Jul 29, 1994
  - 100MG A074380 002 | Jul 29, 1994
  - RENATA: 50MG A074453 001 | Apr 27, 1995
  - 100MG A074453 002 | Apr 27, 1995
  - TEVA: 50MG A074143 001 | Sep 30, 1994
  - 100MG A074143 002 | Sep 30, 1994
  - TEVA PHARMS: 50MG A074333 001 | Jan 27, 1994
  - 100MG A074333 002 | Jan 27, 1994
  - YAOPHARMA CO LTD: 50MG A073288 001 | Mar 25, 1994
  - 100MG A073289 001 | Mar 25, 1994

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### METRIZAMIDE

**INJECTABLE; INJECTION**

| GE HEALTHCARE | 2.5GM/VIAL | N017982 003 | Sep 12, 1983 |
| 3.75GM/VIAL | N017982 001 |
| 6.75GM/VIAL | N017982 002 |
| 13.5GM/VIAL | N017982 004 | Sep 12, 1983 |

### METRONIDAZOLE

**CAPSULE; ORAL**

**METRONIDAZOLE**

**ABLE**

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<td>FLAGYL I.V. RTU IN PLASTIC CONTAINER</td>
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<td>PFIZER</td>
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<td>METRO I.V.</td>
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<td>ABRAXIS PHARM</td>
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<td>INTL MEDICATION</td>
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<td>WATSON LABS</td>
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**TABLET; ORAL**

**METROMIDOL**

| LABS AF | 250MG | A074523 001 | Oct 24, 1996 |
| 500MG | A074523 002 | Oct 24, 1996 |

**METRONIDAZOLE**

**ABLE**

| CHARTWELL MOLECULES | 250MG | N018907 001 | Aug 18, 1983 |
| 500MG | N018930 001 | Aug 18, 1983 |
| FOSUN PHARMA | 250MG | N018930 001 | Aug 18, 1983 |
| 500MG | N018930 002 | Aug 18, 1983 |
| HALSEY | 250MG | A076519 001 | Jun 27, 2003 |
| 500MG | A076519 002 | Jun 27, 2003 |
| IVAX SUB TEVA PHARMS | 250MG | A076519 001 | Jun 27, 2003 |
| 500MG | A076519 002 | Jun 27, 2003 |
| LNK | 250MG | A076519 001 | Jun 27, 2003 |
| 500MG | A076519 002 | Jun 27, 2003 |
| MUTUAL PHARM | 250MG | A076519 001 | Jun 27, 2003 |
| 500MG | A076519 002 | Jun 27, 2003 |
| SUPERPHARM | 250MG | A076519 001 | Jun 27, 2003 |
| 500MG | A076519 002 | Jun 27, 2003 |
| WATSON LABS | 250MG | A076519 001 | Jun 27, 2003 |
| 500MG | A076519 002 | Jun 27, 2003 |

**PROTOSTAT**

| ORTHO MCNEIL PHARM | 250MG | N018871 001 | Mar 02, 1983 |
| 500MG | N018871 002 | Mar 02, 1983 |

**SATRIC**

| SAVAGE LABS | 250MG | A070029 001 | Mar 19, 1985 |
| 500MG | A070029 002 | Mar 19, 1985 |

**TABLET, EXTENDED RELEASE; ORAL**

**FLAGYL ER**

| + GD SEARLE LLC | 750MG | N020868 001 | Nov 26, 1997 |
| METRONIDAZOLE**ABLE** | 750MG | A076462 001 | Jun 25, 2003 |
| ALEMBIC PHARMS LTD | 750MG | A090222 001 | May 05, 2010 |

**METRONIDAZOLE HYDROCHLORIDE**

**INJECTABLE; INJECTION**

| PFIZER | EQ 500MG BASE/VIAL ** | N018353 001 |
| METRONIDAZOLE HYDROCHLORIDE | 500MG | A070295 001 | Oct 15, 1985 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

**METHYLPREDNISOLONE**
TABLET; ORAL
LABORATORIE HRA 250MG N012911 001

**METILETINE HYDROCHLORIDE**
CAPSULE; ORAL
METILETINE HYDROCHLORIDE
150MG ANI PHARMS INC A074450 001 May 16, 1996
200MG A074450 002 May 16, 1996
250MG A074450 003 May 16, 1996

WATSON LABS
150MG A074711 001 Feb 26, 1997
150MG A074865 001 Apr 13, 1998
200MG A074711 002 Feb 26, 1997
200MG A074865 002 Apr 13, 1998
250MG A074711 003 Feb 26, 1997
250MG A074865 003 Apr 13, 1998

**MEXITIL**
+ BOEHRINGER INGEHEIM
150MG N018873 002 Dec 30, 1985
200MG N018873 003 Dec 30, 1985
250MG N018873 004 Dec 30, 1985

**MEZLOCILLIN SODIUM MONOHYDRATE**
INJECTABLE; INJECTION
MEZLIN
BAYER PHARMS
EQ 1GM BASE/VIAL A062333 001
EQ 1GM BASE/VIAL A062372 005 Jan 13, 1983
EQ 1GM BASE/VIAL N050549 001
EQ 2GM BASE/VIAL A062333 002
EQ 2GM BASE/VIAL A062372 001 May 13, 1982
EQ 2GM BASE/VIAL N050549 002
EQ 3GM BASE/VIAL A062333 003
EQ 3GM BASE/VIAL A062372 002 May 13, 1982
EQ 3GM BASE/VIAL N050549 003
EQ 4GM BASE/VIAL A062333 004
EQ 4GM BASE/VIAL A062372 003 May 13, 1982
EQ 4GM BASE/VIAL A062697 002 Jan 22, 1987
EQ 4GM BASE/VIAL N050549 004
EQ 20GM BASE/VIAL A062372 004 Mar 02, 1988
EQ 20GM BASE/VIAL N050549 005 Mar 02, 1988

**MICONAZOLE**
INJECTABLE; INJECTION
MONISTAT
JANSSEN PHARMA 10MG/ML N018040 001

**MICONAZOLE NITRATE**
CREAM; TOPICAL
MONISTAT-DERM
INSIGHT PHARMS 2% N017494 001
CREAM; VAGINAL
MICONAZOLE NITRATE
TEVA 2% A074136 001 Jan 04, 1995
TEVA PHARMS 2% A074030 001 Oct 30, 1992
CREAM, SUPPOSITORY; TOPICAL, VAGINAL
M-ZOLE 7 DUAL PACK
ACTAVIS MID ATLANTIC 2%, 100MG A074586 001 Jul 17, 1997
MICONAZOLE 7 COMBINATION PACK
G AND W LABS 2%, 100MG A076585 001 Mar 26, 2004
LOTION; TOPICAL
MONISTAT-DERM
INSIGHT PHARMS 2% N017739 001
TAMPON; VAGINAL
MONISTAT 5
PERSONAL PRODS 100MG N018592 001 Oct 27, 1989

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

### MIDAZOLAM HYDROCHLORIDE
#### INJECTABLE, INJECTION

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<td>AKORN INC</td>
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<td>APOTHECON</td>
<td>1MG BASE/ML</td>
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### VERSED
#### SYRUP, ORAL

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### MIDODRINE HYDROCHLORIDE
#### TABLET, ORAL

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#### TABLET, ORAL

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### MILRINONE LACTATE
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<td>BAXTER HLTHCARE CORP</td>
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### MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote

MILRINONE LACTATE
INJECTABLE, INJECTION
PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER
+ SANOFI AVENTIS US
  EQ 10MG BASE/100ML ** N020343 001 Aug 09, 1994
+ EQ 15MG BASE/100ML ** N020343 002 Aug 09, 1994
+ EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML) N020343 003 Aug 09, 1994
  **
+ EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML) N020343 004 Aug 09, 1994

MINOCYCLINE HYDROCHLORIDE
CAPSULE, ORAL
MINOCIN
+ PRECISION DERMAT
  EQ 75MG BASE ** N050649 003 Feb 12, 2001
  TRIAX PHARMS
  EQ 50MG BASE N050315 002
  EQ 100MG BASE N050315 001
CAPSULE, EXTENDED RELEASE, ORAL
XIMINO
SUN PHARM IND'S LTD
  EQ 67.5MG BASE N201922 002 Jul 11, 2012
  EQ 112.5MG BASE N201922 001
INJECTABLE, INJECTION
MINOCIN
LEDERLE
  EQ 100MG BASE/VIAL A062139 001
SUSPENSION, ORAL
MINOCIN
PRECISION DERMAT
  EQ 50MG BASE/5ML N050445 001
TABLET, ORAL
MINOCYCLINE HYDROCHLORIDE
+ TRIAX PHARMS
  EQ 50MG BASE ** N050451 003 Aug 10, 1982
  + EQ 100MG BASE ** N050451 002 Aug 10, 1982
TABLET, EXTENDED RELEASE, ORAL
MINOCYCLINE HYDROCHLORIDE
BARR LABS INC
  EQ 45MG BASE A065485 001 Mar 17, 2009
  EQ 80MG BASE A065485 007 Apr 26, 2017
  EQ 90MG BASE A065485 002 Mar 17, 2009
  EQ 105MG BASE A065485 008 Apr 26, 2017
  EQ 135MG BASE A065485 003 Mar 17, 2009
IMPAX LABS INC
  EQ 45MG BASE A090024 001 Feb 03, 2009
  EQ 90MG BASE A090024 002 Feb 03, 2009
  EQ 135MG BASE A090024 003 Feb 03, 2009
MYLAN PHARMS INC
  EQ 45MG BASE A090911 001 Jul 20, 2010
  EQ 90MG BASE A090911 002 Jul 20, 2010
  EQ 135MG BASE A090911 003 Jul 20, 2010
SOLODYN
+ MEDICIS
  EQ 45MG BASE ** N050808 001 May 08, 2006
  + EQ 90MG BASE ** N050808 002 May 08, 2006
  + EQ 135MG BASE ** N050808 003 May 08, 2006

MINOXIDIL
SOLUTION, TOPICAL
MINOXIDIL (FOR MEN)
APOTEX INC 2%
  A074924 001 Apr 29, 1998
BAUSCH AND LOMB 2%
  A074643 001 Apr 09, 1996
COPLEY PHARM 2%
  A074500 001 May 23, 1996
SIGHT PHARMS 2%
  A074743 002 Oct 18, 1996
TEVA 2%
  A074589 001 Apr 05, 1996
MINOXIDIL (FOR WOMEN)
APOTEX INC 2%
  A074924 002 Apr 29, 1998
SIGHT PHARMS 2%
  A074743 003 Oct 18, 1996
MINOXIDIL EXTRA STRENGTH (FOR MEN)
APOTEX INC 5%
  A075839 001 Oct 01, 2001
TABLET, ORAL
LONITEN
+ PHARMACIA AND UPJOHN 2.5MG ** N018154 001
  + 10MG ** N018154 003
MINODYL
QUANTUM PHARMCIS 2.5MG A072153 001 Jul 13, 1988
  10MG A071534 001 Mar 19, 1987
MINOXIDIL
ROYCE LABS 2.5MG A071799 001 Nov 10, 1987
  10MG A071796 001 Nov 10, 1987

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<th><strong>DISCONTINUED DRUG PRODUCT LIST</strong></th>
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<td>Mitoxantrone Hydrochloride</td>
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<td>Fresenius Kabi Oncol</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### MITOXANTRONE HYDROCHLORIDE
**INJECTABLE; INJECTION**
- **NOVANTRONE**
  - EQ 20MG BASE/10ML (EQ 2MG BASE/ML) — N019297 001 Dec 23, 1987
  - EQ 25MG BASE/12.5ML (EQ 2MG BASE/ML) — N019297 002 Dec 23, 1987
  - EQ 30MG BASE/15ML (EQ 2MG BASE/ML) — N019297 003 Dec 23, 1987

### MIVACURIIUM CHLORIDE
**INJECTABLE; INJECTION**
- **MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER**
  - EQ 0.5MG BASE/ML — N020098 002 Jan 22, 1992
  - EQ 50MG BASE/100ML — N020098 003 Jan 22, 1992
- **MIVACURIIUM CHLORIDE SOLUTION; INTRAVENOUS**
  - **ABBVIE**
    - EQ 2MG BASE/ML — A078562 001 Apr 30, 2009
  - **MIYLAN LABS LTD**
    - EQ 2MG BASE/ML — N020098 001 Jan 22, 1992
    - EQ 10MG BASE/5ML (EQ 2MG BASE/ML) — N020098 004 Jan 22, 1992
    - EQ 20MG BASE/10ML (EQ 2MG BASE/ML) — N020098 005 Jan 22, 1992

### MOEXIPRIL HYDROCHLORIDE
**TABLET; ORAL**
- **UNIVASC**
  - EQ 7.5MG ** — N020312 001 Apr 19, 1995
  - 15MG ** — N020312 002 Apr 19, 1995

### MOLINDONE HYDROCHLORIDE
**CAPSULE; ORAL**
- **MOBAN**
  - + **ENDO PHARMS**
    - EQ 5MG ** — N017111 001
    - EQ 10MG ** — N017111 002
    - EQ 25MG ** — N017111 003
- **CONCENTRATE; ORAL**
  - **MOBAN**
    - EQ 20MG/ML — N017938 001

### MOMETASONE FURATE
**CREAM; TOPICAL**
- **ELOCON**
  - EQ 0.1% — N019625 001 May 06, 1987
- **TARO**
  - EQ 0.1% — A076624 001 Dec 03, 2004

### MONOBENZONE
**CREAM; TOPICAL**
- **VALEANT PHARM INTL**
  - EQ 2% — N008173 003

### MONOCTANOIN
**LIQUID; PERFUSION, BILIARY**
- **ETHITEK**
  - EQ 100% — N019368 001 Oct 29, 1985

### MONTELUKAST SODIUM
**TABLET; ORAL**
- **APOTEX CORP**
  - EQ 10MG BASE — A201294 001 Aug 03, 2012
- **APOTEX INC**
  - EQ 4MG BASE — A201508 001 Aug 03, 2012
  - EQ 5MG BASE — A201508 002 Aug 03, 2012

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
MORICIZINE HYDROCHLORIDE

TABLET; ORAL

ETIMIZINE

SHIRE

200MG N019753 001 Jun 19, 1990
250MG N019753 002 Jun 19, 1990
300MG N019753 003 Jun 19, 1990

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

AVINZA

KING PHARMS LLC

30MG N021260 001 Mar 20, 2002
45MG N021260 005 Dec 18, 2008
60MG N021260 002 Mar 20, 2002
75MG N021260 006 Dec 18, 2008
90MG N021260 003 Mar 20, 2002
120MG N021260 004 Mar 20, 2002

INJECTABLE; INJECTION

MORPHINE SULFATE

HOSPIRA INC

15MG/ML N202515 005 Nov 14, 2011
ICU MEDICAL INC

0.5MG/ML N019917 001 Oct 30, 1992
SPECGX LLC

1MG/ML N020631 001 Jul 03, 1996
2MG/ML N020631 002 Jul 03, 1996
WATSON LABS

0.5MG/ML A073373 001 Sep 30, 1991
0.5MG/ML A073375 001 Sep 30, 1991
1MG/ML A073374 001 Sep 30, 1991
1MG/ML A073376 001 Sep 30, 1991

INJECTABLE, LIPOSOMAL; EPIDURAL

DEPODUR

PACIRA PHARMS INC

10MG/ML (10MG/ML) N021671 001 May 18, 2004
10MG/1.5ML (10MG/ML) N021671 002 May 18, 2004
20MG/2ML (10MG/ML) N021671 003 May 18, 2004

TABLET, EXTENDED RELEASE; ORAL

ARYMO ER

+ EGALGET

15MG N208603 001 Jan 09, 2017
30MG N208603 002 Jan 09, 2017
60MG N208603 003 Jan 09, 2017

MORPHINE SULFATE

EPIC PHARMA LLC

15MG A091357 001 Jun 23, 2016
30MG A091357 002 Jun 23, 2016
60MG A091357 003 Jun 23, 2016
100MG A091357 004 Jun 23, 2016
200MG A091357 005 Jun 23, 2016
WATSON LABS

100MG A075656 001 Jan 30, 2001

ORAMORPH SR

XANODYNE PHARMS INC

15MG N019977 001 Nov 23, 1994
30MG N019977 002 Aug 15, 1991
60MG N019977 003 Aug 15, 1991
100MG N019977 003 Aug 15, 1991

MOXALACTAM DISODIUM

INJECTABLE; INJECTION

MOXAM

LILLY

EQ 250MG BASE/VIAL N050550 001
EQ 500MG BASE/VIAL N050550 002
EQ 1GM BASE/VIAL N050550 003
EQ 2GM BASE/VIAL N050550 004
EQ 10GM BASE/VIAL N050550 008

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION; INTRAVENOUS

AVELOX IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER

+ BAYER HLTHCARE

400MG/250ML (1.6MG/ML) ** N021277 001 Nov 30, 2001

MUPIROCIN

OINTMENT; TOPICAL

BACTROBAN

+ GLAXOSMITHKLINE

2% ** N050591 001 Dec 31, 1987

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

### Mupirocin Calcium

**Cream; Topical**

- BACTROBAN + GLAXOSMITHKLINE EQ 2% BASE N050746 001 Dec 11, 1997

**Ointment; Nasal**

- BACTROBAN + GLAXOSMITHKLINE EQ 2% BASE N050703 001 Sep 18, 1995

### Mycophenolate Mofetil

**Capsule; Oral**

- MYCOPHENOLATE MOFETIL APOTEX CORP 250MG A090419 001 Apr 22, 2009
- MYCOPHENOLATE MOFETIL DR REDDYS LABS LTD 250MG A091315 001 Oct 27, 2011
- MYCOPHENOLATE MOFETIL JUBILANT CADISTA 250MG A090762 001 Dec 15, 2014
- MYCOPHENOLATE MOFETIL ZYDUS PHARMS USA INC 250MG A065433 001 May 04, 2009

**Tablet; Oral**

- MYCOPHENOLATE MOFETIL APOTEX 500MG A090499 001 Apr 22, 2009
- MYCOPHENOLATE MOFETIL DR REDDYS LABS LTD 500MG A090464 001 Sep 13, 2010
- MYCOPHENOLATE MOFETIL JUBILANT CADISTA 500MG A090661 001 Dec 15, 2014
- MYCOPHENOLATE MOFETIL ZYDUS PHARMS USA INC 500MG A065477 001 May 04, 2009

### Nabumetone

**Tablet; Oral**

- NABUMETONE COLEY PHARM 750MG A075179 001 Jun 06, 2000
- NABUMETONE OXFORD PHARMS 500MG A079093 001 Feb 27, 2009
- NABUMETONE Sandoz 500MG A079093 002 Feb 27, 2009
- NABUMETONE SIEGEN PHARMS INC 500MG A078420 001 Sep 24, 2008

**Tablet; Oral**

- NABUMETONE SMITHKLINE BEECHAM 500MG ** N019583 001 Dec 24, 1991
- NABUMETONE SMITHKLINE BEECHAM 750MG ** N019583 002 Dec 24, 1991

### Nadolol

**Tablet; Oral**

- NADOLOL CORGARD US WORLDMEDS LLC 120MG N018063 003
- NADOLOL CORGARD US WORLDMEDS LLC 160MG N018063 004

**Tablet; Oral**

- NADOLOL IVAX SUB TEVA PHARMS 120MG A074255 002 Jan 24, 1996
- NADOLOL IVAX SUB TEVA PHARMS 160MG A074255 003 Jan 24, 1996
- NADOLOL TEVA PHARMS 80MG A074368 001 Aug 31, 1994
- NADOLOL TEVA PHARMS 120MG A074368 002 Aug 31, 1994
- NADOLOL TEVA PHARMS 160MG A074368 003 Aug 31, 1994

### Nafcillin Sodium

**Capsule; Oral**

- NAFCELLIN SODIUM WYETH AYERST EQ 250MG BASE N050111 001

**For Solution; Oral**

- NAFCELLIN SODIUM WYETH AYERST EQ 250MG BASE/5ML N050199 001

**Injectable; Injection**

- NAFCELLIN SODIUM APOTHECON EQ 500MG BASE/VIAL A061984 001
- NAFCELLIN SODIUM APOTHECON EQ 1GM BASE/VIAL A061984 002
- NAFCELLIN SODIUM APOTHECON EQ 2GM BASE/VIAL A061984 003
- NAFCELLIN SODIUM APOTHECON EQ 4GM BASE/VIAL A061984 005

**Capsule; Oral**

- NAFCELLIN SODIUM Sandoz EQ 500MG BASE/VIAL A062527 001 Aug 02, 1984
- NAFCELLIN SODIUM Sandoz EQ 1GM BASE/VIAL A062844 001 Oct 26, 1988
- NAFCELLIN SODIUM Sandoz EQ 1.5GM BASE/VIAL A062844 003 Oct 26, 1988
- NAFCELLIN SODIUM Sandoz EQ 2GM BASE/VIAL A062844 004 Oct 26, 1988
- NAFCELLIN SODIUM Sandoz EQ 4GM BASE/VIAL A062844 005 Oct 26, 1988
- NAFCELLIN SODIUM Sandoz EQ 10GM BASE/VIAL A063008 001 Sep 29, 1988

**Capsule; Oral**

- NAFCELLIN SODIUM WATSON LABS INC EQ 500MG BASE/VIAL A061999 001
- NAFCELLIN SODIUM WATSON LABS INC EQ 1GM BASE/VIAL A061999 002

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
NAFCILLIN SODIUM
INJECTABLE; INJECTION
NALLPEN
EQ 1GM BASE/VIAL A062755 001 Dec 19, 1986
EQ 2GM BASE/VIAL A061999 003
EQ 2GM BASE/VIAL A062755 002 Dec 19, 1986
EQ 10GM BASE/VIAL A061999 004

UNIPEN
+ WYETH AYERST EQ 500MG BASE/VIAL ** N050320 001
+ WYETH AYERST EQ 500MG BASE/VIAL ** N050320 002
+ WYETH AYERST EQ 1GM BASE/VIAL ** N050320 003
+ WYETH AYERST EQ 2GM BASE/VIAL ** N050320 004
+ WYETH AYERST EQ 4GM BASE/VIAL ** N050320 005
+ WYETH AYERST EQ 10GM BASE/VIAL ** N050320 006

UNIPEN IN PLASTIC CONTAINER
+ WYETH AYERST EQ 500MG BASE N050462 001

UNIPEN
WYETH AYERST EQ 500MG BASE N050462 001

NAFTIFINE HYDROCHLORIDE
CREAM; TOPICAL
NAFTIN
+ SEBELA IRELAND LTD 1% N019599 001 Feb 29, 1988

NALBUPHINE HYDROCHLORIDE
INJECTABLE; INJECTION
NALBUPHINE
ABRAXIS PHARM 10MG/ML A070751 001 Jul 02, 1986
20MG/ML A070752 001 Sep 24, 1986

NALBUPHINE HYDROCHLORIDE
ABBOTT 20MG/ML A070917 001 Feb 03, 1989
ABBVIE 1.5MG/ML N020200 001 Mar 12, 1993
BARR 10MG/ML A074471 002 Mar 19, 1998
20MG/ML A074471 002 Mar 19, 1998
IGI LABS INC 10MG/ML A072070 001 Apr 10, 1989
10MG/ML A072071 001 Apr 10, 1989
10MG/ML A072072 001 Apr 10, 1989
20MG/ML A072073 001 Apr 10, 1989
20MG/ML A072074 001 Apr 10, 1989
20MG/ML A072075 001 Apr 10, 1989

NUBAIN
+ PAR PHARM INC 10MG/ML ** N018024 001
+ 20MG/ML ** N018024 002 May 27, 1982

NALIDIXIC ACID
SUSPENSION; ORAL
NEGGRAM
SANOFI AVENTIS US 250MG/5ML N017430 001

TABLET; ORAL
NALIDIXIC ACID
SUN PHARM INDUSTRIES 250MG A070270 001 Jun 29, 1988
500MG A070271 001 Jun 29, 1988
1GM A070272 001 Jun 29, 1988
WATSON LABS 250MG A071936 001 Jun 29, 1988
500MG A072061 001 Jun 29, 1988
1GM A071919 001 Jun 29, 1988
NEGGRAM
SANOFI AVENTIS US 250MG N014214 002
500MG N014214 004
1GM N014214 005

NALMEFENE HYDROCHLORIDE
INJECTABLE; INJECTION
REVEX
+ EUROHLTH INTL SARL EQ 0.1MG BASE/ML ** N020459 001 Apr 17, 1995
+ EQ 1MG BASE/ML ** N020459 002 Apr 17, 1995

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### NALOXONE HYDROCHLORIDE

**INJECTABLE; INJECTION**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

**See List Footnote**

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**NALOXONE HYDROCHLORIDE; OXYPHEDRINE HYDROCHLORIDE**
** Discontinued Drug Product List **

** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### NAPROXEN

**TABLET; ORAL**

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### NAPROXEN SODIUM

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**See List Footnote**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### NAPROXEN SODIUM TABLET; ORAL

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Nedocromil Sodium

**Aerosol, Metered; Inhalation**
- **Tilde**
  - **KING PHARMS LLC**
    - 1.75mg/inh N019660 001 Dec 30, 1992

**Solution; Inhalation**
- **Tilde**
  - **SANOFI AVENTIS US**
    - 0.5% N020750 001 Oct 01, 1997

### Nefaazodone Hydrochloride

**Tablet; Oral**
- **Nefaazodone Hydrochloride**
  - **ANI PHARMS INC**
    - 50mg A076072 001 Sep 16, 2003
    - 100mg A076072 002 Sep 16, 2003
    - 150mg A076072 003 Sep 16, 2003
    - 200mg A076072 004 Sep 16, 2003
    - 250mg A076072 005 Sep 16, 2003
  - **DR REDDYS LABS INC**
    - 50mg A076309 001 Sep 16, 2003
    - 100mg A076309 002 Sep 16, 2003
    - 150mg A076309 003 Sep 16, 2003
    - 200mg A076309 004 Sep 16, 2003
    - 250mg A076309 005 Sep 16, 2003
  - **FOSUN PHARMA**
    - 50mg A076302 001 Sep 16, 2003
    - 100mg A076302 002 Sep 16, 2003
    - 150mg A076302 003 Sep 16, 2003
    - 200mg A076302 004 Sep 16, 2003
    - 250mg A076302 005 Sep 16, 2003
  - **IVAX SUB TEVA PHARMS**
    - 50mg A075763 001 Sep 16, 2003
    - 100mg A075763 002 Sep 16, 2003
    - 150mg A075763 003 Sep 16, 2003
    - 200mg A075763 004 Sep 16, 2003
    - 250mg A075763 005 Sep 16, 2003
  - **MYLAN**
    - 50mg A076196 001 Sep 16, 2003
    - 100mg A076196 002 Sep 16, 2003
    - 150mg A076196 003 Sep 16, 2003
    - 200mg A076196 004 Sep 16, 2003
    - 250mg A076196 005 Sep 16, 2003
  - **SUN PHARM INDS LTD**
    - 50mg A076409 001 Sep 16, 2003
    - 100mg A076409 002 Sep 16, 2003
    - 150mg A076409 003 Sep 16, 2003
    - 200mg A076409 004 Sep 16, 2003
    - 250mg A076409 005 Sep 16, 2003
  - **WATSON LABS**
    - 100mg A076073 002 Sep 16, 2003
    - 150mg A076073 003 Sep 16, 2003
    - 200mg A076073 004 Sep 16, 2003
    - 250mg A076073 005 Sep 16, 2003

### Serzone

+ **Bristol Myers Squibb**
  - 50mg ** N020152 001 Dec 22, 1994
  - 100mg ** N020152 002 Dec 22, 1994
  - 150mg ** N020152 003 Dec 22, 1994
  - 200mg ** N020152 004 Dec 22, 1994
  - 250mg ** N020152 005 Dec 22, 1994

### Neliprevir Mesylate

**Powder; Oral**
- **Viracept**
  - **AGOURON PHARMS**
    - EQ 50mg base/scoopful N020778 001 Mar 14, 1997

### Neomycin Sulfate

**Powder; For Rx Compounding**
- **NEO-RX**
  - 100% A061579 001

**Solution; Oral**
- **MYCIFRADIN**
  - PHARMACIA AND UPJOHN EQ 87.5mg base/5ml N050285 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
NEOMYCIN SULFATE

SOLUTION; ORAL
X GEN PHARMS
EQ 87.5MG BASE/5ML
A065010 001 May 23, 2002

TABLET; ORAL
MYCIFRADIN
PHARMACIA AND UPJOHN
EQ 350MG BASE
A060520 001

NEOBIOTIC
PFIZER
EQ 350MG BASE
A060475 001

NEOMYCIN SULFATE
BRISTOL MYERS SQUIBB
500MG
A060365 001
LANNETT
500MG
A060607 001
LILLY
500MG
A060385 001
ROXANE
500MG
A062173 001
SANDOZ
500MG
A061586 001

NEOMYCIN SULFATE; POLYMYXIN B SULFATE
CREAM; TOPICAL
NEOSPORIN
GLAXOSMITHKLINE
EQ 3.5MG BASE/GM; 10,000 UNITS/GM
N050176 002 Jan 14, 1985

OINTMENT; OPHTHALMIC
STATROL
ALCON
EQ 3.5MG BASE/GM; 10,000 UNITS/GM
N050344 002

SOLUTION/DRIPS; OPHTHALMIC
STATROL
ALCON
EQ 3.5MG BASE/ML; 16,250 UNITS/ML
A062339 001 Nov 30, 1984
EQ 3.5MG BASE/ML; 16,250 UNITS/ML
N050456 001

NEOMYCIN SULFATE; POLYMYXIN B SULFATE; PREDNISOLONE ACETATE
SUSPENSION/DRIPS; OPHTALMIC
POLY-PRED
ALLERGAN
EQ 0.35% BASE; 10,000 UNITS/ML; 0.5%
N050081 002

NEOMYCIN SULFATE; PREDNISOLONE ACETATE
OINTMENT; OPHTHALMIC
NEO-Delta-Cortef
PHARMACIA AND UPJOHN
EQ 3.5MG BASE/GM; 0.25%
A061039 002
EQ 3.5MG BASE/GM; 0.5%
A061039 001

SUSPENSION/DRIPS; OPHTALMIC
NEO-Delta-Cortef
PHARMACIA AND UPJOHN
EQ 3.5MG BASE/ML; 0.25%
A061037 001

NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE
OINTMENT; OPHTHALMIC
NEO-Hydreltrasol
MERCK
EQ 3.5MG BASE/GM; EQ 0.25% PHOSPHATE
N050378 001

NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE
CREAM; TOPICAL
MITREX A
SAVAGE LABS
EQ 3.5MG BASE/GM; 0.1%
A062598 001 Jul 21, 1986

NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE
FOUGERA
EQ 3.5MG BASE/GM; 0.1%
A062600 001 Jul 21, 1986
PHARMADERM
EQ 3.5MG BASE/GM; 0.1%
A062595 001 Jul 21, 1986

OINTMENT; TOPICAL
MITREX A
SAVAGE LABS
EQ 3.5MG BASE/GM; 0.1%
A062609 001 May 23, 1986

NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE
FOUGERA
EQ 3.5MG BASE/GM; 0.1%
A062608 001 May 23, 1986
PHARMADERM
EQ 3.5MG BASE/GM; 0.1%
A062607 001 May 23, 1986

NETILMICIN SULFATE
INJECTABLE; INJECTION
NETROMYCIN
SCHERING
EQ 10MG BASE/ML
N050544 001 Feb 28, 1983
EQ 25MG BASE/ML
N050544 002 Feb 28, 1983
EQ 100MG BASE/ML
N050544 003 Feb 28, 1983

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>CHIESI USA INC</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>Prostep Aveva 11mg/24hr</td>
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<td>Polacrilex Gum, Chewing; Buccal</td>
<td>Ivax Sub Teva Pharm 2mg</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<th>Company/Brand</th>
<th>Dosage</th>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
NITROFURAZONE
SOLUTION;TOPICAL
NITROFURAZONE
WENDT 0.2% A087081 001

NITROGLYCERIN
AEROSOL;SUBLINGUAL
NITROGLYCERIN
POHL BOSKAMP 0.4MG/Spray N018705 001 Oct 31, 1985

FILM, EXTENDED RELEASE;TRANSDERMAL
NITROGLYCERIN
LANNETT CO INC 0.2MG/HR A075115 001 Aug 10, 2004
0.4MG/HR A075115 002 Aug 10, 2004
MYLAN TECHNOLOGIES 0.1MG/HR A074992 004 Nov 12, 1999
0.2MG/HR A074992 003 Nov 12, 1999
0.4MG/HR A074992 002 Nov 12, 1999
0.6MG/HR A074992 001 Nov 12, 1999

TRANSDERM-NITRO
+ NOVARTIS 0.1MG/HR ** N020144 001 Feb 27, 1996
+ 0.2MG/HR ** N020144 002 Feb 27, 1996
+ 0.4MG/HR ** N020144 003 Feb 27, 1996
+ 0.6MG/HR ** N020144 004 Feb 27, 1996
+ 0.8MG/HR ** N020144 005 Feb 27, 1996

INJECTABLE;INJECTION
NITRO IV
POHL BOSKAMP 5MG/ML N018672 002 Aug 30, 1983
10MG/ML N018621 001 Jan 05, 1982
A071159 001 Feb 28, 1990

NITRO-BID
SANOFI AVENTIS US 5MG/ML N018621 001 Jan 05, 1982
10MG/ML N018621 002 Jan 05, 1982
A071159 002 Feb 28, 1990

NITROGLYCERIN
ABRAAXIS PHARM 5MG/ML A070077 001 Dec 13, 1985
5MG/ML A071203 001 May 08, 1987
+ HOSPIRA 5MG/ML ** N018531 001
INTL MEDICATION 5MG/ML A070026 001 Sep 10, 1985
LUITPOLD 5MG/ML A071492 001 May 24, 1988
SMITH AND NEPHEW 5MG/ML A070633 001 Jun 19, 1986
5MG/ML A070634 001 Jun 19, 1986

NITROGLYCERIN IN DEXTROSE 5%
HOSPIRA
0.1MG/ML A074083 001 Oct 26, 1994
10MG/100ML A071846 001 Aug 31, 1990
20MG/100ML A071847 001 Aug 31, 1990
40MG/100ML A071848 001 Aug 31, 1990
NITROL
ROPER 0.8MG/ML N018774 002 Jun 19, 1993
NITRONAL
POHL BOSKAMP 1MG/ML N018672 001 Aug 30, 1983
NITROSTAT
PARKE DAVIS 0.8MG/ML A070588 001
5MG/ML A070863 001 Jan 08, 1987
5MG/ML A071888 001 Dec 23, 1983
10MG/ML A070871 001 Jan 08, 1987
10MG/ML A070872 001 Jan 08, 1987
TRIDIL
HOSPIRA
0.5MG/ML A071857 002 Jun 16, 1983
5MG/ML A071857 003 Jun 16, 1983

NIZATIDINE
CAPSULE;ORAL
AXID
SMITHKLINE BEECHAM 150MG N019508 001 Apr 12, 1988
300MG N019508 002 Apr 12, 1988
NIZATIDINE
ANI PHARMS INC 150MG A075461 001 Jul 08, 2002
300MG A075461 002 Jul 08, 2002
APOTEX INC 150MG A076383 001 Jan 23, 2003
300MG A076383 002 Jan 23, 2003
MYLAN PHARMS INC 150MG A075934 001 Jul 09, 2002
300MG A075934 002 Jul 09, 2002

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>MYLAN PHARMS INC</td>
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<td>MYTREX F</td>
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<td>SAVAGE LABS</td>
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<td>PERRIGO NEW YORK</td>
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<td>FLOXIN IN DEXTROSE 5%</td>
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<td>FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER</td>
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** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
**OFLOXACIN**

**INJECTABLE; INJECTION**
- **OFLOXACIN**
  - **BEDFORD**
    - 40MG/ML A075762 001 Jan 16, 2002

**SOLUTION/DROPS; OPHTHALMIC**
- **OFLOXACIN**
  - **APOTEX INC** 0.3% A076513 001 May 14, 2004
  - **SANDOZ** 0.3% A076848 001 Nov 25, 2008

**SOLUTION/DROPS; OTIC**
- **FLOXIN OTIC**
  - **+ DAICHI** 0.3% ** N020799 001 Dec 16, 1997

**TABLET; ORAL**
- **FLOXIN**
  - **JANSSEN PHARMS**
    - 200MG ** N019735 001 Dec 28, 1990
    - 300MG ** N019735 002 Dec 28, 1990
    - 400MG ** N019735 003 Dec 28, 1990
  - **LARKEN LABS**
    - 200MG A076093 001 Sep 02, 2003
    - 300MG A076093 002 Sep 02, 2003
  - **RANBAXY LABS LTD**
    - 200MG A076220 001 Sep 02, 2003
    - 300MG A076220 002 Sep 02, 2003
    - 400MG A076220 003 Sep 02, 2003

**OLANZAPINE**

**TABLET; ORAL**
- **OLANZAPINE**
  - **AJANTA PHARMA LTD**
    - 2.5MG A206711 001 Aug 30, 2016
    - 5MG A206711 002 Aug 30, 2016
    - 7.5MG A206711 003 Aug 30, 2016
    - 10MG A206711 004 Aug 30, 2016
    - 15MG A206711 005 Aug 30, 2016
    - 20MG A206711 006 Aug 30, 2016
  - **MYLAN PHARMS INC**
    - 2.5MG A076866 001 Apr 23, 2012
    - 5MG A076866 002 Apr 23, 2012
    - 7.5MG A076866 003 Apr 23, 2012
    - 10MG A076866 004 Apr 23, 2012
    - 15MG A076866 005 Apr 23, 2012
    - 20MG A076866 006 Apr 23, 2012

**TABLET, ORALLY DISINTEGRATING; ORAL**
- **OLANZAPINE**
  - **AJANTA PHARMA LTD**
    - 5MG A204320 001 May 30, 2017
    - 10MG A204320 002 May 30, 2017
    - 15MG A204320 003 May 30, 2017
    - 20MG A204320 004 May 30, 2017

**OLIVE OIL; SOYBEAN OIL**

**INJECTABLE; INJECTION**
- **CLINOLIPID 20%**
  - **+ BAXTER HLTHCARE CORP**
    - 16%(160GM/1000ML); 4% (40GM/1000ML) N204508 001 Oct 03, 2013

**OLOPATADINE HYDROCHLORIDE**

**SOLUTION/DROPS; OPHTHALMIC**
- **OLOPATADINE HYDROCHLORIDE**
  - **ZAMBON SPA**
    - EQ 0.1% BASE A204706 001 Dec 07, 2015

**OMEGA-3-ACID ETHYL ESTERS TYPE A**

**CAPSULE; ORAL**
- **OMTRYG**
  - **+ OSIMOTICA**
    - 1.2GM CONTAINS AT LEAST 900MG OF THE ETHYL ESTERS OF OMEGA-3 FATTY ACIDS N204977 001 Apr 23, 2014

**OMEGA-3-CARBOXYLIC ACIDS**

**CAPSULE; ORAL**
- **EPANOVA**
  - **+ ASTRazeneca PHARMS**
    - 1GM CONTAINS AT LEAST 850MG OF POLYUNSATURATED FATTY ACIDS N205060 001 May 05, 2014

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<tr>
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<td>EQ 500MG BASE/VIAL</td>
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<tr>
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<td>EQ 1GM BASE/VIAL</td>
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<td>WATSON LABS INC</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
OXACILLIN SODIUM
INJECTABLE; INJECTION
OXACILLIN SODIUM

OXACILLIN SODIUM

 POWDER; INTRAVENOUS
OXACILLIN SODIUM
SANODZ

** See List Footnote

OXALIPLATIN
INJECTABLE; IV (INFUSION)
ELOXATIN

OXALIPLATIN
FRESENIUS KABI ONCOL

OXALIPLATIN
SANODZ INC

OXAMNIQUINE
CAPSULE; ORAL
VANSIL

OXANDROLONE
TABLET; ORAL
OXANDRIN

OXANDROLONE
ROXANE

OXANDROLONE
SANDOZ

OXAPROZIN
TABLET; ORAL
OXAPROZIN

OXAPROZIN
ACTAVIS ELIZABETH

OXAPROZIN
MYLAN

OXAPROZIN
MYLAN PHARMS INC

OXAPROZIN
SANDOZ

OXAPROZIN
WATSON LABS

OXAPROZIN POTASSIUM
TABLET; ORAL
DAYPRO ALTA

OXAZEPAM
CAPSULE; ORAL
OXAZEPAM

AM THERAP

FRONTIDA BIOPHARM

IVAX SUB TEVA PHARMS

MYLAN

WATSON LABS

WATSON LABS TEVA

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### Oxazepam

**Capsule; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serax</td>
<td>10mg **</td>
</tr>
<tr>
<td>AlphaPharma US Pharms</td>
<td>15mg **</td>
</tr>
<tr>
<td>Quantum Pharmics</td>
<td>30mg **</td>
</tr>
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</table>

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parke Davis</td>
<td>15mg</td>
</tr>
<tr>
<td>Sun Pharm Industries</td>
<td>15mg</td>
</tr>
<tr>
<td>Watson Labs</td>
<td>15mg</td>
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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serax</td>
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</tr>
<tr>
<td>AlphaPharma US Pharms</td>
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### Oxcarbazepine

**Tablet; Oral**

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<th>Strength(s)</th>
</tr>
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<tr>
<td>Jubilant Cadista</td>
<td>150mg</td>
</tr>
<tr>
<td>A090239</td>
<td>001 Jan 25, 2010</td>
</tr>
<tr>
<td>300mg</td>
<td></td>
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<tr>
<td>A090239</td>
<td>002 Jan 25, 2010</td>
</tr>
<tr>
<td>600mg</td>
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</tr>
<tr>
<td>A090239</td>
<td>003 Jan 25, 2010</td>
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### Oxyprenolol Hydrochloride

**Capsule; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
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<tbody>
<tr>
<td>Novartis</td>
<td>20mg</td>
</tr>
<tr>
<td>N018166</td>
<td>001 Dec 28, 1983</td>
</tr>
<tr>
<td>40mg</td>
<td></td>
</tr>
<tr>
<td>N018166</td>
<td>002 Dec 28, 1983</td>
</tr>
<tr>
<td>80mg</td>
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<td>N018166</td>
<td>003 Dec 28, 1983</td>
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<tr>
<td>160mg</td>
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<td>N018166</td>
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### Oxtriphylline

**Solution; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parke Davis</td>
<td>100mg/5ml</td>
</tr>
<tr>
<td>N009268</td>
<td>012 Nov 27, 1984</td>
</tr>
<tr>
<td>Oxtriphylline</td>
<td>100mg/5ml</td>
</tr>
<tr>
<td>N088243</td>
<td>001 Dec 05, 1983</td>
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</table>

**Syrup; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Parke Davis</td>
<td>50mg/5ml</td>
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<td>011</td>
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**Tablet, Delayed Release; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parke Davis</td>
<td>100mg</td>
</tr>
<tr>
<td>N009268</td>
<td>003</td>
</tr>
<tr>
<td>200mg</td>
<td></td>
</tr>
<tr>
<td>N009268</td>
<td>007</td>
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**Tablet, Extended Release; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parke Davis</td>
<td>100mg</td>
</tr>
<tr>
<td>N087866</td>
<td>001 Aug 25, 1983</td>
</tr>
<tr>
<td>200mg</td>
<td></td>
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<tr>
<td>N087835</td>
<td>001 Aug 25, 1983</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warner Chilcott LLC</td>
<td>400mg</td>
</tr>
<tr>
<td>A087863</td>
<td>001 May 24, 1983</td>
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<tr>
<td>600mg</td>
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<tr>
<td>A086742</td>
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</tbody>
</table>

### Oxybutynin

**Film, Extended Release; Transdermal**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
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</thead>
<tbody>
<tr>
<td>Barr Labs Div Teva</td>
<td>3.9mg/24hr</td>
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<tr>
<td>A090526</td>
<td>001 Mar 04, 2014</td>
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</table>

**Gel, Metered; Transdermal**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
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<tbody>
<tr>
<td>Gelnique 3%</td>
<td>3%</td>
</tr>
<tr>
<td>N202513</td>
<td>001 Dec 07, 2011</td>
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</tbody>
</table>

### Oxybutynin Chloride

**Syrup; Oral**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ditropan</td>
<td>5mg/5ml **</td>
</tr>
<tr>
<td>N018211</td>
<td>001</td>
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</tbody>
</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

### Oxybutynin Chloride

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>NDC</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ditropan</td>
<td>5mg **</td>
<td>N017577 001</td>
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<tr>
<td>Janssen Pharm</td>
<td>5mg **</td>
<td>A072296 001 Dec 08, 1988</td>
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<td>Quantum Pharmics</td>
<td>5mg</td>
<td>A070746 001 Mar 10, 1988</td>
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<td>USL Pharm</td>
<td>5mg</td>
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<td>Watson Labs</td>
<td>5mg</td>
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**Tablet, Extended Release; Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>NDC</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ditropan XL</td>
<td>15mg **</td>
<td>N020897 003 Jun 22, 1999</td>
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### Oxycodeine Hydrochloride

**Tablet; Oral**

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<th>Brand</th>
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<th>NDC</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Roxicodone</td>
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<td>N020932 001 Oct 26, 1998</td>
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<tr>
<td>Roxane</td>
<td>10mg</td>
<td>N020932 002 Oct 26, 1998</td>
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<tr>
<td>Endo Pharms</td>
<td>5mg</td>
<td>N021610 001 Jun 22, 2006</td>
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<tr>
<td></td>
<td>5mg</td>
<td>N201655 001 Oct 24, 2014</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.5mg **</td>
<td>N201655 002 Oct 24, 2014</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.5mg</td>
<td>N201655 003 Oct 24, 2014</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10mg **</td>
<td>N201655 004 Oct 24, 2014</td>
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<tr>
<td></td>
<td>10mg</td>
<td>N201655 005 Oct 24, 2014</td>
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<td></td>
<td>15mg **</td>
<td>N201655 006 Oct 24, 2014</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15mg</td>
<td>N201655 007 Oct 24, 2014</td>
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<td></td>
<td>20mg **</td>
<td>N201655 008 Oct 24, 2014</td>
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<td></td>
<td>20mg</td>
<td>N201655 009 Oct 24, 2014</td>
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<td>30mg **</td>
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<td></td>
<td>30mg</td>
<td>N201655 011 Oct 24, 2014</td>
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<td></td>
<td>40mg **</td>
<td>N201655 012 Oct 24, 2014</td>
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<td>40mg</td>
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### Oxymerazoline Hydrochloride

**Solution/Drops; Ophthalmic**

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<th>Date</th>
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<tbody>
<tr>
<td>OcuClear</td>
<td>0.025%</td>
<td>N018471 001 May 30, 1986</td>
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### Oxymporphone Hydrochloride

**Injectable; Injection**

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<th>NDC</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Endo Pharms</td>
<td>1mg/ml</td>
<td>N011707 002</td>
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<tr>
<td></td>
<td>1.5mg/ml</td>
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**Suppository; Rectal**

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<th>NDC</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endo Pharms</td>
<td>5mg</td>
<td>N01738 004</td>
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**Tablet, Extended Release; Oral**

<table>
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<th>Brand</th>
<th>Strength</th>
<th>NDC</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Endo Pharms</td>
<td>5mg **</td>
<td>N021610 001</td>
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<tr>
<td></td>
<td>5mg</td>
<td>N201655 001 Dec 09, 2011</td>
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<tr>
<td></td>
<td>7.5mg **</td>
<td>N201655 005 Feb 29, 2008</td>
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<td></td>
<td>7.5mg</td>
<td>N201655 002 Dec 09, 2011</td>
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</tr>
<tr>
<td></td>
<td>10mg **</td>
<td>N201655 006 Dec 09, 2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10mg</td>
<td>N201655 003 Dec 09, 2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15mg **</td>
<td>N201655 007 Dec 09, 2011</td>
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</tr>
<tr>
<td></td>
<td>15mg</td>
<td>N201655 004 Dec 09, 2011</td>
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</tr>
<tr>
<td></td>
<td>20mg **</td>
<td>N201655 008 Dec 09, 2011</td>
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</tr>
<tr>
<td></td>
<td>20mg</td>
<td>N201655 005 Dec 09, 2011</td>
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</tr>
<tr>
<td></td>
<td>30mg **</td>
<td>N201655 009 Dec 09, 2011</td>
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</tr>
<tr>
<td></td>
<td>30mg</td>
<td>N201655 006 Dec 09, 2011</td>
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<tr>
<td></td>
<td>40mg **</td>
<td>N201655 010 Dec 09, 2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40mg</td>
<td>N201655 007 Dec 09, 2011</td>
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**Par Pharm**

<table>
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<td>20mg</td>
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</tr>
<tr>
<td>40mg</td>
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**SUN Pharm INDs LTD**

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<th>NDC</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
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<td>A203506 001 Apr 24, 2015</td>
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</tr>
<tr>
<td>7.5mg</td>
<td>A203506 002 Apr 24, 2015</td>
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</tr>
<tr>
<td>10mg</td>
<td>A203506 003 Apr 24, 2015</td>
<td></td>
</tr>
<tr>
<td>15mg</td>
<td>A203506 004 Apr 24, 2015</td>
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</tr>
<tr>
<td>20mg</td>
<td>A203506 005 Apr 24, 2015</td>
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<td></td>
</tr>
<tr>
<td>40mg</td>
<td>A203506 007 Apr 24, 2015</td>
<td></td>
</tr>
</tbody>
</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
OXYPHENBUTAZONE
TABLET; ORAL
OXYPHENBUTAZONE TABLET; ORAL
WATSON LABS
100MG
A088399 001 Sep 17, 1984
TANDEARIL
NOVARTIS
100MG
N012542 004 Sep 03, 1982

OXYPHENCYCLIMINE HYDROCHLORIDE
TABLET; ORAL
DARICON
PFIZER
10MG
N011612 001

OXYPHENONIUM BROMIDE
TABLET; ORAL
ANTRENYL
NOVARTIS
5MG
N008492 002

OXYTETRACYCLINE
TABLET; ORAL
TERRAMYCIN
PFIZER
250MG
N050287 001

OXYTETRACYCLINE CALCIUM
SYRUP; ORAL
TERRAMYCIN
PFIZER
EQ 125MG BASE/5ML
A060595 001

OXYTETRACYCLINE HYDROCHLORIDE
CAPSULE; ORAL
OXY-KESSO-TETRA
FERRANTE
EQ 250MG BASE
A060179 001

OXYTETRACYCLINE HYDROCHLORIDE
HIKMA PHARMS
EQ 250MG BASE
A060770 001
IMPAF LABS
EQ 250MG BASE
A060760 001
PROTER
EQ 250MG BASE
A060869 001
PUREPAC PHARM
EQ 250MG BASE
A060634 001
TERRAMYCIN
PFIZER
EQ 125MG BASE
N050286 001
EQ 250MG BASE
N050286 002

INJECTABLE; INJECTION
TERRAMYCIN
PFIZER
EQ 250MG BASE/VIAL
A060586 001
EQ 500MG BASE/VIAL
A060586 002

OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE
OINTMENT; OPHTHALMIC
TERRAMYCIN W/ POLYMYXIN B SULFATE
CASPER PHARMA LLC
EQ 5MG BASE/GM; 10,000 UNITS/GM
N061015 001

OINTMENT; OTIC
TERRAMYCIN W/ POLYMYXIN
PFIZER
EQ 5MG BASE/GM; 10,000 UNITS/GM
A061841 001

TABLET; VAGINAL
TERRAMYCIN-POLYMYXIN
PFIZER
EQ 100MG BASE; 100,000 UNITS
A061009 001

OXYTOCIN
INJECTABLE; INJECTION
OXYTOCIN
TEVA PHARMS USA
10USP UNITS/ML (10USP UNITS/ML)
A077453 001 Jan 24, 2008
100USP UNITS/10ML (10USP UNITS/ML)
A077453 002 Jan 24, 2008

OXYTOCIN 10 USP UNITS IN DEXTROSE 5%
+ ABBOTT
1USP UNITS/100ML **
N019185 004 Mar 29, 1985
+ 2USP UNITS/100ML **
N019185 003 Mar 29, 1985

OXYTOCIN 20 USP UNITS IN DEXTROSE 5%
+ ABBOTT
2USP UNITS/100ML **
N019185 002 Mar 29, 1985

OXYTOCIN 5 USP UNITS IN DEXTROSE 5%
+ ABBOTT
1USP UNITS/100ML **
N019185 001 Mar 29, 1985

SYNTOCINON
NOVARTIS
10USP UNITS/ML
N018245 001

SOLUTION; NASAL
SYNTOCINON
RTRX
40USP UNITS/ML
N012285 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

PACITAXEL
INJECTABLE; INJECTION
PACITAXEL
  ACCORD HLTHCARE 6MG/ML A075436 001 Nov 12, 2004
  HOSPIRA 6MG/ML A076233 001 Aug 01, 2002
  MYLAN 6MG/ML A075278 001 Jan 25, 2002
  PLIVA LACHEMA 6MG/ML A077413 001 Mar 12, 2008
  TEVA PHARMS USA 6MG/ML A075297 001 Jan 25, 2002

PALSIPERIDONE
TABLET, EXTENDED RELEASE; ORAL
  + JANSSEN PHARMS 12MG ** N021999 004 Dec 19, 2006

PALONOSETRON HYDROCHLORIDE
CAPSULE; ORAL
  ALOXI EQ 0.5MG BASE ** N022233 001 Aug 22, 2008

SOLUTION; INTRAVENOUS
PALONOSETRON HYDROCHLORIDE
  DR REDDYS LABS LTD EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML) N203050 001 Mar 01, 2016
  EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML) N203050 002 Mar 01, 2016

PAMIDRONATE DISODIUM
INJECTABLE; INJECTION
  AREDIA
    + NOVARTIS 30MG/VIAL ** N020036 001 Oct 31, 1991
    60MG/VIAL N020036 003 May 06, 1993
    90MG/VIAL N020036 004 May 06, 1993

PAMIDRONATE DISODIUM
AEGSEN
  30MG/VIAL A075594 001 May 06, 2002
  90MG/VIAL A075594 002 May 06, 2002

MN PHARMS
  30MG/VIAL A078300 001 Mar 10, 2009
  90MG/VIAL A078300 002 Mar 10, 2009

PANCRELIPASE (AMYLASE; LIPOASE; PROTEASE)
CAPSULE; ORAL
  COTAZYM
    ORGANON USA INC 30,000USP UNITS; 8,000USP UNITS; 30,000USP UNITS N020580 001 Dec 09, 1996

CAPSULE, DELAYED RELEASE; ORAL
ULTRESA
  + FOREST LABS INC 27,600USP UNITS; 13,800USP UNITS N022222 001 Mar 01, 2012
  + 41,400USP UNITS; 20,700USP UNITS N022222 002 Mar 01, 2012
  + 46,000USP UNITS; 23,000USP UNITS N022222 003 Mar 01, 2012

PANCURONIUM BROMIDE
INJECTABLE; INJECTION
PANCURONIUM BROMIDE
  ELKINS SINN 1MG/ML A072058 001 Mar 23, 1988
  2MG/ML A072059 001 Mar 23, 1988
  2MG/ML A072060 001 Mar 23, 1988

HOSPIRA
  2MG/ML A072321 001 Jan 19, 1989

IGI LABS INC
  1MG/ML A072210 001 Mar 31, 1988
  2MG/ML A072211 001 Mar 31, 1988
  2MG/ML A072212 001 Mar 31, 1988
  2MG/ML A072213 001 Mar 31, 1988

PAVULON
  + ORGANON USA INC 1MG/ML N017015 002
  + 2MG/ML N017015 001

PANTOPRAZOLE SODIUM
TABLET, DELAYED RELEASE; ORAL
PANTOPRAZOLE SODIUM
  SUN PHARM INDS LTD EQ 20MG BASE A077058 001 Sep 10, 2007
  EQ 20MG BASE A200794 001 May 02, 2012
  EQ 40MG BASE A077058 002 Sep 10, 2007
  EQ 40MG BASE A200794 002 May 02, 2012

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
## PARAMETHADIONE
**CAPSULE; ORAL**
- **ABBVIE**
  - 150MG N006800 003
  - 300MG N006800 001

**SOLUTION; ORAL**
- **ABBVIE**
  - 300MG/ML N006800 002

## PARAMETHASONE ACETATE
**TABLET; ORAL**
- **HALDRONE**
  - **LILLY**
    - 1MG N012772 005
    - 2MG N012772 006

## PARGYLINE HYDROCHLORIDE
**TABLET; ORAL**
- **EUTONYL**
  - **ABBOTT**
    - 10MG N013448 002
    - 25MG N013448 003
    - 50MG N013448 004

## PARICALCITOL
**CAPSULE; ORAL**
- **ZEMPLAR**
  - **ABBVIE**
    - 4MCG ** N021606 003 May 26, 2005

## PAROMOMYCIN SULFATE
**CAPSULE; ORAL**
- **HUMATIN**
  - **KING PFIZER**
    - EQ 250MG BASE A062310 001
  - **PARKEDALE**
    - EQ 250MG BASE A060521 001

**SYRUP; ORAL**
- **HUMATIN**
  - **PARKE DAVIS**
    - EQ 125MG BASE/5ML A060522 001

## PAROXETINE HYDROCHLORIDE
**CAPSULE; ORAL**
- **PAXIL**
  - **APOTEX TECHNOLOGIES**
    - EQ 10MG BASE ** N020885 001 Oct 09, 1998
    - EQ 20MG BASE ** N020885 002 Oct 09, 1998
    - EQ 30MG BASE ** N020885 003 Oct 09, 1998
    - EQ 40MG BASE ** N020885 004 Oct 09, 1998

**SUSPENSION; ORAL**
- **PAXIL**
  - **APOTEX INC**
    - EQ 10MG BASE/5ML A077395 001 Dec 05, 2006

**TABLET; ORAL**
- **PAXIL**
  - **APOTEX TECHNOLOGIES**
    - EQ 50MG BASE N020031 004 Dec 29, 1992

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

#### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

<table>
<thead>
<tr>
<th><strong>PAZOPANIB HYDROCHLORIDE</strong></th>
<th><strong>TABLET;ORAL</strong></th>
<th><strong>VOTRIENT</strong></th>
<th><strong>NOVARTIS PHARMS CORP</strong></th>
<th><strong>EQ 400MG BASE</strong></th>
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<tr>
<th><strong>PEGINESATIDE ACETATE</strong></th>
<th><strong>SOLUTION;INTRAVENOUS, SUBCUTANEOUS</strong></th>
<th><strong>OMONTYS</strong></th>
<th><strong>TAKEDA PHARMS USA</strong></th>
<th><strong>EQ 10MG BASE/ML (EQ 10MG BASE/ML)</strong></th>
<th><strong>N202799 007 Mar 27, 2012</strong></th>
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<td><strong>OMONTYS PRESERVATIVE FREE</strong></td>
<td><strong>TAKEDA PHARMS USA</strong></td>
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<td><strong>EQ 6MG BASE/0.5ML (EQ 6MG BASE/0.5ML)</strong></td>
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| **PEMIROLAST POTASSIUM** | **SOLUTION/DROPS;OPHTHALMIC** | **ALAMAST** | **SANTEN 0.1%** | **N021079 001 Sep 24, 1999** |

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<tr>
<th><strong>PEMOLINE</strong></th>
<th><strong>TABLET;ORAL</strong></th>
<th><strong>CYLERT</strong></th>
<th><strong>ABBOTT</strong></th>
<th><strong>18.75MG</strong></th>
<th><strong>N016832 001</strong></th>
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<tr>
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<td><strong>37.5MG</strong></td>
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<td><strong>75MG</strong></td>
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<th><strong>ACTAVIS ELIZABETH</strong></th>
<th><strong>18.75MG</strong></th>
<th><strong>A075595 001 Feb 28, 2000</strong></th>
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<td><strong>75MG</strong></td>
<td><strong>A075595 003 Feb 28, 2000</strong></td>
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| **FOSSUM PHARMA** | **18.75MG** | **A075286 001 Dec 27, 1999** |
|                  | **37.5MG**   | **A075286 002 Jun 30, 1999** |
|                  | **75MG**     | **A075286 003 Jun 30, 1999** |

| **MALLINCKRODT** | **18.75MG** | **A075726 003 Mar 30, 2001** |
|                 | **37.5MG**  | **A075726 002 Mar 30, 2001** |
|                 | **75MG**    | **A075726 001 Mar 30, 2001** |

| **TEVA PHARMS** | **18.75MG** | **A075530 003 Feb 22, 2000** |
|                | **37.5MG**  | **A075530 001 Jan 29, 1999**  |
|                | **75MG**    | **A075530 002 Jan 29, 1999**  |

| **VINTAGE PHARMS** | **18.75MG** | **A075328 001 Apr 19, 2000** |
|                   | **37.5MG**  | **A075328 002 Apr 19, 2000**  |
|                   | **75MG**    | **A075328 003 Apr 19, 2000**  |

| **WATSON LABS**  | **18.75MG** | **A075287 001 Jun 13, 2001** |
|                 | **37.5MG**  | **A075287 002 Sep 18, 2000** |
|                 | **75MG**    | **A075287 003 Sep 18, 2000**  |

| **TABLET, CHEWABLE;ORAL** | **CYLERT** | **ABBOTT** | **37.5MG** | **N017703 001** |

| **FEBRUTOLOL SULFATE** | **TABLET;ORAL** | **LEVATOL** | **+ AUXILIUM PHARMS LLC** | **10MG ** | **N018976 001 Dec 30, 1987** |
|                        |                |            |                         | **20MG ** | **N018976 004 Jan 05, 1989** |

| **PENICILLAMINE** | **CAPSULE;ORAL** | **CUPRIMINE** | **ATON** | **125MG** | **N019853 002** |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
<thead>
<tr>
<th>Product Description</th>
<th>Company</th>
<th>Unit Strength</th>
<th>Federal Register Note</th>
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<tr>
<td><em>Penicillin G Benzathine</em></td>
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<tr>
<td><strong>Penicillin G Benzathine</strong></td>
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<td><strong>Penicillin G Potassium</strong></td>
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</tbody>
</table>
**DISCONTINUED DRUG PRODUCT LIST**

**See List Footnote**

**PENICILLIN G POTASSIUM**

**TABLET; ORAL**

**PENICILLIN G POTASSIUM**

- 250,000 UNITS: A060781 002
- 400,000 UNITS: A060781 003
- 500,000 UNITS: A060781 005
- 800,000 UNITS: A060781 004

**PUREPAC PHARM**

- 200,000 UNITS: A061588 001
- 250,000 UNITS: A061588 002
- 400,000 UNITS: A061588 003

**TEVA**

- 200,000 UNITS: A060306 001
- 250,000 UNITS: A060306 002
- 400,000 UNITS: A060306 003
- 500,000 UNITS: A060306 004

**WYETH AYERST**

- 200,000 UNITS: A060413 001
- 250,000 UNITS: A060413 002
- 400,000 UNITS: A060413 003

**PENTIDS '200'**

- APOTHECON: 200,000 UNITS: A062155 001

**PENTIDS '250'**

- APOTHECON: 250,000 UNITS: A062155 002

**PENTIDS '400'**

- APOTHECON: 400,000 UNITS: A060392 004
- 400,000 UNITS: A062155 003

**PENTIDS '800'**

- APOTHECON: 800,000 UNITS: A060392 005
- 800,000 UNITS: A062155 004

**PFIZERPEN G**

- **PFIZER**
  - 50,000 UNITS: A060075 001
  - 100,000 UNITS: A060075 002
  - 200,000 UNITS: A060075 003
  - 250,000 UNITS: A060075 004
  - 400,000 UNITS: A060075 005
  - 800,000 UNITS: A060075 006

**PENICILLIN G PROCAINE**

**INJECTABLE; INJECTION**

**DURACILLIN A.S.**

- LILLY: 300,000 UNITS/ML: A060093 001

**PENICILLIN G PROCAINE**

- **CONSOLIDATED PHARM**
  - 300,000 UNITS/ML: A060800 001
  - 600,000 UNITS/1.2ML: A060800 002

**PARKE DAVIS**

- 300,000 UNITS/ML: A062029 001

**PFIZER**

- 300,000 UNITS/VIAL: A060099 001
  - 1,500,000 UNITS/VIAL: A060099 002

**PFIZERPEN-AS**

- **PFIZER**
  - 300,000 UNITS/ML: A062866 001
  - 600,000 UNITS/ML: A062866 002

**PENICILLIN G SODIUM**

**INJECTABLE; INJECTION**

**PENICILLIN G SODIUM**

- **BRISTOL MYERS SQUIBB**
  - 5,000,000 UNITS/VIAL: A061935 001

- **COPANOS**
  - 5,000,000 UNITS/VIAL: A061051 001

- **PHARMACIA AND UPJOHN**
  - 1,000,000 UNITS/VIAL: A061046 001

**INJECTABLE; INTRAMUSCULAR, INTRAVENOUS**

**PENICILLIN G SODIUM**

- **WATSON LABS INC**
  - 5,000,000 UNITS/VIAL: A063014 001 Sep 13, 1988

**PENICILLIN V**

**FOR SUSPENSION; ORAL**

**V-CILLIN**

- LILLY: 125MG/0.6ML: A060002 001

**PENICILLIN V POTASSIUM**

**FOR SOLUTION; ORAL**

**BEEPEN-VK**

- **GLAXOSMITHKLINE**
  - EQ 125MG BASE/5ML: A062270 001
  - EQ 250MG BASE/5ML: A062270 002

**BETAPEN-VK**

- **APOTHECON**
  - EQ 125MG BASE/5ML: A061149 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### PENICILLIN V POTASSIUM

**FOR SOLUTION; ORAL**

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<th>Product</th>
<th>Strength</th>
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<td>Betafen-VK</td>
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<td>A061149 002</td>
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<td>Ledercin-VK</td>
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<td>Pen-Vee K</td>
<td>EQ 125MG BASE/5ML</td>
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<td>Penicillin V Potassium</td>
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<td>Vertids</td>
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<td>Vertids '125'</td>
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<td>Apothecan</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### PENICILLIN V POTASSIUM

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### VEETIDS

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### PENTAGASTRIN

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<table>
<thead>
<tr>
<th>Strength</th>
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<tbody>
<tr>
<td>0.25MG/ML **</td>
<td>N017048 001</td>
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### PENTAMIDINE ISETHIONATE

<table>
<thead>
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<th>For Solution; Inhalation</th>
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<tr>
<td>NEBUVENT</td>
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<table>
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<tr>
<td>FRESENIUS KABI USA</td>
<td>N019887 002</td>
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### PENTACARINAT

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<tr>
<td>ARMOUR PHARM</td>
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<tr>
<td>PENTAMIDINE ISETHIONATE</td>
</tr>
<tr>
<td>BAXTER HLSHCARE</td>
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<tr>
<td>HOSPIRA</td>
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<tr>
<td>WATSON LABS</td>
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<table>
<thead>
<tr>
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<tr>
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<td>N018238 001</td>
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<tr>
<td>600MG/VIAL</td>
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<td>300MG/VIAL</td>
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### PENTAZOCINE HYDROCHLORIDE

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<tbody>
<tr>
<td>TALWIN 50</td>
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<td>SANOFI AVENTIS US</td>
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<table>
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### PENTAZOCINE LACTATE

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<td>+ HOSPIRA</td>
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<table>
<thead>
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<tbody>
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<td>EQ 30MG BASE/ML</td>
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### PENTETATE CALCIUM TRISODIUM YB-169

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### PENTOBARBITAL

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<tbody>
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### PENTOBARBITAL SODIUM

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<tr>
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<td>50MG</td>
<td>A084093 001</td>
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### SODIUM PENTOBARBITAL

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<td>EVERYLIFE</td>
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<td>HALSEY</td>
<td>A084677 001</td>
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<tr>
<td>IVAX SUB TEVA PHARMS</td>
<td>A083461 001</td>
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<tr>
<td>PARKE DAVIS</td>
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<td>PERRIGO</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
# Discontinued Drug Product List

**See List Footnote**

## Pentobarbital Sodium
### Capsule; Oral
- SODIUM PENTOBARBITAL
  - PUREPAC PHARM: 100MG
  - VALEANT PHARM INTL: 100MG
  - WATSON LABS: 100MG
  - WYETH AYERST: 100MG

### Injectable; Injection
- PENTOBARBITAL SODIUM
  - ELKINS SINN: 50MG/ML
  - SODIUM PENTOBARBITAL
  - WYETH AYERST: 50MG/ML

### Suppository; Rectal
- NEMBUTAL
  - OAK PHARMS: 30MG, 60MG, 120MG, 200MG

### Tablet; Oral
- PENTOBARBITAL SODIUM
  - VITARINE: 100MG
- SODIUM PENTOBARBITAL
  - NEXGEN PHARMA INC: 100MG

## Pentolinium Tartrate
### Injectable; Injection
- ANSOLYSEN
  - WYETH AYERST: 10MG/ML

## Pentoxifylline
### Tablet, Extended Release; Oral
- PENTOXIFYLLINE
  - ACTAVIS ELIZABETH: 400MG
  - HERITAGE PHARMS INC: 400MG
  - IMPAX LABS: 400MG
  - PLIVA: 400MG
  - TEVA: 400MG, 200MG, 120MG
  - WATSON LABS: 400MG

### Trental
- + US PHARM HOLDINGS: 400MG **

## Perfluoron
### Liquid; Oral
- ALLIANCE PHARM: 100%

## Perfluoropolyethylene
### Paste; Topical
- SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS
  - US ARMY: 50%; 50%

## Pergolide Mesylate
### Tablet; Oral
- PERGOLIDE MESYLATE
  - IVAX SUB TEVA PHARMS: EQ 0.05MG BASE, EQ 0.25MG BASE
  - PAR PHARM: EQ 0.05MG BASE, EQ 0.25MG BASE
  - PERMAX: EQ 0.05MG BASE, EQ 0.25MG BASE
  - VALEANT PHARM INTL: EQ 0.05MG BASE

### Pereindopril Erbumine
### Tablet; Oral
- ACEON
  - + SYMPLEMED PHARMS LLC: 2MG, 4MG, 8MG

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

<table>
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<th>Formulation</th>
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<th>Approval Date</th>
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<td><strong>PERINDOPRIL ERBUMINE</strong></td>
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<td>A090463 003</td>
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<td>APOTEX</td>
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<td>LUPIN LTD</td>
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**PERPHENAZINE**

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<td></td>
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<td>SCHERING</td>
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**PHENACEMIDE**

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**PHENAZOPYRIDINE HYDROCHLORIDE; SULFAMETHOXAZOLE**

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<th>Formulation</th>
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**PHENAZOPYRIDINE HYDROCHLORIDE; SULFAMETHOXAZOLE; TRIMETHOPRIM**

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<th>Formulation</th>
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<tbody>
<tr>
<td><strong>TABLET; ORAL</strong></td>
<td>SULFAMETHOXAZOLE AND TRIMETHOPRIM AND PHENAZOPYRIDINE HYDROCHLORIDE</td>
<td>N021105 001</td>
<td>Jun 26, 2001</td>
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**PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE**

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**PHENDIMETRAZINE TARTRATE**

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<td>PHENAZINE</td>
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<td><strong>PHENDIMETRAZINE TARTRATE</strong></td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote

PHENDIMETRAZINE TARTRATE
CAPSULE; ORAL
PHENDIMETRAZINE TARTRATE
VITARINE 35MG A086403 001
35MG A086408 001
35MG A086410 001
35MG A087424 001

SPRX-3
SOLVAY 35MG A085897 001

STATOBEX
TEVA 35MG A085507 001

X-TROZINE
SHIRE RICHWOOD 35MG A087394 001 Sep 22, 1982

CAPSULE, EXTENDED RELEASE; ORAL
BONTRIL
VALEANT 105MG A088021 001 Sep 21, 1982

MELFIAT-105
NUMARK 105MG A087487 001 Oct 13, 1982

PHENDIMETRAZINE TARTRATE
GRAHAM DM 105MG A087214 001 May 26, 1982
105MG A088020 001 Aug 16, 1982
105MG A088028 001 Aug 16, 1982
105MG A088062 001 Sep 13, 1982
105MG A088063 001 Sep 10, 1982
105MG A088111 001 Oct 18, 1982

VIRTUS PHARMS
SPRX-105
NUMARK 105MG A088024 001 Dec 22, 1982

X-TROZINE L.A.
SHIRE RICHWOOD 105MG A087371 001 Aug 24, 1982

TABLET; ORAL
ADPHEN
FERNDALE LABS 35MG A083655 001

ALPHAZINE
SANDOX 35MG A085034 001

CAM-METRAZINE
ABC HOLDING 35MG A085511 001
CAMALL 35MG A085756 001
CHARTWELL RX 35MG A083922 001
35MG A085318 001
35MG A085320 001
35MG A085321 001

DI-METREX
PVT FORM 35MG A085698 001

MELFIAT
NUMARK 35MG A083790 002

METRA
FOREST PHARMS 35MG A083754 001

PHENAZINE
MAST MM 35MG A087305 001

PHENAZINE-35
ABC HOLDING 35MG A085512 001

PHENDIMETRAZINE TARTRATE
BARR 35MG A083644 001
35MG A083684 001
35MG A083686 001
35MG A083687 001
35MG A084831 001
35MG A084834 001
35MG A084835 001

CHARTWELL RX 35MG A085761 001
35MG A085941 001 Jun 27, 1983

FERNDALE LABS 35MG A086834 001 Sep 15, 1983

INWOOD LABS 35MG A084740 001
35MG A084742 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Phendimetrazine Tartrate

**Tablet; Oral**

<table>
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<th>Brand</th>
<th>Strength</th>
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<td>KV PHARM</td>
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<td>NEXGEN PHARMA INC</td>
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<td>USL PHARMA</td>
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<td>X-TROZINE</td>
<td>SHIRE RICHWOOD</td>
<td>35mg</td>
<td>A086551 001</td>
</tr>
<tr>
<td>X-TROZINE</td>
<td>SHIRE RICHWOOD</td>
<td>35mg</td>
<td>A086552 001</td>
</tr>
<tr>
<td>X-TROZINE</td>
<td>SHIRE RICHWOOD</td>
<td>35mg</td>
<td>A086553 001</td>
</tr>
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<td>X-TROZINE</td>
<td>SHIRE RICHWOOD</td>
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### Phenindione

**Tablet; Oral**

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<tr>
<th>Brand</th>
<th>Strength</th>
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<th>Notes</th>
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<tbody>
<tr>
<td>SANOFI AVENTIS US</td>
<td>50mg</td>
<td>N008767 002</td>
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### Phendimetrazine Hydrochloride

**Tablet; Oral**

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<th>Brand</th>
<th>Strength</th>
<th>NDC Number</th>
<th>Notes</th>
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<tbody>
<tr>
<td>BOEHRINGER INGELHEIM</td>
<td>25mg</td>
<td>N010460 005</td>
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**Tablet, Extended Release; Oral**

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<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>BOEHRINGER INGELHEIM</td>
<td>50mg</td>
<td>N011752 004</td>
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</tr>
<tr>
<td>BOEHRINGER INGELHEIM</td>
<td>75mg</td>
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### Phenprocoumon

**Tablet; Oral**

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<tbody>
<tr>
<td>ORGANON USA INC</td>
<td>3mg</td>
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### Phensuximide

**Capsule; Oral**

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<tr>
<td>MILONTIN</td>
<td>PARKE DAVIS</td>
<td>500mg</td>
<td>N008855 004</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## PHENTERMINE HYDROCHLORIDE

**CAPSULE; ORAL**

<table>
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<th>Brand Name</th>
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<th>NDC Code</th>
<th>Date Approved</th>
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<tbody>
<tr>
<td>FASTIN</td>
<td>30MG</td>
<td>N017352 001</td>
<td>Mar 17, 1988</td>
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<tr>
<td>OBESTIN-30</td>
<td>30MG</td>
<td>A087144 001</td>
<td>Sep 8, 1982</td>
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<td>OBY-TRIM</td>
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<td>A087764 001</td>
<td>Mar 18, 1982</td>
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<td>SHIRE RICHWOOD</td>
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<td>A086511 001</td>
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<td>ONA-MAST</td>
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<td>A086516 001</td>
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<td>A085417 001</td>
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<td>A08503 001</td>
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<td>TEVA</td>
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<td>TG UNITED INC</td>
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**TABLET; ORAL**

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<tbody>
<tr>
<td>ONA-MAST</td>
<td>8MG</td>
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<td>ABLE</td>
<td>37.5MG</td>
<td>A04027 001</td>
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<td>8MG</td>
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<td>A085553 001</td>
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<td>8MG</td>
<td>A085671 001</td>
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<td>SANDOZ INC</td>
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<td>A088605 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

### 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

**DISCONTINUED DRUG PRODUCT LIST**

### PHENTERMINE HYDROCHLORIDE

**TABLET; ORAL**

<table>
<thead>
<tr>
<th>Product</th>
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<td>WATSON LABS 8MG</td>
<td>A085739 001</td>
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<tr>
<td>PHENTERMINE HYDROCHLORIDE</td>
<td>TORA 8MG</td>
<td>A084035 001</td>
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<td>PHENTERMINE HYDROCHLORIDE</td>
<td>WILPO 8MG **</td>
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<tr>
<td>PHENTERMINE HYDROCHLORIDE</td>
<td>SANDOIZ 8MG **</td>
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<tr>
<td>PHENTERMINE HYDROCHLORIDE</td>
<td>SUPRENZA 15MG **</td>
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### PHENTERMINE RESIN COMPLEX

**CAPSULE, EXTENDED RELEASE; ORAL**

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<th>Approval Date</th>
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<tbody>
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<td>UCB INC EQ 15MG BASE **</td>
<td>N011613 004</td>
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</tr>
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<td>PHENTERMINE RESIN 30</td>
<td>PHARM RES ASSOC 50%</td>
<td>N011695 002</td>
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<tr>
<td>PHENTERMINE RESIN COMPLEX</td>
<td>LANNETT CO INC EQ 15MG BASE</td>
<td>A040872 002</td>
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</tr>
<tr>
<td>PHENTERMINE RESIN COMPLEX</td>
<td>LANNETT CO INC EQ 30MG BASE</td>
<td>A040872 002</td>
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### PHENTOLAMINE MESYLATE

**INJECTABLE; INJECTION**

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<tr>
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<th>Strength</th>
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<tbody>
<tr>
<td>REGITINE</td>
<td>NOVAPTIS 5MG/VIAL **</td>
<td>N008278 003</td>
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### PHENYL AMINOSALICYLATE

**POWDER; ORAL**

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<th>Strength</th>
<th>Approval Date</th>
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<tbody>
<tr>
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<tr>
<td>PHENY-PAS-TEBAMIN</td>
<td>PHARM RES ASSOC 500MG</td>
<td>N011695 003</td>
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### PHENYLBUTAZONE

**CAPSULE; ORAL**

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<tbody>
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<td>AZOLID</td>
<td>SANOFI AVENTIS 100MG</td>
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<tr>
<td>BUTAZOLIDIN</td>
<td>NOVARTIS 100MG</td>
<td>N008319 009</td>
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<td>PHENYL BUTAZONE</td>
<td>FOSUN PHARMA 100MG</td>
<td>A087774 001</td>
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<td>IVAX PHARMS 100MG</td>
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<td></td>
<td>SUN PHARM INDUSTRIES 100MG</td>
<td>A088994 004</td>
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<td>WATSON LABS 100MG</td>
<td>A087756 001</td>
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<td>TABLET; ORAL</td>
<td>SANOFI AVENTIS 100MG</td>
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<td>BUTAZOLIDIN</td>
<td>NOVARTIS 100MG</td>
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<td>PHENYL BUTAZONE</td>
<td>FOSUN PHARMA 100MG</td>
<td>A084339 001</td>
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<td>SUN PHARM INDUSTRIES 100MG</td>
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<tr>
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<td>WATSON LABS 100MG</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"
**See List Footnote**

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

PREFRIN-A

ALLERGAN 0.12%; 0.1% N007953 001

PHENYTOIN

SUSPENSION; ORAL

DILANTIN-30

PARKE DAVIS 30MG/5ML N008762 002

PHENYTOIN

ACTAVIS MID ATLANTIC 125MG/5ML A089892 001 Sep 25, 1992

PHENYTOIN SODIUM

CAPSULE; ORAL

DIPHENYLAM SODIUM

LANNETT 30MG PROMPT A080857 001

100MG PROMPT A080857 002

EXTENDED PHENYTOIN SODIUM

ANI PHARMS INC

100MG EXTENDED A040436 001 Jun 20, 2003

100MG EXTENDED A089441 001 Dec 18, 1986

WOCKHARDT

30MG EXTENDED A040759 001 Dec 18, 2007

WOCKHARDT USA

100MG EXTENDED A040732 001 Jan 30, 2008

PHENYTEX

WATSON LABS

100MG EXTENDED A088711 001 Dec 21, 1984

PHENYTOIN SODIUM

PHARMERAL

WATSON LABS

100MG PROMPT A085435 001

100MG PROMPT A085894 001

PROMPT PHENYTOIN SODIUM

ANI PHARMS INC

100MG PROMPT A080259 001

WATSON LABS

100MG PROMPT A080905 001

INJECTABLE; INJECTION

DILANTIN

PARKE DAVIS

50MG/ML N010151 001

PHENYTOIN SODIUM

FRESENIUS KABI USA

50MG/ML A089003 001 May 31, 1985

HOSPIRA

50MG/ML A089521 001 Mar 17, 1987

50MG/ML A089744 001 Dec 18, 1987

MARGAM PHARMS LLC

50MG/ML A089501 001 Oct 13, 1987

50MG/ML A089779 001 Nov 27, 1992

SMITH AND NEPHEW

50MG/ML A088519 001 Dec 19, 1984

50MG/ML A088521 001 Dec 18, 1984

SOLOPAK

50MG/ML A088520 001 Dec 17, 1984

WARNER CHILCOTT

50MG/ML A089900 001 Mar 30, 1990

WATSON LABS

50MG/ML A085434 001

PHYTONADIONE

INJECTABLE; INJECTION

AQUAMEPHYTON

+ TELIGENT

1MG/0.5ML ** N012223 002

+ 10MG/ML ** N012223 001

KONAKION

ROCHE

1MG/0.5ML N011745 001

10MG/ML N011745 003

PHYTONADIONE

GLAXOSMITHKLINE

1MG/0.5ML A084060 001

10MG/ML A084060 002

VITAMIN K1

HOSPIRA

10MG/ML A087956 001 Jul 25, 1983

PILOCARPINE

INSERT, EXTENDED RELEASE; OPHTHALMIC

OCUSET PILO-20

AKORN 5MG N017431 001

OCUSET PILO-40

AKORN 11MG N017548 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

PILOCARPINE HYDROCHLORIDE
GEL; OPHTHALMIC
PILOFINE HS
ALCON 4%

PINACIDIL
CAPSULE, EXTENDED RELEASE; ORAL
PINDAC
LEO PHARM 12.5MG
25MG

PINDOLOL
TABLET; ORAL
PINDOLOL
G AND W LABS INC 5MG
5MG
5MG
10MG
10MG
10MG
MYLAN PHARMS INC 5MG
10MG
10MG
NOSTRUM LABS 5MG
10MG
10MG
PUREPAC PHARM 5MG
10MG
WATSON LABS 5MG
10MG
VISKEN
+ NOVARTIS 5MG **
+ 10MG **

PIPECURONIUM BROMIDE
INJECTABLE; INJECTION
ARDUAN
ORGANON USA INC 10MG/VIAL

PIPERACETAZINE
TABLET; ORAL
QUIDE
DOW PHARM 10MG
25MG

PIPERACILLIN SODIUM
INJECTABLE; INJECTION
PIPACIL
WYETH PHARMS INC EQ 2GM BASE/VIAL
+ EQ 2GM BASE/VIAL **
+ EQ 3GM BASE/VIAL
+ EQ 4GM BASE/VIAL
+ EQ 4GM BASE/VIAL **
+ EQ 40GM BASE/VIAL **

PIPERAZINE CITRATE
SYRUP; ORAL
ANTEPAR
GLAXOSMITHKLINE EQ 500MG BASE/5ML
BRYREL
SANOFI AVENTIS US EQ 500MG BASE/5ML
MULTIFUGE
BLULINE EQ 500MG BASE/5ML
PIPERAZINE CITRATE
ALPHARMA US PHARMS EQ 500MG BASE/5ML
LANNETT
LUITPOLD EQ 500MG BASE/5ML
VERMIDOL
SOLVAY EQ 500MG BASE/5ML
TABLET; ORAL
ANTEPAR
GLAXOSMITHKLINE EQ 500MG BASE

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
<table>
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<th>Formulation</th>
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<td>Impax Labs</td>
<td>A080874 001</td>
<td>250MG BASE</td>
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<td>Piperonyl Butoxide; Pyrethrins</td>
<td>Aerosol; Topical</td>
<td>Bayer Healthcare LLC</td>
<td>N021043 001</td>
<td>4%; EQ 0.33% BASE Mar 07, 2000</td>
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<td>Pipobroman</td>
<td>Tablet; Oral</td>
<td>Abbott</td>
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<td>Piputerol Acetate</td>
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<td>Medicis</td>
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<td>Valeant Pharm</td>
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<td>A090184 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
POLYESTRADIOL PHOSPHATE
INJECTABLE; INJECTION
ESTRADURIN
WYETH AYERST
40MG/AMP
N010753 001

POLYETHYLENE GLYCOL 3350
FOR SOLUTION; ORAL
POLYETHYLENE GLYCOL 3350
BRECKENRIDGE PHARM
17GM/SCOOPFUL
A077736 001 May 26, 2006
PADOCK LLC
17GM/SCOOPFUL
A090567 001 Oct 15, 2009
TEVA PHARMS
17GM/SCOOPFUL
A077445 001 May 04, 2006

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE
FOR SOLUTION; ORAL
PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE
MYLAN
420GM/BOT; 1.48GM/BOT; 5.72GM/BOT; 11.2GM/BOT
A090409 001 Apr 02, 2010

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE
FOR SOLUTION; ORAL
CO-LEYE
MYLAN SPECIALITY LP
120GM/PACKET; 1.49GM/PACKET; 3.36GM/PACKET
T; 2.92GM/PACKET; 11.36GM/PACKET
227.1GM/BOT; 2.82GM/BOT; 6.36GM/PAC
RET; 5.53GM/PACKET; 21.5GM/PACKET
227.1GM/BOT; 2.82GM/BOT; 6.36GM/BOT; 5.53G
N/BOT; 21.5GM/BOT
240GM/BOT; 2.98GM/BOT; 6.72GM/BOT; 5.84GM/
BOT; 22.72GM/BOT
360GM/PACKET; 4.47GM/PACKET; 10.08GM/PACK
ET; 8.76GM/PACKET; 34.08GM/PACKET
N018983 005 Oct 26, 1984

CO-LEYE-FLAVORED
MYLAN SPECIALITY LP
227.1GM/BOT; 2.82GM/BOT; 6.36GM/BOT; 5.53G
M/BOT; 21.5GM/BOT
240GM/BOT; 2.98GM/BOT; 6.72GM/BOT; 5.84GM/
BOT; 22.72GM/BOT
N018983 008 Nov 14, 1991

PEG 3350 AND ELECTROLYTES
MYLAN
236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/
BOT; 22.74GM/BOT
A090928 001 Jan 28, 2010

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES
PADOCK LLC
240GM/BOT; 2.98GM/BOT; 6.72GM/BOT; 5.84GM/
BOT; 22.72GM/BOT
A090712 001 Feb 25, 2010

FOR SUSPENSION; ORAL
VINTAGE PHARMS
240GM/BOT; 2.98GM/BOT; 6.72GM/BOT; 5.84GM/
BOT; 22.72GM/BOT
A073428 001 Jan 28, 1992

COLOVAGE
DYNAPHARM
227.1GM/BOT; 2.82GM/BOT; 6.36GM/PAC
RET; 5.53GM/PACKET; 21.5GM/PACKET
A071320 001 Apr 20, 1988

E-Z-EM PREP LYTE
E Z EM
236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/
BOT; 22.74GM/BOT
A071278 001 Nov 21, 1988

GLYCOPREP
GOLDLINE
236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/
BOT; 22.74GM/BOT
A072319 001 Dec 23, 1988

GO-EVAC
VINTAGE PHARMS
236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/
BOT; 22.74GM/BOT
A073433 001 Apr 28, 1992

PEG-LYTE
SANDOZ
236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/
BOT; 22.74GM/BOT
A073098 001 Aug 31, 1993

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
POTASSIUM CHLORIDE
INJECTABLE; INJECTION

POTASSIUM CHLORIDE
1.5MEQ/ML  A083345 001
2MEQ/ML  A083345 002
2.4MEQ/ML  A080205 004
3.2MEQ/ML  A080205 005

INTL MEDICATION
2MEQ/ML  A083163 001
LILLY
2MEQ/ML  N07865 002
LUITPOLD
2MEQ/ML  A080221 001
2MEQ/ML  A080736 001
2MEQ/ML  A087584 001
2MEQ/ML  A087585 001
MILES
1MEQ/ML  A080195 002
2MEQ/ML  A080195 001
3MEQ/ML  A080195 003
4MEQ/ML  A080195 004

PHARMA SERVE NY
2MEQ/ML  A086297 001
2MEQ/ML  A081762 001 Mar 08, 1983

WATSON LABS
2MEQ/ML  A086208 001
2MEQ/ML  A089163 001 Mar 10, 1988
2MEQ/ML  A089421 001 Jan 02, 1987

POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER
+ ICU MEDICAL INC
2MEQ/ML

TABLET, EXTENDED RELEASE; ORAL
K+10
FUTURE PAK  10MEQ  A070999 001 Oct 22, 1987
K+8
FUTURE PAK  8MEQ  A070998 001 Jan 25, 1993
KAON CL
SAVAGE LABS  6.7MEQ  N017046 001
KAON CL-10
SAVAGE LABS  10MEQ  N017046 002

KLOTRIX
+ APOTHECON
10MEQ  N017850 001

POTASSIUM CHLORIDE
COPLEY PHARM
8MEQ  A070618 001 Sep 09, 1987
N+ SCHERING
20MEQ  A076270 001 Jun 27, 1983
+ SLOW-K
10MEQ **  N019439 002 Jun 13, 1986
+ 20MEQ **  N019439 001 Jun 13, 1986

NOVARTIS
8MEQ  N017476 002

TEN-K
NOVARTIS  10MEQ  N019381 001 Apr 16, 1986

POTASSIUM CHLORIDE; SODIUM CHLORIDE
INJECTABLE; INJECTION
POTASSIUM CHLORIDE 0.037% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN  37MG/100ML;900MG/100ML  N019708 001 Sep 29, 1989
POTASSIUM CHLORIDE 0.075% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN  75MG/100ML;900MG/100ML  N019708 002 Sep 29, 1989
POTASSIUM CHLORIDE 0.11% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN  110MG/100ML;900MG/100ML  N019708 003 Sep 29, 1989
POTASSIUM CHLORIDE 0.22% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN  220MG/100ML;900MG/100ML  N019708 005 Sep 29, 1989
POTASSIUM CHLORIDE 0.224% IN SODIUM CHLORIDE 0.9%
+ BAXTER HLTHCARE  224MG/100ML;900MG/100ML  N017648 003
POTASSIUM CHLORIDE 0.3% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
B BRAUN  300MG/100ML;900MG/100ML  N019708 006 Sep 29, 1989
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER
B BRAUN  75MG/100ML;900MG/100ML  N018722 001 Nov 09, 1982
BAXTER HLTHCARE  75MG/100ML;900MG/100ML  N017648 004
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER
B BRAUN  150MG/100ML;900MG/100ML  N018722 002 Nov 09, 1982
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER
B BRAUN  220MG/100ML;900MG/100ML  N018722 003 Nov 09, 1982
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
B BRAUN  300MG/100ML;900MG/100ML  N018722 004 Nov 09, 1982

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
POTASSIUM CHLORIDE; SODIUM CHLORIDE; TROMETHAMINE

INJECTABLE; INJECTION
THAM-E
HOSPIRA
370MG/VIAL; 1.75GM/VIAL; 36GM/VIAL
N013025 001

POTASSIUM CITRATE

FOR SOLUTION; ORAL
POTASSIUM CITRATE
UT SW MEDCTR 10MEQ/PACKET **
N019647 001 Oct 13, 1988

POTASSIUM IODIDE

TABLET; ORAL
THYRO-BLOCK
MEDA PHARMS 130MG
N018307 001

POTASSIUM PERCHLORATE

CAPSULE; ORAL
PERCHLORACAP
MALLINCKRODT 200MG
N017551 001

POVIDONE-IODINE

SOLUTION; TOPICAL
E-Z PREP
CLINIPAD 10%
N019382 001 Jul 25, 1989

PRALIDOXIME CHLORIDE

INJECTABLE; INJECTION
BAXTER HLTHCARE CORP
300MG/ML
N018799 001 Dec 13, 1982

Pramipexole Dihydrochloride

TABLET; ORAL
BOEHRINGER INGELHEIM 1.25MG
N020667 004 Jul 01, 1997

Pramlintide Acetate

INJECTABLE; SUBCUTANEOUS
SYMLIN
ASTRAZENECA AB
EQ 3MG BASE/5ML (EQ 600MCG BASE/ML)
N021332 001 Mar 16, 2005

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
PRAVASTATIN SODIUM
TABLET; ORAL
* BRISTOL MYERS SQUIBB 10MG ** N019898 002 Oct 31, 1991
PRAVACHOL
MYLAN
10MG A077013 001 Oct 23, 2006
20MG A077013 002 Oct 23, 2006
40MG A077013 003 Oct 23, 2006
80MG A077013 004 Dec 28, 2007
PLIVA HRVATSKA DOO
10MG A077730 001 Nov 21, 2006
20MG A077730 002 Nov 21, 2006
30MG A077730 003 Nov 21, 2006
40MG A077730 005 Nov 21, 2006
RANBAXY LABS LTD
10MG A076445 001 Apr 23, 2007
20MG A076445 002 Apr 23, 2007
40MG A076445 003 Apr 23, 2007
80MG A076445 004 Apr 23, 2007

PRAZEPAM
CAPSULE; ORAL
CENTRAX
PARKE DAVIS 5MG N018144 001
10MG N018144 002
20MG N018144 003 May 10, 1982
USL PHARMA 5MG A070427 001 Nov 06, 1987
10MG A070428 001 Nov 06, 1987

PRAZOSIN HYDROCHLORIDE
CAPSULE; ORAL
AM THERAP
EQ 1MG BASE A072782 001 May 16, 1989
EQ 2MG BASE A072783 001 May 16, 1989
EQ 5MG BASE A072784 001 May 16, 1989
ANI PHARMS INC
EQ 1MG BASE A072577 002 May 16, 1989
EQ 2MG BASE A072577 001 May 16, 1989
EQ 5MG BASE A072577 003 May 16, 1989
DAVA PHARMS INC
EQ 1MG BASE A072705 001 May 16, 1989
EQ 2MG BASE A072706 001 May 16, 1989
EQ 5MG BASE A072707 001 May 16, 1989
PUREPAC PHARM
EQ 1MG BASE A072991 001 May 16, 1989
EQ 2MG BASE A072991 002 May 16, 1989
EQ 5MG BASE A072992 001 May 16, 1989
WATSON LABS
EQ 1MG BASE A072352 001 May 16, 1989
EQ 2MG BASE A072333 001 May 16, 1989
EQ 5MG BASE A072609 001 May 16, 1989

TABLET, EXTENDED RELEASE; ORAL
MINIPRESS XL
PFIZER 2.5MG N019775 001 Jan 29, 1992
5MG N019775 002 Jan 29, 1992

PREDNISOLONE
CREAM; TOPICAL
METI-DERM
SCHERING 0.5% N010209 002

SYPURP; ORAL
PREDNISOLONE
APOTEX INC 5MG/5ML A040570 001 Aug 25, 2005
15MG/5ML A040571 001 Aug 25, 2005
IVAX SUB TEVA PHARMS 15MG/5ML A040287 001 May 28, 1999
NESHER PHARMS 5MG/5ML A040423 001 Oct 22, 2001
15MG/5ML A040364 001 Apr 10, 2002
TEVA PHARMS 15MG/5ML A040322 001 Jan 19, 2000
WE PHARMS 15MG/5ML A040192 001 May 28, 1998
PRELONE
MURO 5MG/5ML A089654 001 Jan 17, 1989

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
**PRENISOLONE**

**TABLET; ORAL**

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**CORTALONE**

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**PRENISOLONE**

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**FERRANTE**

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<tr>
<td></td>
<td>2.5MG</td>
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**FOSUN PHARMA**

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<td>HEATHER</td>
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**IMPAX LABS**

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**IVAX SUB TEVA PHARMS**

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**MARSHALL PHARMA**

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**PHOENIX LABS NY**

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**PVT FORM**

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**SPERTI**

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**SUPERPHARM**

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**TEVA**

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**VALEANT PHARM INTL**

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**WATSON LABS**

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**STERANE**

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**PRENISOLONE ACETATE**

**INJECTABLE; INJECTION**

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<tr>
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**PRENISOLONE ACETATE**

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<td>A084492 001</td>
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<td>BEL MAR</td>
<td>25MG/ML</td>
<td>A083738 001</td>
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<td></td>
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<tr>
<td>CENT PHARMS</td>
<td>25MG/ML</td>
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<td>WATSON LABS</td>
<td>25MG/ML</td>
<td>A083398 001</td>
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<td>25MG/ML</td>
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<td></td>
<td>40MG/ML</td>
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**STERANE**

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<tbody>
<tr>
<td>PFIZER</td>
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<td>N011446 001</td>
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</tbody>
</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Prednisolone Acetate

**Suspension; Oral**
- **Flo-Pred Taro**
  - EQ 5 mg BASE/5 mL
  - EQ 15 mg BASE/5 mL
  - N022067 001 Jan 17, 2008
  - N022067 002 Jan 17, 2008

**Suspension/Drops; Ophthalmic**
- **Econopred Alcon**
  - 0.125%
  - N017468 001

**Prednisolone Acetate; Sulfacetamide Sodium**
- **Ointment; Ophthalmic**
  - **Cetapred Alcon**
    - 0.25%; 10%
  - **Metimyd Schering**
    - 0.5%; 10%
  - **Predsulfair Pharmafaire**
    - 0.5%; 10%
  - **Vasocidin Novartis**
    - 0.5%; 10%

**Suspension; Ophthalmic**
- **Isopto Cetapred Alcon**
  - 0.25%; 10%
  - N087547 001

**Suspension/Drops; Ophthalmic**
- **Metimyd Schering**
  - 0.5%; 10%
  - N010210 001

**Predamide**
- **Predsulfair Pharmafaire**
  - EQ 0.2%; 10%
  - EQ 0.5%; 10%

**Predamide Alkon**
- **Predsulfair Pharmafaire**
  - EQ 0.5%; 10%

**Predsulfair II Pharmafaire**
- **Vasocidin Novartis**
  - EQ 0.5%; 10%

**Suspension; Ophthalmic**
- **Sulphrin Bausch and Lomb**
  - 0.5%; 10%
  - N088809 001 Dec 28, 1982

### Prednisolone Sodium Phosphate

**Injetcable; Injection**
- **Hydeltrasol Merck**
  - EQ 20 mg PHOSPHATE/ML
  - N011583 002

**Prednisolone Sodium Phosphate Watson Labs**
- EQ 20 mg PHOSPHATE/ML
  - N080517 001

**Ointment; Ophthalmic, Otic**
- **Hydeltrasol Merck**
  - EQ 0.25% PHOSPHATE
  - N011028 001

**Solution; Oral**
- **Orapred**
  - CONCORDIA PHARMS INC EQ 15 mg BASE/5 mL**
  - A075117 001 Dec 14, 2000

**Prednisolone Sodium Phosphate Amneal Pharms**
- EQ 15 mg BASE/5 mL
  - A078345 003 Mar 10, 2009

**Prednisolone Sodium Phosphate Medicis Pharms**
- EQ 15 mg BASE/5 mL
  - A075250 001 Jul 12, 2002

**Prednisolone Sodium Phosphate Nesh Pharms**
- EQ 5 mg BASE/5 mL
  - A076982 001 May 24, 2005

**Prednisolone Sodium Phosphate Pharm Assoc**
- EQ 15 mg BASE/5 mL
  - A076988 001 May 24, 2005

**Prednisolone Sodium Phosphate Vintage Pharms**
- EQ 5 mg BASE/5 mL
  - A076123 001 Dec 23, 2002

**Prednisolone Sodium Phosphate We Pharms**
- EQ 5 mg BASE/5 mL
  - A078416 001 Oct 31, 2007

**Solution/Drops; Ophthalmic**
- **Inflamase Forte Novartis**
  - EQ 0.9% PHOSPHATE
  - A080751 002

**Inflamase Mild Novartis**
- EQ 0.11% PHOSPHATE
  - A080751 001

**Metretone Schering**
- EQ 0.5% PHOSPHATE
  - A083834 001

**Predair Pharmafaire**
- EQ 0.11% PHOSPHATE
  - A088415 001 Feb 29, 1984

**Predair Forte Pharmafaire**
- EQ 0.9% PHOSPHATE
  - A088165 001 Mar 28, 1983

**Prednisolone Sodium Phosphate Akorn**
- EQ 0.11% PHOSPHATE
  - A083358 001

**Prednisolone Sodium Phosphate Alcon Pharm Ltd**
- EQ 0.11% PHOSPHATE
  - A081043 001 Oct 24, 1991

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Discontinued Drug Product List

**39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST**

**See List Footnote**

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

#### Prednisone

**Tablet; Oral**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Strength</th>
<th>Code</th>
<th>Date Discontinued</th>
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<tbody>
<tr>
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<td>5mg</td>
<td>A085084</td>
<td>002</td>
</tr>
<tr>
<td></td>
<td>10mg</td>
<td>A087773</td>
<td>001 July 13, 1982</td>
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<tr>
<td></td>
<td>20mg</td>
<td>A086813</td>
<td>001</td>
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<tr>
<td></td>
<td>50mg</td>
<td>A086867</td>
<td>001</td>
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<tr>
<td></td>
<td>50mg</td>
<td>A087772</td>
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<tr>
<td>Whiteworth Town Plsn</td>
<td>2.5mg</td>
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<td>001</td>
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<tr>
<td></td>
<td>5mg</td>
<td>A080343</td>
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<td></td>
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<td>20mg</td>
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#### Prilocaine Hydrochloride

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<td>1% **</td>
<td>N014763</td>
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<td>2% **</td>
<td>N014763</td>
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<td></td>
<td>3% **</td>
<td>N014763</td>
<td>003</td>
</tr>
<tr>
<td>Citanest Plain + AstraZeneca</td>
<td>4% **</td>
<td>N014763</td>
<td>007</td>
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<td>Citanest Plain Dental + Dentsply Pharm</td>
<td>4%</td>
<td>N021382</td>
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#### Primidone

**Suspension; Oral**

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<tr>
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<th>Code</th>
<th>Date Discontinued</th>
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<tbody>
<tr>
<td>Nuro Pharma</td>
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**Tablet; Oral**

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<tbody>
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<td>Dr Reddy's Labs Ltd</td>
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<td>250mg</td>
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<td>Hikma Intl Pharmas</td>
<td>50mg</td>
<td>A040667</td>
<td>001 July 27, 2006</td>
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<td>Impax Labs</td>
<td>50mg</td>
<td>A040717</td>
<td>001 Feb 12, 2008</td>
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<td>Watson Labs</td>
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#### Probenecid

**Tablet; Oral**

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<td>+ Merck</td>
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#### Probenecid

**Capsule; Oral**

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<td>Ascot</td>
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<td>500mg</td>
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<td>ROXANE</td>
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<th>Company</th>
<th>Batch No</th>
<th>Date</th>
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<tr>
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<td>Capsule; Oral</td>
<td>500mg</td>
<td>Watson Labs</td>
<td>A083287</td>
<td>Jun 01, 1982</td>
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<tr>
<td>Procaenamide Hydrochloride</td>
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<td>250mg</td>
<td>Watson Labs</td>
<td>A087875</td>
<td>Jun 01, 1982</td>
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<td>Proke Davis</td>
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<td>Procapan</td>
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<td>250mg</td>
<td>Parke Davis</td>
<td>A087502</td>
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<td>Tablet; Oral</td>
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<td>Parke Davis</td>
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<td>Jan 01, 1982</td>
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<td>Abraaxis Pharm</td>
<td>A089416</td>
<td>Nov 17, 1986</td>
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<td>500mg/ML</td>
<td>Abraaxis Pharm</td>
<td>A089415</td>
<td>Nov 17, 1986</td>
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<td>Injection; Injection</td>
<td>500mg/ML</td>
<td>Hospira</td>
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<td>Aug 25, 1987</td>
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<td>Pronestyl</td>
<td>Injection; Injection</td>
<td>500mg/ML</td>
<td>International Medication</td>
<td>A088637</td>
<td>Jul 31, 1984</td>
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<td>Injection; Injection</td>
<td>500mg/ML</td>
<td>Phaffair</td>
<td>A088824</td>
<td>Nov 20, 1985</td>
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<td>Pronestyl</td>
<td>Injection; Injection</td>
<td>500mg/ML</td>
<td>Smith and Nephew</td>
<td>A088830</td>
<td>Nov 20, 1985</td>
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<td>Pronestyl</td>
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<td>Sandoz</td>
<td>A088531</td>
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<td>Watson Labs</td>
<td>A087080</td>
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<td>100mg/ML</td>
<td>West-Ward Pharm Int</td>
<td>A089029</td>
<td>Apr 17, 1986</td>
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<td>Apr 17, 1986</td>
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</tbody>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** See List Footnote

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<tr>
<th>Brand Name</th>
<th>Strength</th>
<th>Code</th>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

**PROGESTERONE**

**INSERT, EXTENDED RELEASE; INTRAUTERINE**

**PROGESTASERT**

ALZA 38MG N017553 001

**PROMAZINE HYDROCHLORIDE**

**CONCENTRATE; ORAL**

**SPARINE**

WYETH AYERST 30MG/ML N010942 001

100MG/ML N010942 004

**INJECTABLE; INJECTION**

PROMAZINE HYDROCHLORIDE

WATSON LABS 25MG/ML A084510 001

50MG/ML A084517 001

**SPARINE**

BAXTER HLTHCARE CORP 25MG/ML N010349 008

50MG/ML N010349 006

**SYRUP; ORAL**

SPARINE

WYETH AYERST 10MG/5ML N010942 003

**TABLET; ORAL**

SPARINE

WYETH AYERST 10MG N010348 006

25MG N010348 001

50MG N010348 002

100MG N010348 003

200MG N010348 004

**PROMETHAZINE HYDROCHLORIDE**

**INJECTABLE; INJECTION**

PHENERGAN

WYETH AYERST 25MG/ML N008857 002

50MG/ML N008857 003

**PROMETHAZINE HYDROCHLORIDE**

ABBOTT

25MG/ML A084223 001

50MG/ML A084222 001

AKORN

25MG/ML A083955 002

50MG/ML A083955 001

BEDFORD LABS

25MG/ML A040524 001 Mar 17, 2004

50MG/ML A040524 002 Mar 17, 2004

HOSPIRA

25MG/ML A040372 001 Jun 08, 2000

50MG/ML A040372 002 Jun 08, 2000

50MG/ML A083838 002

LUITPOLD

25MG/ML A040515 001 Mar 19, 2003

MARSAM PHARMS LLC

25MG/ML A089463 001 May 02, 1988

50MG/ML A089477 001 May 02, 1988

MYLAN INSTITUTIONAL

25MG/ML A040593 001 Nov 08, 2006

50MG/ML A040593 002 Nov 08, 2006

SANDOX

25MG/ML A040454 001 Aug 22, 2002

50MG/ML A040454 002 Aug 22, 2002

TEVA PHARMS USA

25MG/ML ** A040785 001 Sep 26, 2008

50MG/ML ** A040785 002 Sep 26, 2008

WATSON LABS

25MG/ML A083532 001

50MG/ML A084591 001

50MG/ML A080629 002

50MG/ML A083532 002

WOCKHARDT

25MG/ML A040785 001 Sep 26, 2008

50MG/ML A040785 002 Sep 26, 2008

ZIPAN-25

ALTANA 25MG/ML A083997 001

ZIPAN-50

ALTANA 50MG/ML A083997 002

**SUPPOSITORY; RECTAL**

PHENERGAN

+ MYLAN PHARMS INC 12.5MG ** N010926 002

+ 25MG ** N010926 001

+ 50MG ** N011689 001

**PROMETHACON**

POLYMEDICA 25MG A084901 001

50MG A084902 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## DISCONTINUED DRUG PRODUCT LIST

** See List Footnote

### PROMETHAZINE HYDROCHLORIDE

**SUPPOSITORY;RECTAL**

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**SYRUP;ORAL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

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**Notes:**

- The list includes discontinued drugs that were not withdrawn for safety or efficacy reasons.
- Each entry provides the brand name, strength, NDC number, and date of discontinuation.
PROPANEFONE HYDROCHLORIDE
TABLET; ORAL
  PROPANEFONE HYDROCHLORIDE
    NESHER PHARMS
    150MG A076193 001 Feb 07, 2002
    225MG A076193 002 Feb 07, 2002
    300MG A076193 003 Feb 07, 2002
  RYTHMOL
    GLAXOSMITHKLINE LLC
    150MG N019151 001 Nov 27, 1989
    225MG N019151 003 Nov 20, 1992
    300MG N019151 002 Nov 27, 1989

PROPANTHELINE BROMIDE
INJECTABLE; INJECTION
  PRO-BANTHINE
    GD SEARLE LLC
    30MG/VIAL N008843 001
  PRO-BANTHINE
    SHIRE
    7.5MG ** N008732 003
    15MG ** N008732 002
  PRO-PANTHELNE BROMIDE
    ASCOT
    15MG A087666 001 Oct 25, 1982
    HEATHER
    15MG A085780 001
    IMPAX LABS
    15MG A084541 002
    MYLAN
    15MG A083706 001
    PAR PHARM
    15MG A088377 001 Dec 08, 1983
    PVT FORM
    15MG A080977 001
    SANDOX
    15MG A080928 001
    TABLICAPS
    15MG A084428 001
    WATSON LABS
    15MG A083029 002
    15MG A083151 001
  WEST-WARD PHARMS INT
    7.5MG A080927 001

PROPONACAINE HYDROCHLORIDE
SOLUTION/DROPS; OPHTHALMIC
  RAINAIR
    PHARMAFAIR
    0.5% A088087 001 Jun 07, 1983
    OPHTHANE
    + APOTHECON
    0.5% ** N008883 001
    OPHTHETIC
    + ALLERGAN
    0.5% ** N012583 001
    PARACAINE
    OPTOPICS
    0.5% A087681 001 Aug 05, 1982
  PROPARACAINE HYDROCHLORIDE
    SOLA BARNES HIND
    0.5% A084144 001
    0.5% A084151 001

PROPIOLACTONE
SOLUTION; IRRIGATION
  BETAFAONE
    FOREST LABS N/A N011657 001

PROPIOMAZINE HYDROCHLORIDE
INJECTABLE; INJECTION
  LARGON
    WEST-WARD PHARMS INT
    20MG/ML N012382 002

PROPOFOL
INJECTABLE; INJECTION
  DIPRIVAN
    FRESENIUS KABI USA
    10MG/ML N019627 001 Oct 02, 1989
  PROPOFOL
    TEVA PARENTERAL
    10MG/ML A075392 001 Sep 19, 2000
    WEST-WARD PHARMS INT
    10MG/ML A074848 001 Apr 19, 2005

PROPOXYPHEN HYDROCHLORIDE
CAPSULE; ORAL
  DARVON
    XANODYNE PHARM
    32MG N010997 001
    65MG N010997 003
    DOLENE
    HERITAGE PHARMS INC
    65MG A080530 001

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### Discontinued Drug Product List

**See List Footnote**

#### Propoxyphene Hydrochloride Capsule, Oral

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#### Propoxyphene Napsylate Suspension, Oral

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#### Propranolol Hydrochloride Capsule, Extended Release, Oral

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**PROPRANOLOL HYDROCHLORIDE**

**TABLET; ORAL**

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**PROPYLIODONE**

**SUSPENSION; INTRATRACHEAL**

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**PROPYLTHIOURACIL**

**TABLET; ORAL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### PROTAMINE SULFATE
- **Injectable; Injection**
  - Protamine Sulfate
    - Lilly 10mg/ml **
      - Pharmacia and Upjohn 50mg/vial
        - West-Ward Pharmaceuticals Inc 10mg/ml

### PROTEIN HYDROLYSATE
- **Injectable; Injection**
  - Protein Hydrolysate
    - Aminosol 5%
      - AbbVie 5%
    - Hyprotigen 5%
      - B Braun 5%

### PROTIRELIN
- **Injectable; Injection**
  - Protirelin
    - Abbott
    - Thyrel TRH
      - Ferring

### PROTOKYLOL HYDROCHLORIDE
- **Tablet; Oral**
  - Protokylol Hydrochloride
    - Ventaire
      - Sanofi Aventis US 2mg

### PROTRIPTYLINE HYDROCHLORIDE
- **Tablet; Oral**
  - Protriptyline Hydrochloride
    - Vivactil
      - Teva Women 5mg **
        - Novafed 120mg
      - 10mg **
        - Sanofi Aventis 120mg

### PSEUDOEPHEDRINE HYDROCHLORIDE
- **Capsule, Extended Release; Oral**
  - Pseudoephedrine Hydrochloride
    - Novafed
      - Sanofi Aventis US 120mg
    - Sudafed 12 Hour
      - GlaxoSmithKline 120mg **

- **Capsule, Extended Release; Oral**
  - Pseudoephedrine Hydrochloride; Triprolidine Hydrochloride
    - Actifed
      - GlaxoSmithKline 120mg; 5mg
    - Tripolidine and Pseudoephedrine Hydrochlorides
      - KV Pharm 120mg; 5mg

### SYRUP; Oral
- **Syrup**
  - Actahist
    - Cenci 30mg/5ml; 1.25mg/5ml
    - Histafed
      - Cenci 30mg/5ml; 1.25mg/5ml
    - Myfed
      - USL Pharma 30mg/5ml; 1.25mg/5ml
    - Tritron
      - Newtron Pharmas 30mg/5ml; 1.25mg/5ml

### TABLET; Oral
- **Tablet; Oral**
  - AllerFed
    - PVT Form 60mg; 2.5mg
  - Corphed
    - Fosun Pharma 60mg; 2.5mg
    - Pseudoephedrine Hydrochloride and Triprolidine Hydrochloride
      - Sandoz 60mg; 2.5mg
    - Tritron
      - Newtron Pharmas 60mg; 2.5mg
  - Triphed
    - Teva 60mg; 2.5mg
    - Triprolidine and Pseudoephedrine
      - Watson Labs 60mg; 2.5mg
      - West Ward 60mg; 2.5mg
    - Triprolidine Hydrochloride and Pseudoephedrine Hydrochloride
      - Ivax Sub Teva Pharmas 60mg; 2.5mg

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Quetiapine Fumarate

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** See List Footnote

## Quinapril Hydrochloride

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** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>200mg</td>
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| **Quinidine Polyalacturonate** |  |
| Tablet; oral |  |
| Cardiqun | 275mg |
| Pharm Res Assoc |  |
|  |
|  |
| **Quinidine Sulfate** |  |
| Capsule; oral |  |
| CIN-QuIN |  |
| Solvay | 200mg |
| 300mg |
| Quinidine Sulfate |  |
| Lilly | 200mg |
|  |
|  |
| TABLET; ORAL |  |
| CIN-QuIN |  |
| Solvay | 100mg |
| 200mg |
| 300mg |
| Quinidine Sulfate |  |
| Barr | 200mg |
| Contract Pharmacal | 200mg |
| Cycle Pharma Ltd | 200mg |
| 300mg |
| DaVita Pharmaceuticals | 200mg |
| Elkins Sinn | 200mg |
| EveryLife | 200mg |
| Halsey | 200mg |
| Hikma Pharmaceuticals | 200mg |
| Impax Labs | 200mg |
| Ivax Sub Teva Pharmaceuticals | 200mg |
| King Pharmaceuticals | 200mg |
| K V Pharm | 200mg |
| Lannett | 200mg |
| Lederle | 200mg |
| Lilly | 200mg |
| Perrigo | 200mg |
| Pharmavite | 200mg |
| PurePac Pharm | 200mg |
| Sandox | 200mg |
| 300mg |
| Scherer Labs | 200mg |
| Sun Pharma Industries | 100mg |
| Superpharm | 200mg |
| Usl Pharma | 200mg |
| Valeant Pharma International | 200mg |
| Vangard | 200mg |
| Vintage Pharm | 200mg |
| Warner Chilcott | 200mg |
| Watson Labs | 100mg |
| 200mg |
| Whiteworth Town Plsn | 200mg |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### QUINIDINE SULFATE

**TABLET; ORAL**

| Brand Name | Strength | Company | NDC Number | Date
|------------|----------|---------|------------|------
| QUINORA | 200MG | Key Pharms | A083576 001 | 
| | 300MG | Schering | A085222 001 | 
| QUINIDEX | 300MG | Wyeth Pharms Inc | N012796 002 | 
| G AND W LABS INC | 300MG | | A040045 001 | Jun 30, 1994

### RABEPRAZOLE SODIUM

**TABLET, DELAYED RELEASE; ORAL**

| Brand Name | Strength | Company | NDC Number | Date
|------------|----------|---------|------------|------
| ACIPHEX | 10MG | Eisai Inc | N020973 001 | May 29, 2002

### RAMIPRIL

**TABLET, ORAL**

| Brand Name | Strength | Company | NDC Number | Date
|------------|----------|---------|------------|------
| ALTACE | 1.25MG | King Pfizer | N022021 001 | Feb 27, 2007
| | 2.5MG | | N022021 002 | Feb 27, 2007
| | 5MG | | N022021 003 | Feb 27, 2007
| | 10MG | | N022021 004 | Feb 27, 2007
| | 1.25MG | Apotex Inc | A091069 001 | Dec 02, 2015
| | 2.5MG | | A091069 002 | Dec 02, 2015
| | 5MG | | A091069 003 | Dec 02, 2015
| | 10MG | | A091069 004 | Dec 02, 2015
| | 1.25MG | Mylan Pharms Inc | A090650 001 | Jun 30, 2011
| | 2.5MG | | A090650 002 | Jun 30, 2011
| | 5MG | | A090650 003 | Jun 30, 2011
| | 10MG | | A090650 004 | Jun 30, 2011
| | 1.25MG | Zydus Pharms USA Inc | A090697 001 | Sep 24, 2009
| | 2.5MG | | A090697 002 | Sep 24, 2009
| | 5MG | | A090697 003 | Sep 24, 2009
| | 10MG | | A090697 004 | Sep 24, 2009

### RANITIDINE BISMUTH CITRATE

**TABLET, ORAL**

| Brand Name | Strength | Company | NDC Number | Date
|------------|----------|---------|------------|------
| TRITEC | 400MG | Glaxosmithkline | N020559 001 | Aug 08, 1996

### RANITIDINE HYDROCHLORIDE

**CAPSULE, ORAL**

| Brand Name | Strength | Company | NDC Number | Date
|------------|----------|---------|------------|------
| ZANTAC 150 | EQ 150MG BASE | Glaxosmithkline | A075564 001 | Oct 27, 2000
| ZANTAC 300 | EQ 300MG BASE | | A075564 002 | Oct 27, 2000

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
RANITIDINE HYDROCHLORIDE

GRANULE, EFFERVESCENT; ORAL
ZANTAC 150
GLAXO GRP LTD
EQ 150MG BASE/PACKET
N020251 002 Mar 31, 1994

INJECTABLE; INJECTION
RANITIDINE HYDROCHLORIDE
BEDFORD
EQ 25MG BASE/ML
A074764 001 Nov 19, 2004

ZANTAC IN PLASTIC CONTAINER
TELIGENT
EQ 1MG BASE/ML
N019593 002 Sep 27, 1991
EQ 50MG BASE/100ML
N019593 001 Dec 17, 1986

SYRUP; ORAL
RANITIDINE HYDROCHLORIDE
APOTEX INC
EQ 15MG BASE/ML
A077602 001 Sep 17, 2007
RANBAXY
EQ 15MG BASE/ML
A078448 001 Dec 13, 2007
WOCKHARDT
EQ 15MG BASE/ML
A079211 001 May 26, 2009
EQ 15MG BASE/ML
A079212 001 Feb 23, 2009

ZANTAC
+ GLAXO GRP LTD
EQ 15MG BASE/ML
N019675 001 Dec 30, 1988

TABLET; ORAL
RANITIDINE HYDROCHLORIDE
BOEHRINGER INGELHEIM
EQ 150MG BASE
A074662 001 Aug 29, 1997
EQ 300MG BASE
A074662 002 Aug 29, 1997
CONTRACT PHARMACAL
EQ 75MG BASE
A075094 001 Jun 21, 1999
MYLAN
EQ 150MG BASE
A074023 002 Aug 22, 1997
EQ 150MG BASE
A074552 001 Jul 30, 1998
EQ 300MG BASE
A074023 002 Aug 22, 1997
RANBAXY
EQ 75MG BASE
A075254 001 Jan 14, 2000
EQ 150MG BASE
A075000 001 Jan 30, 1998
EQ 300MG BASE
A075000 002 Jan 30, 1998
SANDOX
EQ 75MG BASE
A075519 001 Sep 26, 2002
SUN PHARM INDS LTD
EQ 75MG BASE
A075132 001 Jan 14, 2000
EQ 150MG BASE
A075439 001 Apr 19, 2000
EQ 300MG BASE
A075439 002 Apr 19, 2000
WATSON LABS
EQ 75MG BASE
A075212 001 Jan 14, 2000
EQ 150MG BASE
A074864 001 Oct 20, 1997
EQ 300MG BASE
A074864 002 Oct 20, 1997
WATSON LABS INC
EQ 150MG BASE
A077426 001 Dec 19, 2005
EQ 300MG BASE
A077426 002 Dec 19, 2005
WOCKHARDT
EQ 75MG BASE
A078884 001 Jul 31, 2008
EQ 150MG BASE
A078653 001 Nov 26, 2007
EQ 150MG BASE
A078701 001 Nov 12, 2009
EQ 300MG BASE
A078701 002 Dec 11, 2009

ZANTAC 150
+ GLAXO GRP LTD
EQ 150MG BASE
N018703 001 Jun 09, 1983
ZANTAC 300
+ GLAXO GRP LTD
EQ 300MG BASE
N018703 002 Dec 09, 1985

TABLET, EFFERVESCENT; ORAL
ZANTAC 150
GLAXO GRP LTD
EQ 150MG BASE
N020251 001 Mar 31, 1994
ZANTAC 25
GLAXO GRP LTD
EQ 25MG BASE
N020251 003 Apr 01, 2004
ZANTAC 75
+ SANOFI US
EQ 75MG BASE **
N020745 001 Feb 26, 1998

RANOLAZINE

TABLET, EXTENDED RELEASE; ORAL
RANOLAZINE
LUPIN LTD
500MG
A201046 001 Jul 29, 2013
1GM
A201046 002 Jul 29, 2013

RAPACURONIUM BROMIDE

INJECTABLE; INJECTION
ORGANON USA INC
100MG/VIAL
N020984 001 Aug 18, 1999
200MG/VIAL
N020984 002 Aug 18, 1999

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Approved Drug Product List

### Discontinued Drug Product List

**See List Footnote**

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<th>Strengths</th>
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| | | 0.1MG | A089020 001 | Mar 07, 1985  
| | | 0.25MG | A09019 001 | Mar 07, 1985  
| Reserpine | VALENT PHARM INTL | 0.1MG | N009667 001 |  
| | | 0.25MG | N009667 002 |  
| Reserpine | WATSON LABS | 0.1MG | A080679 001 |  
| | | 0.25MG | A080393 001 |  
| | | 0.5MG | A085401 001 |  
| | | 1MG | A080749 001 |  
| Reserpine | WHITWORTH TOWN PLSN | 0.1MG | A080723 001 |  
| | | 0.25MG | A080723 002 |  
| | | 1MG | A080723 003 |  
| Reserpine | ANDRIL | 0.1MG | N009376 004 |  
| | | 0.25MG | N009376 001 |  
| Serpentine | LANNETT | 0.1MG | N010124 001 |  
| | | 0.25MG | N010124 002 |  

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

### Reserpine

<table>
<thead>
<tr>
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<th>Date of Approval</th>
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### Reserpine; Trichlormethiazide

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<td>Metatensin #2</td>
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### Ribavirin

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<td>Rebetol</td>
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### Rizatriptan Hydrochloride

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<tr>
<td>Alcon</td>
<td>Suspension/Drops, Ophthalmic</td>
<td>1%</td>
<td>N020474 001</td>
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### Risedronate Sodium

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<td>Actonel</td>
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### Risperidone

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<td>Janssen Pharms</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Risperidone**  
**Tablet; Oral**

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<td>3mg</td>
<td>Watson Labs</td>
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<td>4mg</td>
<td>West Ward Pharms</td>
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**Ritodrine Hydrochloride**  
**Inj ectable; Injection**

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<td>15mg/ml</td>
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**Ritonavir**  
**Capsule; Oral**

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**Rivastigmine Tartrate**  
**Solution; Oral**

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<td>2mg/ml</td>
<td>Novartis</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
RIZATRIPTAN BENZOATE

TABLET; ORAL
MAGALT
+ MERCK
RIZATRIPTAN BENZOATE
APOTEX INC

TABLET, ORALLY DISINTEGRATING; ORAL
MAGALT-MLT
+ MERCK
RIZATRIPTAN BENZOATE
APOTEX INC

ROCURONIUM BROMIDE

INJECTABLE; INJECTION
ZEMURON
+ ORGANON USA INC

ROFECOXIB

SUSPENSION; ORAL
VIOXX

TABLET; ORAL
VIOXX

ROFLUMILAST

TABLET; ORAL
ROFLUMILAST
MYLAN PHARMS INC

ROLAPITANT HYDROCHLORIDE

EMULSION; INTRAVENOUS
VARUBI
+ TERSERA THERAPS LLC

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL
ROPINIROLE HYDROCHLORIDE
EPIC PHARMA LLC

TABLET, EXTENDED RELEASE; ORAL
REQUIP XL
+ GLAXOSMITHKLINE LLC
ROPIVACAINE HYDROCHLORIDE
SOLUTION; INJECTION
NAROPIN
FRESENIUS KABI USA
50MG/10ML (5MG/ML) N020533 013 May 01, 1998
75MG/10ML (7.5MG/ML) N020533 012 Sep 24, 1996

ROSE BENGAL SODIUM I-131
INJECTABLE; INJECTION
ROBENGATOPE
BRACCO
0.5mCi/VIAL N016224 001
1mCi/VIAL N016224 002
2mCi/VIAL N016224 003
SODIUM ROSE BENGAL I 131
SORIN
0.5mCi/ML N017318 001

ROSIGLITAZONE MALEATE
TABLET; ORAL
AVANDIA
+ SB PHARMCO
EQ 8MG BASE N021071 004 May 25, 1999
TEVA
EQ 2MG BASE A076747 001 Jan 25, 2013
EQ 4MG BASE A076747 002 Jan 25, 2013
EQ 8MG BASE A076747 003 Jan 25, 2013

RUFINAMIDE
TABLET; ORAL
BANZEL
+ EISAI INC 100MG ** N021911 001 Nov 14, 2008

SAFFLOWER OIL
INJECTABLE; INJECTION
LIPOSYN 10%
ABBOTT 10% (10GM/100ML) N018203 001
LIPOSYN 20%
ABBOTT 20% (20GM/100ML) N018614 001

SAFFLOWER OIL; SOYBEAN OIL
INJECTABLE; INJECTION
LIPOSYN II 10%
HOSPIRA 5%; 5% (5GM/100ML) N018997 001 Aug 27, 1984
LIPOSYN II 20%
HOSPIRA 10%; 10% (10GM/100ML) N018991 001 Aug 27, 1984

SALMETEROL XINAFOATE
AEROSOL, METERED; INHALATION
SEREVENT
GLAXOSMITHKLINE EQ 0.021MG BASE/INH N020236 001 Feb 04, 1994

SAQUINAVIR
CAPSULE; ORAL
FORTOVASE
+ HOFFMANN LA ROCHE 200MG ** N020828 001 Nov 07, 1997

SAQUINAVIR MESYLATE
CAPSULE; ORAL
INVIRASE
+ HOFFMANN LA ROCHE EQ 200MG BASE N020628 001 Dec 06, 1995

SARALASIN ACETATE
INJECTABLE; INJECTION
SARENIN
+ PROCTER AND GAMBLE EQ 0.6MG BASE/ML N018009 001

SECOBARBITAL SODIUM
CAPSULE; ORAL
ANABOLIC
BARR 100MG A084225 001
EVERYLIFE 100MG A085895 001
HALSEY 100MG A084676 001
IVAX PHARMS 100MG A085869 001
KV PHARM 100MG A085288 001
LANNETT 100MG A085900 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
SECOBARTICAL SODIUM
CAPSULE; ORAL
SECOBARTICAL SODIUM
PARKE DAVIS 100MG A084762 001
PENDRIGO 100MG A084561 001
PUREPIC PHARM 100MG A085867 001
VALENT PHARM INTL 100MG A085477 001
VITARINE 100MG A085898 001
100MG A086273 001
WATSON LABS 100MG A085792 001
WESTWARD 100MG A084926 001
WHITEWORTH TOWN PLN 100MG A085798 001
WYETH AYERST 100MG A086390 001

INJECTABLE; INJECTION
SECOBARTICAL SODIUM
ELKINS SINN 100MG/VIAL A083281 001
WYETH AYERST 50MG/ML A083262 001
SECONAL SODIUM LILLY 50MG/ML N007392 002
SUPPOSITORY; RECTAL
SECONAL SODIUM LILLY 30MG A086530 001
60MG A086530 002
120MG A086530 003
200MG A086530 004

SECRETIN
INJECTABLE; INJECTION
SECRETIN-FERRING FERRING 75CU/VIAL N018290 001
SECRETIN SYNTHETIC PORCINE FOR SOLUTION; INTRAVENOUS
CHIRHOCLIN 16MCG/VIAL N021136 001 Apr 04, 2002

SELEGILINE HYDROCHLORIDE
CAPSULE; ORAL
ELDEPRYL + SOMERSET 5MG N020647 001 May 15, 1996
SELEGILINE HYDROCHLORIDE LANNETT CO INC 5MG A075145 001 Sep 15, 2003
TABLET; ORAL
SELEGILINE HYDROCHLORIDE CHARTWELL MOLECULES 5MG A074565 001 Aug 02, 1996
5MG A074641 001 Aug 02, 1996
G AND W LABS INC 5MG A074537 001 Aug 02, 1996
5MG A074744 001 Jan 27, 1997
5MG A074756 001 Nov 25, 1998
SIEGFRIED 5MG A074672 001 Apr 01, 1997
+ SOMERSET 5MG ** N019334 001 Jun 05, 1989

SELENIUM SULFIDE
LOTION/SHAMPOO; TOPICAL
EXSEL ALLERGAN HERBERT 2.5% A083892 001
SELENIUM SULFIDE ACTAVIS MID ATLANTIC 2.5% A084394 001
G AND W LABS INC 2.5% A086209 001
IVAX PHARMS 2.5% A085777 001
SELSEL + CHATTEM 2.5% N007936 001

SELENOMETHIONINE SE-75
INJECTABLE; INJECTION
SELENOMETHIONINE SE 75 GE HEALTHCARE 250uCi/ML N017257 001
MALLINCKRODT 100uCi/ML N017098 001
PHARMALUCENCE 500uCi/ML N017322 001
SETHOTOPE BRACCO 85-550uCi/ML N017047 001

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### SERMORELIN ACETATE

**Injectable; Injection**

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<td><strong>EMD SERONO INC</strong></td>
<td>EQ 0.5MG BASE/VIAL **</td>
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<td>EQ 1MG BASE/VIAL **</td>
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**See List Footnote**

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### SERTRALINE HYDROCHLORIDE

**Concentrate; Oral**

#### SERTRALINE HYDROCHLORIDE

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<tr>
<th>Company</th>
<th>Strength</th>
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<td><strong>KANBAXY LABS LTD</strong></td>
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**Tablet; Oral**

#### SERTRALINE HYDROCHLORIDE

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<td>EQ 200MG BASE **</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

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### SEVELAMER HYDROCHLORIDE

**Capsule; Oral**

#### RENAGEL

<table>
<thead>
<tr>
<th>Company</th>
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<tr>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

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### SIBUTRAMINE HYDROCHLORIDE

**Capsule; Oral**

#### MERIDIA

<table>
<thead>
<tr>
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<td>Actavis Grp Ptc</td>
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<td>Franklin Pharms</td>
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<td>Janssen Prods</td>
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<td>Juvissync</td>
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<td>Simvastatin: Sitagliptin Phosphate</td>
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<td>40Mg; EQ 100Mg Base</td>
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</tbody>
</table>

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
SIROLIMUS
TABLET; ORAL
RAPAMUNE
+ PF PRISM CV 5MG ** N021110 003 Feb 23, 2004

SODIUM BENZOATE; SODIUM PHENYLACETATE
SOLUTION; ORAL
UCEPHAN
B BRAUN 100MG/ML; 100MG/ML N019530 001 Dec 23, 1987

SODIUM BICARBONATE
INJECTABLE; INJECTION
SODIUM BICARBONATE
HOSPIRA INC 0.5MEQ/ML A202679 001 Mar 07, 2017
0.5MEQ/ML A202981 001 Mar 04, 2016
SODIUM BICARBONATE IN PLASTIC CONTAINER
+ ABBOTT 0.9MEQ/ML ** N019443 001 Jun 03, 1986
+ 1MEQ/ML ** N019443 002 Jun 03, 1986

SODIUM BICARBONATE; TARTARIC ACID
GRANULE, EFFERVESCENT; ORAL
BAROS
MALLINCKRODT INC 460MG/GM; 420MG/GM N018509 001 Aug 07, 1985

SODIUM CHLORIDE
INJECTABLE; INJECTION
BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
ABRAXIS PHARM 9MG/ML A088909 001 Feb 07, 1985
SODIUM CHLORIDE
ABBOTT 20GM/100ML N017013 001
B BRAUN 20GM/100ML N017038 001
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
B BRAUN 450MG/100ML N018184 001
MILES 450MG/100ML N018503 001
SODIUM CHLORIDE 0.9%
+ MEDEFIL INC 18MG/2ML (9MG/ML) N202832 002 Jan 06, 2012
+ 22.5MG/2.5ML (9MG/ML) N202832 003 Jan 06, 2012
+ 27MG/3ML (9MG/ML) N202832 004 Jan 06, 2012
+ 45MG/5ML (9MG/ML) N202832 005 Jan 06, 2012
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
ABBOTT 9MG/ML N019218 001 Jul 13, 1984
+ ICU MEDICAL INC 9MG/ML N019217 001 Jul 13, 1984
+ MEDEFIL INC 9MG/ML (9MG/ML) N202832 001 Jan 06, 2012
MILES 900MG/100ML N018502 001
SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER
+ ABRAXIS PHARM 234MG/ML ** N019329 001 Apr 22, 1987
SOLUTION; IRRIGATION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
BAXTER HLTHCARE 450MG/100ML N017864 001
450MG/100ML N018497 001 Feb 19, 1982
HOSPIRA 450MG/100ML N017670 001
450MG/100ML N018380 001
SODIUM CHLORIDE IN PLASTIC CONTAINER
MILES 900MG/100ML N018247 001

SODIUM CHROMATE CR-51
INJECTABLE; INJECTION
CHROMITOPE SODIUM
BRACCO 2mCi/VIAL N013993 002
200uCi/ML N013993 001
SODIUM CHROMATE CR 51
MALLINCKRODT NUCLEAR 100uCi/ML N016708 001

SODIUM FLUORIDE F-18
INJECTABLE; INTRAVENOUS
FLUORINE F-18
+ GE HEALTHCARE 2mCi/ML ** N017042 001
SODIUM FLUORIDE F 18
NIH NCI DCTD 10-200mCi/ML ** N022494 001 Jan 26, 2011
SODIUM FLUORIDE F-18
UIHC PET IMAGING 10-200mCi/ML A204462 001 Nov 17, 2015
UNIV TX MD ANDERSON 10-200mCi/ML A203247 001 Dec 23, 2013

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
SODIUM IODIDE I-123
CAPSULE; ORAL
SODIUM IODIDE I 123
CARDINAL HEALTH 418 400uCi N018671 003 May 27, 1982
GE HEALTHCARE 100uCi N017630 001
SODIUM IODIDE I-123
CAPSULE; ORAL
SODIUM IODIDE I 123
GE HEALTHCARE 2mCi/ML ** N017630 002
SODIUM IODIDE I-131
CAPSULE; ORAL
IODOTOPE
BRACCO 1-130mCi N010929 001
1-150mCi N010929 003
SODIUM IODIDE I 131
CIS
50uCi N017316 001
100uCi N017316 002
JUBILANT DRAXIMAGE 2-200mCi N021305 004 Nov 18, 2004
MALLINKRODT NUCLEAR 0.8-100mCi N016515 002
+ 0.8-100mCi N016517 001
15-100uCi N016517 002
SOLUTION; ORAL
HICON
JUBILANT DRAXIMAGE 1-250mCi/0.25ML N021305 002 Jan 24, 2003
1-500mCi/0.5ML N021305 003 Jan 24, 2003
1-1000mCi/ML N021305 005 Apr 04, 2006
IODOTOPE
BRACCO 7-106mCi/BOT N010929 002
SODIUM IODIDE I 131
CIS
50mCi/ML N017315 001
+ MALLINKRODT NUCLEAR 3.5-150mCi/VIAL N016515 001
SODIUM LACTATE
INJECTABLE; INJECTION
SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER
B BRAUN 1.87GM/100ML N018186 001
BAXTER HLTHCARE 1.87GM/100ML N016692 001
HOSPIRA 1.87GM/100ML N018249 001
SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER
B BRAUN 1.87GM/100ML N020004 001 Apr 21, 1992
SODIUM MONOFLUOROPHOSPHATE
GEL; DENTAL
EXTRA-STRENGTH AIM
CHESBROUGH PONDS 1.2% N019518 002 Aug 06, 1986
PASTE; DENTAL
EXTRA-STRENGTH AIM
CHESBROUGH PONDS 1.2% N019518 001 Jun 03, 1987
SODIUM NITROPRUSSIDE
INJECTABLE; INJECTION
NIPRIDE
ROCHE 50MG/VIAL N017546 001
NITROPRESS
ABBOTT 50MG/VIAL A071555 001 Nov 16, 1987
+ ABBVIE 50MG/VIAL ** N018450 001
HOSPIRA 50MG/VIAL A070566 001 Jun 09, 1986
SODIUM NITROPRUSSIDE
ABRAXIS PHARM 50MG/VIAL A070031 001 Jan 17, 1985
+ BAXTER HLTHCARE 50MG/VIAL ** N018581 001 Jul 28, 1982
TEVA PARENTERAL 25MG/ML A073465 001 Mar 30, 1992
SODIUM PHOSPHATE P-32
SOLUTION; INJECTION, ORAL
PHOSPHOTEPHE
BRACCO 1-8mCi/VIAL N010927 001
SODIUM PHOSPHATE P 32
MALLINCKRODT 0.67mCi/ML N011777 001
1.5mCi/VIAL N011777 002

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<tr>
<th>Drug Name</th>
<th>Strength</th>
<th>Formulation</th>
<th>Company</th>
<th>FDA Approval Code</th>
<th>Approval Date</th>
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<td>Tablet; Oral</td>
<td>Viscicol</td>
<td>Salix Pharm 0.398Gm; 1.102Gm</td>
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<td>Sodium Polystyrene Sulfonate</td>
<td>Powder; Oral, Rectal</td>
<td>Kayexalate</td>
<td>Concordia Pharm 453.6Gm/Bot **</td>
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<td>Elkins Sinn 30%</td>
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<td>Sodium Tetradecyl Sulfate</td>
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<td>Sotradecol</td>
<td>Elkins Sinn 1% **</td>
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<td>Sodium Thiocarbonate</td>
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<td>A088717 001; A088453 001</td>
<td>Sep 11, 1984; Nov 17, 1983</td>
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<td>Genentech 5Mg/Vial; 10Mg/Vial</td>
<td>N019107 001; N019107 002</td>
<td>Oct 17, 1985; Oct 24, 1989</td>
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<td>Somatropin Recombinant</td>
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<td>Asellacrin 10 IU/Vial; Asellacrin 2 IU/Vial; Creosorem 4.8Mg/Vial; Genentech 4 IU/Vial</td>
<td>N017726 001; N017726 002; N019774 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**SOMATROPIN RECOMBINANT**

**INJECTABLE; INJECTION**

**NORDITROPIN NORDIFLEX**

- **30MG/3ML**  
  N021148 007 Mar 10, 2009

**NUTROPIN GENENTECH**

- **5MG/VIAL**  
  N020168 001 Nov 17, 1993
  N020168 002 Nov 17, 1993

**NUTROPIN AQ GENENTECH**

- **10MG/2ML (5MG/ML)**  
  N020522 001 Dec 29, 1995

**NUTROPIN AQ PEN**

- **+ GENENTECH**  
  N020522 002 Apr 22, 2002

**NUTROPIN DEPOT GENENTECH**

- **10MG/2ML (10MG/ML)**  
  N020522 006 Jan 03, 2008

**SAIZEN EMD SERONO**

- **13.5MG/VIAL**  
  N021075 001 Dec 22, 1999
- **18MG/VIAL**  
  N021075 002 Dec 22, 1999
- **22.5MG/VIAL**  
  N021075 003 Dec 22, 1999

**SEROSTIM EMD SERONO**

- **4MG/VIAL**  
  N019764 005 Jan 16, 2007
- **6MG/VIAL**  
  N019764 001 Oct 08, 1996

**SEROSTIM LQ EMD SERONO**

- **8.8MG/VIAL**  
  N020604 004 Sep 06, 2001

**VALTROPIN LG CHEM LTD**

- **5MG/VIAL**  
  N021905 001 Apr 19, 2007

**ZORBTIVE EMD SERONO**

- **4MG/VIAL**  
  N021597 001 Dec 01, 2003
- **5MG/VIAL**  
  N021597 002 Dec 01, 2003
- **6MG/VIAL**  
  N021597 003 Dec 01, 2003

**INJECTABLE; SUBCUTANEOUS**

**SEROSTIM LQ EMD SERONO**

- **6MG/0.5ML (6MG/0.5ML)**  
  N020604 005 Feb 11, 2005

**SORBITOL SOLUTION; IRRIGATION**

**SORBITOL 3% IN PLASTIC CONTAINER**

**BAXTER HLSHCARE**

- **3GM/100ML**  
  N018512 001 May 27, 1982

**SOTALOL HYDROCHLORIDE TABLET; ORAL**

**BETAPACE COVIS PHARMA BV**

- **320MG**  
  N019865 004 Oct 30, 1992

**BETAPACE AF COVIS PHARMA BV**

- **40MG**  
  N021151 006 Apr 02, 2003
- **60MG**  
  N021151 007 Apr 02, 2003
- **100MG**  
  N021151 005 Mar 14, 2003

**SOTALOL HYDROCHLORIDE IMPAX PHARMS**

- **80MG**  
  A075663 001 Nov 07, 2000
- **120MG**  
  A075663 002 Nov 07, 2000
- **160MG**  
  A075663 003 Nov 07, 2000
- **240MG**  
  A075663 004 Nov 07, 2000

**MYLAN**

- **80MG**  
  A075237 001 May 01, 2000
- **100MG**  
  A075237 002 May 01, 2000
- **120MG**  
  A075237 003 May 01, 2000
- **160MG**  
  A075237 004 May 01, 2000
- **240MG**  
  A075237 004 May 01, 2000
- **240MG**  
  A075237 005 May 01, 2000

**SUN PHARM INDUSTRIES**

- **80MG**  
  A075515 001 Oct 15, 2001
- **80MG**  
  A076576 001 Apr 08, 2004
- **120MG**  
  A075515 004 Oct 15, 2001
- **120MG**  
  A076576 002 Apr 08, 2004
- **160MG**  
  A075515 005 Oct 15, 2001
- **160MG**  
  A075515 003 Oct 15, 2001
- **240MG**  
  A075515 003 Oct 15, 2001

**TEVA**

- **80MG**  
  A076883 001 Jul 26, 2004
- **120MG**  
  A076883 002 Jul 26, 2004
- **160MG**  
  A076883 003 Jul 26, 2004

**WATSON LABS**

- **80MG**  
  A075238 001 Jul 13, 2000
- **120MG**  
  A075238 002 Jul 13, 2000
- **160MG**  
  A075238 003 Jul 13, 2000

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Discontinued Drug Product List

**See List Footnote**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Strength</th>
<th>NDC Code</th>
<th>Date</th>
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</thead>
<tbody>
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<td>Travamulsion 10%</td>
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<td>N018660 001</td>
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<td>Travamulsion 20%</td>
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<td>N018758 001</td>
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<td>Sparfloxacin</td>
<td>Tablet; Oral</td>
<td>200 mg</td>
<td>N020677 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### SULFACETAMIDE SODIUM

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

### SULFACYTINE

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### SULFADIAZINE

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
SULFADIAZINE; SULFAMERAZINE
SUSPENSION; ORAL
SULFONAMIDES DUPLEX
LILLY 250MG/5ML; 250MG/5ML  N006317 007

SULFAMETER
TABLET; ORAL
SULLA
BAYER HLTHCARE 500MG  N016000 002

SULFAMETHIZOLE
TABLET; ORAL
MICROSUL
FOREST PHARMS 1GM  A086012 001
PROKLAR
FOREST PHARMS 500MG  A080273 001
THIOSULFIL
WYETH AYERST 250MG  N008565 001
500MG  N008565 004

SULFAMETHOXAZOLE
SUSPENSION; ORAL
GANTANOL
ROCHE 500MG/5ML  N013664 002
TABLET; ORAL
GANTANOL
ROCHE 500MG  N012715 002
GANTANOL-DS
ROCHE 1GM  N012715 003

SULFAMETHOXAZOLE
SUSPENSION; INJECTION
ASCOT 500MG  A087662 001 Oct 20, 1982
AUROLIFE PHARMA LLC 500MG  A085844 001
BARR 500MG  A087189 001 Jul 25, 1983
HEATHER 500MG  A086163 001
WATSON LABS 500MG  A085053 001
1GM  A086000 001

SULFAMETHOXAZOLE
SUSPENSION; ORAL
MICROSUL
UROBAK
SHIONOGI 500MG  A087307 001

SULFAMETHOXAZOLE; TRIMETHOPRIM
INJECTABLE; INJECTION
BACTRIM + SUN PHARM INDs INC 80MG/ML; 16MG/ML **  N018374 001
SEPTRA
BACCHUS PHARMS 80MG/ML; 16MG/ML  N018452 001
SULFAMETHOXAZOLE AND TRIMETHOPRIM
ABRAXIS PHARM 80MG/ML; 16MG/ML  A070223 001 Dec 29, 1987
BEDFORD 80MG/ML; 16MG/ML  A072383 001 Apr 29, 1992
HOSPIRA 80MG/ML; 16MG/ML  A073199 001 Sep 11, 1992
WATSON LABS 80MG/ML; 16MG/ML  A071556 001 Dec 29, 1987
WEST-WARD PHARMS INT 80MG/ML; 16MG/ML  A070627 001 Dec 29, 1987
80MG/ML; 16MG/ML  A070628 001 Dec 29, 1987

SUSPENSION; ORAL
BACTRIM + SUN PHARM INDUSTRIES 200MG/5ML; 40MG/5ML **  N017560 001
BACTRIM PEDIATRIC
SEPTRA
SUN PHARM INDUSTRIES 200MG/5ML; 40MG/5ML **  N017560 002
SEPTRA
MONARCH PHARMS 200MG/5ML; 40MG/5ML **  N017598 001
SEPTRA GRAPE
MONARCH PHARMS 200MG/5ML; 40MG/5ML **  N017598 002 Feb 12, 1986
SULFAMETHOXAZOLE AND TRIMETHOPRIM
ANI PHARMS INC 200MG/5ML; 40MG/5ML  A070028 001 Jun 02, 1987
TEVA 200MG/5ML; 40MG/5ML  A077612 001 Nov 13, 2006
200MG/5ML; 40MG/5ML  A077612 001 Nov 13, 2006
200MG/5ML; 40MG/5ML  A078118 001 Jan 28, 1983
SULFATRIM
PHARM ASSOC 200MG/5ML; 40MG/5ML  N018615 002 Jan 07, 1983
SULMIPRIM
USL PHARMA 200MG/5ML; 40MG/5ML  A070063 001 Aug 01, 1986

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### Sulfamethoxazole and Trimethoprim

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Sulfapyridine**

**Tablet, Oral**

Sulfapyridine Lilly 500MG N000159 001

**Sulfasalazine**

**Suspension, Oral**

Sulfasalazine Pharmacia and Upjohn 250MG/5ML N018605 001

**Tablet, Oral**

Sas-500 Solvay 500MG A083450 001

Sulfasalazine Heritage Pharm Inc 500MG A080197 001

Sandox 500MG A086184 001

SUN Pharm Industries 500MG A089590 001 Oct 19, 1987

Superpharm 500MG A089339 001 Oct 26, 1987

Watson Labs 500MG A084964 001

Superpharm 500MG A087197 001

**Tablet, Delayed Release, Oral**

Sulfasalazine Watson Labs 500MG A088052 001 May 24, 1983

**Sulfinpyrazone**

**Capsule, Oral**

Anturane + Novartis 200MG ** N011556 004

Sulfinpyrazone BARR 200MG A087666 001 Sep 17, 1982

IVAX PharmS 200MG A087770 001 Nov 19, 1982

Par Pharm 200MG A088934 001 Sep 06, 1985

Vangard 200MG A088666 001 Feb 17, 1984

**Tablet, Oral**

Anturane Novartis 100MG ** N011556 003

Sulfinpyrazone BARR 100MG A087665 001 Sep 17, 1982

IVAX PharmS 100MG A087769 001 Jun 01, 1982

Par Pharm 100MG A088933 001 Sep 06, 1985

Watson Labs 100MG A087667 001 May 26, 1982

**Sulfinpyrazone**

**Tablet, Oral**

Gantrisin Roche 500MG N006525 001

Sosol MK Labs 500MG A080036 001

Soxazole Alra 500MG A080366 001

Sulfalar Parke Davis 500MG A084955 001

Sulfisoxazole Ani Pharm Inc 500MG A080142 001

Aurolife Pharma LLC 500MG A085628 001

Barr 500MG A084031 001

Heather 500MG A080189 001

Impax Labs 500MG A080109 001

Lannett 500MG A080085 001

Lederle 500MG A087649 001

Pharminal 500MG A084385 001

Purepac Pharm 500MG A080087 001

Roxane 500MG A080082 001

Valeant Pharm Intl 500MG A080268 002

Vitarine 500MG A087332 001

Watson Labs 500MG A085534 001

West Ward 500MG A080379 001

Sulsoxin Solvay 500MG A080040 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
SULFISOXAZOLE ACETYL
EMULSION; ORAL
LIPO GANTRISIN ROCHE
EQ 1GM BASE/5ML N009182 009
SUSPENSION; ORAL
GANTRISIN PEDIATRIC ROCHE
EQ 500MG BASE/5ML N009182 004
Syrup; ORAL
GANTRISIN ROCHE
SUSPENSION; ORAL
GANTRISIN PEDIATRIC ROCHE
EQ 500MG BASE/5ML N009182 002
SULFISOXAZOLE DIOLAMINE
INJECTABLE; INJECTION
GANTRISIN ROCHE
EQ 400MG BASE/ML N006917 001
OINTMENT; OPHTHALMIC
GANTRISIN ROCHE
EQ 4% BASE N008414 002
SOLUTION/DROPS; OPHTHALMIC
GANTRISIN ROCHE
SULFISOXAZOLE DIOLAMINE SOLA BARNES HIND
EQ 4% BASE A084148 001
SULFOXONE SODIUM
TABLET, DELAYED RELEASE; ORAL
DIASONE SODIUM ABBVIE 165MG N006044 003
SULFUR
POWDER; TOPICAL
BENSULFOID POYTHRESS 33.32% N002918 001
SULINDAC
TABLET; ORAL
CLINORIL + MERCK 150MG ** N017911 001
+ 200MG ** N017911 002
SULINDAC ANI PHARMS INC 150MG A072972 001 Feb 28, 1992
200MG A072973 001 Feb 28, 1992
EPIC PHARMA LLC 150MG A073262 002 Sep 06, 1991
200MG A073262 001 Sep 06, 1991
FOSUN PHARMA 150MG A072712 001 Aug 30, 1991
200MG A072713 001 Aug 30, 1991
SUMATRIPTAN
SPRAY; NASAL
IMITREX GLAXOSMITHKLINE 10MG/SPRAY N020626 002 Aug 26, 1997
SUMATRIPTAN SUCCINATE
INJECTABLE; SUBCUTANEOUS
ALSUMA MERIDIAN MEDCL
SUMATRIPTAN SUCCINATE FRESENIUS KABI USA
EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) N022377 001 Jun 29, 2010
INJECTALLIA EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) A079240 002 Sep 18, 2009
EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) A079240 001 Sep 18, 2009
SANDOZ INC EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) A090310 001 Aug 11, 2010
TEVA PARENTERAL EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) A078067 002 Feb 06, 2009
EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) A078067 001 Feb 06, 2009
TEVA PARENTERAL EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) A078318 001 Feb 06, 2009
EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) A078318 002 Feb 06, 2009
SUMAVEL DOSEPRO + ENDO VENTURES LTD EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) N022239 002 Nov 26, 2013
+ EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) N022239 001 Jul 15, 2009
SYSTEM; IONTOPHORESIS ZECUITY + TEVA BRANDED PHARM EQ 6.5MG BASE/4HR N202278 001 Jan 17, 2013

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## SUMATRIPTAN SUCCINATE

**TABLET; ORAL**

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**See List Footnote**

## SUPROFEN

**SOLUTION; DROPS; OPHTHALMIC**

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## SUTILAINS

**OINTMENT; TOPICAL**

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## TACRINE HYDROCHLORIDE

**CAPSULE; ORAL**

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## TALBUTAL

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

**See List Footnote**

** **

### TEMAZEPAM

**CAPSULE; ORAL**

<table>
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<th>QUANTUM PHARMICS</th>
<th>15MG</th>
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**TEMPERED PHARM BARR**

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**SUN PHARM INDUSTRIES**

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**USL PHARMA**

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**WATSON LABS**

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<td>30MG</td>
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**TEMAZEPAM**

**DURAMED PHARMS BARR**

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**USL PHARMA**

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**WATSON LABS**

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### TEMOZOLOMIDE

**CAPSULE; ORAL**

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<td>20MG</td>
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**VUMON**

| + HQ SPECI TECH PHARMA | 10MG/ML | N020119 001 Jul 14, 1992 |

### TESISINOIDE

**INJECTABLE; INJECTION**

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<th>VUMON</th>
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### TERRAZOSIN HYDROCHLORIDE

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<tr>
<td>+ ABBOTT</td>
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<tr>
<td>+ ABBOTT</td>
<td>N020347 003 Dec 14, 1994</td>
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<tr>
<td>+ ABBOTT</td>
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**RANBAXY LABS LTD**

| EQ 1MG BASE | A075384 001 Dec 01, 2000 |
| EQ 2MG BASE | A075384 002 Dec 01, 2000 |

**SANDOZ**

| EQ 1MG BASE | A075667 001 Jul 28, 2000 |
| EQ 2MG BASE | A075667 002 Jul 28, 2000 |

**TABLET; ORAL**

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<td>ABBOTT</td>
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<td>ABBOTT</td>
<td>N019057 004 Aug 07, 1987</td>
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**IVAX SUB TEVA PHARMS**

| EQ 1MG BASE | A074530 001 Apr 21, 2000 |
| EQ 2MG BASE | A074530 002 Apr 21, 2000 |

**SANDOZ**

| EQ 1MG BASE | A074315 001 Dec 31, 1998 |
| EQ 2MG BASE | A074315 002 Dec 31, 1998 |

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**See List Footnote**
### Terazosin Hydrochloride

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** See List Footnote

### Terbinafine

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<tr>
<td>LAMISIL</td>
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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Cream; Topical</td>
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<tr>
<td>LAMISIL</td>
<td>1%</td>
<td>ND20192 001 Dec 30, 1992</td>
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<td>Granule; Oral</td>
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<td>LAMISIL</td>
<td>EQ 125mg BASE/PACKET</td>
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<td>LAMISIL</td>
<td>GLAXOSMITHKLINE CONS 1%</td>
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<table>
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<tr>
<td>APOTEX</td>
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<td>EQ 250mg BASE</td>
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<td>ROXANE</td>
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### Terbutaline Sulfate

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<td>Aerosol, Metered; Inhalation</td>
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<tr>
<td>BRETHAIRE</td>
<td>NOVARTIS 0.2mg/INH</td>
<td>N018762 001 Aug 17, 1984</td>
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<tr>
<td>BRICANYL</td>
<td>SANOFI AVENTIS US 0.2mg/INH</td>
<td>N018000 001 Mar 19, 1985</td>
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| Injectable; Injection |                |                 |
| BRETHINE         |                 |                 |
| BRICANYL         | 1mg/ml **       | N018571 001     |
| SANOFI AVENTIS US | 1mg/ml          | N017466 001     |
| TERBUTALINE SULFATE |                 |                 |
| TEVA PHARMS USA  | 1mg/ml          | A076853 001 Jul 20, 2004 |

| Tablet; Oral |                |                 |
|             | SANOFI AVENTIS US 2.5mg | N017618 001     |
|             |                 | N017618 002     |

### Terconazole

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<tr>
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<td>TERAZOL 7</td>
<td>0.4%</td>
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| Suppository; Vaginal |                |                 |
| TERAZOL 3 | 80mg            | N019641 001 May 24, 1988 |
| TERAZONAZOLE |                 |                 |
| FOUGERA PHARMS | 80mg            | A076850 001 Jul 12, 2006 |

### Teriparatide Acetate

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<tr>
<td>PARATHAR</td>
<td>SANOFI AVENTIS US 200 UNITS/VIAL</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>TESTOLACTONE</td>
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<td>TESLAC BRISTOL MYERS SQUIBB</td>
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<td>TESLAC BRISTOL MYERS SQUIBB</td>
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<td>TESTOSTERONE</td>
<td>FILM, EXTENDED RELEASE; TRANSDERMAL</td>
<td>ANDRODERM ALLERGAN SALES LLC</td>
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<td>ALZA</td>
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<td>ALZA</td>
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<td>TESTOSTERONE CYCLONATE</td>
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<td>DEPO-TESTOSTERONE PHARMACIA AND UPJOHN</td>
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<td>DELATESTRYL ENDO PHARMS</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## TESTOSTERONE PROPIONATE

**INJECTABLE; INJECTION**

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<td>100MG/ML</td>
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## TETRACYCLINE HYDROCHLORIDE

**CAPSULE; ORAL**

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<td>BRISTACLYCINE</td>
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<td>250MG</td>
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**WARNER CHILCOTT**

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**FANNMYCIN**

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<td>PHARMACIA AND UPJOHN</td>
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**RETET**

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<td>250MG</td>
<td>WYETH AYERST</td>
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**SUMYCIN**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### THALLOUS CHLORIDE TL-201

**INJECTABLE, INJECTION**

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### THEOPHYLLINE

**CAPSULE, ORAL**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**THEOPHYLLINE**

**CAPSULE, EXTENDED RELEASE; ORAL**

**THEOPHYL-SR**
- ORTHO MCNEIL PHARM
  - 125MG A086480 001 Feb 08, 1985
  - 250MG A086471 001 Feb 08, 1985

**THEOPHYLLINE**
- CENT PHARMS
  - 125MG A088654 001 Feb 12, 1985
  - 250MG A088689 001 Feb 12, 1985
- HOSPIRA
  - 100MG A089976 001 Jan 04, 1995
  - 200MG A089977 001 Jan 04, 1995
  - 300MG A089932 001 Jan 04, 1995
- INWOOD LABS
  - 100MG A040052 001 Feb 14, 1994
  - 125MG A040052 002 Feb 14, 1994
  - 200MG A040052 003 Feb 14, 1994
  - 300MG A040052 004 Feb 14, 1994
- SANOZ
  - 260MG A087462 001 May 11, 1982

**THEOPHYLLINE-SR**
- SCHERER RP
  - 300MG A088255 001 Jun 12, 1986

**THEOVENT**
- SCHERING
  - 125MG A087010 001 Jan 31, 1985
  - 250MG A087910 001 Jan 31, 1985

**ELIXIR; ORAL**

**ELIXOMIN**
- CENCI
  - 80MG/15ML A088303 001 Jan 25, 1984
- LANNETT
  - 80MG/15ML A084578 001

**THEOLIXIR**
- PANTAY
  - 80MG/15ML A084559 001

**THEOPHYL-225**
- ORTHO MCNEIL PHARM
  - 112.5MG/15ML A086485 001

**THEOPHYLLINE**
- ALPHARMA US PHARMS
  - 80MG/15ML A089223 001 May 27, 1988
- CENCI
  - 80MG/15ML A087679 001 Apr 15, 1982
- CHARTWELL RX
  - 80MG/15ML A085952 001
- HALSEY
  - 80MG/15ML A085169 001
- PHARM ASSOC
  - 80MG/15ML A086720 001
- PRECISION DOSE
  - 80MG/15ML A085863 001
- ROXANE
  - 80MG/15ML A084739 001
- TARO
  - 80MG/15ML A089626 001 Oct 28, 1988
- WOCKHARDT
  - 80MG/15ML A086748 001

**INJECTABLE; INJECTION**

**THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER**
- B BRAUN
  - 40MG/100ML N019083 001 Nov 07, 1984
  - 80MG/100ML N019083 002 Nov 07, 1984
- B BRAUN
  - 160MG/100ML N019083 003 Nov 07, 1984
- B BRAUN
  - 200MG/100ML N019083 004 Nov 07, 1984
- B BRAUN
  - 200MG/100ML N019826 004 Aug 14, 1992
- B BRAUN
  - 4MG/ML N019122 002 Nov 07, 1984
  - 40MG/100ML N019122 003 Nov 07, 1984
  - 400MG/100ML N019826 005 Aug 14, 1992

**THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER**
- BAXTER HLTHCARE
  - 4MG/ML N018649 007 Jul 26, 1982
  - 80MG/100ML N018649 001 Jul 26, 1982
  - 160MG/100ML N018649 002 Jul 26, 1982
  - 200MG/100ML N018649 003 Jul 26, 1982
  - 320MG/100ML N018649 006 Nov 13, 1985
  - 400MG/100ML N018649 005 Jul 26, 1982
- + HOSPIRA INC
  - 4MG/ML N019211 007 Dec 14, 1984
  - 40MG/100ML N019211 001 Dec 14, 1984
  - 80MG/100ML N019211 002 Dec 14, 1984
  - 160MG/100ML N019211 003 Dec 14, 1984
  - 200MG/100ML N019211 004 Dec 14, 1984
  - 320MG/100ML N019211 006 Jan 20, 1988

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**THEOPHYLLINE**

**INJECTABLE; INJECTION**
Theophylline in Dextrose 5% in Plastic Container
400mg/100ml  N019211  005  Dec 14, 1984

**SOLUTION; ORAL**

Aerolate
Fleming Pharms 150mg/15ml  A089141  001  Dec 03, 1986
Theolair 3m 80mg/15ml  A086107  001
Theophylline Roxane 80mg/15ml  A087449  001  Sep 15, 1983
Suspension; Oral
Elixiricon
Forest Labs 100mg/5ml  A085502  001

**SYRUP; ORAL**

Accubron
Sanofi Aventis Us 150mg/15ml  A088746  001  Nov 22, 1985
Aquaphyllin
Ferndale Labs 80mg/15ml  A087917  001  Jan 18, 1983
Slo-Phyllin
Sanofi Aventis Us 80mg/15ml  A085187  001
Theoclear-80
Cent Pharms 80mg/15ml  A087095  001  Mar 01, 1982
Theophylline
Alpharma Us Pharms 80mg/15ml  A086001  001
150mg/15ml  A086545  001

**TABLET; ORAL**

Quibron-T
Monarch Pharms 300mg  A088656  001  Aug 22, 1985
Slo-Phyllin
Sanofi Aventis Us 100mg  A085202  001
200mg  A085204  001
Theoclear-100
Cent Pharms 100mg  A085353  002
Theoclear-200
Cent Pharms 200mg  A085353  001
Theolair
Medicis 125mg  A086399  001
250mg  A086399  002
Theophylline
Orthon McNeil Pharm 225mg  A084726  001
Tablet, Chewable; Oral
Theophyl
Orthon McNeil Pharm 100mg  A086506  001  Sep 12, 1985

**TABLET, EXTENDED RELEASE; ORAL**

Duraphyl
Forest Labs 100mg  A088503  001  Apr 03, 1985
200mg  A088504  001  Apr 03, 1985
300mg  A088505  001  Apr 03, 1985
Labid
Warner Chilcott 250mg  A087225  001
Quibron-T/Sr
Monarch Pharms 300mg  A087563  001  Jun 21, 1983
Sustaire
Roerig 100mg  A085665  001
300mg  A085665  002
T-Phyl
Pharm Res Assoc 200mg  A088253  001  Aug 17, 1983
Theo-Dur
Schering 100mg  A085328  001
200mg  A086998  001
300mg  A085328  002
450mg  A089131  001  Jun 25, 1986
Theochron
Nostrum Pharms Llc 300mg  A087400  002  Jan 11, 1983
Theolair-Sr
3m 200mg  A088369  001  Jul 16, 1987
250mg  A086363  002  Jul 16, 1987
300mg  A088364  001  Jul 16, 1987

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

THEOLAIR-SR

THEOPHYLLINE
ABLE

INWOOD LABS
TEVA PHARMS
UNI-DUR
SCHERING

THEOPHYLLINE SODIUM GLYCINATE

ELIXIR; ORAL

SYNOPHYLATE

CENT PHARMS
ASBRON

NOVARTIS

THIABENDAZOLE

SUSPENSION; ORAL

MINTEZOL

MERCK SHARP DOHME

TABLET, CHEWABLE; ORAL

MINTEZOL

MERCK SHARP DOHME

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

BETALIN S

LILLY

THIAMINE HYDROCHLORIDE

ABRAXIS PHARM
AKORN
BEL MAR
DELL LABS
HOSPIRA
LUITPOLD
PARKE DAVIS
WATSON LABS
WEST-WARD PHARMS INT

THIAMYLAL SODIUM

INJECTABLE; INJECTION

SURITAL

PAKEDALE

THIETHYLPRAZINE MALATE

INJECTABLE; INJECTION

TORECAN

NOVARTIS

THIETHYLPRAZINE MALATE

SUPPOSITORY; RECTAL

TORECAN

NOVARTIS

TABLET; ORAL

TORECAN

NOVARTIS

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
## THIOPENTAL SODIUM

**SUSPENSION; RECTAL**

ABBOTT

400MG/GM

N011679 001

## THIOPENTAL SODIUM

**SUSPENSION; ORAL**

**ABBOTT**

## THIORIDAZINE

**SUSPENSION; ORAL**

**MELLARIL-S**

NOVARTIS

EQ 25MG HYDROCHLORIDE/5ML **

N017923 001

EQ 100MG HYDROCHLORIDE/5ML **

N017923 002

## THIORIDAZINE HYDROCHLORIDE

**CONCENTRATE; ORAL**

**MELLARIL**

NOVARTIS

30MG/ML **

N011808 012

100MG/ML **

N011808 018

## THIORIDAZINE HYDROCHLORIDE

**ACTAVIS MID ATLANTIC**

100MG/ML

A088229 001 Aug 23, 1983

**ALPHARMA US PHARMS**

30MG/ML

A087766 001 Apr 26, 1983

100MG/ML

A089603 001 Nov 09, 1987

**HI TECH PHARMA**

30MG/ML

A040125 001 Aug 16, 1996

100MG/ML

A040126 001 Aug 16, 1996

**PHARM ASSOC**

30MG/ML

A040187 001 Aug 28, 1997

100MG/ML

A040213 001 May 29, 1998

**SANDOZ**

100MG/ML

A088307 001 Nov 23, 1983

A088308 001 Nov 23, 1983

**WOCKHARDT**

30MG/ML

A088258 001 Jul 25, 1983

100MG/ML

A088227 001 Jul 05, 1983

## THIORIDAZINE HYDROCHLORIDE

**INTENSOL**

ROXANE

30MG/ML

A088941 001 Dec 16, 1985

100MG/ML

A088942 001 Dec 16, 1985

## TABLET; ORAL

**MELLARIL**

+ NOVARTIS

10MG **

N011808 003

15MG **

N011808 016

25MG **

N011808 006

50MG **

N011808 011

100MG **

N011808 009

150MG **

N011808 017

200MG **

N011808 015

## THIORIDAZINE HYDROCHLORIDE

**ANI PHARMS INC**

10MG

A088270 001 Apr 14, 1983

10MG

A088493 001 May 17, 1985

15MG

A088271 001 Apr 14, 1983

25MG

A088272 001 Apr 14, 1983

50MG

A088194 001 Apr 14, 1983

100MG

A088273 001 Oct 03, 1983

100MG

A088456 001 May 17, 1985

**FOSUN PHARMA**

10MG

A088131 001 Aug 30, 1983

15MG

A088132 001 Aug 30, 1983

25MG

A088133 001 Aug 30, 1983

50MG

A088134 001 Aug 30, 1983

100MG

A088135 001 Nov 20, 1984

150MG

A088136 001 Sep 17, 1986

200MG

A088137 001 Sep 17, 1986

**MUTUAL PHARM**

10MG

A088375 001 Nov 18, 1983

25MG

A087264 001 Nov 18, 1983

50MG

A088370 001 Nov 18, 1983

100MG

A088379 001 Nov 16, 1983

**MYLAN**

10MG

A088332 001 Jun 27, 1983

25MG

A088333 001 Jun 27, 1983

50MG

A088334 001 Jun 27, 1983

100MG

A088335 001 Nov 18, 1983

**PAR PHARM**

10MG

A088351 001 Dec 05, 1983

15MG

A088352 001 Dec 05, 1983

25MG

A088356 001 Dec 05, 1983

50MG

A088322 001 Dec 05, 1983

100MG

A088480 001 Dec 29, 1983

150MG

A089764 001 Feb 09, 1988

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
### THIORIDAZINE HYDROCHLORIDE
#### TABLET; ORAL

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### THIOTEPHA
#### INJECTABLE; INJECTION

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### THIOTHIXENE
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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| **THIOTHIXENE HYDROCHLORIDE** |  |
| **CONCENTRATE; ORAL** |  |
| NAVANE |  |
| PFIZER | EQ 5MG BASE/ML N016758 001 |
| THIOTHIXENE HYDROCHLORIDE |  |
| ALPHARMA US PHARMS | EQ 5MG BASE/ML A070969 001 Oct 16, 1987 |
| PACO | EQ 1MG BASE/ML A071917 001 Sep 20, 1989 |
| TEVA | EQ 5MG BASE/ML A071939 001 Dec 16, 1988 |
| TEVA PHARMS | EQ 5MG BASE/ML A071184 001 Jun 22, 1987 |
| THIOTHIXENE HYDROCHLORIDE INTENSOL |  |
| CYCLE PHARMS LTD | EQ 5MG BASE/ML A073494 001 Jun 30, 1992 |

| **INJECTABLE; INJECTION** |  |
| NAVANE |  |
| PFIZER | EQ 2MG BASE/ML N016904 001 |
|  | EQ 10MG BASE/VIAL N016904 002 |

| **THYROGLOBULIN** |  |
| **TABLET; ORAL** |  |
| PROLOID |  |
| PARKE DAVIS | 16MG N002245 009 |
|  | 32MG N002245 005 |
|  | 65MG N002245 002 |
|  | 100MG N002245 008 |
|  | 130MG N002245 010 |
|  | 200MG N002245 007 |
|  | 325MG N002245 004 |
| IMPAX LABS | 64.8MG A080151 001 |

| **THYROTROPIN** |  |
| **INJECTABLE; INJECTION** |  |
| THYTROPAR | 10 IU/VIAL N008682 001 |

| **TIAGABINE HYDROCHLORIDE** |  |
| **TABLET; ORAL** |  |
| GABITRIL |  |
| CEPHALON | 6MG N020646 006 Nov 29, 2005 |
|  | 8MG N020646 007 Nov 29, 2005 |
|  | 10MG N020646 008 Nov 29, 2005 |
|  | 20MG N020646 004 Sep 30, 1997 |

| **TICARCILLIN DISODIUM** |  |
| **INJECTABLE; INJECTION** |  |
| TICAR |  |
| GLAXOSMITHKLINE | EQ 1GM BASE/VIAL N050497 001 |
|  | EQ 3GM BASE/VIAL N050497 002 |
|  | EQ 6GM BASE/VIAL N050497 003 |
|  | EQ 20GM BASE/VIAL N050497 004 |
|  | EQ 30GM BASE/VIAL N050497 005 Apr 04, 1984 |

| **TICLOPIDINE HYDROCHLORIDE** |  |
| **TABLET; ORAL** |  |
| TICLID |  |
| ROCHE PALO | 125MG N019979 001 Mar 24, 1993 |
|  | 250MG N019979 002 Oct 31, 1991 |
| ACTAVIS ELIZABETH | 250MG A075253 001 Aug 20, 1999 |
| MYLAN | 250MG A075161 001 Sep 13, 1999 |
|  | 250MG A075316 001 Nov 02, 1999 |
| WATSON LABS | 250MG A075309 001 Apr 26, 2000 |
| YAOPHARMA CO LTD | 250MG A075318 001 Aug 20, 1999 |

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## Ticlopidine Hydrochloride

**Tablet; Oral**

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## Tildurionate Disodium

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## Timolol Maleate

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<td>10mg **</td>
<td>N018017 002</td>
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<td></td>
<td>20mg **</td>
<td>N018017 004</td>
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## Timolol Maleate

**Quantum Pharmics**

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<td>5mg</td>
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## Tinzaparin Sodium

**Injectable; Injection**

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<td>Innohep</td>
<td>20,000 IU/ML</td>
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## Tioconazole

**Cream; Topical**

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<td>Pfizer</td>
<td>1%</td>
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## Tirofiban Hydrochloride

**Injectable; Injection**

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## Tizanidine Hydrochloride

**Tablet; Oral**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### TOBRAMYCIN

**Tobramycin Solution/Drops; Ophthalmic**
- **Manufacturer:** ALCON PHARMS LTD
  - Strength: 0.3%
  - NDC: A063176 001
  - Date: May 25, 1994
- **Manufacturer:** APOTEX INC
  - Strength: 0.3%
  - NDC: A065087 001
  - Date: Feb 25, 2002

**Tobramycin Sulfate; Injectable; Injection**
- **Manufacturer:** LILLY
  - Strength: 10mg BASE/ML
  - NDC: A062008 004
  - Date: Jan 04, 1986
  - Additional: EQ 40mg BASE/ML
  - NDC: A062006 001
  - Date: Apr 29, 1987
- **Manufacturer:** HOSPIRA
  - Strength: 10mg BASE/ML
  - NDC: A063080 001
  - Date: Apr 30, 1991
  - Additional: EQ 40mg BASE/ML
  - NDC: A063119 001
  - Date: Jul 29, 1991
- **Manufacturer:** IGI LABS INC
  - Strength: 10mg BASE/ML
  - NDC: A063120 001
  - Date: Jul 29, 1991
  - Additional: EQ 40mg BASE/ML
  - NDC: A063121 001
  - Date: Oct 31, 1994
- **Manufacturer:** APOTHECON
  - Strength: 10mg BASE/ML
  - NDC: A064021 001
  - Date: Nov 09, 1984
  - Additional: EQ 40mg BASE/ML
  - NDC: A064022 001
  - Date: May 29, 1991

**Tobramycin Sulfate (Pharmacy Bulk)**
- **Manufacturer:** HOSPIRA
  - Strength: 40mg BASE/ML
  - NDC: A063116 001
  - Date: May 18, 1992

### TOCAINE HYDROCHLORIDE

**Tocainide Hydrochloride; Tablet; Oral**
- **Manufacturer:** ASTRAZENECA
  - Strength: 400mg
  - NDC: N018257 001
  - Date: Nov 09, 1984
  - Additional: 600mg
  - NDC: N018257 002
  - Date: Nov 09, 1984

### TOLAZAMIDE

**Tolazamide; Tablet; Oral**
- **Manufacturer:** BARR
  - Strength:
    - 100mg
      - NDC: A070162 001
      - Date: Jan 14, 1986
    - 250mg
      - NDC: A070163 001
      - Date: Jan 14, 1986
    - 500mg
      - NDC: A070164 001
      - Date: Jan 14, 1986
  - Additional: 250mg
    - NDC: A070165 001
    - Date: Jan 10, 1986
  - Additional: 500mg
    - NDC: A070166 001
    - Date: Jan 10, 1986
    - Additional: 500mg
      - NDC: A070167 001
      - Date: Jan 10, 1986
  - Additional: 250mg
    - NDC: A071355 001
    - Date: Jul 16, 1987
  - Additional: 250mg
    - NDC: A070169 001
    - Date: Apr 02, 1986
  - Additional: 500mg
    - NDC: A070168 001
    - Date: Jan 09, 1986

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**TOLEZAMIDE**

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**TOLAZOLINE HYDROCHLORIDE**

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**TOLBUTAMIDE**

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**TOLBUTAMIDE SODIUM**

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| **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** |
### Tolmetin Sodium

- **Tablet; Oral**
  - **Tolmetin Sodium**
    - **EQ 600mg Base**
      - SUN PHARM INDUSTRIES
      - EQ 200mg Base
      - A074729 001 Feb 27, 1997
      - A073310 001 Nov 27, 1991

### Tolterodine Tartrate

- **Tablet; Oral**
  - **Tolterodine Tartrate**
    - **1mg**
      - A073310 001 Nov 27, 1991
      - A200164 001 Sep 25, 2012
    - **2mg**
      - A200164 002 Sep 25, 2012

### Tolvaptan

- **Tablet; Oral**
  - **Samsca**
    - **60mg**
      - N022275 003 May 19, 2009

### Topiramate

- **Capsule; Oral**
  - **Topamax Sprinkle**
    - **Janssen Pharm**
      - **50mg**
        - N020844 003 Oct 26, 1998
  - **Topiramate**
    - **Barr**
      - **15mg**
        - A076448 001 Apr 15, 2009
      - **25mg**
        - A076448 002 Apr 15, 2009
      - **Fosun Pharma**
        - **15mg**
          - A079206 001 Oct 14, 2009
        - **25mg**
          - A079206 002 Oct 14, 2009
      - **Mylan**
        - **15mg**
          - A078418 001 Oct 14, 2009
        - **25mg**
          - A078418 002 Oct 14, 2009
  - **Tablet; Oral**
    - **Topamax**
      - **Janssen Pharm**
        - **300mg**
          - N020505 003 Dec 24, 1996
        - **400mg**
          - N020505 006 Dec 24, 1996
      - **Actavis Totowa**
        - **25mg**
          - A078637 001 Feb 27, 2013
        - **50mg**
          - A078637 002 Feb 27, 2013
        - **100mg**
          - A078637 003 Feb 27, 2013
        - **200mg**
          - A078637 004 Feb 27, 2013
      - **Barr**
        - **25mg**
          - A076315 001 Mar 27, 2009
        - **100mg**
          - A076315 002 Mar 27, 2009
        - **200mg**
          - A076315 003 Mar 27, 2009
      - **Hikma Pharm**
        - **25mg**
          - A091185 001 Nov 25, 2013
        - **50mg**
          - A091185 002 Nov 25, 2013
        - **100mg**
          - A091185 003 Nov 25, 2013
        - **200mg**
          - A091185 004 Nov 25, 2013
      - **Mylan**
        - **25mg**
          - A076314 001 Mar 27, 2009
        - **50mg**
          - A076314 002 Mar 27, 2009
        - **100mg**
          - A076314 003 Mar 27, 2009
        - **200mg**
          - A076314 004 Mar 27, 2009
      - **Pliva Hrvatska DoO**
        - **25mg**
          - A077905 001 Mar 30, 2009
        - **50mg**
          - A077905 002 Mar 30, 2009
        - **100mg**
          - A077905 003 Mar 30, 2009
        - **200mg**
          - A077905 004 Mar 30, 2009
      - **Roxane**
        - **25mg**
          - A076306 001 Mar 27, 2009
        - **50mg**
          - A076306 002 Mar 27, 2009
        - **100mg**
          - A076306 003 Mar 27, 2009
        - **200mg**
          - A076306 004 Mar 27, 2009
      - **Watson Labs**
        - **25mg**
          - A077643 001 Feb 27, 2009
        - **50mg**
          - A077643 002 Feb 27, 2009
        - **100mg**
          - A077643 003 Feb 27, 2009
        - **200mg**
          - A077643 004 Feb 27, 2009
      - **Wockhardt USA**
        - **25mg**
          - A090353 001 Sep 01, 2010
        - **50mg**
          - A090353 002 Sep 01, 2010
        - **100mg**
          - A090353 003 Sep 01, 2010
        - **200mg**
          - A090353 004 Sep 01, 2010

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

### TOPOTECAN HYDROCHLORIDE

**Injectable; Injection**

- **Topotecan Hydrochloride**
  - Fresenius Kabi Oncol EQ 4MG Base/Vial A091376 001 Nov 29, 2010
  - Sun Pharm Inds Ltd EQ 4MG Base/Vial A202203 001 Aug 29, 2013

**Solution; Intravenous**

- Topotecan
  - **Sandoz Inc** EQ 1MG Base/ML (EQ 1MG Base/ML) **
    - EQ 3MG Base/3ML (EQ 1MG Base/ML) **
    - EQ 4MG Base/4ML (EQ 1MG Base/ML) **
    - N200199 001 Feb 25, 2011
    - N200199 002 Feb 25, 2011
    - N200199 003 Feb 25, 2011

### TORSEMIDE

**Injectable; Injection**

- **Demadex**
  - Roche 50MG/5ML (10MG/ML) **
  - 20MG/2ML (10MG/ML) **
  - N020137 002 Aug 23, 1993
  - N020137 001 Aug 23, 1993

- **Luitpold**
  - West-Ward Pharms Int 20MG/2ML (10MG/ML)
  - 50MG/5ML (10MG/ML)
  - A090656 001 Apr 21, 2011
  - A090656 002 Apr 21, 2011
  - A078007 001 Jun 11, 2008
  - A078007 002 Jun 11, 2008

### TRAMADOL HYDROCHLORIDE

**Tablet; Oral**

- **Tramadol Hydrochloride**
  - Accord Ltlcare 50MG
  - Actavis Elizabeth 50MG
  - Asta 50MG
  - Fosun Pharma 50MG
  - Ivax Sub Teva Pharms 50MG
  - Mylan Pharms Inc 50MG
  - Northstar Ltlcare 50MG
  - Watson Labs 50MG

- **Ultram**
  - Janssen Pharms 100MG
  - Purdue Pharma 100MG **
  - 200MG **
  - 300MG **

- **Ultram ER**
  - Valeant Pharms 100MG
  - 200MG
  - 300MG

- **Tablet, Orally Disintegrating; Oral**
  - Rybix ODT
  - Shionogi Inc 50MG

### TRAMETINIB DIMETHYL SULFOXIDE

**Tablet; Oral**

- **Mekinist**
  - Novartis Pharms Corp EQ 1MG

### TRANDOLAPRIL

**Tablet; Oral**

- **Mavik**
  - Abbott 1MG
  - 2MG
  - 4MG

- **Trandolapril**
  - CIPLA 1MG
  - 2MG

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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**TRANEXAMIC ACID**

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<th>Strength</th>
<th>NDC</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TRAVOPROST</strong></td>
<td>SOLUTION/DROPS; OPHTHALMIC</td>
<td>TRAVATAN</td>
<td>0.003% **</td>
<td>N204822 001</td>
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**TRAZODONE HYDROCHLORIDE**

<table>
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<tr>
<th>Drug Product</th>
<th>Type</th>
<th>Manufacturer</th>
<th>Strength</th>
<th>NDC</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TRAZODONE HYDROCHLORIDE</strong></td>
<td>TABLET; ORAL</td>
<td>DESYREL</td>
<td>50MG **</td>
<td>N018207 001</td>
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<td></td>
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<td>100MG **</td>
<td>N018207 002</td>
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<td></td>
<td>150MG **</td>
<td>N018207 003</td>
<td>Mar 25, 1985</td>
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<td></td>
<td></td>
<td></td>
<td>300MG **</td>
<td>N018207 004</td>
<td>Nov 07, 1988</td>
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**TREATODINE**

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<thead>
<tr>
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<th>Date</th>
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<tbody>
<tr>
<td><strong>TREATODINE</strong></td>
<td>TABLET, EXTENDED RELEASE; ORAL</td>
<td>OLEPTRO</td>
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**TRETINOIN**

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</thead>
<tbody>
<tr>
<td><strong>TRETINOIN</strong></td>
<td>CAPSULE; ORAL</td>
<td>ALLERGAN SALES LLC</td>
<td>0.0375%</td>
<td>A090098 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
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<tr>
<th>Drug Product</th>
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<tbody>
<tr>
<td>TRETINOIN CREAM</td>
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<td>A202209 001 Oct 11, 2012</td>
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<tr>
<td>TRETINOIN SOLUTION</td>
<td>0.05%</td>
<td>N016921 001</td>
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<td>TRETINOIN SWAB</td>
<td>0.05%</td>
<td>A074873 001 Jun 19, 1998</td>
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<td>TRETINOIN SWAB</td>
<td>0.05%</td>
<td>A075260 001 Jan 25, 1999</td>
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<td>TRETINOIN TUBE</td>
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<td>1MG</td>
<td>N011161 009</td>
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<td>TRIAMCINOLONE TABLET</td>
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<td>N011161 004</td>
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<td>TRIAMCINOLONE TABLET</td>
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<td>N011161 007</td>
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<td>TRIAMCINOLONE TABLET</td>
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<td>N011161 011</td>
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<td>TRIAMCINOLONE TABLET</td>
<td>16MG</td>
<td>N011161 010</td>
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<td>TRIAMCINOLONE AEROSOL</td>
<td>0.025%</td>
<td>N018117 001 Apr 23, 1982</td>
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<td>A083017 003</td>
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<tr>
<td>TRIAMCINOLONE CREAM</td>
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<td>A083016 004</td>
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<td>TRIAMCINOLONE CREAM</td>
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<td>A088820 001 Oct 16, 1984</td>
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<td>FLUTEX IVAX PHARMS</td>
<td>0.25%</td>
<td>A085539 001</td>
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<td>FLUTEX IVAX PHARMS</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### TRIAMCINOLONE ACETONIDE

#### CREAM; TOPICAL

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Approval Code</th>
<th>Approval Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>KENALOG</td>
<td>DELCOR ASSET CORP</td>
<td>0.5%</td>
<td>A083943 001</td>
<td>2019</td>
</tr>
<tr>
<td>KENALOG-H</td>
<td>DELCOR ASSET CORP</td>
<td>0.1%</td>
<td>A086240 001</td>
<td>2019</td>
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<tr>
<td>TRIACET</td>
<td>TEVA</td>
<td>0.025%</td>
<td>A084908 001</td>
<td>2019</td>
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<td></td>
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<td>0.5%</td>
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<tr>
<td>TRIACORT</td>
<td>SOLVAY</td>
<td>0.1%</td>
<td>A087113 001</td>
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#### TRIAMCINOLONE ACETONIDE INJECTABLE; INJECTION

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Approval Code</th>
<th>Approval Year</th>
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<tbody>
<tr>
<td>TRIATEX</td>
<td>IVAX PHARMS</td>
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<td>A087430 001</td>
<td>1988</td>
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<td>0.1%</td>
<td>A087429 001</td>
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<td>A087428 001</td>
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#### TRIAMCINOLONE ACETONIDE OINTMENT; TOPICAL

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Approval Code</th>
<th>Approval Year</th>
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<tbody>
<tr>
<td>ARISTOCORT</td>
<td>ASTELLAS</td>
<td>0.1%</td>
<td>A083380 001</td>
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<td>INJECTABLE; INJECTION</td>
<td>3MG/ML</td>
<td>N019503 001</td>
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<td>PARNELL</td>
<td>10MG/ML</td>
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<td>SANOX INC</td>
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<td>A090164 001</td>
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<td>WATSON LABS</td>
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<td>A085825 001</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

**See List Footnote**
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<td><strong>ARISTOCORT A</strong></td>
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<td><strong>FLUTEX PASTE; DENTAL</strong></td>
<td><strong>IVAX PHARMS</strong></td>
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<td><strong>FLUTEX</strong></td>
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<td>MYLAN PHARMS INC</td>
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<td><strong>TRIAMCINOLONE ACETONIDE</strong></td>
<td>MORTON GROVE</td>
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<td>TARO</td>
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<td><strong>SPRAY, METERED; NASAL</strong></td>
<td>ALLERNAZE</td>
<td>0.05MG/SPRAY</td>
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<td>Feb 04, 2000</td>
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<td><strong>TRIAMCINOLONE ACETONIDE</strong></td>
<td>LUPIN ATLANTIS</td>
<td>0.05MG/SPRAY</td>
<td>N020120</td>
<td>Feb 04, 2000</td>
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<td>NASACORT HFA</td>
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<td><strong>PERRIGO ISRAEL</strong></td>
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<td>A078104</td>
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<tr>
<td><strong>ARISTOCORT</strong></td>
<td>FOSUN PHARMA</td>
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<td>40MG/ML</td>
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<td><strong>SYRUP; ORAL</strong></td>
<td>ARISTOCORT</td>
<td>2MG/5ML</td>
<td>N011960</td>
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<tr>
<td><strong>KENACORT</strong></td>
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<td>4MG BASE/5ML</td>
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<td><strong>HALCION</strong></td>
<td>PHARMACIA AND UPJOHN</td>
<td>0.125MG</td>
<td>A074446</td>
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<td>WATSON LABS</td>
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<td><strong>TRICHLOROMETHAIZIDE</strong></td>
<td>TABLET; ORAL</td>
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<td>N012594</td>
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<td><strong>METARYDRIN</strong></td>
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<td>4MG</td>
<td>N012594</td>
<td>Jun 16, 1988</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
## TRICHLORPETHIAZIDE

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<td>Trichlomex</td>
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<td>Lannett</td>
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<td>Trichlormas</td>
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<td>Mast Mm</td>
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<td>Par Pharm</td>
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<td>Sandox</td>
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## TRICLOFOS SODIUM

<table>
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<th>1.5gm/15ml</th>
<th>750mg</th>
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<tbody>
<tr>
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## TRIDIHEXETHYL CHLORIDE

<table>
<thead>
<tr>
<th>Injectable/Injection</th>
<th>10mg/ml</th>
<th>25mg</th>
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<tr>
<td>Lederle</td>
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</table>

## TRIFLUOPERAZINE HYDROCHLORIDE

### Concentrate/Oral

**Stelazine**
- **Glaxosmithkline**
  - EQ 1mg BASE/ML **

**injectable/injection**
- **Wockhardt**
  - EQ 10mg BASE/ML
  - EQ 10mg BASE/ML

### TABLET/Oral

**Stelazine**
- **Glaxosmithkline**
  - EQ 2mg BASE/ML **

**Duramed pharms barr**
- EQ 1mg BASE
  - EQ 2mg BASE
  - EQ 5mg BASE
  - EQ 10mg BASE

**Ivax pharms**
- EQ 1mg BASE
  - EQ 2mg BASE
  - EQ 5mg BASE
  - EQ 10mg BASE

**Sandoz**
- EQ 1mg BASE
  - EQ 2mg BASE
  - EQ 5mg BASE
  - EQ 10mg BASE

**Watson labs**
- EQ 1mg BASE
  - EQ 2mg BASE
  - EQ 5mg BASE
  - EQ 10mg BASE

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**DISCONTINUED DRUG PRODUCT LIST**

TRIFLUPROMAZINE

**SUSPENSION; ORAL**

VESPRIN

APOTHECON  

EQ 50MG HYDROCHLORIDE/5ML  

N011491 004

TRIFLUPROMAZINE HYDROCHLORIDE

**INJECTABLE; INJECTION**

VESPRIN

APOTHECON  

3MG/ML  

N011325 005  

10MG/ML  

N011325 004  

20MG/ML  

N011325 001

TABLET; ORAL

VESPRIN

BRISTOL MYERS SQUIBB  

10MG  

N011123 001  

25MG  

N011123 002  

50MG  

N011123 003

TRIHEXYPHENIDYL HYDROCHLORIDE

**CAPSULE, EXTENDED RELEASE; ORAL**

ARTANE

LEDERLE  

5MG  

N006773 010  

5MG  

N012947 001

ELIXIR; ORAL

ARTANE

LEDERLE  

2MG/5ML  

N006773 009

TRIHEXYPHENIDYL HYDROCHLORIDE

PHARM VENTURES  

2MG/5ML  

A089514 001 Apr 07, 1989

TABLET; ORAL

ARTANE

* LEDERLE  

2MG **  

N006773 005  

5MG **  

N006773 003

TREMIN

SCHERING  

2MG  

A080381 001  

5MG  

A080381 003

TRIHEXYPHENIDYL HYDROCHLORIDE

HIKMA PHARMS  

2MG  

A040337 002 Feb 16, 2000  

5MG  

A040337 001 Feb 16, 2000

NYLOS  

5MG  

A085622 001

VANGARD  

2MG  

A088035 001 Jul 30, 1982  

WATSON LABS  

2MG  

A040184 001 Feb 06, 1998  

5MG  

A040184 002 Feb 06, 1998

5MG  

A085105 001

TRILOSTANE

**CAPSULE; ORAL**

MODRASTANE

BIOENVISION  

30MG  

N018719 002 Dec 31, 1984  

60MG  

N018719 001 Dec 31, 1984

TRIMEPRAZINE TARTRATE

**CAPSULE, EXTENDED RELEASE; ORAL**

TEMARIL

ALLERGAN HERBERT  

EQ 5MG BASE  

N011316 004

SYRUP; ORAL

TEMARIL

ALLERGAN HERBERT  

EQ 2.5MG BASE/5ML  

N011316 003

TRIMEPRAZINE TARTRATE

ALPHARMA US PHARMS  

EQ 2.5MG BASE/5ML  

A085015 001 Feb 18, 1982  

MORTON GROVE  

EQ 2.5MG BASE/5ML  

A088285 001 Apr 11, 1985

TABLET; ORAL

TEMARIL

ALLERGAN HERBERT  

EQ 2.5MG BASE  

N011316 001

TRIMETHADIONE

**CAPSULE; ORAL**

TRIDIONE

ABBVIE  

300MG  

N005856 005

SOLUTION; ORAL

TRIDIONE

ABBVIE  

200MG/5ML  

N005856 002

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Manufacturer</th>
<th>ATC Code</th>
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<tbody>
<tr>
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<td>TRIMETHOBENZAMIDE HYDROCHLORIDE</td>
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<td>TRIMETHOBENZAMIDE HYDROCHLORIDE</td>
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<td>HOSPIRA</td>
<td>100MG/ML</td>
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<td>SMITH AND NEPHEW</td>
<td>100MG/ML</td>
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<td>SOLOPAK</td>
<td>100MG/ML</td>
<td>A089043 001 Apr 04, 1986</td>
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<td>WATSON LABS</td>
<td>100MG/ML</td>
<td>A086577 001 Oct 19, 1982</td>
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<td>TRIMETHOPRIM</td>
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<td>PROLOPRIM MONARCH PHARMS 100MG</td>
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<td>USL PHARMA</td>
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<td>A017943 001 Jul 14, 1982</td>
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<td>Injectable; Injection</td>
<td>TRIMETHOPRIM SUN PHARM INDUSTRIES 100MG</td>
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<td>TEVA</td>
<td>200MG **</td>
<td>A070494 001 Jan 22, 1986</td>
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<td>TRIMPEX</td>
<td>100MG</td>
<td>A070495 001 Sep 24, 1986</td>
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<td>Solution; Oral</td>
<td>TRIMETHOPRIM HYDROCHLORIDE MEDIMUNE ONCOLOGY EQ 25MG BASE/VIAL</td>
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<td>ALLEGIS</td>
<td>EQ 25MG BASE/5ML</td>
<td>N074374 001 Jun 23, 1995</td>
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<td>TRIMETREXATE GLUCURONATE</td>
<td>Injectable; Injection</td>
<td>TRIMETREXATE GLUCURONATE NEUTREXIN</td>
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<tr>
<td>MEDIMUNE ONCOLOGY</td>
<td>EQ 25MG BASE/VIAL</td>
<td>N020326 001 Dec 17, 1993</td>
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<tr>
<td>NEUTREXIN</td>
<td>EQ 200MG BASE/VIAL</td>
<td>N020326 002 Jul 31, 1998</td>
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<td>TRIMIPRAMINE MALEATE</td>
<td>Capsule; Oral</td>
<td>TRIMIPRAMINE MALEATE USL PHARMA EQ 25MG BASE</td>
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<td>CAPSULE; Oral</td>
<td>EQ 50MG BASE</td>
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<td>TRIOXSALEN</td>
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<td>TRIOXSALEN VALLENT PHARM INTL 5MG</td>
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<td>TRISORALEN</td>
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<td>TRIPLENNAMINE CITRATE</td>
<td>Elixir; Oral</td>
<td>TRIPLENNAMINE CITRATE PBZ NOVARTIS EQ 25MG HYDROCHLORIDE/5ML</td>
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<td>PBZ</td>
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<td>TRIPLENNAMINE HYDROCHLORIDE</td>
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<td>NOVARTIS 50MG</td>
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<td>ANABOLIC</td>
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<td>BARR</td>
<td>50MG</td>
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<td>HEATHER</td>
<td>50MG</td>
<td>A083989 001</td>
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<tr>
<td>IMPAX LABS</td>
<td>50MG</td>
<td>A080785 001</td>
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<td>LANNETT</td>
<td>50MG</td>
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<td>NYLOS</td>
<td>50MG</td>
<td>A085412 001</td>
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<tr>
<td>PARKE DAVIS</td>
<td>25MG</td>
<td>A083625 001</td>
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<tr>
<td>PARKE DAVIS</td>
<td>50MG</td>
<td>A083626 001</td>
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<td>WATSON LABS</td>
<td>50MG</td>
<td>A080713 001</td>
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<td>TRIPLENNAMINE HYDROCHLORIDE</td>
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<td>WATSON LABS 50MG</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
### TRIPELENAMINE HYDROCHLORIDE
- **Tablet; Oral**: Tripeplenamine Hydrochloride 50mg, PBZ-SR Novartis 50mg, 100mg N010533 002 N010533 001

### TRIPLE SULFA (SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE)
- **Cream; Vaginal**: Gyne-Sulf G and W Labs 3.7%; 2.86%; 3.42% A088607 001 Jun 09, 1986
  - Sultrim Ortho McNeil Pharm 3.7%; 2.86%; 3.42% N005794 001
  - Triple Sulfa Alpharma US Pharms 3.7%; 2.86%; 3.42% A087864 001 Sep 01, 1982
    - Fougera 3.7%; 2.86%; 3.42% A086424 001
    - Perrigo New York 3.7%; 2.86%; 3.42% A087285 001 Nov 15, 1982
  - Trysul Savage Labs 3.7%; 2.86%; 3.42% A087887 001 Jul 23, 1982
  - Vagilia G and W Labs Inc 3.7%; 2.86%; 3.42% A088821 001 Nov 09, 1987
  - Sulfatin Ortho McNeil Pharm 184mg; 143.75mg; 172.5mg N005794 002
  - Triple Sulfa Alpharma US Pharms 184mg; 143.75mg; 172.5mg A088463 001 Jan 03, 1985
    - Fougera 184mg; 143.75mg; 172.5mg A088462 001 Jan 03, 1985

### TRIPROLIDINE HYDROCHLORIDE
- **Syrup; Oral**: Actidil Glaxosmithkline 1.25mg/5ml N011496 002 Jul 01, 1983
  - Myidyl Usl Pharma 1.25mg/5ml A087963 001 Jan 18, 1983
  - Triprolidine Hydrochloride Alpharma US Pharms 1.25mg/5ml A085940 001
    - Halsey 1.25mg/5ml A087356 001 Jan 17, 1985
      - Pharmassoc 1.25mg/5ml A087514 001 Feb 10, 1982
  - Tablet; Oral: Actidil Glaxosmithkline 2.5mg N011110 002 Jul 01, 1983
  - Triprolidine Hydrochloride Vitarine 2.5mg A085610 001
    - Watson Labs 2.5mg A085094 001

### TRISULFAPYRIMIDINES (SULFADIAZINE; SULFAMERAZINE; SULFAMETHAZINE)
- **Suspension; Oral**: Lantrisul Lannett 167mg/5ml; 167mg/5ml; 167mg/5ml A080123 002
  - Neotrizine Lilly 167mg/5ml; 167mg/5ml; 167mg/5ml N006317 012
  - Sulflagoid Forest Pharma 167mg/5ml; 167mg/5ml; 167mg/5ml A080100 001
  - Sulfose Wyeth Ayerst 167mg/5ml; 167mg/5ml; 167mg/5ml A080013 002
  - Terfonyl Bristol Myers Squibb 167mg/5ml; 167mg/5ml; 167mg/5ml N006904 002
  - Triple Sulfa Alpharma US Pharms 167mg/5ml; 167mg/5ml; 167mg/5ml A080280 001
  - Triple Sulfas Lederle 167mg/5ml; 167mg/5ml; 167mg/5ml N006920 003
  - Tablet; Oral: Neotrizine Lilly 167mg; 167mg; 167mg N006317 011
    - Sulfa-Triple #2 Impax Labs 167mg; 167mg; 167mg A080079 001
    - Sulflagoid Forest Pharma 167mg; 167mg; 167mg A080099 001

**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
** Discontinued Drug Product List **

### Trisulfapyrimidines (Sulfadiazine; Sulfamerazine; Sulfamethazine)

<table>
<thead>
<tr>
<th>Tablet; Oral</th>
<th>Brand Name</th>
<th>Combinations</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>Sulfose</td>
<td>Wyeth Ayerst</td>
<td>167mg;167mg;167mg</td>
<td>A080013 001</td>
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<tr>
<td>Tertonyl</td>
<td>Bristol Myers Squibb</td>
<td>167mg;167mg;167mg</td>
<td>N006904 001</td>
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<tr>
<td>Triple Sulfa</td>
<td>Purepac Pharm</td>
<td>167mg;167mg;167mg</td>
<td>A080086 001</td>
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<tr>
<td>Triple Sulfas</td>
<td>Lederle</td>
<td>167mg;167mg;167mg</td>
<td>N006920 002</td>
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<tr>
<td>Triple Sulfoid</td>
<td>Pal Pak</td>
<td>167mg;167mg;167mg</td>
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### Troglitazone

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<tbody>
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<td>Prelay</td>
<td>Sankyo</td>
<td>200mg</td>
<td>N020719 001 Jan 29, 1997</td>
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<td></td>
<td>300mg</td>
<td>N020719 003 Aug 04, 1997</td>
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<td></td>
<td></td>
<td>400mg</td>
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<tr>
<td>Rezulin</td>
<td>Pfizer Pharms</td>
<td>200mg</td>
<td>N020720 001 Jan 29, 1997</td>
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<td>300mg</td>
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<td>400mg</td>
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### Trolamine Polypeptide Oleate Condensate

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<td>Cerumenex</td>
<td>Pharm Res Assoc</td>
<td>10%</td>
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### Troleandomycin

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<th>Manufacturer</th>
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<tr>
<td>TAO</td>
<td>Pfizer</td>
<td>Eq 250mg Base</td>
<td>N050336 002</td>
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<td>Suspension; Oral</td>
<td>TAO</td>
<td>Eq 125mg Base/5ml</td>
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### Tromethamine

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<td>Tham + Hospira</td>
<td>3.6gm/100ml</td>
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### Tropicamide

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<tr>
<td>Mydriacyl</td>
<td>Alcon</td>
<td>0.5% **</td>
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<td></td>
<td></td>
<td>1% **</td>
<td>N012111 004</td>
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<td>Mydriafair</td>
<td>Pharmafair</td>
<td>0.5%</td>
<td>A088274 001 Sep 16, 1983</td>
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<td>Tropicamide</td>
<td>Akorn</td>
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<td>A088447 001 Aug 28, 1985</td>
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<td>Alcon Pharms Ltd</td>
<td>1%</td>
<td>A089172 001 Dec 28, 1990</td>
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<td>Miza Pharms USA</td>
<td>0.5%</td>
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<td>Watson Labs</td>
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### Trospium Chloride

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<td>Sanctura Xr</td>
<td>Allergan</td>
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<td>Trospium Chloride</td>
<td>Uspner Smith Labs</td>
<td>60mg</td>
<td>A091635 001 Apr 29, 2015</td>
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<td>Tablet; Oral</td>
<td>Allergan</td>
<td>20mg **</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<td>TROVAFLOXACIN MESYLATE</td>
<td>TABLET; ORAL</td>
<td>TROVAN</td>
<td>Pfizer Eq</td>
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<td>Dec 18, 1997</td>
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<td>TROVAFLOXACIN MESYLATE</td>
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<td>Eq 200mg Base</td>
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<td>TUBOCURARINE CHLORIDE</td>
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<td>TUBOCURARINE CHLORIDE</td>
<td>Bristol Myers Squibb</td>
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<td>Hospira</td>
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<td>TUBOCURARINE CHLORIDE</td>
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<td>Lilly</td>
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<td>BILOPAQUE</td>
<td>GE Healthcare</td>
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<td>UNOPROSTONE ISOPROPYL</td>
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<td>RESCULA</td>
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<td>STERILE UREA</td>
<td>Hospira</td>
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<td>May 10, 2001</td>
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<td>OTSUKA AMERICA</td>
<td>N020586 002</td>
<td>May 10, 2001</td>
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<td>Helicosol Metabolic Solutions</td>
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<td>Pylori-Chek Breath Test</td>
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<td>UROFOLLITROPIN</td>
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<td>METRODIN</td>
<td>Serono</td>
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<td>UROFOLLITROPIN</td>
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<td>Ferring Bravelle +</td>
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<td>Fertinex Serono</td>
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<td>Aug 23, 1996</td>
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*Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons***
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
# DISCONTINUED DRUG PRODUCT LIST

**See List Footnote**

## Vancomycin Hydrochloride

**Injectable; Injection**

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## Vancomycin Hydrochloride

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**

## Vardenafil Hydrochloride

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## Vecuronium Bromide

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## Velaglucerase Alfa

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## Venlafaxine Hydrochloride

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## Venlafaxine Hydrochloride

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## Effexor

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**VERATRUM VIRIDE ROOT**

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**VIDARABINE**

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**VINBLASTINE SULFATE**

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<td>10MG/VIAL</td>
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<td>10MG/VIAL</td>
<td>A089565 001 Aug 18, 1987</td>
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**VINCRISTINE SULFATE**

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<td>1MG/VIAL</td>
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<td>1MG/ML</td>
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<td>5MG/VIAL</td>
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**VINORELBINE TARTRATE**

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**VIOMYCIN SULFATE**

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**VITAMIN A**

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
VITAMIN A PALMITATE
CAPSULE; ORAL

AFAXIN
STERLING WINTHROP

A083187 001

ALPHALIN
LILLY

A080883 001

DEL-VI-A
DEL RAY LABS

A080830 001

VI-DOM-A
BAYER PHARMS

A080972 001

VITAMIN A
BANNER PHARMACAPS

A080702 001

BRISTOL MYERS SQUIBB
CHASE CHEM

A080746 001

ELKINS SINN
EVERYLIFE

A083207 001

EVERYLIFE

A085479 001

IMFAX LABS

A080953 001

IVAX SUB TEVA PHARMS

A080955 001

A083035 001

A083190 001

A083457 002

A083457 001

WEST WARD

A080967 001

WHARTON LABS

A083665 001

VITAMIN A PALMITATE
ARCUM
BANNER PHARMACAPS

A083311 001

A083321 001

A083948 001

A083981 001

VITAMIN A SOLUBILIZED
TEVA

INJECTABLE; INJECTION

VITAMIN A PALMITATE
BEL MAR

A080819 001

VORICONAZOLE
FOR SUSPENSION; ORAL
VORICONAZOLE
MYLAN PHARMS INC

A202361 001 May 28, 2013

200MG/5ML

WORTIOXETINE HYDROBROMIDE
TABLET; ORAL
TRINTELLIX
+ TAKEDA PHARMS USA

N204447 003 Sep 30, 2013

EQ 15MG BASE **

WARFARIN POTASSIUM
TABLET; ORAL
ATHROMBIN-K
PHARM RES ASSOC

2MG

N011771 007

5MG

N011771 004

10MG

N011771 005

25MG

N011771 006

WARFARIN SODIUM
INJECTABLE; INJECTION
COUMADIN
BRISTOL MYERS SQUIBB

N009218 024 Feb 07, 1995

5MG/VIAL

50MG/VIAL

75MG/VIAL

N009218 020

N009218 012

TABLET; ORAL
ATHROMBIN
PHARM RES ASSOC

5MG

N011771 003

10MG

N011771 002

25MG

N011771 001

PANWARFIN
ABBOTT

2MG

N017020 001

2.5MG

N017020 002

5MG

N017020 003

7.5MG

N017020 004

** Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons **
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<th>Drug Product</th>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
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<tr>
<th>Name</th>
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<tr>
<td>ZALEPLON</td>
<td>Capsule; Oral</td>
<td>MYLAN</td>
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<td>ZIPRASIDONE HYDROCHLORIDE</td>
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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
**See List Footnote**

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<tr>
<td>ZOLPIDEM TARTRATE</td>
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**ZONISAMIDE**

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**ZONISAMIDE**

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<tr>
<td>ZONEGRAN</td>
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ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of Orphan Designations and Approvals is available at:

http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm
### Drug Products Which Must Demonstrate In Vivo Bioavailability Only If Product Fails to Achieve Adequate Dissolution

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Dosage Forms</th>
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<tbody>
<tr>
<td>Acetaminophen; Aspirin; Butalbital</td>
<td>Capsule or Tablet; Oral</td>
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<tr>
<td>160-165mg; 325mg; 50mg; 160-165mg; 50mg</td>
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<td>Acetaminophen; Aspirin; Butalbital; Caffeine</td>
<td>Capsule or Tablet; Oral</td>
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<td>Acetaminophen; Butalbital; Caffeine</td>
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<td>Aspirin; Butalbital</td>
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## APPENDIX A - PRODUCT NAME INDEX

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## APPENDIX A - PRODUCT NAME INDEX

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ARI KAYCE KI T, AMI KACI N SULFATE
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ARI PI PRAZOLE, ARI PI PRAZOLE LAUROX L
ARI STADA, ARI PI PRAZOLE LAUROX L
ARI STADA I NI TI O KI T, ARI PI PRAZOLE LAUROX L
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BYVALSON, NEBIVOLOL HYDROCHLORIDE

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CADUET, AMLODIPINE BESYLATE
CAFCIT, CAFFEINE CITRATE
CAFERGOT, CAFFEINE CITRATE
CALAN, VERAPAMIL HYDROCHLORIDE
CALAN SR, VERAPAMIL HYDROCHLORIDE
CALCIUM ACETATE, CALCIUM ACETATE
CALCIUM CHLORIDE, CALCIUM CHLORIDE
CALCIUM DISODIUM VERSENATE, EDETATE CALCIUM DISODIUM
CALCIUM GLUCONATE, CALCIUM GLUCONATE
CAMBIA, DICLOFENAC POTASSIUM
CAMILA, NORETHINDRONE
CAMPTOSAR, IRINOTECAN HYDROCHLORIDE
CANASA, FLUOROURACIL
CARAC, FLUOROURACIL
CARAFATE, SUCRALFATE
CARBOCAINE, MEPIVACAINE HYDROCHLORIDE
CARBOCAYAMINE, CARBOCAYAMINE
CARBOPLATIN, CARBOPLATIN
CARDENE IN 0.83% SODIUM CHLORIDE IN PLASTIC CONTAINER, NICARDIPINE HYDROCHLORIDE
CARDIOLITE, TECHNETIUM TC-99M SESTAMIBI KIT
CARDIZEM, DILTIAZEM HYDROCHLORIDE
CARDIZEM CD, DILTIAZEM HYDROCHLORIDE
CARDIZEM LA, DILTIAZEM HYDROCHLORIDE
CARDURA, DOXAZOSIN MESYLATE
CARDURA XL, DOXAZOSIN MESYLATE
CARNITOR, LEVOCARNITINE
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CAROSPIR, SPIRONOLACTONE
CARTEOLOL HYDROCHLORIDE, CARTEOLOL HYDROCHLORIDE
CARTIA XT, DILTIAZEM HYDROCHLORIDE
CARVEDILOL, CARVEDILOL
CARVEDILOL PHOSPHATE, CARVEDILOL PHOSPHATE
CASODEX, BICALUTAMIDE
CASPOFUNGIN ACETATE, CASPOFUNGIN ACETATE
CASPORYN HC, HYDROCORTISONE
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CATAPRES, CLONIDINE HYDROCHLORIDE
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CAYSTON, AZTREONAM
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CEFAZOLIN AND DEXTROSE, CEFAZOLIN SODIUM
CEFAZOLIN N IN PLASTIC CONTAINER, CEFAZOLIN SODIUM
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CEPHALEXIN, CEPHALAXIN
CEPA, CYCLOSPORIN
CEFIDE, ELI GLUSTAT TARTRATE
CEREBYX, FOSPHENYTOIN N SODIUM
CERETEC, TECHNETIUM TC-99M EXAMETAZIME KIT
CEREZYME, I M GLUCERASE
CERI NTA, ETHYL NYL ESTRADIOL
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CERVET L, DI NOPROSTONE
CESAMET, NABI LONE
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CETIRIZINE HYDROCHLORIDE ALLERGY, CETIRIZINE HYDROCHLORIDE (OTC)
CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE, CETIRIZINE HYDROCHLORIDE
CETIRIZINE HYDROCHLORIDE HIVES, CETIRIZINE HYDROCHLORIDE (OTC)
CETIRIZINE HYDROCHLORIDE HIVES RELIEF, CETIRIZINE HYDROCHLORIDE (OTC)
CETRXAL, CI PROFOXACIN HYDROCHLORIDE DE
CETROTI DE, CETRORELIX
CETYLEV, ACETYLCYSTEINE NE
CEVI MELI NE HYDROCHLORIDE DE, CEVI MELI NE HYDROCHLORIDE DE
CHANTI X, VARENI CL NE TARTRATE
CHEMET, SUCCI MER
CHENODIOL, CHENODIOL
CHG SCRUB, CHLORHEXIDI NE GLUCONATE (OTC)
CHI LOREN S ADV L, 1 IBUPROFEN (OTC)
CHI LOREN S ADV L ALLERGY SI NUS, CHLORPHENIRAM NE MALEATE (OTC)
CHI LOREN S ADV L COLD, 1 IBUPROFEN (OTC)
CHI LOREN S ADV L-FLAVORED, 1 IBUPROFEN (OTC)
CHI LOREN S ALLERGA ALLERGY, FEXOFENADI NE HYDROCHLORIDE DE (OTC)
CHI LOREN S CETIRI ZI NE HYDROCHLORIDE DE ALLERGY, CETIRI ZI NE HYDROCHLORIDE DE (OTC)
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CHOLAC, LACTULOSE
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CINACALCET HYDROCHLORIDE, CINACALCET HYDROCHLORIDE
CINVANTI, APREPITANT
CIPRO, CIPROFLOXACIN
CIPRO, CIPROFLOXACIN HYDROCHLORIDE
CIPRO HC, CIPROFLOXACIN HYDROCHLORIDE
CIPRODEX, CIPROFLOXACIN
CIPROFLOXACIN, CIPROFLOXACIN
CIPROFLOXACIN EXTENDED RELEASE, CIPROFLOXACIN
CIPROFLOXACIN N I N DEXTROSE 5% I N PLASTIC CONTAINER, CIPROFLOXACIN N
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C S- PYRQ, TECHNETIUM TC-99M PYROPHOSPHATE KIT
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C SATRACURIUM BENzosULFATE PRESERVATIVES FREE, C SATRACURIUM BENzosULFATE
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CLINDAMYCIN PHOSPHATE, CLINDAMYCIN PHOSPHATE
CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE, BENZOYL PEROXIDE
CLINDAMYCIN PHOSPHATE AND TRETINOIN, CLINDAMYCIN PHOSPHATE
CLINDAMYCIN PHOSPHATE IN DEXTROSE 5%, CLINDAMYCIN PHOSPHATE
CLEMIPOL AGEL, CLINDAMYCIN PHOSPHATE
CLEMIPOL AGEL, CLINDAMYCIN PHOSPHATE
CLINDAMYCIN PHOSPHATE IN DEXTROSE 5%, CLINDAMYCIN PHOSPHATE
CLEMIPOL AGEL, CLINDAMYCIN PHOSPHATE
CLEMIPOL AGEL, CLINDAMYCIN PHOSPHATE
APPENDIX A - PRODUCT NAME INDEX

** C **

- CLINIMIX 5/15 SULFITE FREE IN DEXTROSE 15% IN PLASTIC CONTAINER, AMINO ACIDS
- CLINIMIX 5/20 SULFITE FREE IN DEXTROSE 20% IN PLASTIC CONTAINER, AMINO ACIDS
- CLINIMIX 5/25 SULFITE FREE IN DEXTROSE 25% IN PLASTIC CONTAINER, AMINO ACIDS
- CLINIMIX 5/35 SULFITE FREE IN DEXTROSE 35% IN PLASTIC CONTAINER, AMINO ACIDS
- CLINIMIX E 2.75/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER,
- CLINIMIX E 2.75/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER,
- CLINIMIX E 2.75/5 SULFITE FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC CONTAINER,
- CLINIMIX E 4.25/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER,
- CLINIMIX E 4.25/20 SULFITE FREE W/ ELECT IN DEXTROSE 20% W/ CALCIUM IN PLASTIC CONTAINER,
- CLINIMIX E 4.25/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER,
- CLINIMIX E 4.25/5 SULFITE FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC CONTAINER,
- CLINISOL 15% SULFITE FREE IN PLASTIC CONTAINER, AMINO ACIDS
- CLOBAZAM
- CLOBETASOL PROPIionate, CLOBETASOL PROPIionate
- CLOBETASOL PROPIionate (EMOLLIENT), CLOBETASOL PROPIionate
- CLOBEX, CLOBETASOL PROPIionate
- CLODERM, CLOCORTOLONE PI VALATE
- CLOFARABI NE, CLOFARABI NE
- CLOLAR, CLOFARABI NE
- CLOM PHENE CI TRATE, CLOM PHENE CI TRATE
- CLOM PRAM NE HYDROCHLORI DE, CLOM PRAM NE HYDROCHLORI DE
- CLONAZEPAM CLONAZEPAM
- CLONI DI NE, CLONI DI NE
- CLOPI DOGREL BI SULFATE, CLOPI DOGREL BI SULFATE
- CLORAZEPATE DI POTASSI UM, CLORAZEPATE DI POTASSI UM
- CLOSTOP, CLOSTRO DE, CLOSTOP, CLOSTRO DE
- CLOTRIMAZOLE, CLOTRIMAZOLE (OTC)
- CLOTRIMAZOLE AND BETAMETHASONE DI PROPIionate, BETAMETHASONE DI PROPIionate
- CLOZAPI NE, CLOZAPI NE
- CLOZARI L, CLOZAPI NE
- COARTEM, ARTEMETHER
- CODEI NE SULFATE, CODEI NE SULFATE
- COGENTI N, BENZTROPI NE MESYLATE
- COL- PROBENECI D, COLCHI CI NE
- COLAZAL, BALSALAZI DE DI SODI UM
- COLCHI CI NE, COLCHI CI NE
- COLCRYS, COLCHI CI NE
- COLESEVELAM HYDROCHLORI DE, COLESEVELAM HYDROCHLORI DE
- COLESTI D, COLESTI POL HYDROCHLORI DE
- COLESTI POL HYDROCHLORI DE, COLESTI POL HYDROCHLORI DE
- COLOGATE TOTAL, SODI UM FLUORI DE (OTC)
- COLOCORT, HYDROCORTI SONE
- COLPREP KIT, MAGNESI UM SULFATE
- COLY- MYGI N M COLI STI METHATE SODI UM
- COLY- MYGI N S, COLI STI SULFATE
- COLYTE WITH FLAVOR PACKS, POLYETHYLENE GLYCOL 3350
- COMBI CAN, BRI MONI DI NE TARTRATE
- COMBI PATCH, ESTRADI OL
- COMBI VENT RESPI MAT, ALBUTEROL SULFATE
- COMBI VR, LAM VUDI NE
- COMETRI Q, CABOZANTI NI B S- MALATE
- COMPLERA, EMTRI CI TABI NE
- COMPR, PROCHLORPERAZI NE
- COMPAR, ENACAPONE
- CONCERTA, METHYLPHENI DATE HYDROCHLORI DE
- CONDYLOX, PODOFI LOX
- CONRAY, IOTHALAMATE MEGLUM NE
CONRAY 43, iothalamate meglumine
CONSENSI, amlodipine besylate
CONSTI LAC, lactulose
CONTRAVE, buproprion hydrochloride
CONZI P, tramadol hydrochloride
 COPAXONE, glatiramer acetate
COPI KTRA, dulexi si b
CORDRAN, flurandrenolide
CORDRAN SP, flurandrenolide
COREG, carvedilol
COREG CR, carvedilol phosphate
CORGARD, nadolol
CORLANOR, ivabradine hydrochloride
CORLOPAM, fenoldopam mesylate
CORMAX, clobetasol propionate
CORPHEDRA, ephedrine sulfate
CORTEF, hydrocortisone
CORTENEMA, hydrocortisone
CORTI FOAM, hydrocortisone acetate
CORTI SONE ACETATE, corti sone acetate
CORTI SPORI N, baci traci N zinc
CORTI SPORI N, hydrocortisone acetate
CORTROSYN, cosyntropin
CORVERT, ibutilide fumarate
CORZIDE, bendroflumethiazide
COSMEGEN, dactinomycin
COSOPT, dorzolamide hydrochloride
COSOPT PF, dorzolamide hydrochloride
COSYNTROPIN, cosyntropin
COTELLIC, cobimetinib fumarate
COTEMPLA XR-ODT, methylphenidate
COUMADIN, warfarin sodium
COZAAR, losartan potassium
CREON, pancrelipase (amylase
CRESEMBA, isavuconazonium sulfate
CRIXIVAN, indinavir sulfate
CROMOLYN SODIUM, cromolyn sodium (OTC)
CROMOLYN SODIUM, cromolyn sodium
CROTAN, crotamiton
CRYSELLE, ethinyl estradiol
CUBICIN, daptomycin
CUBICIN RF, daptomycin
CUPRIC CHLORIDE IN PLASTIC CONTAINER, cupric chloride
CUPRIMINE, penicillamine
CUROSURF, poractant alfa
CUVPOSA, glycopyrrolate
CYANOCOBALAMIN, cyanocobalamin
CYANOKIT, hydroxocobalamin
CYCLAFEM 0.5/35, ethinyl estradiol
CYCLAFEM 1/35, ethinyl estradiol
CYCLAFEM 7/7/7, ethinyl estradiol
CYCLESSA, desogestrel
CYCLOBENZAPRI NE HYDROCHLORIDE, cyclobenzaprine hydrochloride
CYCLOGINYL, cyclopentolate hydrochloride
CYCLOMORI L, cyclopentolate hydrochloride
CYCLOPHOSPHAM DE, cyclophosphamide
CYCLOSET, bromocriptine mesylate
CYCLOSPORI NE, cyclosporine
CYKLOKAPRON, tranexamic acid
CYMBALTA, duloxetine hydrochloride
CYONAZ, ethinyl estradiol
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<td>D.H.E. 45, DI HYDROERGOTAMINE MESYLATE</td>
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<td>DACARBAZINE, DACARBAZINE</td>
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<td>DACTIOMYCIN, DACTIOMYCIN</td>
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<td>DAFALANSE, DAFALANSE</td>
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<td>DAKLINZA, DACLATASVIR DIHYDROCHLORIDE</td>
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<td>DALFAMPRIDINE, DALFAMPRIDINE</td>
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<td>DALIRESP, ROFLUMILAST</td>
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<td>CYSTO-CONRAY II IOTHALAMATE MEGLUMINE</td>
<td>DELFLEX W DEXTROSE 1.5% LOW MAGNESIUM 1 N PLASTIC CONTAINER, CALCIMM CHLORIDE</td>
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<td>CYSTO-CONRAY II IOTHALAMATE MEGLUMINE</td>
<td>DELFLEX W DEXTROSE 4.25% LOW MAGNESIUM 1 N PLASTIC CONTAINER, CALCIMM CHLORIDE</td>
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<td>CYSTO-CONRAY II IOTHALAMATE MEGLUMINE</td>
<td>DELFLEX W DEXTROSE 4.25% LOW MAGNESIUM 1 N PLASTIC CONTAINER, CALCIMM CHLORIDE</td>
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<td>CYSTO-CONRAY II IOTHALAMATE MEGLUMINE</td>
<td>DELSTRIQ, DORAVIR RIBOE</td>
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<td>DELSYM, DEXTROMETHORPHAN POLI STI REX (OTC)</td>
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<td>DELZICOL, MESALAMINE</td>
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<td>DEMECOLCYCLIC NE HYDROCHLORIDE DE, DEMECOLCYCLIC NE HYDROCHLORIDE DE</td>
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<td>DEMEROL, Meperi DI DE HYDROCHLORIDE DE</td>
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<td>DENVAN, DENVAN</td>
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<td>CYSTO-CONRAY II IOTHALAMATE MEGLUMINE</td>
<td>DEPAON, VALPROATE SODIUM</td>
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DEPAKENE, VALPROIC ACID
DEPAKOTE, DIVALPROEX SODIUM
DEPAKOTE ER, DIVALPROEX SODIUM
DEPEN, PENICILLAMINE
DEPO-ESTRADIOL, ESTRADIOL CYPIONATE
DEPO-ESTRADIOL, ESTRADIOL CYPIONATE
DEPO-MEDROL, METHYLPRERDNI SOLONE ACETATE
DEPO-PROVERA, MEDROXYPROGESTERONE ACETATE
DEPO-TESTOSTERONE, TESTOSTERONE CYPROionate
DERMA-SMOOTHE/FS, FLUCO NOLONE ACETONIC DE
DERMAZET, BETAMETHASONE VALERATE
DERMATOP, PREDN CARBATE
DERMATOP E EMOLLIENT, PREDN CARBATE
DERMOTIC, FLUCO NOLONE ACETONIC DE
DESCOVY, EMTRICITABINE
DESERFAL, DEFEROXAMEN NE MESYLATE
DESLORATADINE, DESLORATADINE
DESPRESSIN ACETATE, DESMOPRESSIN ACETATE
DESPRESSIN ACETATE (NEEDS NO REFRIGERATION), DESMOPRESSIN ACETATE
DESOGEN, DESOGESTREL
DESOGEN AND ETHYL NOL, ESTRADIOL, DESOGESTREL
DESIGNATE, DEXON DE
DESONI DE, DESONI DE
DESONI, DESONI DE
DESOXIMETASONE, DESOXIMETASONE
DESOXYN, METHAMPHETAMINE UROCHLORO DE
DESIGN, METHAMPHETAMINE NE HYDROCHLORO DE
DESIGN, METHAMPHETAMINE NE HYDROCHLORO DE
DESIGN, METHAMPHETAMINE NE HYDROCHLORO DE
DESIGN, METHAMPHETAMINE NE HYDROCHLORO DE
DETRTOL, TOLTERODINE TARTRATE
DETRTOL LA, TOLTERODINE TARTRATE
DEXAMETHASONE, DEXAMETHASONE
DEXAMETHASONE IN INTENSOL, DEXAMETHASONE
DEXAMETHASONE, DEXAMETHASONE
DEXAMETHASONE SODIUM PHOSPHATE, DEXAMETHASONE SODIUM PHOSPHATE
DEXAMETHASONE SODIUM PHOSPHATE PRESERVATIVE FREE, DEXAMETHASONE SODIUM PHOSPHATE
DEXASPORIN, DEXAMETHASONE
DEXCHLORPHENIRAMINE RAM NE MALATE, DEXCHLORPHENIRAMINE RAM NE MALATE
DEXEDRINE, DEXTROAMPHETAMINE SULFATE
DEXFERRUM I RON DEXTRAN
DEXI LANT, DEXLANSOPRAZOLE
DEXLANSOPRAZOLE, DEXLANSOPRAZOLE
DEXMEDOTOM D IN NE HYDROCHLORO DE, DEXMEDOTOM DI NE HYDROCHLORO DE
DEXMEDOTOM D IN NE HYDROCHLORO DE, DEXMEDOTOM DI NE HYDROCHLORO DE
DEXMEDOTUM D IN NE HYDROCHLORO DE, DEXMEDOTUM DI NE HYDROCHLORO DE
DEXRAXAZONE HYDROCHLORO DE, DEXRAXAZONE HYDROCHLORO DE
DEXENZIA, DEXAMETHASONE
DEXTRAAMP SACHARATE, AMP ASPARTATE, DEXTRAAMP SULFATE AND AMP SULFATE, AMPHETAMINE
DEXTRAAMP SACHARATE, AMP ASPARTATE, DEXTRAAMP SULFATE AND AMP SULFATE, AMPHETAMINE
DEXTRAAMP SACHARATE, AMP ASPARTATE, DEXTRAAMP SULFATE AND AMP SULFATE, AMPHETAMINE
DEXTRAAMPHETAM NE SULFATE, DEXTRAAMPHETAM NE SULFATE
DEXTRAAMPHETAM NE SULFATE, DEXTRAAMPHETAM NE SULFATE
DEXTRAMETHOPHAN HYDROBROM DE AND QUI NI DI NE SULFATE, DEXTRAMETHOPHAN HYDROBROM DE
DEXTRAMETHOPHAN POLI STI REX, DEXTRAMETHOPHAN POLI STI REX (UTC)
DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 10% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% IN HALF-STRENGTH LACTATED RINGER'S IN PLASTIC CONTAINER, CALCIUM CHLORIDE)
DEXTROSE 20% IN PLASTIC CONTAINER, DEXTROSE
** D **

DEXTROSE 25% DEXTROSE
DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 30% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 40% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND ELECTROLYTE NO. 48 IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND LACTATED RINGER’S IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.224% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.33% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN LACTATED RINGER’S IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DEXTROSE 5% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ (K), DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ (K), DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 30MEQ, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 40MEQ, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 5MEQ, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 5MEQ (K), DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ (K) IN PLASTIC CONTAINER, DEXTROSE
DIABETA, GLYBURIDE
DIACOMIT, STIRIPENTOL
DIAMOX, ACETAZOLAMIDE
DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DIANEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DIANEAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DIANEAL PD-2 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER, CALCIUM CHLORIDE
DIASTAT, DIAZEPAM
DIASTAT ACUDIAL, DIAZEPAM
DIAZEPAM, DIAZEPAM
DIAZEPAM INTENSOL, DIAZEPAM
DIBENZYLINE, PHENOXYBENZAMINE HYDROCHLORIDE
DICLEG 5, DOXYLAMINE SUCCINATE
DICLOFENAC POTASSIUM, DICLOFENAC POTASSIUM
DICLOFENAC SODIUM, DICLOFENAC SODIUM
DICLOFENAC SODIUM AND MISOPROSTOL, DICLOFENAC SODIUM
DICLOXACILLIN SODIUM, DICLOXACILLIN SODIUM
DICYCLOMINE HYDROCHLORIDE, DICYCLOMINE HYDROCHLORIDE
DICYCLOMINE HYDROCHLORIDE (PRESERVATIVE FREE), DICYCLOMINE HYDROCHLORIDE
DIDANOSINE, DIDANOSINE
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<td>DIFFERIN, ADAPALENE</td>
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<td>DIFICID, FIDAXOMICIN</td>
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<td>DIFLUCAN, FLUCONAZOLE</td>
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<td>DILANTIN, PHENYTOIN</td>
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<td>DILANTIN, PHENYTOIN SODIUM</td>
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<td>DILANTIN-125, PHENYTOIN</td>
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<td>DILATRATE-SR, ISOSORBIDE DINITRATE</td>
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<td>DIPHENHYDRAMINE HYDROCHLORIDE PRESERVATIVE FREE, DIPHENHYDRAMINE HYDROCHLORIDE</td>
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<td>DIPROLENE AF SODIUM</td>
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<td>DORAL, QUAZEPAM</td>
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<td>DORYX, DOXYCYCLINE HYCLATE</td>
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<td>DORYX MPC, DOXYCYCLINE HYCLATE</td>
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<td>DOTAREM, GADOTERATE MEGLUMINE</td>
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<td>DOXERCALCIFEROL, DOXERCALCIFEROL</td>
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<td>DOXIL (LIPOSOMAL), DOXORUBICIN HYDROCHLORIDE</td>
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DOXYCYCLINE, DOXYCYCLINE
DOXYCYCLINE, DOXYCYCLINE HYCLATE
DOXYLAMINE SUCCINATE, DOXYLAMINE SUCCINATE (OTC)
DOXYLAMINE SUCCINATE AND PYRIDOXINE HYDROCHLORIDE, DOXYLAMINE SUCCINATE
DRAX EXAMETAZIME, TECHNETIUM TC-99M EXAMETAZIME KIT
DRAXIMAGE MDP-25, TECHNETIUM TC-99M MEDRONATE
DRI SDOL, ERGOCALCI FEROL
Droxarabine, DROXARABINE
DROPERIDOL, DROPERIDOL
DROSPIRENONE AND ETHINYL ESTRADIOL, DROSPIRENONE
DROSPIRENONE, ETHINYL ESTRADIOL AND LEVOMEFOLATE CALCULUM, DROSPIRENONE
DROXIA, HYDROXYUREA
DTA, BENZOLYL PEROXIDE
DUAVEE, BAZEDOXINE ACETATE
DUETACT, GLI Mepy ri DE
DUXI S, FAMOTIDI NE
DULERA, FORMOTEROL FUMARATE
DULOKETI NE HYDROCHLORIDE DE, DULOKETI NE HYDROCHLORIDE DE
DUODOTE, ATROPINE NE
DUPA, CARBI DO PA
DURACLON, CLONI DI NE HYDROCHLORIDE DE
DURAGESI C-100, FENTANYL
DURAGESI C-12, FENTANYL
DURAGESI C-25, FENTANYL
DURAGESI C-37, FENTANYL
DURAGESI C-50, FENTANYL
DURAGESI C-75, FENTANYL
DURAMPH PF, MORPHINE SULFATE
DURAPREP, I ODIN NE POVACRYLEX (OTC)
DUREZOL, DI FLUPREDNATE
DURLAZA, ASPIRIN R IN
DUTASTERI DE, DUTASTERI DE
DUTASTERI DE AND TAMUSULO IS N HYDROCHLORIDE DE, DUTASTERI DE
DUTOPROL, HYDROCHLOROTHIAZIDE AZI DE
DUVOI D, BETHANECHOL CHLORIDE DE
DUZALLO, ALLOPURINOL NOL
DYANAVEL XR, AMPHETAMINE NE
DYAZIDE, HYDROCHLOROTHIAZIDE AZI DE
DYCLONINE HYDROCHLORIDE DE
DYM ST, AZELASTINE HYDROCHLORIDE DE
DYNA MNE, NICECYCLINE HYDROCHLORIDE DE
DYRENIUM, TRI AMERENE

** E **

E-Z SCRUB 201, POVIDONE-IODINE (OTC)
E-Z SCRUB 241, POVIDONE-IODINE (OTC)
E-Z HD, BARIUM SULFATE
E-Z-PAQUE, BARIUM SULFATE
E.E.S., ERYTHROMYCIN ETHYL SUCCINATE
E.E.S. 400, ERYTHROMYCIN ETHYL SUCCINATE
EC- NAPROSYN, NAPROKEN
ECOZOLE, ECOCZOLE NI TRATE
ECOZOLE NI TRATE
ECOZOLE, ECOCZOLE NI TRATE
EDARBI, AZI LSARTAN KAMEDOXOM L
EDARBYCLOR, AZI LSARTAN KAMEDOXOM L
EDNORMETR, ETHACRINE NITRATE SODIUM
EDNORMETR, ETHACRINE NITRATE SODIUM
EDEX, ALPROSTADIL L
ELODUR, ZOLPIDEM TARTRATE
EDURANT, R I LIPPI RI NE HYDROCHLORIDE DE
EFAVIRENZ, EFAVIRENZ
EFAVIRENZ, EMTRI CI TABI NE, AND TENOFOVIR DI SOPROXYL FUMARATE, EFAVIRENZ

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EPINEPHRINE, EPINEPHRINE
EPINEPHRINE (AUTOINJECTOR), EPINEPHRINE
EPIPEN, EPINEPHRINE
EPIPEN JR., EPINEPHRINE
EPIRUBICIN HYDROCHLORIDE, EPIRUBICIN HYDROCHLORIDE
EPITOL, CARBAZEPINE
EPIVIR, LAMIVUDINE
EPIVIR-HBV, LAMIVUDINE
EPLERENONE, EPLERENONE
EPROSTENOL SODIUM, EPROSTENOL SODIUM
EPROSARTAN MESYLATE, EPROSARTAN MESYLATE
EPTI FI BATI DE, EPTI FI BATI DE
EPZI COM, ABACAVIR R SULFATE
EQUETRO, CARBAZEPINE NE
ERAXI S, ANI DULAFUNG N
ERGICAL FEROL, ERGICAL FEROL
ERGOLOI D MESYLATES, ERGOLOI D MESYLATES
ERGOMAR, ERGOTAM NE TARTRATE
ERGOTAM NE TARTRATE AND CAFFEINE, CAFFEINE NE
ERI VEDGE, VI SMODEGI B
ERLEADA, APALUTAM DE
ERRI N, NORETHER NDRONE
ERTACZO, SERTACONAZOLE NI TRATE
ERTAPENEM SODIUM, ERTAPENEM SODIUM
ERY-TAB, ERYTHROMYC N
ERYC, ERYTHROMYC N
ERYGEL, ERYTHROMYC N
ERYPED, ERYTHROMYC N ETHYLSUCCI NATE
ERYTHROC N, ERYTHROMYC N LACTOBI NATE
ERYTHROC N STEARATE, ERYTHROMYC N STEARATE
ERYTHROCIC N, ERYTHROMYC N
ERYTHROCIC N AND BENZOYL PEROXI DE, BENZOYL PEROXI DE
ERYTHROCIC N ETHYLSUCCI NATE, ERYTHROMYC N ETHYLSUCCI NATE
ESBRI ET, PI RFENI DONE
ESC TALOPRAM OKALATE, ESC TALOPRAM OKALATE
ESKATA, HYDROGEN PEROXI DE
ESMOLOL HYDROCHLORIDE, ESMOLOL HYDROCHLORIDE
ESMOLOL HYDROCHLORIDE DE DOUBLE STRENGTH IN PLASTI C CONTAI NER, ESMOLOL HYDROCHLORIDE DE
ESMOLOL HYDROCHLORIDE DE IN PLASTI C CONTAI NER, ESMOLOL HYDROCHLORIDE DE
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ESOMEPRAZOLE MAGNESI UM ESOMEPRAZOLE MAGNESI UM
ESOMEPRAZOLE SODIUM ESOMEPRAZOLE SODIUM
ESOMEPRAZOLE STRONTI UM ESOMEPRAZOLE STRONTI UM
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ESTAZOLAM ESTAZOLAM
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ESTRADIOL AND NORGESTIMATE, ESTRADIOL
ESTRADIOL VALERATE, ESTRADIOL VALERATE
ESTRING, ESTRADIOL
ESTROGEL, ESTRADIOL
ESTROPIATE, ESTROPIATE
ESTROSTEP FE, ETHI NYL ESTRADIOL
ESZOPOR CLONE, ESZOPOR CLONE
ETHACRYNATE SODI UM ETHACRYNATE SODI UM
ETHACRYNYL ACID ETHACRYNYL ACID
ETHAMBUTOL HYDROCHLORIDE, ETHAMBUTOL HYDROCHLORIDE DE
ETHAMOL DE ETHANOLAMINE OLEATE
ETHOSUXIMIDE DE ETOSUXIMIDE DE
ETHYLOXIDE ACETATE AND ETHI NYL ESTRADIOL, ETHI NYL ESTRADIOL
ETHYLDE, AMI FOSI NE
ETI DRONATE AND SODI UM ETI DRONATE AND SODI UM
ETODOLAC, ETODOLAC
ETOM DATE, ETOM DATE
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ETOPOPHOS PRESERVATIVE FREE, ETOPOSI DE PHOSPHATE
ETOPOSI DE, ETOPOSI DE
EUCRI SA, CRI SABOROLE
EURAX, CROTAMITON
EUTHYROX, LEVOTHYROXINE SODIUM **
EVAM ST, ESTRADIOL OL
EVEROLI MUS,EVEROLI MUS
EVI STA, RALOXI FENE HYDROCHLORIDE DE
EVOCLI N, CLI NDAMYCI N PHOSPHATE
EVOVELA, MELPHALAN HYDROCHLORIDE DE
EVOTAZ, ATAZANAVI R SULFATE
EVOXAC, CEVI MELI NE HYDROCHLORIDE DE
EVZI O, NALOKONE HYDROCHLORIDE DE
EXALGO, HYDROMORPHONE HYDROCHLORIDE DE
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EXELON, RI VASTI GM NE
EXELON, RI VASTI GM NE TARTRATE
EXEMESTANE, EXEMESTANE
EXFORGE, AMLODI PI NE BESYLALE
EXFORGE HCT, AMLODI PI NE BESYLALE
EXI DI NE, CHLORHEXI DI NE GLUCONATE (OTC)
EX JADE, DEFERASI ROK
EXONDYS 51, ETEPILI RSEN
EXPAREL, BUPI VACAI NE
EXTENDED PHENYTOI N SODI UM PHENYTOI N SODI UM
EXTI NA, KETOCONAZOLE
EXTRANEAL, I CODEXTRI N
EZALLOR, ROBUNASTATI N CALCUM UM
EZETI M BE, EZETI M BE
EZETI M BE AND ATORVASTATI N CALCUM UM ATORVASTATI N CALCUM UM
EZETI M BE AND SI MASTATI N, EZETI M BE

** F **

FABI OR, TAZAROTENE
FACTI VE, GEM FLOXACI N MESYLALE
FALLBACK SOLO, LEVONORGESTREL (OTC)
FALM NA, ETHI NYL ESTRADIOL OL
FAMICI CLOVI R, FAMICI CLOVI R
FAMOTI DI NE, FAMOTI DI NE (OTC)
FAMOTI DI NE, FAMOTI DI NE
FAMOTI DI NE PRESERVATIVE FREE, FAMOTI DI NE
FAMOTI DI NE PRESERVATIVE FREE I N PLASTIC CONTAINER, FAMOTI DI NE
FAMOTI DI NE, CALCUM UM CARBONATE, AND MAGNESIUM UM HYDROXY DE, CALCUM UM CARBONATE (OTC)
FANAPT, I LOPERI DONE
FARESTON, TOREM FENE CI TRATE
FARXI GA, DAPAGLI FLOCI N
FARYDAK, PANOBIO HOSTAT LACTATE
FASLODEX, FULVESTRANT
FAYOSI M, ETHI NYL ESTRADIOL OL
FAZACLO ODT, CLOZAPI NE
FELBAMATE, FELBAMATE
FELBATOL, FELBAMATE
FELDENE, PI ROXI CAM
FELODI PI NE, FELODI PI NE
FEMARA, LETROZOLE
FEMCON FE, ETHI NYL ESTRADIOL OL
FEMHRT, ETHI NYL ESTRADIOL OL
FEMRI NG, ESTRADIOL ACETATE
FENOFI BRATE, FENOFI BRATE
FENOFI BRATE ( M CRONI ZED), FENOFI BRATE
FENOFI BRI C ACI D, CHOLI NE FENOFI BRATE
FENOGLI DE, FENOFI BRATE
FENOLDOPAM MESYLALE, FENOLDOPAM MESYLALE
** F **

- Fenoprofen Calcium, Fenoprofen Calcium
- Fentanyl Citrate, Fentanyl Citrate
- Fentanyl Citrate Preservative Free, Fentanyl Citrate
- Fentanyl-100, Fentanyl
- Fentanyl-12, Fentanyl
- Fentanyl-25, Fentanyl
- Fentanyl-37, Fentanyl
- Fentanyl-50, Fentanyl
- Fentanyl-62, Fentanyl
- Fentanyl-75, Fentanyl
- Fentanyl-87, Fentanyl
- Fentora, Fentanyl Citrate
- Ferahe, Ferumoxytol
- Ferrlecit, Ferrous Fumarate
- Ferrlecit, Ferric Gluconate
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- Fexofenadine Hydrochloride Allergy, Fexofenadine Hydrochloride (OTC)
- Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride, Fexofenadine Hydrochloride (OTC)
- Fesoterodine Fumarate, Fesoterodine Fumarate
- Festic, Fesoterodine Fumarate
- Fetzima, Levomilnacipran Hydrochloride
- Fexofenadine Hydrochloride HIVES, Fexofenadine Hydrochloride (OTC)
- Fiasp, Insulin Aspart
- Fiasp FlexTouch, Insulin Aspart
- Fibricor, Fenofibrate
- Finacea, Azelanime Acetate
- Finasteride, Finasteride
- Fioricet W/ Codeine, Acetaminophen
- Fiorinal, Aspirin
- Fiorinal W/ Codeine, Aspirin
- Firazyr, Icatibant Acetate
- Firdapse, Amifampridine Phosphate
- Firmagon, Degarelix Acetate
- Firvanq Kit, Vancomycin Hydrochloride
- Flac, Fluocinolone Acetonide
- Flagyl, Metronidazole
- Flagyl I. V. RTU in Plastic Container, Metronidazole
- Flarex, Fluorometholone Acetate
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- Flavoxate Hydrochloride, Flavoxate Hydrochloride
- Flecainde, Flecainide Acetate
- Flector, Epoprostenol Sodium
- Floxuridine, Floxuridine
- Fludarabine Phosphate, Fludarabine Phosphate
- Fludrocortisone Acetate, Fludrocortisone Acetate
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- Flumazenil, Flumazenil
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- Fluconazole 1 N Sodium Chloride 0.9% in Plastic Container, Fluconazole
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- Furosemide, Furosemide
- Fluocinolone Acetonide, Fluocinolone Acetonide
- Fluocinolone, Fluocinolone
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** F **

- Fluocinonide Acetonide
- Fluocinolone Acetonide
- Fluocinonide Emulsified Base
- Fluorescein Sodium
- Fluoroplex
- Fluorouracil
- Fluvoxamine Maleate
- Fml
- Focalin
- Dextromethorphan Hydrobromide
- Folic Acid
- Follistim AQ
- Foloyn
- Fomepizole
- Fondaparinux Sodium
- Forane
- Forfivo Xl
- Fortamet
- Fortaz
- Forstea
- Fosamatan
- Foscan
- Fosademycin
- Frava
- Fosaprepitant Dimeglumine
- Foscarin
- Fosphenytoin Sodium
- Fosrenol
- Frumil
- Fubectl
- Fucetazone
- Fusilev
- Fuzeon
- Fyavol
- Gyroflax
- ** G **

- Gabapentin
- Gabitril
- Gabapentin Sodium
- Gabapentin Dihydrate
- Gabapentin Extended Release
- Galantamine Hydrobromide
- Gadavist
- Galafold
- Galantamine Hydrobromide
- Gallium Citrate Ga 67
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GLYXAMBI, EMPAGLI FLOZI N
GOCOVRI, AMANTADINE HYDROCHLORIDE
GOLYTELY, POLYETHYLENE GLYCOL 3350
ONAL-F, FOLLI TROP N ALFA/ BETA
ONAL-F RFF, FOLLI TROP N ALFA/ BETA
ONAL-F RFF REDI-JECT, FOLLI TROP N ALFA/ BETA
ONTRO, NI TROGLYCELI N
GORELTO, COCAI NE HYDROCHLORI NE
GRALI SE, GABAPENTI N
GRANIS TRON HYDROCHLORI DE, GRANIS TRON HYDROCHLORI DE
GRANIS TRON HYDROCHLORI DE PRESERVATI VE FREE, GRANIS TRON HYDROCHLORI DE
GRI-PEG, GRI SEOFULVI N, ULTRAM CROSI ZE
GRI SEOFULVI N, GRI SEOFULVI N, M CROSI ZE
GRI SEOFULVI N, ULTRAM CROSI ZE, GRI SEOFULVI N, ULTRAM CROSI ZE
GRI SEOFULVI N, ULTRAM CROSI ZE, GRI SEOFULVI N, ULTRAM CROSI ZE
GUI FENESI N, GUI FENESI N (OTC)
GUI FENESI N AND DEXTROMETHORPHAN HYDROBROM DE, DEXTROMETHORPHAN HYDROBROM DE (OTC)
GUI FENESI N AND PSEUDOEPHEDRI NE HYDROCHLORI DE, GUI FENESI N (OTC)
GUANABENZ ACETATE, GUANABENZ ACETATE
GUANIACI NE HYDROCHLORI DE, GUANIACI NE HYDROCHLORI DE
GUANACI NE HYDROCHLORI DE, GUANACI NE HYDROCHLORI DE
GYNAZOLE-1, BUTOCONAZOLE NI TRATE

** H **

H. P. ACTHAR GEL, CORTI COTROPI N
HABI TROL, NI COTI NE (OTC)
HAIE LEY 1, 5/30, ETHI NYL ESTRADI OL
HAIE LEY FE 1, 5/30, ETHI NYL ESTRADI OL
HAIE LEY FE 1/20, ETHI NYL ESTRADI OL
HALAEN, ERI BULI N MESYLATE
HALCI ON, TRI AZOLAM
HALDOL, HALOPERI DOL DECANOATE
HALDOL, HALOPERI DOL LACTATE
HALOBETASOL PROPI ONATE, HALOBETASOL PROPI ONATE
HALOG, H. L. NONI DE
HALOPERI DOL, HALOPERI DOL
HALOPERI DOL, HALOPERI DOL LACTATE
HALOPERI DOL DECANOATE, HALOPERI DOL DECANOATE
HARVONI, LEDI PASVI R
HEATHER, NORETHI NDORNE
HECTORHOL, DOXERICALI FEROL
HEMBATE, CARBOPROST TROMETHAM NE
HEMANGEOLE, PROPRANOLOL HYDROCHLORI DE
HEPARI N SODI UM HEPARI N SODI UM
HEPARI N SODI UM 1, 000 UNIT TS AND SODI UM CHLORI DE 0.9% IN PLASTI C CONTAI NER, HEPARI N SODI UM
HEPARI N SODI UM 1, 000 UNIT TS N SODI UM CHLORI DE 0.9% IN PLASTI C CONTAI NER, HEPA I N SODI UM
HEPARI N SODI UM 10, 000 UNIT TS IN DEXTROSE 5% IN PLASTI C CONTAI NER, HEPARI N SODI UM
HEPARI N SODI UM 12, 500 UNIT TS IN DEXTROSE 5% IN PLASTI C CONTAI NER, HEPARI N SODI UM
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HEPARI N SODI UM 25, 000 UNIT TS IN SODI UM CHLORI DE 0.45% IN PLASTI C CONTAI NER, HEPARI N SODI UM
HEPARI N SODI UM IN PLASTI C CONTAI NER, HEPARI N SODI UM
HEPARI N SODI UM PRESERVATI VE FREE, HEPARI N SODI UM
HEPATAM EI NE 8% AM NO AO DS
HEPATOLI TE, TECHNETI UM TC-99M DI SOFENI N KI T
HEPSERA, ADEFI O R DI PI VOKI L
HER STYLE, LEVONORGESTREL (OTC)
HETLIOZ, TASIMELTEON
HEXALEN, ALTRETAM NE
HI BI CLENS, CHLORHEXI DI NE GLUCONATE (OTC)
HI BI STAT, CHLORHEXI DI NE GLUCONATE (OTC)
** APPENDIX A - PRODUCT NAME INDEX **

** H **

HICON, SODIUM IODIDE I-131
HIPREX, METHENAMINE HIPPURATE
HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE
HOMATROPINE METHYLBROMIDE
HORIZANT, GABAPENTIN ENACARBIL
HUMALOG, INSULIN LISPRO RECOMBINANT
HUMALOG KWIKPEN, INSULIN LISPRO PROTAG NE RECOMBI NANT
HUMALOG M X 50/50, I NSULI N LI SPRO PROTAG NE RECOMBI NANT
HUMALOG M X 50/50 KW KPEN, I NSULI N LI SPRO PROTAG NE RECOMBI NANT
HUMALOG M X 75/25, I NSULI N LI SPRO PROTAG NE RECOMBI NANT
HUMALOG M X 75/25 KW KPEN, I NSULI N LI SPRO PROTAG NE RECOMBI NANT
HUMATROPE, SOMATROPIN RECOMBI NANT
HUMULIN N 70/30, I NSULI N RECOMBI NANT HUMAN (OTC)
HUMULIN N 70/30 PEN, I NSULI N RECOMBI NANT HUMAN (OTC)
HUMULIN N R, I NSULI N HUMAN
HUMULIN N R, I NSULI N RECOMBI NANT HUMAN (OTC)
HUMULIN N R KW KPEN, I NSULI N HUMAN
HUMULIN N R PEN, I NSULI N RECOMBI NANT HUMAN (OTC)
HUMULIN N, I NSULI N SUSP I SOPHANE RECOMBI NANT HUMAN (OTC)
HUMULIN N R, I NSULI N HUMAN
HUMULIN N R, I NSULI N RECOMBI NANT HUMAN (OTC)
HYCAMTIN, TOPOTECAN HYDROCHLORIDE
HYDRA-ZIDE, HYDRALAZINE HYDROCHLORIDE
HYDRA-ZI DE, HYDRALAZINE NE HYDROCHLORIDE DE
HYDRALAZI NE HYDROCHLORIDE DE, HYDRALAZI NE HYDROCHLORIDE DE
HYDREA, HYDROXYUREA
HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
HYDROCODONE BI TARTRATE AND ACETAM NOPEN, ACETAM NOPEN
HYDROCODONE BI TARTRATE AND CHLORPHENI RAM NE MALEATE, CHLORPHENI RAM NE MALEATE
HYDROCODONE BI TARTRATE AND HOMATROPI NE METHYLBRM DE, HOMATROPI NE METHYLBRM DE
HYDROCODONE BI TARTRATE AND I BUPROFEN, HYDROCODONE BI TARTRATE
HYDROCODONE BI TARTRATE AND PSEUDOCEPHERI NE HYDROCHLORI DE, HYDROCODONE BI TARTRATE
HYDROCODONE BI TARTRATE, CHLORPHENI RAM NE MALEATE AND PSEUDOCEPHERI NE HYDROCHLORI DE,
HYDROCODONE POLI STI REX AND CHLORPHENI RAM NE POLI STI REX, CHLORPHENI RAM NE POLI STI REX
HYDROCODONE POLI STI REX AND CHLORPHENI RAMNE POLI STI REX, CHLORPHENI RAM NE POLI STI REX
HYDROCODONE SONE, HYDROCODONE SONE
HYDROCODONE SONE AND ACETI C ACI D, ACETI C ACI D, GLACI AL
HYDROCODONE SONE BUTYRATE, HYDROCODONE SONE BUTYRATE
HYDROCODONE SONE IN ABSORBASE, HYDROCODONE SONE
HYDROCODONE SONE VALERATE, HYDROCODONE SONE VALERATE
HYDROMORPHONE HYDROCHLORIDE DE, HYDROMORPHONE HYDROCHLORIDE DE
HYDROCODALAM N, HYDROCODALAM N
HYDROXYCHLOROQUINE SULFATE, HYDROXYCHLOROQUINE SULFATE
HYDROXYPROGESTERONE CAPROATE, HYDROXYPROGESTERONE CAPROATE
HYDROXUREA, HYDROXUREA
HYDROXYZI NE HYDROCHLORI DE, HYDROXYZI NE HYDROCHLORI DE
HYDROXYZI NE PAMDATE, HYDROXYZI NE PAMDATE
HYLENEX RECOMBI NANT, HYALURONI DASE RECOMBI NANT HUMAN
HYSI NGLA, HYDROCODONE BI TARTRATE
HYZAAR, HYDROCHLOROTHI AZI DE

** I **

I BANDRONATE SODI UM, I BANDRONATE SODI UM
I BRANCE, PALBOCI CLI B
I BU TAB, I BUPROFEN
I BU TAB 200, I BUPROFEN (OTC)
I BUPROFEN, I BUPROFEN (OTC)
I BUPROFEN, I BUPROFEN
I BUPROFEN AND DI PHENYDRAM NE CI TRATE, DI PHENYDRAM NE CI TRATE (OTC)
I BUPROFEN AND DI PHENYDRAM NE HYDROCHLORI DE, DI PHENYDRAM NE HYDROCHLORI DE (OTC)
I BUPROFEN AND PHENYLEPHRI NE HYDROCHLORI DE, I BUPROFEN (OTC)
I BUPROFEN AND PSEUDOCEPHERI NE HYDROCHLORI DE, I BUPROFEN (OTC)
I BUPROFEN LYSI NE, I BUPROFEN LYSI NE
I BUPROFEN SODI UM, I BUPROFEN SODI UM (OTC)
I BUPROFEN LYSI NE, I BUPROFEN LYSI NE
I BUPROFEN SODI UM, I BUPROFEN SODI UM (OTC)
I BUPROFEN HLY, I BUPROFEN (OTC)
I BUPROFEN HLY, I BUPROFEN (OTC)
I BUTI LI DE FUMARATE, I BUTI LI DE FUMARATE
I C GREEN, I NDICYANI NE GREEN
I CLEVI A, ETHYL ESTRADI OL
ICLUSIG, PONATINIB HYDROCHLORIDE
IDAMYCIN PFS, IDARUBICIN HYDROCHLORIDE
IDARUBICIN HYDROCHLORIDE
IDARUBICIN HYDROCHLORIDE PFS, IDARUBICIN HYDROCHLORIDE
IDHIFA, ENASIDENIB MESYLATE
IDKIT:HP, CITRIC ACID
IFEX, IFOSFAMIDE
IFOSFAMIDE, IFOSFAMIDE
ILEVRO, NEPAFENAC
IMPERI, LOPERAMIDE HYDROCHLORIDE
IMPEVILO, LOPERAMIDE HYDROCHLORIDE
IMT N I B MESYLATE, IMT N I B MESYLATE
IMURAN, AZATHIOPRINE
IMVEXXY, ESTRADIOL
INAPSINE, DROPERIDOL
INBRIJA, LEVODOPA
INCASSIA, NORETHINDRONE
INCRELEX R, N-RECASMID N RECOMBID NANT
INCURSE ELLIPTA, UMECLIDINI N OX CHLORE DE
INJECTAFER, FERRIC CARBOXYMALTOSE
INLYTA, AXITINIB
INNOPRAN XL, PROPRANOLOL HYDROCHLORIDE
INSPRA, EPLERENONE
INTUNIV, GUANFACINE HYDROCHLORIDE
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<td>SRADI PI NE</td>
<td>I Sradi Pi Ne</td>
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<td>STALOL</td>
<td>Ti Molol Maleate</td>
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<td>Rom Depsi N</td>
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<td>SUPREL</td>
<td>I Soprote no De Hydrochlori De</td>
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<tr>
<td>TRACAZOLE</td>
<td>I Tracazole</td>
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<tr>
<td>VERMECT N</td>
<td>I Vermect N</td>
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<tr>
<td>VIV BLOCK</td>
<td>Bentiquamat (OTC)</td>
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<tr>
<td>XEMPA KIT</td>
<td>I Xabepi Lone</td>
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** J **
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### ** J **

- Jublia, Efinacozole
- Juluca, Dolutegravir Sodium
- Junel 1.5/30, Ethinyl Estradiol
- Junel 1/20, Ethinyl Estradiol
- Junel FE 1.5/30, Ethinyl Estradiol
- Junel FE 1/20, Ethinyl Estradiol
- Junor Strength Advil, Ibuprofen (OTC)
- Junor Strength Ibuprofen, Ibuprofen (OTC)
- Junor Strength Motrin, Ibuprofen (OTC)
- Juxtapid, Lomitapide
- Jynarque, Tolvaptan

### ** K **

- K-Tab, Potassium Chloride
- Kabiven in Plastic Container, Aminos
- Kadian, Morphine Sulfate
- Kaitlib FE, Ethinyl Estradiol
- Kaletra, Lopinavir
- Kalexate, Sodi um Polystyrene Sulfonate
- Kalli Ga, Desogestrel
- Kalynco, I Vacaftor
- Kapspargo Spri Nkle, Metoprolool Succi Nate
- Kapvay, Cloni Di Ne Hydrochloride De
- Karbi NaL Er, Carbo Noxam Ne Maleate
- Kari Va, Desogestrel
- KazaNo, Alogli PtI N Benzoate
- Keflex, Cephalexi N
- Kelnor, Ethi Nyl Estradiol
- Kenalog, Tri Ac Nocone Acetoni De
- Kenalog-10, Tri Ac Nocone Acetoni De
- Kenalog-40, Tri Ac Nocone Acetoni De
- Kereale, Cangrelor
- Keppra, LEVETI RACETAM
- Keppra Xr, LEVETI RACETAM
- Kerydi N, Tavaborole
- Ketalar, Ketami Ne Hydrochloride De
- Ketan ne Hydrochloride De, Ketami Ne Hydrochloride De
- Ketoconazole, KETOCONAZOLE
- Ketoprofen, Ketoprofen
- Ketorolac Trometham Ne, Ketorolac Trometham Ne
- Ketoti Fen Fumarate, Ketoti Fen Fumarate (OTC)
- Ketozole, KETOCONAZOLE
- Keveyi S, Di Chlorphenarnam De
- Khapzory, LevoLeucovori N
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- Ki M DeSS, Desogestrel
- Ki Nevac, SNCali De
- Ki Onex, Sodi um Polystyrene Sulfonate
- Kiqali, Rl Boci Cli B Succi Nate
- Kiqali Femara Co-Pack (Copackaged), LETROZOLE
- Ki Tabi S Pak, Tobramycin N
- Klaron, Sulfacetam De Sodi um
- Klonopi N, Clonazepam
- Klor-con, Potassi Um Chlori De
- Klor-con M10, Potassi Um Chlori De
- Klor-con M15, Potassi Um Chlori De
- Klor-con M20, Potassi Um Chlori De
- Kombi Glyze Xr, Metform N Hydrochloride De
- Korylm, Mepr Cam N Fepr Stone
- KovanaZe, Okymetazoli Ne Hydrochloride De
- Kri Ntafel, TaFenoqui Ne Succi Nate
- Kurvelo, Ethi Nyl Estradiol
- Kuman, Sapropteri N Di Hydrochlori De
- Kypella, Deokycholi C Aci D
- Kyleena, Levonorgestrel
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KYPROLIS, CARFILZOMIB

** L **
LABETALOL HYDROCHLORIDE, LABETALOL HYDROCHLORIDE DE
LACRISERT, HYDROXYPROPYL CELLULOSE
LACTATED RINGER'S AND DEXTROSE 5% IN PLASTIC CONTAINER, CALCIUM CHLORIDE
LACTATED RINDER'S IN PLASTIC CONTAINER, CALCIUM CHLORIDE
LACTULOSE, LACTULOSE
LAMICITAL, LAMOTRIGINE
LAMICITAL CD, LAMOTRIGINE
LAMICITAL ODT, LAMOTRIGINE
LAMICITAL XR, LAMOTRIGINE
LAMISIL, TERBINAFINE HYDROCHLORIDE (OTC)
LAMISIL, TERBINAFINE HYDROCHLORIDE
LAMISIL AT, TERBINAFINE (OTC)
LAMISIL AT, TERBINAFINE HYDROCHLORIDE (OTC)
LAMIVUDINE, LAMIVUDINE
LAMIVUDINE AND ZIDOVUDINE, LAMIVUDINE
LAMOTRIGINE, LAMOTRIGINE
LANIAZID, ISONIAZID
LANORINAL, ASPIRIN
LANOXIN, DIGOXIN
LANOXIN PEDIATRIC, DIGOXIN
LANSOPRAZOLE, LANSOPRAZOLE (OTC)
LANSOPRAZOLE, LANSOPRAZOLE
LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN, AMOXICILLIN
LANTHANUM CARBONATE, LANTHANUM CARBONATE
LANTUS, I NSULI N GLARGE NE RECOMB NANT
LANTUS SOLOSTAR, I NSULI N GLARGE NE RECOMB NANT
LARI N 1.5/30, ETHYL NYL ESTRADIOL OL
LARI N 1/20, ETHYL NYL ESTRADIOL OL
LARI N 24 FE, ETHYL NYL ESTRADIOL OL
LARI N FE 1.5/30, ETHYL NYL ESTRADIOL OL
LARI N FE 1/20, ETHYL NYL ESTRADIOL OL
LAROTID, AMOXICILLIN
LARYNG-O-JET KIT, LIDOCAINE HYDROCHLORIDE
LASIX, FUROSEMIDE
LASTACAFT, ALCAFTADINE
LATANOPROST, LATANOPROST
LATUDA, LURASI DONE HYDROCHLORIDE DE
LAX-LYTE WITH FLAVOR PACKS, POLYETHYLENE GLYCOL 3350
LAZANDA, FENTANYL CI TRATE
LEFLUNOMIDE DE, LEFLUNOMIDE DE
LENI MA, LENVATI N B MESYLATE
LERI BANE, ETHYL NYL ESTRADIOL OL
LESCOL XL, FLUVASTATI N SODI UM
LESSI NA-28, ETHYL NYL ESTRADIOL OL
LETAI RI S, AMBRI SENTAN
LETROZOLE, LETROZOLE
LEUCOVORI N CALCI UM LEUCOVORI N CALCI UM
LEUCOVORI N CALCI UM PRESERVATI VE FREE, LEUCOVORI N CALCI UM
LEUKERAN, CHLORAMBUCI L
LEUPROL DE ACETATE, LEUPROL DE ACETATE
LEVVALBUTEROL HYDROCHLORIDE DE, LEVALBUTEROL HYDROCHLORIDE DE
LEVEMI R, I NSULI N DETEM R RECOMB NANT
LEVEMI R FLEXTOUCH, I NSULI N DETEM R RECOMB NANT
LEVETI RACETAM LEVETI RACETAM
LEVETI RACETAM I NSULI N SODI UM CHLORI DE, LEVETI RACETAM
LEVETI TRA, VARDENAFI L HYDROCHLORI DE
LEV-T, LEVOTHYROXI NE SODI UM **
LEVOBUNOLOL HYDROCHLORIDE DE, LEVOBUNOLOL HYDROCHLORIDE DE
LEVOCARNI TI NE, LEVOCARNI TI NE
LEVOCETI RI ZI NE DI HYDROCHLORI DE, LEVOCETI RI ZI NE DI HYDROCHLORI DE (OTC)
LEVOCETI RI ZI NE DI HYDROCHLORI DE, LEVOCETI RI ZI NE DI HYDROCHLORI DE
**L**

LEVOFLOXACIN, LEVOFLOXACIN
LEVOFLOXACIN I N DEXTROSE 5% I N PLASTI C CONTAI NER, LEVOFLOXACIN N
LEVOLEUCOVORI N CALCI UM, LEVOLEUCOVORI N CALCI UM
LEVONEST, ETHI NYL ESTRADI OL
LEVONORGESTREL, LEVONORGESTREL (OTC)
LEVONORGESTREL, LEVONORGESTREL
LEVONORGESTREL AND ETHI NYL ESTRADI OL, ETHI NYL ESTRADI OL
LEVONORGESTREL AND ETHI NYL ESTRADI OL AND ETHI NYL ESTRADI OL, ETHI NYL ESTRADI OL
LEVOPHED, NOREPI NEPHRINE BI TARTRATE
LEVORA 0.15-30-28, ETHI NYL ESTRADI OL
LEVORPHANOL TARTRATE, LEVORPHANOL TARTRATE
LEVOTHYROXI NE SODI UM LEVOTHYROXI NE SODI UM
LEVOTHYROXI NE SODI UM LEVOTHYROXI NE SODI UM **
LEVOTYL, LEVOTHYROXI NE SODI UM **
LEVULAN, AM NOLEVULI NI C ACI D HYDROCHLORI DE
LEXAPRO, ESCI TALOPRAM OKALATE
LEXI SCAN, REGADENOSON
LEXI VA, FOSAMPRENAVI R CALCI UM
LI ALDA, MESALAM NE
LI BRAX, CHLORD AZEOXI DE HYDROCHLORI DE
LI BRI UM CHLORD AZEOXI DE HYDROCHLORI DE
LI CART, DI CLOFENAC EPOCAM NE
LI DEX, FLUCI NONI DE
LI DEX- E, FLUCI NONI DE
LI DOCAI NE, LI DOCAI NE
LI DOCAI NE AND PRI LOCAI NE, LI DOCAI NE
LI DOCAI NE HYDROCHLORI DE, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE 0.2% AND DEXTROSE 5% I N PLASTI C CONTAI NER, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE 0.4% AND DEXTROSE 5% I N PLASTI C CONTAI NER, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE 0.8% AND DEXTROSE 5% I N PLASTI C CONTAI NER, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE 5% AND DEXTROSE 7.5% LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE AND EPI NEPHRINE, EPI NEPHRINE
LI DOCAI NE HYDROCHLORI DE I N PLASTI C CONTAI NER, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE PERSERATI VE FREE I N PLASTI C CONTAI NER, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE FLU SCOUS, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE VI SCOUS, LI DOCAI NE HYDROCHLORI DE
LI DODERM, LI DOCAI NE
LI GNONSPAN FORTE, EPI NEPHRINE BI TARTRATE
LI GNONSPAN STANDARD, EPI NEPHRINE BI TARTRATE
LI LETTA, LEVONORGESTREL
LI NCOMM N, LI NCOMM N HYDROCHLORI DE
LI NCOMM N, LI NCOMM N HYDROCHLORI DE
LI NDANE, LI NDANE
LI NEZOLI D, LI NEZOLI D
LI NEZOLI D I N SODI UM CHLORI DE 0.9% I N PLASTI C CONTAI NER, LI NEZOLI D
LI NZESS, LI NACLONI DE
LI ORESAL, BACLOFEN
LI OTHYRONI NE SODI UM LI OTHYRONI NE SODI UM
LI PI ODOL, ETI ODIZED OL
LI PI TOR, ATORVASTATI N CALCI UM
LI POI FEN, FENOFL BRATE
LI QUI D E-Z PAQUE, BARI UM SULFATE
LI SI NOPRI L, LI SI NOPRI L
LI SI NOPRI L AND HYDROCHLORI THI AZI DE, HYDROCHLORI THI AZI DE
LI THI UM CARBONATE, LI THI UM CARBONATE
LI THI UM CI TRATE, LI THI UM CI TRATE
LI THOBI D, LI THI UM CARBONATE
LI THOSTAT, ACETOHYDROAM C ACI D
LI VALQ, PI TAVASTATI N CALCI UM
LI LOESTRI N FE, ETI NYL ESTRADI OL
LI LA SI NEPSE, ETI NYL ESTRADI OL
LI LOZUMADI M NE, DROSPI RENINE
LI LOO D, HYDROCORTI SONE BUTYRATE
LI LOO D LI POCREAT HYDROCORTI SONE BUTYRATE
** L **

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<th>Product Name</th>
<th>Brand Name</th>
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<td>LONHALA MAGNAI R KI T, GLYCOPRROLATE</td>
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<td>LUPASA, LEUROL DE ACETATE</td>
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<td>LUPRON DEPOT, LEUROL DE ACETATE</td>
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<td>LURASIS DONY HYDROCHLORIDE, LURASIS DONY HYDROCHLORIDE</td>
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<td>LUTATHERA, LUTETI UM DOTATE LUT-177</td>
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<td>LUTRAT DEPOT KI T, LEUROL DE ACETATE</td>
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<td>LYRI CA CR, PREGABALI N</td>
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<td>LYSODRENI, M TOTANE</td>
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<td>LYSTED A, TRANEXAM C ACI D</td>
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M ZOLE 3 COMBINATION PACK, MICONAZOLE NI TRATE (OTC)
M V.I. ADULT, ASCORBI C ACI D
M V.I. ADULT (PHARMACY BULK PACKAGE), ASCORBI C ACI D
M V.I. PEDIATRIC, ASCORBI C ACI D
MACRI LEN, MACI MORELI N ACETATE
MACROBI, N TI TROFURANTO N
MACRODANTIN, N TI TROFURANTO N MACROCRYSTALLI NE
MACUGEN, PEGAPTANIB B SODI UM
MAGNESI UM SULFATE, MAGNESI UM SULFATE
MAGNESI UM SULFATE, MAGNESI UM SULFATE
MAGNESI UM SULFATE IN DEXTROSE 5% IN PLASTIC CONTAINER, MAGNESI UM SULFATE
MAGNESI UM SULFATE IN PLASTIC CONTAINER, MAGNESI UM SULFATE
MAGNEVI ST, GADOPENTETATE DI MEGLUMI NE
MAKENA, HYDROXYPROGESTERONE CAPROATE
MAKENA (AUTO IN ECTOR), HYDROXYPROGESTERONE CAPROATE
MAKENA PRESERVATIVE FREE, HYDROXYPROGESTERONE CAPROATE
MALARONE, ATоваQUONE
MALARONE PEDIATRIC, ATоваQUONE
MALATHON, MALATHON
MANGANESE CHLORIDE IN PLASTIC CONTAINER, MANGANESE CHLORIDE DE
MANNITOL 10% IN PLASTIC CONTAINER, MANNITOL
MANNITOL 15% IN PLASTIC CONTAINER, MANNITOL
MANNITOL 20% IN PLASTIC CONTAINER, MANNITOL
MANNITOL 25% IN PLASTIC CONTAINER, MANNITOL
MANNITOL 5% IN PLASTIC CONTAINER, MANNITOL
MARPOTI LI NE HYDROCHLORIDE DE, MARPOTI LI NE HYDROCHLORIDE DE
MARCAI NE, BUPI VACAI NE HYDROCHLORIDE DE
MARCAI NE HYDROCHLORIDE DE, BUPI VACAI NE HYDROCHLORIDE DE
MARCAI NE HYDROCHLORIDE DE PRESERVATI VE FREE, BUPI VACAI NE HYDROCHLORIDE DE
MARCAI NE HYDROCHLORIDE DE W EPI NEPHRI I NE, BUPI VACAI NE HYDROCHLORIDE DE
MARCAI NE HYDROCHLORIDE DE W EPI NEPHRI I NE PRESERVATIVE FREE, BUPI VACAI NE HYDROCHLORIDE DE
MARCI NOL, DRONABI NOL
MARLI SSA, ETHI NYL ESTRADI OL
MARPLAN, I S CARBOXAZI D
MARQIBO KIT, VINCRISTINE SULFATE
MATULANE, PROCARBAZI NE HYDROCHLORIDE DE
MECLIZINE HYDROCHLORIDE, MECLIZINE HYDROCHLORIDE
MECLOFENAMATE SODI UM, MECLOFENAMATE SODI UM
MEGACE ES, MEGESTROL ACETATE
MEGALAM AME HYDROCHLORIDE DE, MECAMYLAM AME HYDROCHLORIDE DE
MECLOXITI N IN PLASTIC CONTAINER, MECLOXITI N SODI UM
MEGACE ES, MEGESTROL ACETATE
MEGATOP, ALBUMS N ODITI NATED T-131 SERUM
MEGASCE ES, MEGESTROL ACETATE
MEKAMT, BI NI METI N B
MEKTOVI, BINIMETINIB
MELOXICAM, MELOXICAM
MELPHALAN, MELPHALAN
MELPHALAN HYDROCHLORIDE DE, MELPHALAN HYDROCHLORIDE DE
MENAMTE NE HYDROCHLORIDE DE, MENAMTE NE HYDROCHLORIDE DE
MEMBRANE BLUE, TRYPAN BLUE
MEN’S ROGAINE, MINOXIDIL (OTC)
MENEST, ESTROGENS, ESTERIFIED
MENOPUR, MENOTROPINS (FSH)
MENOSTAR, ESTRADIOL
MENTAX, BUTENAFINE HYDROCHLORIDE
MEPERI DI NE HYDROCHLORIDE DE, MEPERI DI NE HYDROCHLORIDE DE
MEPERI DI NE HYDROCHLORIDE DE PRESERVATIVE FREE, MEPERI DI NE HYDROCHLORIDE DE
MEPHYTON, PHYTONADIONE
MEPROBAMATE, MEPROBAMATE
MEPRON, ATOVACUONE
MERCAPTOPURIN, MERCAPTOPURIN
MEROPEM, MEROPENEM
MEROPEM AND SODIUM CHLORIDE IN DUPLEX CONTAINER, MEROPENEM
MERMEN, MEROPENEM
MESALAM NE, MESALAM NE
MESNA, MESNA
MESNEX, MESNA
METHADONE HYDROCHLORIDE, METHADONE HYDROCHLORIDE
METHADONE HYDROCHLORIDE INTENSOL, METHADONE HYDROCHLORIDE
METHAMPHETAMINE HYDROCHLORIDE, METHAMPHETAMINE HYDROCHLORIDE
METHAZOLAMIDE, METHAZOLAMIDE
METHENAMINE HIPPURATE, METHENAMINE HIPPURATE
METHERGINE, METHYLERGONOVINE MALEATE
METHIMAZOLE, METHIMAZOLE
METHOCARBAMOL, METHOCARBAMOL
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METROCREAM, METRONIDAZOLE
METROGEL, METRONIDAZOLE
METROGEL-VAGINAL, METRONIDAZOLE
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METRONIDAZOLE IN PLASTIC CONTAINER, METRONIDAZOLE
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MIBELAS 24 FE, ETHINYL ESTRADIOL
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MICARDIS HCT, HYDROCHLOROTHIAZIDE
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M DDORI NE HYDROCHLORIDE DE, M DDORI NE HYDROCHLORIDE DE
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M RVASO, BRI VASIN DE NITRATRATHERED
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M TI GARE, COLCHICINE
M TI GQ, MORPHINE SULFATE
M TOMCI N, M TOMCI N
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M TOXANTRONE HYDROCHLORIDE DE, M TOXANTRONE HYDROCHLORIDE DE
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MOEXIPRIL HYDROCHLORIDE, MOEXIPRIL HYDROCHLORIDE
MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
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MONUROL, FOSFOMYCIN TROMETHAMINE
MORPHABOND ER, MORPHINE NE SULFATE
MORPHINE SULFATE, MORPHINE SULFATE
MOTEGRI TY, PRUCALOPRI DE SUCCI NATE
MOTOFEN, ATROPINE SULFATE
MOTRIN IB, IBUPROFEN (OTC)
MOVANTIK, NALOXEGOL OXALATE
MOXI PREP, ASCORBIC C ACI D
MOXEEZA, MDXI FLOXACI N HYDROCHLORI DE
MOXII DECTI N, MDXI DECTI N
MOXI FLOXACI N HYDROCHLORI DE, MDXI FLOXACI N HYDROCHLORI DE
MOXI FLOXACI N HYDROCHLORI DE I N SODI UM CHLORI DE 0.8% I N PLASTIC CONTAINER, MDXI FLOXACI N
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MUJCI NEX D, GUAI FENESI N (OTC)
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MULTAQ, DRONEDARONE HYDROCHLORI DE
MULTI HANCE, GADOBENATE DI MEGLUM NE
MULTI HANCE MULTI PACK, GADOBENATE DI MEGLUM NE
MUPI ROCI N, MUPI ROCI N
MUPI ROCI N, MUPI ROCI N CALCI UM
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MYDAYI S, AMPHETAM NE ASPARATE
MYDRI ACYL, TROPIC CAM DE
MYFORTI C, MYCOPHENOLI C ACI D
MYKACET, NYSATI N
MYLEN, BUSULFAN
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MYOVI EW 30 ML, TECHNETIUM T 99M TETROFOSM N KI T
MYRBIETR Q, M RABEGRON
MYSONLI NE, PRI M DON
MYSTI N, CROFELEMER
MYZI LRA, ETHI NYL ESTRADIOL

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NABUMETONE, NABUMETONE
Nadolol, NADOLOL
Nadolol AND BENDROFLUMETHI AZI DE, BENDROFLUMETHI AZI DE
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NORVASC, AMLODIPINE BESYLATE
NORVIR, RITONAVIR
NOVAFI L, POSACONAZOLE
NOXI VENT, E NVIDIA C OXI DE
NUCYNATA, TAPENTadol HYDROCHLORIDE
NUCYNATA ER, TAPENTadol HYDROCHLORIDE
NUDEXTA, DEXTROMETHORPHAN HYDROBROMIDE
NULYTELY, POLYETHYLENE GLYCOL 3350
NULYTELY-FLAVORED, POLYETHYLENE GLYCOL 3350
NUPLAZID, PIMAVANSERIN TARTRATE
NUTASTORE, L-GLUTAMINE
NUTRI LI PI D 10% SOYBEAN OIL
NUTRI LI PI D 20% SOYBEAN OIL
NUTROPI N AQ NUSPI N, SOMATROPIN RECOMBI NANT
NUVARI NG, ETHYL ESTRADIOL
NUVESSA, METRONIDAZOLE
NUX O I L, ARMODAFI N
NUZYRA, OMADACYCLINE TOSylATE
NYLI A 1/35, ETHYL ESTRADIOL
NYLI A 7/7/7, ETHYL ESTRADIOL
NYMALI ZE, NI MODI PI NE
NYSTATIN, NYSTATIN
NYSTATIN AND TRIAMCINOLONE ACETONIDE DE, NYSTATIN
NYSTOP, NYSTATIN

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OBREDON, GUAI FENESI N
OCALI VA, OBITI CHOLI C ACI D
OCITREOSCAN, INDU UM I N-111 PENTETRETOI DE KIT
OCITREO TO DE ACETATE, OCITREO TO DE ACETATE
OCITREO TO DE ACETATE (PRESERVATI VE FREE), OCITREO TO DE ACETATE
OCUFEN, FLURBIPROFEN SODIUM
OCUFLOX, OFLOXACIN
OCUFLOXACIN
OCFASY, EMTRI CI TABI NE
ODDOLQ, SODI DEG B PHOSPHATE
OFEEV, NTI NITEDIANI B ESYLATE
OFI RNEM, ACETAM NONPHEN
OFLOXACIN, OFLOXACIN
OGEN 5, ESTROPI PATE
OGESTREOL 0.5/50-28, ETHYL ESTRADIOL
OLANZAPINE, OLANZAPINE
OLANZAPINE AND FLUOXETINE HYDROCHLORIDE, FLUOXETINE HYDROCHLORIDE
OLMESARTAN MEDOXOMIL, OLMESARTAN MEDOXOMIL
OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
APPENDIX A - PRODUCT NAME INDEX

** O **

OLMESARTAN MEDOXOMIL, AMLODI NE AND HYDROCHLOROTHI AZI DE, AMLODI NE BESYLA TE
CLOPATADE NE HYDROCHLORI DE, CLOPATADE NE HYDROCHLORI DE
OLUM ANT, BARI CI TI NI B
OLUX, CLOBETASOL PROPIONATE
OLUX E, CLOBETASOL PROPIONATE
OMEGA-3-AC D ETHYL ESTERS, OMEGA-3-AC D ETHYL ESTERS
OMEGAVEN, FI SH OI L TRI GLYCERI DES
OMEPAZOLE, OMEPAZOLE (OTC)
OMEPAZOLE, OMEPAZOLE
OMEPAZOLE AND CLARI THROMCY CI N AND AMOX CI L LI N, AMOX CI L LI N
OMEPAZOLE AND SODI UM BI CARBONATE, OMEPAZOLE (OTC)
OMEPAZOLE AND SODI UM BI CARBONATE, OMEPAZOLE
OMEPAZOLE MAGNESI UM OMEPAZOLE MAGNESI UM (OTC)
OM DRI A, KETOROLAC TROMETHAM NE
OMNARI S, CI CLESONI DE
OMNI PAQUE 12, I OHEXOL
OMNI PAQUE 140, I OHEXOL
OMNI PAQUE 180, I OHEXOL
OMNI PAQUE 240, I OHEXOL
OMNI PAQUE 300, I OHEXOL
OMNI PAQUE 350, I OHEXOL
OMNI PAQUE 9, I OHEXOL
OMNI PRED, PREDNI SOLONE ACETATE
OMNI SCAN, GADDI AMI DE
OMNI TROPE, SOMATROPI N RECOMB I NANT
ONDANSETRON, ONDANSETRON
ONDANSETRON HYDROCHLORI DE, ONDANSETRON HYDROCHLORI DE
ONDANSETRON HYDROCHLORI DE PRESERVATIVE FREE, ONDANSETRON HYDROCHLORI DE
ONEXTON, BENZOYL PEROXI DE
ONFI, CLOBAZAM
ONGLYZA, SAXAGLI PTI N HYDROCHLORI DE
ONI VYDE, I RI NOTE CAN HYDROCHLORI DE
ONINEL, I TRACONAZOLE
ONPATRO, PATI S SODI UM
ONZETRA XSAI L, SUMATRI PTAN SUCCI NATE
OPANA, OKYPMORPHONE HYDROCHLORI DE
OPCI CON ONE-STEP, LEVONORGESTREL (OTC)
OPCON-A, NAPHAZOLONE HYDROCHLORI DE (OTC)
OPTIN T, MACI TENTAN
OPTI PRANOLOL, METI PRANOLOL HYDROCHLORI DE
OPTI RAY 240, I OVERSOL
OPTI RAY 300, I OVERSOL
OPTI RAY 320, I OVERSOL
OPTI RAY 350, I OVERSOL
OPTI SON, ALBUM N HUMAN
ORABLOC, ARTI CAI NE HYDROCHLORI DE
ORACEA, DOXYCYCLES NE
ORALTAG, I OHEXOL
ORAP, PI MOZI DE
ORAPRED ODT, PREDNI SOLONE SODI UM PHOSPHATE
ORAQI X, LI DOCAI NE
ORAVESE, PHENTOLAMINE MESYLATE
ORAVI G, M CONAZOLE
ORBACTI V, ORI TAVANG N DI PHOSPHATE
OREN TRAM TREPROSTI N L SI OLAN NE
ORFADI N, NI TI SI NONE
ORI LI SSA, ELAGOLI X SODI UM
ORKAMBI, I VACAFCTOR
ORPHENADRI NE CI TRATE, ORPHENADRI NE CI TRATE
ORPHENADRI NE CI TRATE, ASPI RI N, AND CAFFE I NE, ASPI RI N
ORSYTH A, ETHI NL ESTRADI OL
ORTHO CYCLEN-28, ETHI NL ESTRADI OL
ORTHO TRI - CYCLEN, ETHI NL ESTRADI OL
ORTHO TRI - CYCLEN LO, ETHI NL ESTRADI OL
ORTHO NOVUM 1/35 - 28, ETHI NL ESTRADI OL
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<tr>
<td>ORTHO-NOVUM 7/7/7-28, ETHINYL ESTRADIOL</td>
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<td>ORVATEN, M DODRI NE HYDROCHLORIDE</td>
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<td>OSELTAM VI R PHOSPHATE, OSELTAM VI R PHOSPHATE</td>
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<td>OSERNI, ALOGLIPTIN BENZOATE</td>
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<td>OSM TROL 10% IN WATER, MANNITOL</td>
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<td>OSM TROL 10% IN WATER IN PLASTIC CONTAINER, MANNITOL</td>
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<td>OSM TROL 15% IN WATER, MANNITOL</td>
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<td>OSM TROL 15% IN WATER IN PLASTIC CONTAINER, MANNITOL</td>
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<td>OXYTROL, OXYBUTYNI N</td>
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<td>OXYTROL FOR WOMEN, OXYBUTYNI N (OTC)</td>
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<td>OZEMPIC, SEMAGLUTIDE</td>
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<td>OZURDEX, DEXAMESTASONE</td>
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| PACERONE, AMODARONE HYDROCHLORIDE |
| PACI TAXEL, PACI TAXEL |
| PACI TAXEL, PACI TAXEL |
| PALI PERI DONE, PALI PERI DONE |
| PALONOSTETRON HYDROCHLORIDE |
| PANELYR, NORTI PTYL IN NE HYDROCHLORIDE |
| PAN DRONATE DI SODIUM |
| PAN DRONATE DI SODIUM |
| PAN CREASE, PANCRELI PASE (AMYLASE) |
| PANCRONUM BROM DE, PANCRONUM BROM DE |
| PANDER, HYDROCORTISONE PROBUDATE |
| PANRETI N, ALI TRETI NOI |
| PANTOPRAZOLE SODIUM |
| PANTOPRAZOLE SODIUM |
| PARAGARD T 380A, COPPER |
| PAREMYD, HYDROXYAMPETAMINE |
| PARI CALCI TOL, PARI CALCI TOL |
| PARLODEL, BROMOCRI PTI NE MESYLATE |
| PARNATE, TRANYLCYPROM NE SULFATE |
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APPENDIX A - PRODUCT NAME INDEX

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PHENYTOIN SODIUM, PHENYTOIN SODIUM
PHILITH, ETHINYL ESTRADIOL
PHOSLO GELCAPS, CALCIUM ACETATE
PHOSLYTRA, CALCIUM ACETATE
PHOSPHOLINE IODIDE, ECHOTHIOPHATE IODIDE
PHOTOFRI N, PORFI MER, SODIUM
PHOTREX A, RI BOFLAV I, SODIUM 5'S-T- PHOSPHATE SODIUM
PHOTREX A, VI SCSUS, N DEXTRAN 20% RI BOFLAV I SODIUM
PHOLKI LULLM B22K 4/0 1 N PLASTI C CONTAI NER, CALCI UM CHLORI DE
PHOLKI LULLM BK 4/2,5 1 N PLASTI C CONTAI NER, CALCI UM CHLORI DE
PHYSI OLYTE I N PLASTI C CONTAI NER, MAGNESI UM CHLORI DE
PHYSI OSOL I N PLASTI C CONTAI NER, MAGNESI UM CHLORI DE
PHYTONADI ONE, PHYTONADI ONE
PI CATO I NGENOL MEBUTATE
PI FELTROI DORAVI RI NE
PI LOCARI NE HYDROCHLORI DE, PI LOCARI NE HYDROCHLORI DE
PI MECROI NUS, PI MECROI NUS
PI MDZI DE, PI MDZI DE
PI MIREA, DESOGESTREL
PI NDOLOL, PI NDOLOL
PI OGLI TAZONE HYDROCHLORI DE, PI OGLI TAZONE HYDROCHLORI DE
PI OGLI TAZONE HYDROCHLORI DE AND GLI MEPI RI DE, GLI MEPI RI DE
PI OGLI TAZONE HYDROCHLORI DE AND METFORMI N HYDROCHLORI DE, METFORMI N HYDROCHLORI DE
PI PERACI LLI N PI PERACI LLI N SODI UM
PI PERACI LLI N AND TAZOBACTAM PI PERACI LLI N SODI UM
PI RIMELLA I/35, ETHI NYL ESTRADI OL
PI RIMELLA 7/7/7, ETHI NYL ESTRADI OL
PI ROXI CAM PI ROXI CAM
PI TAVASTATI N CALCI UM PI TAVASTATI N CALCI UM
PI TOCI N OXYTOCI N
PLAN B ONE-STEP, LEVONORGESTREL (OTC)
PLAQUENIL I HYDROXYCHLOROQUII SULFATE
PLASMA-LYTE 148 I N WATER I N PLASTI C CONTAI NER, MAGNESI UM CHLORI DE
PLASMA-LYTE A I N PLASTI C CONTAI NER, MAGNESI UM CHLORI DE
PLAVIX I CLOPI DOREL BI SULFATE
PLEGI SOL I N PLASTI C CONTAI NER, CALCI UM CHLORI DE
PLENUM I ASCORBI C ACI D
PLI AGLI S, LI DOCAI NE
PODIFI LOK, PODIFI LOK
POLIOM I DEXCHLORPHENI RAMI NE MALEATE
POLOC AI NE MEPI VACAI NE HYDROCHLORI DE
POLOC AI NE-MPF MEPI VACAI NE HYDROCHLORI DE
POLYETHYLENE GLYCOL 3350, POLYETHYLENE GLYCOL 3350 (OTC)
POLYETHYLENE GLYCOL 3350, POLYETHYLENE GLYCOL 3350
POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES, POLYETHYLENE GLYCOL 3350
POLYMXI N B SULFATE, POLYMXI N B SULFATE
POLYTRI M POLYMXI N B SULFATE
POMALYST I POMALI DOM DE
PONSTEL I MEFENAM C ACI D
PORTI A 28, ETHI NYL ESTRADI OL
POTASSI UM ACETATE, POTASSI UM ACETATE
POTASSI UM CHLORI DE, POTASSI UM CHLORI DE
POTASSI UM CHLORI DE 0.037% I N DEXTROSE 10% AND SODIUM CHLORIDE 0.2% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.037% I N DEXTROSE 10% AND SODIUM CHLORIDE 0.45% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.037% I N DEXTROSE 10% AND SODIUM CHLORIDE 0.9% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.037% I N DEXTROSE 5% AND SODIUM CHLORIDE 0.11% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.037% I N DEXTROSE 5% AND SODIUM CHLORIDE 0.2% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.037% I N DEXTROSE 5% AND SODIUM CHLORIDE 0.3% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.037% I N DEXTROSE 5% AND SODIUM CHLORIDE 0.45% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.037% I N DEXTROSE 5% AND SODIUM CHLORIDE 0.9% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.075% I N DEXTROSE 10% AND SODIUM CHLORIDE 0.2% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.075% I N DEXTROSE 10% AND SODIUM CHLORIDE 0.45% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.075% I N DEXTROSE 10% AND SODIUM CHLORIDE 0.9% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.075% I N DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% I N PLASTIC CONTAINER, POTASSI UM CHLORIDE 0.075% I N DEXTROSE 5% AND SODIUM CHLORIDE 0.11% I N PLASTIC CONTAINER.
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POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER,
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POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER,
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POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER,
POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER,
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POTASSIUM IODIDE, POTASSIUM IODIDE (OTC)
POVIDONE IODINE, POVIDONE-IODINE (OTC)
PRADAXA, DABIGATRAN ETEXILATE
PRALIDOXIME CHLORIDE, PRALIDOXIME CHLORIDE
PRAMIPEXOLE DIHYDROCHLORIDE, PRAMIPEXOLE DIHYDROCHLORIDE
PRAMOSONE, HYDROCORTISONE ACETATE
PRANDIN, REPAGLINIDE
PRASUGREL, PRASUGREL HYDROCHLORIDE
PRAVACHOL, PRAVASTATIN SODIUM
PRAVASTATIN SODIUM, PRAVASTATIN SODIUM
PRAZIQUANTEL, PRAZIQUANTEL
PRAZOSIN HYDROCHLORIDE, PRAZOSIN HYDROCHLORIDE
PRE-OP, HEXACHLOROPHENE
PRE-OP II, HEXACHLOROPHENE
PRE-PEN, BENZYLPIENI CI LLOYL POLYLYSATE
PRECEDEX, DEXMEDETOM DI NE HYDROCHLORI DE
PREMIDONE, HYDROBENZI SONE ACETATE
PRANDI N, REPA GI N DE
PRASUGREL, PRASUGREL HYDROCHLORI DE
PRAVACHOL, PRAVASTATI N SODI UM
PRAVASTATI N SODI UM, PRAVASTATI N SODI UM
PRAZI QUANTEL, PRAZI QUANTEL
PRAZOSI N HYDROCHLORI DE, PRAZOSI N HYDROCHLORI DE
PRE-OP, HEXACHLOROPHANE
PRE-OP II, HEXACHLOROPHENE
PRE-PEN, BENZYLPIENI CI LLOYL POLYLYSATE
PRECCRED, DEXMEDETOMI DI NE HYDROCHLORI DE
PRECESE, ACARBOSE
PRED FORTE, PREDNI SOLONE ACETATE
PRED M LD, PREDNI SOLONE ACETATE
PRED- G, CENTAMI CI N SULFATE
PREND CARBATE, PREDNI CARBATE
PRENDI SOLONE, PREDNI SOLONE
PRENDI SOLONE SODI UM PHOSPHATE, PREDNI SOLONE SODI UM PHOSPHATE
PRENDI SONE, PREDNI SONE
PRENDI SONE I NTENSOL, PREDNI SONE
PREGNYNL, GONADOTROPII N, CHORI ON C
PRELONE, PREDNI SOLONE
PREMARI N, ESTROGENS, CONJUGATED
PREMOSOL 10% IN PLASTIC CONT AI NER, AM NO ACI D 5
PREMOSOL 6% IN PLASTIC CONTAI NER, AM NO ACI D 5
PREMPHASE 14/14, ESTROGENS, CONJUGATED
PREMPRO, ESTROGENS, CONJUGATED
PREPI DI L, DI NO PROSTONE
PREPOPI K, CI TRIC ACI D
PRESTAL A, AILODI PII NE BESYLA TE
PREVA C D, LAN SOPROZOLE
PREVA C D 24 HR, LANSO PROZOLE (OTC)
PREVA LTE, CHOLESTRYRAM NE
PREVANTIC S CS MAXI SWABSTI OK, CHLORHEXI DI NE GLUCONATE (OTC)
PREVANTIC S SWAB, CHLORHEXI DI NE GLUCONATE (OTC)
PREVANTIC S SWABSTI OK, CHLORHEXI DI NE GLUCONATE (OTC)
PREVI FEM, ETHI NYL ESTRADI OL
PREVYM S, LETERMDI R
PREZCOBI X, COBI CI STAT
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PROPOFOL, PROPOFOL
PROPRANOLOL HYDROCHLORIDE DE, PROPRANOLOL HYDROCHLORIDE
PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
PROPYLTHIOURACIL, PROPYLTHIOURACIL
PROSCAR, FINASTERIDE
PROSOL 20% SULFITE FREE IN PLASTIC CONTAINER, AMINO ACIDS
PROSTIN E2, DINOPROSTONE
PROSTIN VR PEDIATRIC, ALPROSTADIL
PROTAMINE SULFATE, PROTAMINE SULFATE
PROTONIX, PANTOPRAZOLE SODIUM
PROTONIX IV, PANTOPRAZOLE SODIUM
PROTOPAM CHLORIDE, PRALIDOXIME CHLORIDE
PROTOPIC, TACROLIMUS
PROTRIPTYLINE HYDROCHLORIDE, PROTRIPTYLINE HYDROCHLORIDE
PROVAYBLUE, METHYLENE BLUE
PROVENTI L-HFA, ALBUTEROL SULFATE
PROVERA, MEDROXYPROGESTERONE ACETATE
PROVI GI, MODAFI NI
PROVOCOCHOLI NE, METHACHOLI NE CHLORI DE
PROZAC, FLUOXETINE HYDROCHLORIDE DE
PROZAC WEEKLY, FLUOXETINE HYDROCHLORIDE DE
PSEUDEPHEDRINE HYDROCHLORIDE DE, PSEUDEPHEDRINE HYDROCHLORIDE DE (OTC)
PULM CORT FLEXHALER, BUDESONIDE DE
PULM CORT RESPULES, BUDESONIDE DE
PUR-WASH, PURIFIED WATER (OTC)
PURLAX, MERCAPTOPURINE NE
PURLAX, MERCAPTOPURINE NE
PYLERA, BISMUTH SUBCITRATE POTASSIUM DE
PYRAZINAMIDE, PYRAZINAMIDE
PYRIDOSTIGMINE BROMIDE, PYRIDOSTIGMINE BROMIDE
PYRIDOXINE HYDROCHLORIDE, PYRIDOXINE HYDROCHLORIDE
PYTEST, UREA, C-14
PYTEST K, UREA, C-14

** Q **

QURELIS, LI SI NOPRI L
OBEREZKA, GLYCOPYRROLONEUM TOSYLA TE
QM I Z ODT, MELOXI CAM
QNASL, BECLOMETHASONE DI PROPIONATE
QOLI ANA, BRI NODI NE TARTRATE
QSYM A, PHENTERM NE HYDROCHLORO DE
QTERN, DAPAGLIFLOZIN
QUADRAMET, SAMARUM SM 153 LEXI DRONAM PENTASODIUM
QUALAQUIA, QUI NI NE SULFATE
QUARTETTE, ETHNYL NYL ESTRADIOL O L
QUASENSE, ETHNYL ESTRADIOL O L
QUDEXY XR, TOPI RAMATE
QUEL CI N, SUCCHNYLCHOLI NE CHLORI DE
QUETI API NE FUMARATE, QUETI API NE FUMARATE
QUI LLI CHEW ER, METHYLPHENIDI DATE HYDROCHLORI DE
QUI LLI VANT XR, METHYLPHENIDI DATE HYDROCHLORI DE
QUI NAPR L HYDROCHLORI DE, QUI NAPR L HYDROCHLORI DE
QUI NAPR L HYDROCHLORI DE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
QUI NARETI C, HYDROCHLOROTHI AZI DE
QUI NI DI NE GLUCONATE, QUI NI DI NE GLUCONATE
QUI NI DI NE SULFATE, QUI NI DI NE SULFATE
QUI NI DI NE SULFATE, QUI NI DI NE SULFATE
QUOTENZA, CAPSAI CI N
QVAR REDIHALER, BECLOMETHASONE DI PROPIONATE

** R **

R-GENE 10, ARGN NI NE HYDROCHLORI DE
RABEPRAZOLE SODIUM, RABEPRAZOLE SODIUM
RADAVAC, EDRAVACONE
RADOGARDASE (PRUSSIAN BLUE), FERRIC HEXACYANOFRATE(III)
** R **

RADIOGENIX SYSTEM, TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR
RALOXIFENE HYDROCHLORIDE, RALOXIFENE HYDROCHLORIDE
RAMELTEON, RAMELTEON
RAMIPRIL, RAMIPRIL
RANEXA, RANOLAZINE
RANITIDINE, RANITIDINE
RANITIDINE HYDROCHLORIDE, RANITIDINE HYDROCHLORIDE
RASAGILINE MESYLATE, RASAGILINE MESYLATE
RASUVO, METHOTREXATE
RAYALDEE, CALCIFEDIOL
RAYOS, PREDNISONE
RAYOS, PREDNISONE
RAZADYNE, GALANTAMINE HYDROBROMIDE
RAZADYNE ER, GALANTAMINE HYDROBROMIDE
READI-CAT 2, BARIUM SULFATE
READI-CAT 2 SMOOTHIES, BARIUM SULFATE
READYPREP CHG, CHLORHEXIDINE GLUCONATE (OTC)
REBETOL, RIBAVIRIN
RECLAST, ZOLEDRONIC ACID
RECTIV, NITROGLYCERIN
REGLAN, METOCLOPRAMIDE HYDROCHLORIDE
REGONOL, PYRIDIUM CHLORIDE
RELENZA, ZANAMIVIR
REMICADE, M TAZAPI NE
REMICADE, M TAZAPI NE
REMYFAM L, HYDROCLORIC ACID
REMYFAM L, HYDROCLORIC ACID
RELAPAX, ELEUTERITE HYDROBROMIDE
REMOCAT, M TAZAPI NE
REMOCAT, M TAZAPI NE
REMIFENTANIL HYDROCHLORIDE, REMIFENTANIL HYDROCHLORIDE
REMOSA, TREATMENT FOR N
RENVELA, SEVELAMER HYDROCHLORIDE
RENEWEL, SEVELAMER CARBONATE
REPAGLINIDE, REPAGLINIDE
REPREXAIN, HYDROCODONE
RESPONT, DELAVIRDINE MESYLATE
RESTASIS, CYCLOSPORINE
RESTASIS MULTIDOSE, CYCLOSPORINE
RESTORIL, TEMAZEPAM
RETIN-A, TRETINOIN
RETIN-A MICRO, TRETINOIN
RETISERT, FLUOCINOLONE ACETONIDE
RETOVIR, RIBAVIRIN
REVATIO, SILDENAFIL CITRATE
REXULTI, BREXIPRAZOLE
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SOLODYN, MINOCYCLINE HYDROCHLORIDE
SOLOSEC, SECNIDAZOLE
SOLTAMOX, TAMOXIFEN CITRATE
SOLU-CORTEF, HYDROCORTISONE SODIUM, SODIUM SUCCHIATE
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SPI RONOLACTONE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
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SPRI TAM, LEVETI RACETAM
SPRI XI, KETOROLAC TROMETHAMINE
SPRYCEL, DASATI NI B
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STENDRA, AVANAFI L
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STERIL LE WATER FOR 1 NJ ECTI ON, STERIL LE WATER FOR 1 NJ ECTI ON
STERIL LE WATER FOR 1 NJ ECTI ON IN PLASTIC CONTAINER, STERIL LE WATER FOR 1 NJ ECTI ON
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STERIALC, TALC

STIE-CORT, HYDROCORTISONE

STIMATE (NEEDS NO REFRIGERATION), DESMOPRESSIN ACETATE

STIOLTO RESPIMAT, OLODATEROL HYDROCHLORIDE

STIVARGA, REGORAFENIB

STRATTERA, ATOMOXETINE HYDROCHLORIDE

STREPTOMYCIN SULFATE, STREPTOMYCIN SULFATE

STRIANT, TESTOSTERONE

STRI B LD, COBI CI STAT

STRI BLD, COBI CI STAT

STRONGLY NOT RECOMMENDED FOR CLINICAL USE

STRONTIUM CHLORIDE SR-89, STRONTIUM CHLORIDE SR-89

SUBLIMAZE PRESERVATIVE FREE, FENTANYL CI TRATE

SUBLOCADRE, BUPRENORPHINE

SUBOXONE, BUPRENORPHINE HYDROCHLORIDE

SUBSYS, FENTANYL

SUCCHYLONE NE CHLORIDE, SUCCHYLONE NE CHLORIDE

SUCRALFATE, SACROSIDASE

SUDAFED 12 HOUR, PSEUDOCHEPHEDRINE HYDROCHLORIDE (OTC)

SUDAFED 24 HOUR, PSEUDOCHEPHEDRINE HYDROCHLORIDE (OTC)

SUFENTA PRESERVATIVE FREE, SUFENTANIL CI TRATE

SUFENTANIL CI TRATE, SUFENTANIL CI TRATE

SULAIR, NO SODI PI NE

SULFACETAM DE SODI UM SULFACETAM DE SODI UM

SULFACETAM DE SODI UM AND PREDNI SOLONE SODI UM PHOSPHATE, PREDNI SOLONE SODI UM PHOSPHATE

SULFADIAZINE, SULFADIAZINE

SULFAMETHOXAZOLE AND TRIMETHOPRIM, SULFAMETHOXAZOLE

SULFASALAZINE, SULFASALAZINE

SULINDAC, SULINDAC

SUMATRIPTAN, SUMATRIPTAN

SUMATRIPTAN AND NAPROKEN SODIUM, NAPROKEN SODIUM

SYMDEKO (COPACKAGED), IVACAFTOR

SYMJEPI, EPINEPHRINE

SYMLIN, PRAMLINTIDE ACETATE

SYMPAZAN, CLOBAZAM

SYMPROIC, NALDEMEDINE TOSYLATE

SYNALAR, FLUCONOLONE ACETONIDE

SYNAREL, NAFARELIN ACETATE

SYNTAXIS, DRONABINOL

SYNERA, LIDOCAINE

SYNERCID, DALFOPRISTIN

SYNJARDY, EMPAGLIFLOZIN

SYNJARDY XR, EMPAGLIFLOZIN
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TOBRAMYCIN N SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, TOBRAMYCIN N SULFATE
TOBREX, TOBRAMYCIN
TODAY, NONOXYNOL-9 (OTC)
TOFRANIL, IMIPRAMINE HYDROCHLORIDE
TOLAK, FLUOROURACIL
TOLAGUANOL, FLUOROURACIL
TOLAZAM DE, TOLAZAM DE
TOLBUTAM DE, TOLBUTAM DE
TOLCAPONE, TOLCAPONE
TOLMETIN SODIUM, TOLMETIN SODIUM
TOLSURA, ITRACONAZOLE
TOLTERODINE TARTRATE, TOLTERODINE TARTRATE
TOPAMAX, TOPIRAMATE
TOPICORT, DESOXIMETASONE
TOPOPROL-XL, METOPROLOL SUCC NATE
TOREM FENE CI TRATE, TOREM FENE CI TRATE
TORI SEL, TEMSI ROLI MUS
TORSEM DE, TORSEM DE
TOSASCATE, DEKRAZOKAN NE HYDROCHLORI DE
TOUJ EO MAX SOLOSTAR, INSULIN GLARGINE RECOMB NANT
TOUJ EO SOLOSTAR, INSULIN GLARGINE RECOMB NANT
TOVI AZ, FESOTERODI NE FUMARATE
TPN ELECTROLYTES IN PLASTIC CONTAINER, CALCI UM CHLORI DE
TPOIOX, TECOM RI NAT
TRACLEER, BOSENTAN
TRACI ENTA, LI NAGLI PTI N
TRAMadol HYDROCHLORI DE, TRAMadol HYDROCHLORI DE
TRAMadol HYDROCHLORI DE AND ACETAM NOPHEN, ACETAM NOPHEN
TRANADATE, LABETALOL HYDROCHLORI DE
TRANADOLAPI L, TRANDOLAPI L
TRANEXAM C ACI D, TRANEXAM C ACI D
TRANSDERM SCOP, SCOPOLAM NE
TRANKENE, CLORAZEPATE DI POTASSI UM
TRANYLCPROM NE SULFATE, TRANYLCPROM NE SULFATE
TRAVASOL 10% IN PLASTIC CONTAINER, AM NO ACI DS
TRAVASOL 5.5% IN PLASTIC CONTAINER, AM NO ACI DS
TRAVATAN Z, TRAVOPROST
TRAVOPROST
TRAZODONE HYDROCHLORI DE, TRAZODONE HYDROCHLORI DE
TREANDA, BENDAMUSTI NE HYDROCHLORI DE
TRECATOR, ETHI ONAM DE
TREDEGAN ELLI PTA, FLUTI CASONE FURUATE
TRELSTAR, TRI PTORELI N PAMDATE
TREPROSTI N L, TREPROSTI N L
TRESEI BA, INSULIN GLUDEC
TRETI NOI N, TRETI NOI N
TREXALL, METHOTREXATE SOCI UM
TREXI MET, NAPROXEN SOCI UM
TREZI X, ACETAM NOPHEN
TRI LO SPRI NTIC, ETHI NYL ESTRADI OL
TRI ESTARYLIA, ETHI NYL ESTRADI OL
TRI LEGEST 21, ETHI NYL ESTRADI OL
TRI LEGEST FE, ETHI NYL ESTRADI OL
TRI LI NYA, ETHI NYL ESTRADI OL
TRI LO ESTARYLIA, ETHI NYL ESTRADI OL
TRI LO M LI, ETHI NYL ESTRADI OL
TRI LUMA, FLUCI NOLONE ACETONI DE
TRI M LI, ETHI NYL ESTRADI OL
TRI NOPI NYL 28-DAY, ETHI NYL ESTRADI OL
TRI-PREVIFEM, ETHINYL ESTRADIOL
TRI-SPRINTEC, ETHINYL ESTRADIOL
TRIACIN-C, CODEINE PHOSPHATE
TRIAMCINOLONE ACETATE, TRIAMCINOLONE ACETONIDE
TRIAMCINOLONE ACETONIDE, TRIAMCINOLONE ACETONIDE (OTC)
TRIAMCINOLONE ACETONIDE, TRIAMCINOLONE ACETONIDE
TRIAMCINOLONE ACETONIDE IN ABSORBASE, TRIAMCINOLONE ACETONIDE
TRIAMTERENE AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
TRIAZOLAM, TRIAZOLAM
TRIBENZOR, AMLODIPINE BESYLATE
TRICOR, FENOFIBRATE
TRIDERM, TRIAMCINOLONE ACETONIDE
TRIDIONE, TRIMETHADIONE
TRIENTINE HYDROCHLORIDE, TRIENTINE HYDROCHLORIDE
TRIESENCE, TRIAMCINOLONE ACETONIDE
TRIFERIC, FERRIC PYROPHOSPHATE CITRATE
TRIFLUOPERAZINE HYDROCHLORIDE, TRIFLUOPERAZINE HYDROCHLORIDE
TRIFLURIDINE, TRIFLURIDINE
TRIGLIDE, FENOFIBRATE
TRIHEXYPHENIDYL HYDROCHLORIDE, TRIHEXYPHENIDYL HYDROCHLORIDE
TRILEPTAL, OXCARBAZEPINE
TRILIPIX, CHOLINE FENOFIBRATE
TRILYTE, POLYETHYLENE GLYCOL 3350
TRIMETHOBENZAMIDE HYDROCHLORIDE, TRIMETHOBENZAMIDE HYDROCHLORIDE
TRIMETHOBENZAMIDE HYDROCHLORIDE PRESERVATIVE FREE, TRIMETHOBENZAMIDE HYDROCHLORIDE
TRIMETHOPRIM, TRIMETHOPRIM
TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE, POLYMYXIN B SULFATE
TRIMIPRAMINE MALEATE, TRIMIPRAMINE MALEATE
TRINTELLIX, VORTIOXETINE HYDROBROMIDE
TRIOSTAT, LIOTHYRONINE SODIUM
TRITODUR KIT, TRIPTORELIN PAMOATE
TRISENOX, ARSENIC TRIOXIDE
TRIUMEQ, ABACAVIR SULFATE
TRIVAGIZOLE 3, CLOTRIMAZOLE (OTC)
TRIVORA-28, ETHINYL ESTRADIOL
TRIZIVIR, ABACAVIR SULFATE
TROKENDI XR, TOPIRAMATE
TROPHAMINE, AMINO ACIDS
TROPHAMINE 10%, AMINO ACIDS
TROPICACYL, TROPICAMIDE
TROPICAMIDE, TROPICAMIDE
TROSPIUM CHLORIDE, TROSPIUM CHLORIDE
TRULANCE, PLECANATIDE
TRUSOPT, DORZOLAMIDE HYDROCHLORIDE
TRUVADA, EMTRICITABINE
TUDORZA PRESSAIR, ACLIDINIUM BROMIDE
TUSSICAPS, CHLORPHENIRAMINE POLISTIREX
TUSSIGON, HOMATROPINE METHYLBROMIDE
TUXARIN ER, CHLORPHENIRAMINE MALEATE
TUZISTRA XR, CHLORPHENIRAMINE POLISTIREX
TWYNSTA, AMLODIPINE BESYLATE
TYBOST, Cobicistat
TYDAMY, DROSPERENONE
TYGACIL, TIGECYCLINE
TYKERB, LAPATINIB DITOSYLATE
TYLENOL, ACETAMINOPHEN (OTC)
TYLENOL W CODEINE NO. 3, ACETAMINOPHEN
TYLENOL W CODEINE NO. 4, ACETAMINOPHEN
TYMLOS, ABALOPARATIDE
TYZICLID LSB, TETRAHYDROZOLIDINE HYDROCHLORIDE
APPENDIX A - PRODUCT NAME INDEX

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ULESFIA, BENZYL ALCOHOL
ULORI C, FEBUXOSTAT
ULTACAN, ARTI CAI NE HYDROCHLORI DE
ULTACAN FORTE, ARTI CAI NE HYDROCHLORI DE
ULTANE, SEVOFLURANE
ULTI VA, REM FENTANI L HYDROCHLORI DE
ULTRA-TECHNIKOW FM, TECHNETI UM TC-99M SODI UM PERTECHNETATE GENERATOR
ULTRACET, ACETAMINOPHEN
ULTRAM, TRAMADOL HYDROCHLORI DE
ULTRAVATE, HALOBETASOL PROPIONATE
ULTRAVIST (PHARMACY BULK), IOPROMIDE
ULTRAVIST 240, IOPROMIDE
ULTRAVIST 300, IOPROMIDE
ULTRAVIST 370, IOPROMIDE
UNASYN, AMPI CI LLI N SODI UM
UNI SOM, DOXYLAM NE SUCCHI NATE (OTC)
UNI THROI D, LEVOTHYROXI NE SODI UM **
UPTRAVI, SELEXIPAG
URECHOL I NE, BETHANECHOL CHLORI DE
UREX, METHENAM NE HI PPURATE
URO T-K, POTASSI UM CI TRATE
UROKATRAL, ALFUZOSINI HYDROCHLORI DE
URSO 250, URSDOL OL
URSO FORTE, URSDOL OL
URSODOL OL, URSDOL OL
UTIBRON, GLYCOPYRROLATE
UVADEX, METHOKSALEN

** V **

VABOMERE, MEROPENEM
VAG FEM, ESTRADIOL CL
VAGI STAT-1, TI OCONAZOLE (OTC)
VALACYCLOVI R HYDROCHLORI DE, VALACYCLOVI R HYDROCHLORI DE
VALCHLOR, NECLORETHAM NE HYDROCHLORI DE
VALCYTE, VALGANCIOI CLOVI R HYDROCHLORI DE
VALIUM, DI AZEPAM
VALNAC, BETAMETHASONE VALERATE
VALPROATE SODI UM, VALPROATE SODI UM
VALPROI C ACI D, VALPROI C ACI D
VALSARTAN, VALSARTAN
VALSARTAN AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
VALSTAR PRESERVATI VE FREE, VALRUBI CI N
VALTREX, VALACYCLOVI R HYDROCHLORI DE
VANCOCI N HYDROCHLORI DE, VANCOCI N HYDROCHLORI DE
VANCOCI N HYDROCHLORI DE I N PLASTI C CONTAI NER, VANCOCI N HYDROCHLORI DE
VANCOCI N HYDROCHLORI DE, VANCOCI N HYDROCHLORI DE
VANCOCI N HYDROCHLORI DE I N PLASTI C CONTAI NER, VANCOCI N HYDROCHLORI DE
VANDASOLE, METRONI DAZOLE
VANI QA, EFLOLINI THI NE HYDROCHLORI DE
VANOS, FLUOCI NONI DE
VANTA, STRELI N ACETATE
VAPRI SOL I N 5% DEXTROSE I N PLASTI C CONTAI NER, CON VAPTAN HYDROCHLORI DE
VARDENAFI L HYDROCHLORI DE, VARDENAFI L HYDROCHLORI DE
VARI BAR HONEY, BARI UM SULFATE
VARI BAR NECTAR, BARI UM SULFATE
VARI BAR PUDI NG, BARI UM SULFATE
VARI BAR THI N HONEY, BARI UM SULFATE
VARI THENA, POLI DOCANOL
VARUBI, ROLAPI TANT HYDROCHLORI DE
VASCYPE, I COSAPENT ETHYL
VATERETI C, ENALAPRI I MALEATE
VASOCTRI CT, VASOPRESSI N
VASOTEC, ENALAPRI I MALEATE
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ZI PRASIDONE HYDROCHLORIDE, ZI PRASIDONE HYDROCHLORIDE
ZI PSOR, CLOFENAC POTASSIUM
ZI RAN, GANCILOVIR R
ZI THROMAX, AZITHROMYCIN
ZOCOL, SI MAASTATI N
ZOFRAN, ONDANSETRON HYDROCHLORIDE
ZOFRAN OD, ONDANSETRON
ZOHYDRO ER, HYDROCODONE BITARTRATE
ZOLADEX, GOSERELI N ACETATE
ZOLEDRON C , ZOLEDRON C ACI D
ZOLEDRON C ACI D, ZOLEDRON C ACI D
ZOLI NZA, VORI NOSTAT
ZOLM TRI PTAN, ZOLM TRI PTAN
ZOLOFT, SERTRALINE HYDROCHLORIDE
ZOLPI DEM TARTRATE, ZOLPI DEM TARTRATE
ZOLPI M ST, ZOLPI DEM TARTRATE
ZOMACTON, SOMATROPI N
ZOMETA, ZOLEDRON C ACI D
ZOMI G, ZOLM TRI PTAN
ZOMI G ZMT, ZOLM TRI PTAN
ZONALON, DOXEPIN N HYDROCHLORIDE
ZONEGRAN, ZONISAMIDE
ZONI SAM DE, ZONI SAM DE
ZONTI VI TY, VORAPAXAR SULFATE
ZORBSTI VE, SOMATROPI N RECOMBINANT
ZORTRESS, EVEROLIMUS
ZORVOLEX, CLOFENAC
ZOSYN, PI PERACETAMOL SODIUM
ZOSYN IN PLASTIC CONTAINER, PI PERACETAMOL SODIUM
ZOVIA 1/35E-28, ETHINYL ESTRA DIOL
ZOVIA 1/50E-28, ETHINYL ESTRA DIOL
ZOVITAX, ACYCLOVIR
ZUBSOLV, BUPRENORPHINE HYDROCHLORIDE
ZUMANDIMINE, DROSPIRENONE
ZUPLENZ, ONDANSETRON
ZURAMI C, LESNIURAD
ZUTRI PRO, CHLORPHENIRAMINE MALEATE
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ZYMAR, GATI FLOXACIN
ZYMEX, GATI FLOXACIN
ZYPITAMAG, PITAVASTATIN MAGNESIUM
ZYPREXA, OLANZAPINE
ZYPREXA RELPREVV, OLANZAPINE PAMOATE
ZYPREXA ZYDIS, OLANZAPINE
ZYRTEC ALLERGY, CETIRIZINE HYDROCHLORIDE
ZYRTEC-D 12 HOUR, CETIRIZINE HYDROCHLORIDE
ZYTIGA, ABIRATERONE ACETATE
ZYVOX, LINEZOLID
### Appendix B - Product Name Sorted by Applicant

#### 3D Imaging Drug

* 3D Imaging Drug Design and Development LLC
  - Ammonia N 13, Ammonia N-13
  - Fluodeoxyglucose F18, Fluodeoxyglucose F-18
  - Sodium Fluoride F-18, Sodium Fluoride F-18

* 3M
  - Peri Dex, Chlorhexi Di Ne Gluconate
  - 3M Health Care Inc
    - Avagard, Alcohol (OTC)
    - Duraprep, Iodine Poacrylex (OTC)

* 3M Drug Delivery
  - 3M Drug Delivery Systems
    - Fentanyl-100, Fentanyl
    - Fentanyl-12, Fentanyl
    - Fentanyl-25, Fentanyl
    - Fentanyl-50, Fentanyl
    - Fentanyl-75, Fentanyl
    - Proventi L Hfa, Albuterol Sulfate

* 3M Health Care
  - 3M Health Care InfecTi On Preventi On Di V
    - Soluprep, Chlorhexi Di Ne Gluconate (OTC)

#### 60 Degrees Pharma

* 60 Degrees Pharmaceuti Cals LLC
  - Arakoda, Tafenoquie Succi Nate

#### AAA USA Inc

* Advanced Accelerator Appli Cat i ons USA Inc
  - Lutathera, Lutei Um Dotatate Lu-177
  - Netspot, Gallium Dotatate Ga-68

* Aai Pharma LLC
  - Aazasan, Azathi Opri Ne

#### Abbvie

* Abbvie E i NC
  - Androgel, Testosterone
  - Creon, Pancri Lase (Amylase
  - Cyclospori Ne, Cyclospori Ne
  - Depacon, Valproate Soda Um
  - Depakene, Valproe C Aci D
  - Depakote Er, Di Valproe Sax Bromate
  - Depakote, Di Valproe Sax Bromate
  - Gengraf, Cyclospori Ne
  - K-Tab, Potassium Um Chlori De
  - Kaletra, Lopin Navi R
  - Mari Nol, Dronabi Nol
  - Niaspan, Niaci N
  - Ni Mbex Preservati Ve Free, Ci Satracuri Ums BESYLATE
  - Ni Mbex, Ci Satracuri Ums BESYLATE
  - Norvi R, Ri Tonavi R
  - Survant, Beractant
  - Synthco D, Levothyrocine Soda Um **
  - Tarka, Trandolapri L
  - TRi Cor, Fenofi Brate
  - TRI Di ONE, TRI Methadi ONE
  - TRI Li Pi X, Choli Ne Fenofi Brate
  - Ultane, Sevoflurane
  - Zemplar, Paricalcito L

#### Abbvie Endocrine

* Abbvie E Endocri Ne Inc
  - Lupaneta Pack, Leuprolide De Acetate
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **

ABBVIE ENDOCRINE INC
* ABBVIE ENDOCRINE INC
  LUPRON DEPOT, LEUPROLIDE ACETATE
  LUPRON DEPOT-PED, LEUPROLIDE ACETATE

ABBVIE INC
* ABBVIE INC
  DUOPA, CARBI DOPA
  MAVYRET, GLCHAPREV R
  NORV R, RYTONAVI R
  ORI LI SSA, ELAGOLI X SODIUM
  TECHNIVIE, OMBITASVIR
  VI EK RA PK (COPACKAGED), DASABUM R SODIUM
  VI EK RA X, DASABUM R SODIUM

ABHAI INC
* ABHAI INC
  DEXMETHYLPHENIDATE HYDROCHLORIDE, DEXMETHYLPHENIDATE HYDROCHLORIDE
  METHYLPHENIDATE HYDROCHLORIDE, METHYLPHENIDATE HYDROCHLORIDE

ABHAI LLC
* ABHAI LLC
  BUTALBITAL, ACETAMINOPHEN AND CAFFEINE, ACETAMINOPHEN
  HYDROCODONE BI TARTRATE AND ACETAMINOPHEN, ACETAMINOPHEN
  HYDROCODONE BI TARTRATE AND HOMATROPI NE METHYL BROMIDE, HOMATROPI NE METHYL BROMIDE
  METHYLPHENIDATE DATE HYDROCHLORIDE, METHYLPHENIDATE DATE HYDROCHLORIDE
  OXYBUTYNIN N CHLORIDE, OXYBUTYNIN N CHLORIDE
  OXYCODONE AND ACETAMINOPHEN, ACETAMINOPHEN
  OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE
  URSDOL OL, URSDOL OL

ABON PHARMS LLC
* ABON PHARMACEUTICALS LLC
  CLOFARABI NE, CLOFARABI NE

ABRAIX S BI OSCI ENCE
* ABRAX S BI OSCI ENCE LLC
  ABRAXANE, PACLI TAXEL

ABRAIX S PHARM
* ABRAX S PHARMACEUTICAL PRODUCTS
  CLI NDAMICY N PHOSPHATE IN DEXTROSE 5% CLI NDAMICY N PHOSPHATE

ACADEM C PHARMS INC
* ACADEMIC PHARMACEUTICALS LLC
  BRETYLYL UM TOSYLATE, BRETYLYL UM TOSYLATE

ACADIA PHARMS INC
* ACADIA PHARMACEUTICALS LLC
  NUPLAZID, PIMAVANSERIN TARTRATE

ACCELER LABS
* ACCELER LABS LLC
  CARISOPRODOL, CARISOPRODOL

ACCORD HLTHCARE
* ACCORD HEALTHCARE INC
  ACETAZOLAMIDE, ACETAZOLAMIDE
  ALLOPURINOL, ALLOPURINOL
  AM TRI PTYLI NE HYDROCHLORIDE, AM TRI PTYLI NE HYDROCHLORIDE
  AMLODI PI N BESYLATE, AMLODI PI N BESYLATE
  ANASTROZOLE, ANASTROZOLE
  ARI PI PRAZOLE, ARI PI PRAZOLE
  ATORVASTATI N CALCI UM, ATORVASTATI N CALCI UM
  AZACI DI N, AZACI DI N
  BENDAMUSTI NE HYDROCHLORIDE, BENDAMUSTI NE HYDROCHLORIDE
  BI CALUTAMINE, BI CALUTAMINE
  BI VALI RUDI N, BI VALI RUDI N
  BUPROPI ON HYDROCHLORIDE, BUPROPI ON HYDROCHLORIDE
  BUSPI RONE, HYDROCHLORIDE, BUSPI RONE, HYDROCHLORIDE
  CAPECI TABI NE, CAPECI TABI NE
  CARBI DOPA AND LEVODOPA, CARBI DOPA
  CARBOPLATI N, CARBOPLATI N
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**ACTAVIS LABS UT INC**

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  * BUTALI TAL, ACETAM NOPHEN AND CAFFEEI NE, ACETAM NOPHEN
  * CLU NIANDMCI N PHOSPHATE AND BENZOYL PEROXI DE, BENZOYL PEROXI DE
  * CLU DNOI DI, CLU DNOI DI NE
  * DOCOSANOL, DOCOSANOL (OTC)
  * EMLA, LI DOCAI NE
  * FI ORI CET W CODEI NE, ACETAM NOPHEN
  * FLUCCI NOLONE ACETONI DE, FLUCCI NOLONE ACETONI DE
  * LI DOCAI NE, LI DOCAI NE
  * NORI NYL 1+50 28-DAY, MESTRANOL
  * PROGHESTERONE, PROGHESTERONE
  * TESTOSTERONE, TESTOSTERONE

* ACTAVIS LABORATORIES Ut INC Indirect wholly owned sub of Teva Pharmaceuticals Inc US Inc
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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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<td>EPI RUBI CI N HYDROCHLORIDE DE</td>
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<td>FI NASTERI DE</td>
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<td>FLUDARABI NE HYDROPHOSPHATE</td>
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<td>GEMO TABI NE HYDROCHLORIDE DE</td>
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<td>OXALI PLATI N</td>
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<td>PACLI TAKEL</td>
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** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

** A **

* ACTAVIS TOTOWA LLC
  TOPOTECAN HYDROCHLORIDE, TOPOTECAN HYDROCHLORIDE
  VI NORELBI NE TARTRATE, VI NORELBI NE TARTRATE

* ACTAVIS TOTOWA LLC AN I NDENT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC
  FI NASTERI DE, FI NASTERI DE

* ACTELI ON PHARMS
  ACTELI ON PHARMACEUTICALS LTD
  TRACLEER, BOSENTAN

* ACTELI ON PHARMS LTD
  ACTELI ON PHARMACEUTICALS LTD
  OPUSUM T, MACI TENTAN
  TRACLEER, BOSENTAN
  UPTRAVI, SELLEXI PAG
  VELETRI, EPOPROSTENOL SODIUM
  VENTAVI S, LOPROST
  ZAVESCA, M GLUSTAT

* ACTIENT PHARMS
  ACTIENT PHARMACEUTICALS LLC
  THEO-24, THEOPHYLLINE

* ADAMAS PHARMA
  ADAMAS PHARMA LLC
  GOCOVRI, AMANTADINE HYDROCHLORIDE

* ADAM S PHARMS CORP
  ADAM S PHARMACEUTICALS CORP
  SYM EPI, EPI NEPHRINE

* ADAPT
  ADAPT PHARMA OPERATIONS LTD
  NARCAN, NALOXONE HYDROCHLORIDE

* ADARE PHARMS INC
  ADARE PHARMACEUTICALS INC
  THEO-24, THEOPHYLLINE

* ADDMORE SAS
  ADDMORE SAS
  SI KLOS, HYDROXYUREA

* ADIENNE SA
  ADIENNE SA
  TEPADNA, THI OTEPA

* AEGEARI ON
  AEGEARI ON PHARMACEUTICALS LLC
  IUXTAPE D, LOM TAPID MESYLATE

* AERI E PHARMS INC
  AERI E PHARMACEUTICALS INC
  RHOPRESSA, NETARSUDI LI MEISYLATE

* AGI OS PHARMS INC
  AGI OS PHARMACEUTICALS INC
  TI BSOVO, I VOSI DERNI B

* AGOURON PHARMS
  AGOURON PHARMACEUTICALS LLC
  VI RACEPT, NELFINAVIR MESYLATE

* AI LEX PHARMS LLC
  AI LEX PHARMACEUTICALS LLC
  BI SMUTH SUBSALI CYLATE, METRONIDAZOLE AND TETRACYCLINE HYDROCHLORIDE
  BI SMUTH CROMOLYN SODIUM, CROMOLYN SODIUM
  SODIUM PHENYLACETATE AND SODIUM BENZOATE, SODIUM BENZOATE

* AII PHARMS INC
  AII PHARMACEUTICALS LLC
  VI NASTIRI DE, VI NASTIRI DE

* AJANTA PHARMA LTD
  AJANTA PHARMA LTD
  ALMOTRIPTAN MALATE, ALMOTRIPTAN MALATE
  AMLODIPINE BESYLATE AND OLMESARTAN MEDOXOMIL, AMLODIPINE BESYLATE
  AMLODIPII PE AND OLMESARNTAN MEDOXOM I, AMLODIPII PE BESYLATE
  ARIPRIL PRAZOLE, ARIPRIL PRAZOLE

* ALIMENTUM LTD
  ALIMENTUM LTD
  ARIMIDEX, LIVESTRIDE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **

* AJANTA PHARMA LTD
  CLONDI NE HYDROCHLORIDE, CLONDI NE HYDROCHLORIDE
  DOXYCYCLINE HYDROCHLORIDE, DOXYCYCLINE HYDROCHLORIDE
  DULOKETI NE HYDROCHLORIDE, DULOKETI NE HYDROCHLORIDE
  ELETRI PTAN HYDROBROMIDE, ELETRI PTAN HYDROBROMIDE
  ENTACAPONE, ENTACAPONE
  FENOBIRATE (M CRONI ZED), FENOBIRATE
  FENOBIRATE, FENOBIRATE
  LANSOPRAZOLE, LANSOPRAZOLE
  MEMANTI NE HYDROCHLORIDE, MEMANTI NE HYDROCHLORIDE
  MONTELUKAST SODIUM, MONTELUKAST SODIUM
  OMEPRAZOLE AND SODIUM BI CARBONATE, OMEPRAZOLE
  RANITIDINE HYDROCHLORIDE, RANITIDINE HYDROCHLORIDE
  SILODOSIN, SILODOSIN
  VORICONAZOLE, VORICONAZOLE
  ZOLM TRI PTAN, ZOLM TRI PTAN

AKARX INC
* AKARX INC
  DOPTELET, AVATROMBOPAG MALEATE

AKCEA THERAPIES
* AKCEA THERAPEUTICS CS INC
  TEGSEDI, I NOTERSEN SODIUM

AKORN
* AKORN INC
  ADENOSINE, ADENOSINE
  AK FLUOR 10%, FLUORESCEIN SODIUM
  AK FLUOR 25%, FLUORESCEIN SODIUM
  AKBETA, LEVOBUNOLOL HYDROCHLORIDE
  AKPENTOLATE, CYCLOPENTOLATE HYDROCHLORIDE
  AKTON, LIDOCAINE HYDROCHLORIDE
  AKTOB, TOBRAMYCIN
  ALFENTA, ALFENTANIL HYDROCHLORIDE
  ATROPINE SULFATE, ATROPINE SULFATE
  AZELASTINE HYDROCHLORIDE, AZELASTINE HYDROCHLORIDE
  BACITRACIN ZINC AND POLYMYXIN B SULFATE, BACITRACIN ZINC AND POLYMYXIN B SULFATE
  BACITRACIN, BACITRACIN
  BAL, DIMERCAPROL
  BALANCED SALT, CALCIUM CHLORIDE
  BETAXOLOL HYDROCHLORIDE, BETAXOLOL HYDROCHLORIDE
  BROMIDI NE TARTRATE, BROMIDI NE TARTRATE
  CALCI TRI OL, CALCI TRI OL
  CARBOPLATI NE, CARBOPLATI NE
  CI CLOPR OX, CI CLOPR OX
  CLI NDAMYCIN PHOSPHATE, CLI NDAMYCIN PHOSPHATE
  CLOBETASOL PROPionate, CLOBETASOL PROPionate
  CROMOLYN SODIUM, CROMOLYN SODIUM
  DEMECLOCYCLINE HYDROCHLORIDE, DEMECLOCYCLINE HYDROCHLORIDE
  DESOKI METASONE, DESOKI METASONE
  DI CLOFENAC SODIUM, DI CLOFENAC SODIUM
  DI FLORASONE DI ACETATE, DI FLORASONE DI ACETATE
  EPTI FI BATTI DE, EPTI FI BATTI DE
  ERYTHROMYCIN, ERYTHROMYCIN
  ETHAMBUTOL HYDROCHLORIDE, ETHAMBUTOL HYDROCHLORIDE
  ETHOSUXI M DE, ETHOSUXI M DE
  FLUCONAZOLE ACETONI DE, FLUCONAZOLE ACETONI DE
  GENTAK, GENTAMICIN SULFATE
  GENTAMICIN SULFATE, GENTAMYCIN SULFATE
  HALOPERIDOL, HALOPERIDOL LACTATE
  HYDRAZINE NE HYDROCHLORIDE, HYDRAZINE NE HYDROCHLORIDE
  HYDROMORPHONE HYDROCHLORIDE, HYDROMORPHONE HYDROCHLORIDE
  IC GREEN, IC GREEN
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

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<td>RI FAMPI N, RI FAMPI N</td>
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<td>ZOLEDRONIC ACID, ZOLEDRONIC ACID</td>
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **

* AKORN INC
  ROPIVACAINE HYDROCHLORIDE, ROPIVACAINE HYDROCHLORIDE
  TOBRAMYCI N, TOBRAMYCI N
  TRI METHOPRI M SULFATE AND POLYMIXI N B SULFATE, POLYMIXI N B SULFATE
  ZOLEDRONI C ACI D, ZOLEDRONI C ACI D

ALCON
* ALCON LABORATORI ES I NC
  BSS PLUS, CALCI UM CHLORI DE
  BSS, CALCI UM CHLORI DE
  M OSTAT, CARBACHOL
  NAPHTON-A, NAPHAZOLI NE HYDROCHLORI DE (OTC)

ALCON LABS
* ALCON LABORATORI ES LTD
  TETRACAI NE HYDROCHLORI DE, TETRACAI NE HYDROCHLORI DE

ALCON LABS I NC
* ALCON LABORATORI ES I NC
  ALCAI NE, PROPARACAI NE HYDROCHLORI DE
  CYCLOGYL, CYCLOPENTOLATE HYDROCHLORI DE
  CYCLOMIDRI L, CYCLOPENTOLATE HYDROCHLORI DE
  FLUORESO TE, FLUORESCENI N SODI UM
  I SOPTO ATROP I NE, ATROP I NE SULFATE

ALCON PHARMS LTD
* ALCON PHARMACEUTI CALS LTD
  BETADI NE, POVI DONI DO I ODI NE
  KETOTI FEN FUMARATE, KETOTI FEN FUMARATE (OTC)

ALEMBI C LTD
* ALEMBI C LTD
  LE THI UM CARBONATE, LE THI UM CARBONATE
  ROPI NI ROLE HYDROCHLORI DE, ROPI NI ROLE HYDROCHLORI DE

ALEMBI C PHARMS LTD
* ALEMBI C PHARMACEUTI CALS LTD
  ACYCLORI R, ACYCLOR R
  AMANTADI NE HYDROCHLORI DE, AMANTADI NE HYDROCHLORI DE
  AMLODI PI NE AND OLMESARTAN MEDOKOM L, AMLODI PI NE BESYLATE
  AMLODI PI NE BESYLATE AND VALSARTAN, AMLODI PI NE BESYLATE
  API PI PRAZOLE, API PI PRAZOLE
  BUPROPI ON HYDROCHLORI DE, BUPROPI ON HYDROCHLORI DE
  Candesartan CI LEXETI L, Candesartan CI LEXETI L
  CELECOXI B, CELECOXI B
  CLONI DI NE HYDROCHLORI DE, CLONI DI NE HYDROCHLORI DE
  DARI FENACI N HYDROBROMI DE, DARI FENACI N HYDROBROMI DE
  DESVENLAFAXI NE SUCCI NATE, DESVENLAFAXI NE SUCCI NATE
  DESVENLAFAXI NE, DESVENLAFAXI NE
  DONEPEZI L HYDROCHLORI DE, DONEPEZI L HYDROCHLORI DE
  DOKCYCLI NE HYCLATE, DOKCYCLI NE HYCLATE
  DOKCYCLI NE, DOKCYCLI NE
  DULOKETI NE HYDROCHLORI DE, DULOKETI NE HYDROCHLORI DE
  FAMOTI DI NE, FAMOTI DI NE
  FENOFI BRI C ACI D, CHOLI NE FENOFI BRATE
  FLUKETI NE HYDROCHLORI DE, FLUKETI NE HYDROCHLORI DE
  HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  I RBESARTAN AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  I RBESARTAN, I RBESARTAN
  I TRACONAZOLE, I TRACONAZOLE
  LAMOTRI GI NE, LAMOTRI GI NE
  LEFLUNOMI DE, LEFLUNOMI DE
  LI NEZOLI D, LI NEZOLI D
  LI THI UM CARBONATE, LI THI UM CARBONATE
  LOSARTAN POTASSI UM AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  LOSARTAN POTASSI UM LOSARTAN POTASSI UM
  MEMANTI NE HYDROCHLORI DE, MEMANTI NE HYDROCHLORI DE
  MEPROBAMATE, MEPROBAMATE
  METOPROLOL TARTRATE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  METOPROLOL TARTRATE, METOPROLOL TARTRATE
  METRONI DAZOLE, METRONI DAZOLE
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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<tr>
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **

| ALKEM LABORATORI ES LTD | RASAGILINE MESYLATE, RASAGILINE MESYLATE |
| ALKEM LABORATORI ES LTD | RI LUZOLE, RI LUZOLE |
| ALKEM LABORATORI ES LTD | RI ZATRI PTAN BENZOATE, RI ZATRI PTAN BENZOATE |
| ALKEM LABORATORI ES LTD | ROSUVASTATI N CALCI UM, ROSUVASTATI N CALCI UM |
| ALKEM LABORATORI ES LTD | TAMUSLOSI N HYDROCHLORI DE, TAMUSLOSI N HYDROCHLORI DE |
| ALKEM LABORATORI ES LTD | TRAMADOL HYDROCHLORI DE AND ACETAM NOPYHEN, ACETAM NOPYHEN |
| ALKEM LABORATORI ES LTD | TRI AMI NOLONE ACETONI DE, TRI AMI NOLONE ACETONI DE |

** ALKERMES **

| ALKERMES | VI VI TROL, NALTREXONE |

** ALKERMES INC **

| ALKERMES INC | VIVITROL, NALTREXONE |

** ALLEGANCE HOLDINGS LLC **

| ALLEGANCE HEALTHCARE CORP | POVI DONE I OD NE, POVI DONE-I OD NE (OTC) |

** ALLEGIS **

| ALLEGIS | PRI M3OL, TRI METHOPRI M HYDROCHLORI DE |

** ALLERGAN **

| ALLERGAN | ACULAR LS, KETOROLAC TROMETHAM NE |
| ALLERGAN | ALPHAGAN P, BRI MONI DI NE TARTRATE |
| ALLERGAN | BLEPH-10, SULFACETAM DE SODI UM |
| ALLERGAN | GENOPTI C, GENTAM CI N SULFATE |
| ALLERGAN | ZYMAXI D, GATI FLOXACI N |

** ALLERGAN INC **

| ALLERGAN INC | ACULAR, KETOROLAC TROMETHAM NE |
| ALLERGAN INC | ACUVAI L, KETOROLAC TROMETHAM NE |
| ALLERGAN INC | ACZONE, DAPSONE |
| ALLERGAN INC | ALACRI L, NEDOCROM L SODI UM |
| ALLERGAN INC | ALPHAGAN P, BRI MONI DI NE TARTRATE |
| ALLERGAN INC | AVAGE, TAZAROTENE |
| ALLERGAN INC | COMBI GAN, BRI MONI DI NE TARTRATE |
| ALLERGAN INC | ELESTAT, EPI NASTI NE HYDROCHLORI DE |
| ALLERGAN INC | LASTACAFT, ALCAFTADI NE |
| ALLERGAN INC | LATISE, BI MATOPROST |
| ALLERGAN INC | LUM GAN, BI MATOPROST |
| ALLERGAN INC | OCUFLOX, OFLOXACI N |
| ALLERGAN INC | OZURIDEX, DEXAMETHASONE |
| ALLERGAN INC | POLYTRI M, POLYMIXI N B SULFATE |
| ALLERGAN INC | RESTASI S, MULTI DOSE, CYCLOSPORI NE |
| ALLERGAN INC | TAZORAC, TAZAROTENE |
| ALLERGAN INC | ZYMAR, GATI FLOXACI N |

** ALLERGAN PHARMACEUTICALS **

| ALLERGAN PHARMACEUTICALS | BETAGAN, LEVOBUNOLOL HYDROCHLORI DE |
| ALLERGAN PHARMACEUTICALS | BLEPHAG DE S. Q. P., PREDNISOLONE ACETATE |
| ALLERGAN PHARMACEUTICALS | BLEPHAG DE, PREDNISOLONE ACETATE |
| ALLERGAN PHARMACEUTICALS | FML FORTE, FLUOROMETHOLONE |
| ALLERGAN PHARMACEUTICALS | FML, FLUOROMETHOLONE |
| ALLERGAN PHARMACEUTICALS | OCUFEN, FLURBI PROFEN SODI UM |
| ALLERGAN PHARMACEUTICALS | PRED FORTE, PREDNISOLONE ACETATE |
| ALLERGAN PHARMACEUTICALS | PRED M LD, PREDNISOLONE ACETATE |
| ALLERGAN PHARMACEUTICALS | PRED G, GENTAM CI N SULFATE |

** ALLERGAN HOLDINGS LLC **

| ALLERGAN HOLDINGS LLC | VI BERZI, ELUXADOLI NE |

** ALLERGAN SALES LLC **

| ALLERGAN SALES LLC | ACTI GALL, URSODI OL |
| ALLERGAN SALES LLC | ALORA, ESTRADI OL |
| ALLERGAN SALES LLC | ANDRODERM TESTOSTERONE |
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **

* ALLERGAN SALES LLC
  AVYCAZ, AVI BACTAM SODI UM
  BENTYL PRESERVATI VE FREE, DI CYCLOM NE HYDROCHLOR DE
  BENTYL, DI CYCLOM NE HYDROCHLOR DE
  BREV Con 28-Day, ETH Nyl Estradi Ol
  BYSTOLI C, NIBI VOLOL HYDROCHLOR DE
  BYVALSON, NIBI VOLOL HYDROCHLOR DE
  CANASA, MESAAM NE
  CARAFATE, SUCRAFATE
  CELEXA, CI TALOPRAME HYDROBROM DE
  CONDYLOX, PODOFI LOK
  CR N N, PROGESTERONE
  DALVANCE, DALBAVANCI N HYDROCHLOR DE
  ESTRACE, ESTRADI Ol
  FETZI MA, LEVOM LNAI PRAN HYDROCHLOR DE
  FI ORI NAL W CODEI NE, ASPI RI N
  FI ORI NAL, ASPI RI N
  GELNI QUE, OXYBUTYNI N CHLORI DE
  I NFED, I RON DEXTRAN
  KADI AN, MORPHI NE SULFATE
  LEXAPRO, ESCI TALOPRAM OXALATE
  LI NZESS, LI NACLON DE
  MI CROZI DE, HYDROCHLOROTHI AZI DE
  NAMENDA, MEMANTI NE HYDROCHLORI DE
  NAMZARI C, DONEPEZLI HYDROCHLORI DE
  NORI Nyl I+35 21-Day, ETH Nyl Estradi Ol
  NORI Nyl I+35 28-Day, ETH Nyl Estradi Ol
  OXYTROL FOR WOMEN, OXYBUTYNI N (OTC)
  OXYTROL, OXYBUTYNI N
  PYLERA, BI SMITH SUBCI TRATE POTASSI UM
  PAFALO, SI LODOI N
  RECTI V, NI TRIO GLYCIERI N
  SAVELLA, M NACI PRAN HYDROCHLORI DE
  TEFLARQ, CEFTAROLI NE FOSAM I
  TRELLAR, TRIP TORELI N PAMDATE
  URSO 250, URSODI OL
  URSO FORTE, URSODI OL
  VI I BRYD, VI LAZODONE HYDROCHLORI DE
  VRAYLAR, CARI PRAZI NE HYDROCHLORI DE

ALLERQUEST
* ALLERQUEST LLC
  PRE-PEN, BENZYLPENI CI LLOYD POLYLYSI NE

ALLI ED
* ALLI ED PHARMA I NC
  CLARI THROMCYI N, CLARI THROMCYI N
  ROSEVASTATI N CALCI UM ROSEVASTATI N CALCI UM

ALLI ED PHARMA I NC
* ALLI ED PHARMA I NC
  CLARI THROMCYI N, CLARI THROMCYI N

ALLOS
* ALLOS THERAPEUTIC N INC
  FOLOTYN, PRALATREXATE

ALM RALL
* ALM RALL LLC
  SEYSARA, SARECYCI NE HYDROCHLORI DE

ALNYLAM PHARMS I NC
* ALNYLAM PHARMACEUTICALS INC
  ONPATTRO, PATI SI RAN SODI UM

ALPHARMA PHARMS
* ALPHARMA PHARMACEUTICALS LLC
  EMBEDA, MORPHI NE SULFATE

ALRA
* ALRA LABORATORIES INC
  CHOLAC, LACTULOSE
  CONSTITUT, LACTULOSE
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

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* AMERI CAN ANTI BI OTI CS I NC
  AMOXI CI LLI N, AMOXI CI LLI N

AM PHARMA USA
* AMAG PHARMA USA I NC
  MAKENA (AUTO INJECTOR), HYDROXYPROGESTERONE CAPROATE
  MAKENA PRESERVATIVE FREE, HYDROXYPROGESTERONE CAPROATE
  MAKENA, HYDROXYPROGESTERONE CAPROATE

AMAG PHARMS INC
* AMAG PHARMACEUTICALS INC
  FERAHIME, FERUMOXYTOL
  I NTRAROSA, PRASTERONE

AMARI PHARM
* AMARI PHARMACEUTICALS I RELAND LTD
  I COSAPENT ETHYL

AMERI GEN PHARMS LTD
* AMERI GEN PHARMA INC
  BEXAROTENE, BEXAROTENE
  CARBI DOPA, CARBI DOPA
  CYCLOPHOSPHAM DE, CYCLOPHOSPHAM DE
  FENOFI BRATE (M CRONI ZED), FENOFI BRATE
  I NDAPAM DE, I NDAPAM DE
  M GLUSTAT, M GLUSTAT
  TEMOZOLOM DE, TEMOZOLOM DE

AMGEN
* AMGEN I NC
  CI NACALCET HYDROCHLORIDE

AMGEN INC
* AMGEN INC
  CORLANOR, I VABRAI DI NE HYDROCHLORIDE

AM CUR THERAPS US
* AM CUR THERAPEUTICS CS I US INC
  GALAFOLD, I GALASTAT HYDROCHLORIDE

AMNEAL PHARM
* AMNEAL PHARMACEUTICALS INC
  ACEBUTOLOL HYDROCHLORIDE, ACEBUTOLOL HYDROCHLORIDE
  BETHANECHOL CHLORIDE, BETHANECHOL CHLORIDE
  DEMECLOCYCNI NE HYDROCHLORIDE, DEMECLOCYCNI NE HYDROCHLORIDE
  FLECAI NI DE ACETATE, FLECAI NI DE ACETATE
  FOLI C ACI D, FOLI C ACI D
  GUANFACI NE HYDROCHLORIDE, GUANFACI NE HYDROCHLORIDE
  HYDROXYZI NE HYDROCHLORIDE, HYDROXYZI NE HYDROCHLORIDE
  PRI M DONE, PRI M DONE

AMNEAL PHARMS
* AMNEAL PHARMACEUTICALS INC
  ACRYLONI R, ACRYLONI R
  ALBUTEROL SULFATE, ALBUTEROL SULFATE
  ARPI PRAZOLE, ARPI PRAZOLE
  ATOVAQUONE, ATOVAQUONE
  CALCI TRI OL, CALCI TRI OL
  CALCI UM ACETATE, CALCI UM ACETATE
  CAPECI TABI NE, CAPECI TABI NE
  CETI RI ZI NE HYDROCHLORIDE, CETI RI ZI NE HYDROCHLORIDE
  CHI LDREN S, CETI RI ZI NE HYDROCHLORIDE DE ALLERGY, CETI RI ZI NE HYDROCHLORIDE DE (OTC)
  CHI LDREN S, CETI RI ZI NE HYDROCHLORIDE DE HI VES RELI EF, CETI RI ZI NE HYDROCHLORIDE DE (OTC)
  CLI NDAMICI N PALM TATE HYDROCHLORIDE, CLI NDAMICI N PALM TATE HYDROCHLORIDE
  CLOPI DOGREL BI SULFATE, CLOPI DOGREL BI SULFATE
  DI CLOFENAC SODIUM AND M SOPROSTOL, DI CLOFENAC SODIUM
  DI CLOFENAC SODIUM UM, DI CLOFENAC SODIUM UM
  DI VALPROEX SODIUM UM, DI VALPROEX SODIUM UM
  ENTECAVIR R, ENTECAVIR R
  ESCI TALOPLAN OXALATE, ESCI TALOPLAN OXALATE
  ESTRADI OL, ESTRADI OL
  FELBAMATE, FELBAMATE
## Appendix B - Product Name Sorted by Applicant

### **A**

- Amneal Pharmaceuticals
  - Gabapentin, Gabapentin
  - Hydrocodone Bi-Tartrate and Acetaminophen, Acetaminophen
  - I Nidomethacin, I Nidomethacin
  - Itraconazole, Itraconazole
  - Levitriacetam, Levitriacetam
  - Li Docai NE, Li Docai NE
  - Li Nezoli D, Li Nezoli D
  - Lorazepam, Lorazepam
  - Merosenem, Merosenem
  - Metaxonone, Metaxalone
  - Mometasone Furoate, Mometasone Furoate
  - Montelukast Sodium, Montelukast Sodium
  - Niacin, Niacin
  - Nitrofurantoin (Monohydrate/Macrocrystals), Nitrofurantoin
  - Nizatidine, Nizatidine
  - Nor-Ethindrone Acetate, Nor-Ethindrone Acetate
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  - Oxycodone, Oxycodone
  - Pantoprazole Sodium, Pantoprazole Sodium
  - Potassum, Potassum
  - Promethazine, Promethazine
  - Rabeprozole Sodium, Rabeprozole Sodium
  - Raloxifene Hydrochloride, Raloxifene Hydrochloride
  - Tramadol Hydrochloride, Tramadol Hydrochloride
  - Venlafaxine Hydrochloride, Venlafaxine Hydrochloride
  - Voriconazole, Voriconazole
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  - Doxycycline, Doxycycline
- Amneal Pharmaceuticals Cals of New York LLC
  - Abiraterone, Abiraterone
  - Alosetron Hydrochloride, Alosetron Hydrochloride
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  - Aspirin, Aspirin
  - Benazepril Hydrochloride, Benazepril Hydrochloride
  - Celecoxib, Celecoxib
  - Dutasteride, Dutasteride
  - Eptifibatide, Eptifibatide
  - Exemestane, Exemestane
  - Guai Fenesi, Guai Fenesi
  - Levonorgestrel and Ethyl Estradiol, Levonorgestrel
  - Methotrexate, Methotrexate
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

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  * Enokapari N Soci Um (Preservative Free), Enokapari N Soci Um
  * Kotorolac Trometham Ne, Kotorolac Trometham Ne

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** ANTARES PHARMA INC **

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** APC PHARMS LLC **
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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Get the full version of this document from the source link provided.
## APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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* APOTEX INC
  - DROSPIRENONE AND ETHINYL ESTRADIOL,
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  - DULOKETI NE HYDROCHLORIDE,
  - DULOKETI NE HYDROCHLORIDE
  - DUTASTERI DE,
  - DUTASTERI DE
  - ENOXAPARI N SODIUM (PRESERVATIVE FREE),
  - ENOXAPARI N SODIUM
  - ESCI TALOGRAM OXALATE,
  - ESCI TALOGRAM OXALATE
  - EZETI M BE,
  - EZETI M BE
  - FENOFI BRATE (M CRONI ZED),
  - FENOFI BRATE
  - FLUTI CASONE PROFI ONATE,
  - FLUTI CASONE PROFI ONATE (OTC)
  - GEM TABI NE HYDROCHLORIDE,
  - GEM TABI NE HYDROCHLORIDE
  - GRAN SETRON HYDROCHLORIDE,
  - GRANI SETRON HYDROCHLORIDE
  - GUANFACI NE HYDROCHLORIDE,
  - GUANFACI NE HYDROCHLORIDE
  - I BANDRONATE SODIUM,
  - I BANDRONATE SODIUM
  - I MATI NI B MESYLATE,
  - I MATI NI B MESYLATE
  - I M QUI MOD.
  - I M QUI MOD
  - I PRATROPI UM BROM DE,
  - I PRATROPI UM BROM DE
  - I RBESARTAN AND HYDROCHLOROTHI AZI DE,
  - HYDROCHLOROTHI AZI DE
  - LAM VUDI NE,
  - LAM VUDI NE
  - LAMOTRI GI NE,
  - LAMOTRI GI NE
  - LETROZOLE,
  - LETROZOLE
  - LEVETI RACETAM,
  - LEVETI RACETAM
  - LEVOCETI RI ZI NE DI HYDROCHLORIDE,
  - LEVOCETI RI ZI NE DI HYDROCHLORIDE
  - LEVOFLOKACI N,
  - LEVOFLOKACI N
  - LEVONORGESTREL,
  - LEVONORGESTREL (OTC)
  - LOVASTATI N,
  - LOVASTATI N
  - MEMANTI NE HYDROCHLORIDE,
  - MEMANTI NE HYDROCHLORIDE
  - M DOORI NE HYDROCHLORIDE,
  - M DOORI NE HYDROCHLORIDE
  - MODAFI NI L,
  - MODAFI NI L
  - MODEXI PRI L HYDROCHLORIDE,
  - MODEXI PRI L HYDROCHLORIDE
  - MOMETASONE FURATE,
  - MOMETASONE FURATE
  - MOXI FLOKACI N HYDROCHLORIDE,
  - MOXI FLOKACI N HYDROCHLORIDE
  - MYCOPHENOLIC ACID,
  - MYCOPHENOLIC ACID
  - NABUMETONE,
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  - NATLEXONE HYDROCHLORIDE,
  - NATLEXONE HYDROCHLORIDE
  - OFLOKACI N,
  - OFLOKACI N
  - OLANZAPI NE,
  - OLANZAPI NE
  - OLOPATADI NE HYDROCHLORIDE,
  - OLOPATADI NE HYDROCHLORIDE
  - OMEGA-3 ACID D ETHYL ESTERS,
  - OMEGA-3 ACID D ETHYL ESTERS
  - OXCARBAZEPI NE,
  - OXCARBAZEPI NE
  - PANTOPRAZOLE SODIUM,
  - PANTOPRAZOLE SODIUM
  - POTASSI UM CHLORIDE,
  - POTASSI UM CHLORIDE
  - PRAM PEXOLE DI HYDROCHLORIDE,
  - PRAM PEXOLE DI HYDROCHLORIDE
  - PRAVASTATI N SODIUM,
  - PRAVASTATI N SODIUM
  - QUETI API NE FUMARATE,
  - QUETI API NE FUMARATE
  - RANITI NI DI NE HYDROCHLORIDE,
  - RANITI NI DI NE HYDROCHLORIDE (OTC)
  - RANITI NI DI NE HYDROCHLORIDE,
  - RANITI NI DI NE HYDROCHLORIDE
  - RASO SEDRONATE SODIUM,
  - RASO SEDRONATE SODIUM
  - RASO SPIRONE DONE,
  - RASO SPIRONE DONE
  - RASO VASTI GM NE TARTRATE,
  - RASO VASTI GM NE TARTRATE
  - RASO VASTI GM NE TARTRATE,
  - RASO VASTI GM NE TARTRATE
  - ROSUVASTATI N CALCI UM,
  - ROSUVASTATI N CALCI UM
  - SERTRALI NE HYDROCHLORIDE,
  - SERTRALI NE HYDROCHLORIDE
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  - SUMATI PTAN SUCCI NAT
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  - TEMOZOLOM DE
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  - TENOFOVI R DI SOPROXI L FUMARATE
  - TERA FLUNON DE,
  - TERA FLUNON DE
  - TI GECYCLI NE,
  - TI GECYCLI NE
  - TI MOLOL MALEATE,
  - TI MOLOL MALEATE
  - TI ZANI DI NE HYDROCHLORIDE,
  - TI ZANI DI NE HYDROCHLORIDE
  - TRAMADOL HYDROCHLORIDE AND ACETAM NOPHEN,
  - ACETAM NOPHEN
  - TRANEXAM C ACI D,
  - TRANEXAM C ACI D
  - TRAVOPROST,
  - TRAVOPROST
  - TRAZODONE HYDROCHLORIDE,
  - TRAZODONE HYDROCHLORIDE
  - VALACYCLOVIR HYDROCHLORIDE,
  - VALACYCLOVIR HYDROCHLORIDE
  - ZI PRASI DON HYDROCHLORIDE,
  - ZI PRASI DON HYDROCHLORIDE
  - ZOLEDRONI C ACI D,
  - ZOLEDRONI C ACI D
** Appendix B - Product Name Sorted by Applicant **

** A **

- APOTEX INC
  - ZOLPIDEM TARTRATE
  - ACYCLOVIR
  - ALLOPURINOL
  - BALSALAZIDE DISODIUM
  - BUPROPION HYDROCHLORIDE
  - CARBAMAZEPINE
  - CARVEDILOL
  - CILOSTAZOL
  - CITALOPRAM HYDROBROMIDE
  - DESMOPRESSIN ACETATE
  - DILTIAZEM HYDROCHLORIDE
  - ENALAPRIL MALEATE AND HYDROCHLOROTHIO AZI DE
  - ETODOLAC
  - AZELASTINE HYDROCHLORIDE
  - BUDESONIDE
  - DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)
  - FLUTICASONE PROPIONATE
  - KETOROLAC TROMETHAMINE
  - RISPERIDONE

- APOTEX TECHNOLOGIES INC
  - DILTZAC
  - GALANTAMINE HYDROBROMIDE

- APOTHECON INC
  - KENALOG-10
  - KENALOG-40

- APP PHARMS LLC
  - DIPHENHYDRAMINE HYDROCHLORIDE

- APPCO PHARMA LLC
  - CHLORTHALI DONE
  - FLUCETI NE HYDROCHLORI DE
  - HYDRAZI NE HYDROCHLORI DE
  - OXYBUTYNI N CHLORI DE

- APRECI A PHARMS
  - SPRI TAM

- APTAPHARMA INC
  - IBUPROFEN

- AQUA PHARMA INC
  - CORDRAN SP
  - CORDRAN
### Appendix B - Product Name Sorted by Applicant

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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

* AUCTA PHARMA EU LIMITS LLC
  VI GAORDONE, VI GABATRI N

** AUROBI NDO **

* AUROBI NDO PHARMA LTD
  AMODI CI LLI N, AMODI CI LLI N
  CEFADROXIL, CEFADROXIL/CEFADROXIL HEM HYDRATE
  CI TALOPRAM HYDROBROM DE, CI TALOPRAM HYDROBROM DE
  CLARI THROMCIC N, CLARI THROMCIC N
  DOMEPEZI L HYDROCHLOR DE, DOMEPEZI L HYDROCHLOR DE
  LI SI NOPR L, LI SI NOPR L
  METFORM N HYDROCHLOR DE, METFORM N HYDROCHLOR DE
  M RTAZAPI NE, M RTAZAPI NE
  NEVI RAPI NE, NEVI RAPI NE
  ZI DOVUDI NE, ZI DOVUDI NE

** AUROBI NDO PHARMA **

* AUROBI NDO PHARMA
  AMPI CI LLI N AND SULBACTAM, AMPI CI LLI N SODI UM

* AUROBI NDO PHARMA LTD
  ALENDRONATE SODI UM, ALENDRONATE SODI UM
  AMLODI PI NE BESYLATE, AMLODI PI NE BESYLATE
  AMPI CI LLI N SODI UM, AMPI CI LLI N SODI UM
  ATENOLOL, ATENOLOL
  BENAZEPRI L HYDROCHLOR DE, BENAZEPRI L HYDROCHLOR DE
  BI SOPROLOL FUMARATE, BI SOPROLOL FUMARATE
  CARI SOPROLOL, CARI SOPROLOL
  CARVEDI LOL, CARVEDI LOL
  CEFADROXIL, CEFADROXIL/CEFADROXIL HEM HYDRATE
  CEFNI NI R, CEFNI NI R
  CEPFODOXI ME PROKETI L, CEPFODOXI ME PROKETI L
  CEPFROZI L, CEPFROZI L
  CHI LDREN S CETI RI ZI NE HYDROCHLOR DE ALLERGY, CETI RI ZI NE HYDROCHLOR DE (OTC)
  CHI LDREN S CETI RI ZI NE HYDROCHLOR DE HI VES RELI EF, CETI RI ZI NE HYDROCHLOR DE (OTC)
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  CLI NDAMYCI N HYDROCHLOR DE, CLI NDAMYCI N HYDROCHLOR DE
  CYCLOBENZAPRI NE HYDROCHLOR DE, CYCLOBENZAPRI NE HYDROCHLOR DE
  DI DANSI NE, DI DANSI NE
  FI NASTERI DE, FI NASTERI DE
  FLUCONAZOLE, FLUCONAZOLE
  FLUZOXIN, FLUZOXIN
  FOCSI NOPR L SODI UM AND HYDROCHLOR DE AZI DE, FOSI NOPR L SODI UM
  GLYBURI DE AND METFORM N HYDROCHLOR DE, GLYBURI DE
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  HYDROCHLOR DE AZI DE, HYDROCHLOR DE AZI DE
  LAMOTRI GI NE, LAMOTRI GI NE
  LEVETI RACETAM, LEVETI RACETAM
  LOSARTAN POTASSI UM AND HYDROCHLOR DE AZI DE, HYDROCHLOR DE AZI DE
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  PERI NOPR L EERUM NE
  SULFAMETHOXAZOLE AND TRI METHOPR M, SULFAMETHOXAZOLE
  SUMATRI PTAN SUCCI NATE, SUMATRI PTAN SUCCI NATE
  TERBI NAFI NE HYDROCHLOR DE, TERBI NAFI NE HYDROCHLOR DE
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## APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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<tr>
<td>CLOZAPI NE</td>
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** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **

* AUROBINDO PHARMA LTD
  REPAGLII NI DE, REPAGLII NI DE
  R I SEDRONATE SODIUM, R I SEDRONATE SODIUM
  R I SPERI DONE, R I SPERI DONE
  R I TONAVI R, R I TONAVI R
  R I VASTI GM NE TARTRATE, R I VASTI GM NE TARTRATE
  R I ZATRI PTAN BENZOATE, R I ZATRI PTAN BENZOATE
  ROCURONI UM BROM DE, ROCURONI UM BROM DE
  ROPI VACAI NE HYDROCHLORI DE, ROPI VACAI NE HYDROCHLORI DE
  ROSUVASTATI N CALCI UM, ROSUVASTATI N CALCI UM
  SEVELAMER CARBONATE, SEVELAMER CARBONATE
  SI LIDENAFI L CI TRATE, SI LIDENAFI L CI TRATE
  SI LODOSI N, SI LODOSI N
  SI MPESSE, ETHI NYL ESTRADIOL
  SUMATRTI PTAN AND NAPROXEN SODIUM UM NAPROXEN SODIUM UM
  SUMATRTI PTAN SUCCI NATE, SUMATRTI PTAN SUCCI NATE
  TAMUSULOSI N HYDROCHLORI DE, TAMUSULOSI N HYDROCHLORI DE
  TELM SARTAN AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  TELM SARTAN, TELM SARTAN
  TENOFOVI R DI SOPROXI L FUMARATE, TENOFOVI R DI SOPROXI L FUMARATE
  TERI FLUNOM DE, TERI FLUNOM DE
  TRAMADOL HYDROCHLORI DE AND ACETAM NOPHEN, ACETAM NOPHEN
  TRAMADOL HYDROCHLORI DE, TRAMADOL HYDROCHLORI DE
  TRANEXAM C ACI D, TRANEXAM C ACI D
  TRI - LO - M LI, ETHI NYL ESTRADIOL
  TRI - M LI, ETHI NYL ESTRADIOL
  VALGANCI CLOVI R HYDROCHLORI DE, VALGANCI CLOVI R HYDROCHLORI DE
  VALSARTAN AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  VALSARTAN, VALSARTAN
  VANCOMYCI N HYDROCHLORI DE, VANCOMYCI N HYDROCHLORI DE
  VECURONI UM BROM DE, VECURONI UM BROM DE
  VORI CONAZOLE, VORI CONAZOLE
  ZI PRASI DONE HYDROCHLORI DE, ZI PRASI DONE HYDROCHLORI DE
  ZOLEDRONI C ACI D, ZOLEDRONI C ACI D
  ZOM TRI PTAN, ZOM TRI PTAN
  ZUMANDIMI N NE, DROSI RENONE

* AUROBINDO NDO PHARMA LTD INC
  ZI DOUDI NE, ZI DOUDI NE

* AUROLI FE PHARMA LLC
  ACETAM NOPHEN AND CODEI NE PHOSPHATE, ACETAM NOPHEN
  BUTALBI TAL, ACETAM NOPHEN AND CAFFEI NE, ACETAM NOPHEN
  CH ILDREN S FEXOFENADI NE HYDROCHLORI DE ALLERGY, FEXOFENADI NE HYDROCHLORI DE (OTC)
  DEXTROAMP SACCHARATE, AMP ASPARATE, DEXTROAMP SULFATE AND AMP SULFATE, AMPHETAM NE
  DEXTROAMPETAM NE SULFATE, DEXTROAMPETAM NE SULFATE
  DUTASTERI DE, DUTASTERI DE
  FEXOFENADI NE HYDROCHLORI DE ALLERGY, FEXOFENADI NE HYDROCHLORI DE (OTC)
  GLYCOPYRRolate, GLYCOPYRRolate
  HYDROCODONE BI TARTRATE AND ACETAM NOPHEN, ACETAM NOPHEN
  HYDROCODONE BI TARTRATE AND I BUPROFEN, HYDROCODONE BI TARTRATE
  HYDROMORPHON HYDROCHLORI DE, HYDROMORPHON HYDROCHLORI DE
  LORAZEPAM, LORAZEPAM
  METHADONE HYDROCHLORI DE, METHADONE HYDROCHLORI DE
  METHYLPHENI DATE HYDROCHLORI DE, METHYLPHENI DATE HYDROCHLORI DE
  OMEPRAZOLE AND SODI UM BI CARBONATE, OMEPRAZOLE
  OMEPRAZOLE AND SODI UM BI CARBONATE, OMEPRAZOLE (OTC)
  OXYCODONE AND ACETAM NOPHEN, ACETAM NOPHEN
  OXYCODONE HYDROCHLORI DE, OXYCODONE HYDROCHLORI DE
  PHENTERM NE HYDROCHLORI DE, PHENTERM NE HYDROCHLORI DE

* AUSTARPHARMA LLC
  M ETHOCARBAMOL, M ETHOCARBAMOL
  SERTRALI NE HYDROCHLORI DE, SERTRALI NE HYDROCHLORI DE

AUX LI UM PHARMS INC
### Appendix B - Product Name Sorted by Applicant

**A**

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<thead>
<tr>
<th>Applicant</th>
<th>Products</th>
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<tr>
<td>AUXILIUM PHARMACEUTICS INC</td>
<td>TESTOPEL, TESTOSTERONE, THEO-24, THEOPHYLLINE NE</td>
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<td>DILATRATE-SR, ISOSORBIDE DI TRATE, EDEX, ALPROSTADI L, ROBAXI N, METHOCARBAMOL, ROBAXI N-750, METHOCARBAMOL, SEMPREX-D, ACRI VASTI NE, STRIANT, TESTOSTERONE, TESTIM, TESTOSTERONE, THEO-24, THEOPHYLLINE NE</td>
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<td>AVACOR PRODS</td>
<td>Minoxidil Extra Strength (For Men), Minoxidil (OTC)</td>
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<td>AVADEL LEGACY</td>
<td>BLOXIVERZ, NEOSTIGMINE METHYL SULFATE, VAZCULEP, PHENYLEPHRINE NE HYDROCHLORIDE DE</td>
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<td>AVADEL SPECIALT</td>
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<td>AVANI R PHARMS</td>
<td>ONZETRA XSAIL, SUMATRIPTAN SULFATE</td>
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<td>AVEMAX PHARMA</td>
<td>I BUPROPION, BUPROPION (OTC)</td>
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<td>AVENTI INC</td>
<td>PYTEST KIT, UREA, C-14</td>
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<td>AVERI TUS</td>
<td>QUTENZA, CAPSAICIN</td>
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<td>AVEVA DRUG DELIVERY SYSTEMS INC</td>
<td>CLONIDINE, CLONIDINE, FENTANYL-100, FENTANYL, FENTANYL-12, FENTANYL, FENTANYL-25, FENTANYL-37, FENTANYL-50, FENTANYL-62, FENTANYL-75, FENTANYL-87, FENTANYL, NI COTI NE, NI COTI NE (OTC)</td>
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</tbody>
</table>
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** A **

** B BRAUN **

ACETIC ACID 0.25% IN PLASTIC CONTAINER, ACETIC ACID, GLacial
AM NO ACI DS, AM NO ACI DS
BALANCED SALT, CALCIUM CHLORIDE
CEFAZOLIN AND DEXTROSE, CEFAZOLIN SODIUM
CEFEPI ME AND DEXTROSE IN DUPLEX CONTAINER, CEFEPI ME HYDROCHLORIDE
CEFOTETAN AND DEXTROSE IN DUPLEX CONTAINER, CEFOTETAN DISODIUM
CEFOXITIN AND DEXTROSE IN DUPLEX CONTAINER, CEFOTETAN DISODIUM
DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 70% IN PLASTIC CONTAINER, DEXTROSE
DOPAMINE HYDROCHLORIDE AND DEXTROSE 5% IN PLASTIC CONTAINER, DOPAMINE HYDROCHLORIDE
DOPAMINE HYDROCHLORIDE AND DEXTROSE 5% IN PLASTIC CONTAINER, DOPAMINE HYDROCHLORIDE
FREAMEX HBC 6.9% AM NO ACI DS
FREAMEX HBC 10% AM NO ACI DS
FREAMEX 3% W ELECTROLYTES, AM NO ACI DS
FREAMEX 8.5% W ELECTROLYTES, AM NO ACI DS
GLYCINE 1.5% IN PLASTIC CONTAINER, GLYCINE
HEPARI N SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, HEPARIN
HEPARI N SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER, HEPARIN
HEPARI N SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER, HEPARIN
HEPATAMINE 8% AM NO ACI DS
I SOLYTE P IN DEXTROSE 5% IN PLASTIC CONTAINER, DEXTROSE
I SOLYTE S IN PLASTIC CONTAINER, MAGNESIUM CHLORIDE
I SOLYTE S PH 7.4 IN PLASTIC CONTAINER, MAGNESIUM CHLORIDE
LACTATED Ringer SOLUTION IN PLASTIC CONTAINER, CALCIUM CHLORIDE
LI DOCA 1 IN DEXTROSE 5% IN PLASTIC CONTAINER, DEXTROSE
LI DOCA 5 IN DEXTROSE 5% IN PLASTIC CONTAINER, DEXTROSE
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**B**

- **B BRAUN MEDICAL INC**
  - Lidocaine Hydrochloride 0.4% and Dextrose 5% in Plastic Container, Lidocaine
  - Lidocaine Hydrochloride 0.8% and Dextrose 5% in Plastic Container, Lidocaine
  - Mannitol 10% in Plastic Container, Mannitol
  - Mannitol 15% in Plastic Container, Mannitol
  - Mannitol 20% in Plastic Container, Mannitol
  - Mannitol 5% in Plastic Container, Mannitol
  - Metro I.V. in Plastic Container, Metro I.V.
  - Nephramine 5.4%, Amino Acids
  - Nutrilipid 10%, Soybean Oil
  - Nutrilipid 20%, Soybean Oil
  - Physiolyte in Plastic Container, Magnesi um Chloride
  - Potassium Chloride 0.037% in Dextrose 10% and Sodium Chloride 0.2% in Plastic Container
  - Potassium Chloride 0.037% in Dextrose 10% and Sodium Chloride 0.45% in Plastic Container
  - Potassium Chloride 0.037% in Dextrose 10% and Sodium Chloride 0.9% in Plastic Container
  - Potassium Chloride 0.037% in Dextrose 5% and Sodium Chloride 0.11% in Plastic Container
  - Potassium Chloride 0.037% in Dextrose 5% and Sodium Chloride 0.2% in Plastic Container
  - Potassium Chloride 0.037% in Dextrose 5% and Sodium Chloride 0.33% in Plastic Container
  - Potassium Chloride 0.037% in Dextrose 5% and Sodium Chloride 0.45% in Plastic Container
  - Potassium Chloride 0.037% in Dextrose 5% and Sodium Chloride 0.9% in Plastic Container
  - Potassium Chloride 0.075% in Dextrose 10% and Sodium Chloride 0.2% in Plastic Container
  - Potassium Chloride 0.075% in Dextrose 10% and Sodium Chloride 0.45% in Plastic Container
  - Potassium Chloride 0.075% in Dextrose 10% and Sodium Chloride 0.9% in Plastic Container
  - Potassium Chloride 0.075% in Dextrose 3.3% and Sodium Chloride 0.3% in Plastic Container
  - Potassium Chloride 0.075% in Dextrose 5% and Sodium Chloride 0.11% in Plastic Container
  - Potassium Chloride 0.075% in Dextrose 5% and Sodium Chloride 0.2% in Plastic Container
  - Potassium Chloride 0.075% in Dextrose 5% and Sodium Chloride 0.33% in Plastic Container
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  - Potassium Chloride 0.075% in Dextrose 5% and Sodium Chloride 0.9% in Plastic Container
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  - Potassium Chloride 0.11% in Dextrose 10% and Sodium Chloride 0.9% in Plastic Container
  - Potassium Chloride 0.11% in Dextrose 3.3% and Sodium Chloride 0.3% in Plastic Container
  - Potassium Chloride 0.11% in Dextrose 5% and Sodium Chloride 0.11% in Plastic Container
  - Potassium Chloride 0.11% in Dextrose 5% and Sodium Chloride 0.2% in Plastic Container
  - Potassium Chloride 0.11% in Dextrose 5% and Sodium Chloride 0.33% in Plastic Container
  - Potassium Chloride 0.11% in Dextrose 5% and Sodium Chloride 0.45% in Plastic Container
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  - Potassium Chloride 0.15% in Dextrose 3.3% and Sodium Chloride 0.3% in Plastic Container
  - Potassium Chloride 0.15% in Dextrose 5% and Sodium Chloride 0.11% in Plastic Container
  - Potassium Chloride 0.15% in Dextrose 5% and Sodium Chloride 0.2% in Plastic Container
  - Potassium Chloride 0.15% in Dextrose 5% and Sodium Chloride 0.33% in Plastic Container
  - Potassium Chloride 0.15% in Dextrose 5% and Sodium Chloride 0.45% in Plastic Container
  - Potassium Chloride 0.15% in Dextrose 5% and Sodium Chloride 0.9% in Plastic Container
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  - Potassium Chloride 0.3% in Dextrose 10% and Sodium Chloride 0.9% in Plastic Container
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  - Potassium Chloride 0.3% in Dextrose 5% and Sodium Chloride 0.11% in Plastic Container
  - Potassium Chloride 0.3% in Dextrose 5% and Sodium Chloride 0.2% in Plastic Container
  - Potassium Chloride 0.3% in Dextrose 5% and Sodium Chloride 0.33% in Plastic Container
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**B BRAUN MEDICAL INC**

- POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER,
- POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER,
- POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% IN PLASTIC CONTAINER,
- DEXTROSE POTASSIUM CHLORIDE, POTASSIUM CHLORIDE
- PROCALAM NE, AM NO ACI DS
- RESECTI SOL IN PLASTIC CONTAINER, MANNITOL
- SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, SODIUM CHLORIDE
- SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, SODIUM CHLORIDE
- SODIUM CHLORIDE 3% IN PLASTIC CONTAINER, SODIUM CHLORIDE
- SODIUM CHLORIDE 5% IN PLASTIC CONTAINER, SODIUM CHLORIDE
- SORBITOL 3.3% IN PLASTIC CONTAINER, SORBITOL
- STERILE WATER FOR INJECTION IN PLASTIC CONTAINER, STERILE WATER FOR INJECTION
- STERILE WATER IN PLASTIC CONTAINER, STERILE WATER FOR IRRIGATION
- THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER, THEOPHYLLINE
- THEOPHYLLINE NE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER, THEOPHYLLINE NE
- THEOPHYLLINE NE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER, THEOPHYLLINE NE
- THEOPHYLLINE NE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER, THEOPHYLLINE NE
- THEOPHYLLINE NE 0.32% AND DEXTROSE 5% IN PLASTIC CONTAINER, THEOPHYLLINE NE
- TROPHAMINE NE 10% AM NO ACI DS
- TROPHAMINE NE, AM NO ACI DS

**B BRAUN MEDICAL INC**

- CLOROTEKAL, CHLOROPROCAINE HYDROCHLORIDE
- LIDOCAINE HYDROCHLORIDE, LIDOCAINE HYDROCHLORIDE
- MEROPENEM AND SODIUM CHLORIDE IN DUPLEX CONTAINER, MEROPENEM

**BARR**

- AMLODI NE HYDROCHLORIDE DE, AMLODI NE HYDROCHLORIDE DE
- ANAGRELIDE DE HYDROCHLORIDE DE, ANAGRELIDE DE HYDROCHLORIDE DE
- ARANELLE, ETHYL NYL ESTRADIOL
- ASPIRIN AND DI PYRI DAMOLE, ASPIRIN AND DI PYRI DAMOLE
- BALZI VA-28, ETHYL NYL ESTRADIOL
- BUPRENORPHINE NE HYDROCHLORIDE DE, BUPRENORPHINE NE HYDROCHLORIDE DE
- CHLORDIAZEPOXIDE HYDROCHLORIDE, CHLORDIAZEPOXIDE HYDROCHLORIDE DE
- CLONAZEPAM, CLONAZEPAM
- DANOZAL, DANOZAL
- DEMECLOCYCLINE NE HYDROCHLORIDE DE, DEMECLOCYCLINE NE HYDROCHLORIDE DE
- DEXTROAMPHETAMINE NE SULFATE AND AMP SULFATE, AMP SULFATE NE DEXTROAMPHETAMINE NE SULFATE
- DI AZEPAM, DI AZEPAM
- DI PHENHYDRAMINE NE HYDROCHLORIDE DE, DI PHENHYDRAMINE NE HYDROCHLORIDE DE
- DI PYRI DAMOLE, DI PYRI DAMOLE
- DROPSI RENONE AND ETHYL NYL ESTRADIOL, DROPSI RENONE
- DUTASTERIDE, DUTASTERIDE
- ESTRADIOL AND NORETHINDRONE ACETATE, ESTRADIOL
- ESTRADIOL AND NORGESTREL, ESTRADIOL
- ETHAMBUTOL HYDROCHLORIDE DE, ETHAMBUTOL HYDROCHLORIDE DE
- FEXOFENADINE NE HYDROCHLORIDE DE, FEXOFENADINE NE HYDROCHLORIDE DE
- FLUDEOXYPHYLLENE ACETATE, FLUDEOXYPHYLLENE ACETATE
- FLUCETTE NE HYDROCHLORIDE DE, FLUCETTE NE HYDROCHLORIDE DE
- GALANTAM NE HYDROBROMIDE, GALANTAM NE HYDROBROMIDE
- HYDROMORPHONE HYDROCHLORIDE DE, HYDROMORPHONE HYDROCHLORIDE DE
- HYDROXYUREA, HYDROXYUREA
- HYDROXYZINE NE PAMATE, HYDROXYZINE NE PAMATE
- ISONI AZI D, ISONI AZI D
- JUNEL 1.5/30, ETHYL NYL ESTRADIOL
- JUNEL 1/20, ETHYL NYL ESTRADIOL
- JUNEL FE 1.5/30, ETHYL NYL ESTRADIOL
- JUNEL FE 1/20, ETHYL NYL ESTRADIOL
- KARI VA, DESOGESTREL
- KELNOR, ETHYL NYL ESTRADIOL
- LEFLUNOMIDE, LEFLUNOMIDE
- LESSI NA-28, ETHYL NYL ESTRADIOL
**APPENDIX B** - PRODUCT NAME SORTED BY APPLICANT

**B**

* BARR LABORATORIES INC
  MEDROXYPROGESTERONE ACETATE, MEDROXYPROGESTERONE ACETATE
  MEFLOQUINE HYDROCHLORIDE, MEFLOQUINE HYDROCHLORIDE
  MEGESTROL ACETATE, MEGESTROL ACETATE
  METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE
  METHOTREXATE SODIUM, METHOTREXATE SODIUM
  MEGESTROL ACETATE, MEGESTROL ACETATE
  NALTREXONE HYDROCHLORIDE, NALTREXONE HYDROCHLORIDE
  NACI N, NACI N
  NORETHINDRONE ACETATE, NORETHINDRONE ACETATE
  NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE, ETHINYL ESTRADIOL
  NORTREL 0.5/35-28, ETHINYL ESTRADIOL
  NORTREL 1/35-21, ETHINYL ESTRADIOL
  NORTREL 1/35-28, ETHINYL ESTRADIOL
  NORTREL 7/7/7, ETHINYL ESTRADIOL
  ONDANSETRON, ONDANSETRON
  PHENTERMINE HYDROCHLORIDE, PHENTERMINE HYDROCHLORIDE
  PORTIA-28, ETHINYL ESTRADIOL
  PRAMIPEXOLE DIHYDROCHLORIDE, PRAMIPEXOLE DIHYDROCHLORIDE
  SPRINTEC, ETHINYL ESTRADIOL
  TEMOZOLOMIDE, TEMOZOLOMIDE
  TREVALL, METHOTREXATE SODIUM
  TRI-LEGEST 21, ETHINYL ESTRADIOL
  TRI-LEGEST FE, ETHINYL ESTRADIOL
  TRI-SPRINTEC, ETHINYL ESTRADIOL
  WARFARIN SODIUM, WARFARIN SODIUM
  BARR PHARMACEUTICALS
  LEUCOVORIN CALCIUM, LEUCOVORIN CALCIUM

*BARR LABS DI V TEVA*

* BARR LABORATORIES INC SUB TEVA PHARMACEUTICALS USA
  ACAMPROSATE CALCIUM, ACAMPROSATE CALCIUM
  BUDESONIDE, BUDESONIDE

*BARR LABS I NC*

* BARR LABORATORIES ES I NC
  ACI TRET N, ACI TRET N
  CLOZAPINE, CLOZAPINE
  DEXTROAMINO SUGAR, DEXTROAMINO SACCHARATE, AMP ASPARTATE, DEXTROAMINO SULFATE AND AMP SULFATE, AMPHETAMINE
  ETHINYL ESTRADIOL
  METHYLPHENIDATE HYDROCHLORIDE, METHYLPHENIDATE HYDROCHLORIDE
  M NOCYCLIC ACID HYDROCHLORIDE, M NOCYCLIC ACID HYDROCHLORIDE
  NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE, ETHINYL ESTRADIOL
  NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL, ETHINYL ESTRADIOL
  OLANZAPINE, OLANZAPINE
  OLOPATADINE HYDROCHLORIDE, OLOPATADINE HYDROCHLORIDE
  OXYCODONE HYDROCHLORIDE AND IBUPROFEN, IBUPROFEN
  TRETINOIN, TRETINOIN
  TRI LO SPRI NTEC, ETHINYL ESTRADIOL

*BAUSCH AND LOMB*

* BAUSCH AND LOMB I NC
  ALAWAY, KETOTIFEN FUMARATE (OTC)
  ALBUTEROL SULFATE, ALBUTEROL SULFATE
  ALEX, LОТЕПРЕДНОЛ ЕТАБОНАТ
  BESI VANCE, BESI FLOKACI N HYDROCHLORIDE
  CARTIOL, CARTIOL HYDROCHLORIDE
  DI CLOFENAC SODIUM, DI CLOFENAC SODIUM
  DORZOLAMIDE HYDROCHLORIDE, DORZOLAMIDE HYDROCHLORIDE
  DORZOLAMIDE HYDROCHLORIDE AND TI MOLOL MALEATE, DORZOLAMIDE HYDROCHLORIDE
  DORZOLAMIDE HYDROCHLORIDE AND DI CLOFENAC SODIUM
  FLURIBI PROFEN SODIUM, FLURIBI PROFEN SODIUM
  I PRATROPIUM BROMIDE, I PRATROPIUM BROMIDE
  I STALOLO, INI MOLOL MALEATE
  LATANOPROST, LATANOPROST
  LОТЕПРЕДНОЛ ЕТАБОНАТ
  M OCHOL-E, ACETYLCOLL ACID CHLORIDE
  OFLAKOL N, OFLOKACI N
  OPCON-A, NAPHAZOLINE HYDROCHLORIDE (OTC)
  PROLENSA, BROMFENAC SODIUM
** B **

* BAUSCH AND LOMB INC

** RETISERT, FLUOCINOLONE ACETONIDE DE **

** TROPI CAM DE, TROPI CAM DE **

** VI TRASE, HYALURONIC DASE **

** VYZULTA, LATANOPROSTENE BUNOC **

** ZI RAN, GANCI CLOVI R **

** ZYLET, LOTEPRERGON EL ETABONATE **

* BAUSCH AND LOMB PHARMACEUTICALS INC

** BACITRACIN ZINC AND POLYMYXIN B SULFATE, BACITRACIN ZINC **

** BRIMONIDINE TARTRATE, BRIMONIDINE TARTRATE **

** CROMOLYN SODIUM, CROMOLYN SODIUM (OTC) **

** DESMOPRESSIN ACETATE, DESMOPRESSIN ACETATE **

** DEXAMETHASONE SODIUM PHOSPHATE, DEXAMETHASONE SODIUM PHOSPHATE **

** DEXASPORIN, DEXAMETHASONE **

** ERYTHROMICYCI N, ERYTHROMICYCI N **

** FLUNI SOLI DE, FLUNI SOLI DE **

** GENTAM CI N SULFATE, GENTAM CI N SULFATE **

** I PRATROPI UM BROM DE, I PRATROPI UM BROM DE **

** LEVOBUNOLOL HYDROCHLORIDE DE, LEVOBUNOLOL HYDROCHLORIDE DE **

** NEOMCIYCI N AND POLYMCIYCI N B SULFATES AND BACI TRACI N ZI NC, BACI TRACI N ZI NC **

** NEOMCYCI N AND POLYMCIYCI N B SULFATES AND DEXAMETHASONE, DEXAMETHASONE **

** NEOMCIYCI N AND POLYMCIYCI N B SULFATES AND GRAM CI DI N, GRAM CI DI N **

** NEOMCIYCI N AND POLYMCIYCI N B SULFATES AND HYDROCORTI SONE, HYDROCORTI SONE **

** NEOMCIYCI N AND POLYMCIYCI N B SULFATES, BACI TRACI N ZI NC AND HYDROCORTI SONE, BACI TRACI N ZI NC **

** OFLOKACI N, OFLOKACI N **

** OPTI PRANOLOL, METI PRANOLOL HYDROCHLORIDE DE **

** OTI C AI R, HYDROCORTI SONE **

** PENTOLAI R, CYCLOPENTolate HYDROCHLORIDE DE **

** PREDNI SOLONE SODIUM PHOSPHATE, PREDNI SOLONE SODIUM PHOSPHATE **

** PROPARACAI NE HYDROCORTI DE, PROPARACAI NE HYDROCORTI DE **

** SULFACETAM DE SODI UM, SULFACETAM DE SODI UM **

** TI MOLOL MALEATE, TI MOLOL MALEATE **

** TOBRAMCYCI N AND DEXAMETHASONE, DEXAMETHASONE **

** TOBRAMYCI N, TOBRAMYCI N **

** TRI METHOPRI M SULFATE AND POLYMCIYCI N B SULFATE, POLYMCIYCI N B SULFATE **

** TROPI CAM DE, TROPI CAM DE **

* BAUSCH AND LOMB INC

* BAXTER HEALTHCARE CORP

** ACETI C ACI D 0.25% I N PLASTI C CONTAI NER, ACETI C ACI D, ACI D AL **

** AM NOACETI C ACI D 1.5% I N PLASTI C CONTAI NER, GLUCI NRE **

** ANCEF I N PLASTI C CONTAI NER, CEFAZOLI N SODI UM **

** BACTOCI LL I N PLASTI C CONTAI NER, OKACI LLI N SODI UM **

** BREVI BLOC DOUBLE STRENGTH I N PLASTI C CONTAI NER, ESMOLOL HYDROCHLORIDE DE **

** BREVI BLOC I N PLASTI C CONTAI NER, ESMOLOL HYDROCHLORIDE DE **

** BREVI BLOC, ESMOLOL HYDROCHLORIDE DE **

** CARDI OPLACI C I N PLASTI C CONTAI NER, CALCI UM CHLORI DE **

** CEFEPI ME I N PLASTI C CONTAI NER, CEFETRAI ME HYDROCHLORIDE DE **

** CEFTRI AXONE I N PLASTI C CONTAI NER, CEFTRI AXONE SODI UM **

** CLIN I N M X 2.75/10 SULFI TE FREE I N DEXTROSE 10% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 2.75/10 SULFI TE FREE I N DEXTROSE 25% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 2.75/5 SULFI TE FREE I N DEXTROSE 5% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 4.25/10 SULFI TE FREE I N DEXTROSE 10% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 4.25/20 SULFI TE FREE I N DEXTROSE 20% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 4.25/25 SULFI TE FREE I N DEXTROSE 25% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 5/10 SULFI TE FREE I N DEXTROSE 10% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 5/15 SULFI TE FREE I N DEXTROSE 15% I N PLASTI C CONTAI NER, AM NO ACI D5 **

** CLIN I N M X 5/20 SULFI TE FREE I N DEXTROSE 20% I N PLASTI C CONTAI NER, AM NO ACI D5 **
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** B **

* BAXTER HEALTHCARE CORP *

CLINIMIX 5/25 SULFITE FREE IN DEXTROSE 25% IN PLASTIC CONTAINER, AMINO ACIDS
CLINIMIX 5/35 SULFITE FREE IN DEXTROSE 35% IN PLASTIC CONTAINER, AMINO ACIDS
CLINIMIX E 2.75/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC C
CLINIMIX E 2.75/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC C
CLINIMIX E 2.75/5 SULFITE FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC C
CLINIMIX E 4.25/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC C
CLINIMIX E 4.25/20 SULFITE FREE W/ ELECT IN DEXTROSE 20% W/ CALCIUM IN PLASTIC C
CLINIMIX E 4.25/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC C
CLINIMIX E 4.25/5 SULFITE FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC CONTAINER,
CLINIMIX E 5/10 SULFITE FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER,
CLINIMIX E 5/15 SULFITE FREE W/ ELECT IN DEXTROSE 15% W/ CALCIUM IN PLASTIC CONTAINER,
CLINIMIX E 5/20 SULFITE FREE W/ ELECT IN DEXTROSE 20% W/ CALCIUM IN PLASTIC CONTAINER,
CLINIMIX E 5/25 SULFITE FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER,
CLINIMIX E 5/35 SULFITE FREE W/ ELECT IN DEXTROSE 35% W/ CALCIUM IN PLASTIC CONTAINER,
CLINISOL 15% SULFITE FREE IN PLASTIC CONTAINER, AMINO ACIDS
CYCLOPHOSPHAMIDE, CYCLOPHOSPHAMIDE
DEXTROSE 10% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND ELECTROLYTE NO. 48 IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.224% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.15MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.2MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.3MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.4MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.5MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.6MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.7MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.8MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.9MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.1MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.15MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.2MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.3MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.4MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.5MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.6MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.7MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.8MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.9MEQ IN PLASTIC CONTAINER,
DEXTROSE 5% SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 1MEQ IN PLASTIC CONTAINER,
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

* BAXTER HEALTHCARE CORP *

BAXTER HEALTHCARE CORP

LACTATED RINGER'S IN PLASTIC CONTAINER, CALCUIUM CHLORIDE

LI DOCAI NE HYDROCHLORIDE DE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER, LI DOCAI NE

LI DOCAI NE HYDROCHLORIDE DE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER, LI DOCAI NE

LI DOCAI NE HYDROCHLORIDE DE 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER, LI DOCAI NE

MESNEX, MESNA

M LRI NONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER, NALUPEX IN PLASTIC CONTAINER, NAFCILLIN SODIUM

NEXTERONE, AM CADORENE HYDROCHLORIDE DE

NI TROGLYCERI IN DEXTROSE 5% IN PLASTIC CONTAINER, NISOL TROL 10% IN WATER IN PLASTIC CONTAINER, NISOL TROL 20% IN WATER IN PLASTIC CONTAINER

NISOL TROL 5% IN WATER IN PLASTIC CONTAINER, PENCI LI LI N G POTASSIUM CHLORIDE

PITASSTE IN WATER IN PLASTIC CONTAINER, PENICILLIN G POTASSIUM CHLORIDE

PITASSTE IN WATER IN PLASTIC CONTAINER, PENICILLIN G SODIUM CHLORIDE 0.9%

POTASSIUM CHLORIDE 0.15% IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER, POTASSIUM CHLORIDE 10 MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

PREMASOL 10% IN PLASTIC CONTAINER, AM NO ACI DS

PREMASOL 6% IN PLASTIC CONTAINER, AM NO ACI DS

RI GAII S IN PLASTIC CONTAINER, CALCIUM CHLORIDE

SEVOFLURANE, SEVOFLURANE

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER, SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

SODIUM CHLORIDE 3% IN PLASTIC CONTAINER, SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER, SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

SORBITOL 3% IN PLASTIC CONTAINER, SORBITOL 3% IN PLASTIC CONTAINER

STERI LE WATER FOR IRRIGATION IN PLASTIC CONTAINER, STERI LE WATER FOR IRRIGATION IN PLASTIC CONTAINER

STERI LE WATER FOR IRRIGATION IN PLASTIC CONTAINER, STERI LE WATER FOR IRRIGATION IN PLASTIC CONTAINER

SUPRANE, SEVOFLURANE

TI SU SOL IN PLASTIC CONTAINER, MAGNESIUM SULFATE

TI SU SOL IN PLASTIC CONTAINER, MAGNESIUM SULFATE

TRAVASOL 10% IN PLASTIC CONTAINER, AM NO ACI DS

TRAVASOL 5.5% IN PLASTIC CONTAINER, AM NO ACI DS

TRAVASOL 8.5% IN PLASTIC CONTAINER, AM NO ACI DS

VANCOCIN HYDROCHLORIDE DE IN PLASTIC CONTAINER, VANCOMYCIN HYDROCHLORIDE DE

* BAXTER HEALTHCARE INTERNATIONAL SPECIALTIES DIV *
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

* BAXTER HEALTHCARE INTERNATIONAL
  ** BAXTER HEALTHCARE INTERNATIONAL SPECIALTY THERAPIES DIV **
  
  BAXTER HEALTHCARE CORP
  *
  BI VALI RUDI N I N 0.9% SODIUM CHLORIDE, BI VALI RUDI N
  BUPI VACAE NE HYDROCHLORIDE DE, BUPI VACAE NE HYDROCHLORIDE DE
  CEFAZOLI N I N PLASTI C CONTAINER, CEFAZOLI N SODIUM UM
  CI PROFLOKACI N I N DEXTROSE 5% I N PLASTI C CONTAINER, CI PROFLOKACI N
  CI PROFLOKACI N, CI PROFLOKACI N
  CI NA MCI N PHOSPHATE I N 0.9% SODIUM CHLORIDE, CI NA MCI N PHOSPHATE
  CI NA MCI N PHOSPHATE I N 5% DEXTROSE I N PLASTIC CONTAINER, CI NA MCI N PHOSPHATE
  DEXMEDETOMIDINE DI NE HYDROCHLORIDE DE, DEXMEDETOMIDINE DI NE HYDROCHLORIDE DE
  FLUCONAZOLE I N SODIUM CHLORIDE DE 0.9% FLUCONAZOLE
  FUROSEM DE, FUROSEM DE
  KETOROLAC TROMETHAMINE, KETOROLAC TROMETHAMINE
  LEVOFLOKACI N I N DEXTROSE 5% I N PLASTIC CONTAINER, LEVOFLOKACI N
  LEVOFLOKACI N, LEVOFLOKACI N
  METOPROLOL TARTRATE, METOPROLOL TARTRATE
  METRONIDAZOLE I N PLASTIC CONTAINER, METRONIDAZOLE
  NOREPIPHRINE BITARTRATE, NOREPINEPHRINE BITARTRATE
  ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE, ONDANSETRON HYDROCHLORIDE DE
  ONDANSETRON HYDROCHLORIDE DE, ONDANSETRON HYDROCHLORIDE DE
  PHOCI LLUM B22K 4/0 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PHOCI LLUM BK 4/2.5 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PRI SMASOL B22K 4/0 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PRI SMASOL BKG 0/2.5 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PRI SMASOL BKG 2/0 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PRI SMASOL BKG 2/3.5 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PRI SMASOL BKG 4/0 1.2 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PRI SMASOL BKG 4/2.5 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  PRI SMASOL BK 0/0 1.2 I N PLASTIC CONTAINER, CALCIUM CHLORIDE DE
  TOBRAMYCIN SULFATE, TOBRAMYCIN SULFATE

* BAXTER HEALTHCARE CORP
  *
  BAXTER HEALTHCARE CORP ANESTHESIA AND CRITICAL CARE
  *
  PROTOPAM CLORIDE, PRALIDOXIME CHLORIDE

* BAYER
  *
  BAYER HEALTHCARE LLC
  *
  ALEVE, NAPROXEN SODIUM (OTC)
  ALEVE D S I NUS & COLD, NAPROXEN SODIUM (OTC)

* BAYER HEALTHCARE PHARMACEUTICALS INC
  *
  BAYER HEALTHCARE PHARMACEUTICALS INC
  *
  ADEMPAS, RICI QUAT
  ANELI Q, DROPSI RENONE
  AVELOX, MOXIFLOXACIN HYDROCHLORIDE
  BEYAZ, DROPSI RENONE
  BI LTRI CI DE, PRAZI QUANTEL
  CI PRO, CI PROFLOKACI N
  CI PRO, CI PROFLOKACI N HYDROCHLORIDE
### Appendix B - Product Name Sorted by Applicant

** B **

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Product Name</th>
<th>Type</th>
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<td>CLIMARA, ESTRADIOL</td>
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<td></td>
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<td>GADAVI ST, GADOBUTROL</td>
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<td></td>
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<td>Hydrochloride</td>
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<td>STI VARGA, REGORAFENI B</td>
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<td>YASMIN N, DROSPI RENONE</td>
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<td>** BAYSHORE PHARMS LLC**</td>
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<td>DI PHENOXYLATE HYDROCHLORIDE DE AND ATROPI NE SULFATE</td>
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<td>METHSCOPOLAM NE BRM DE, METHSCOPOLAM NE BRM DE</td>
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<td>SODI UM POLYSTYRENE SULFONATE, SODI UM POLYSTYRENE SULFONATE</td>
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<td>TACROLI MUS, TACROLI MUS</td>
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<td>** BELOTENA I NC**</td>
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<td>I SOSULFAN BLUE, I SOSULFAN BLUE</td>
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** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

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<tr>
<th>Applicant</th>
<th>Products</th>
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<tr>
<td>BEXIMCO PHARMS USA</td>
<td>Metformin Hydrochloride, Metformin Hydrochloride, Methocarbamol, Nadolol, Sotalol Hydrochloride, Sotalol Hydrochloride</td>
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<td>BEXIMCO USA</td>
<td>Carvedilol, Carvedilol</td>
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<td>BI - COASTAL PHARMA</td>
<td>Duvo C, Betanechol Hydrochloride</td>
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<td>BIO NUCLEONICS CS</td>
<td>Strontium Chloride Sr-89, Strontium Chloride Sr-89</td>
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<td>BIO PHARM INC</td>
<td>Carvedilol, Carvedilol, Cyproheptadine Hydrochloride, Lactulose, Memantine Hydrochloride</td>
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<td>BIOCODEX SA</td>
<td>Dioptin T, Steril Pentol</td>
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<td>BI OCON LTD</td>
<td>Rosuvastatin N, Calci um, Rosuvastatin N, Calci um</td>
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<td>BI OCRYST</td>
<td>Rapivar, Peramivir</td>
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<td>BI OFRONTERA</td>
<td>Ameluz, Amnolevulin N, Acid Hydrochloride</td>
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<td>BI OGEN I DEC</td>
<td>Spiropra, Nusinersen Sodium</td>
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<td>BI OGEN I DEC INC</td>
<td>Tefci Dera, Di Methyl Fumarate</td>
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<td>BI OMARI N PHARM</td>
<td>Kuvan, Sapropterin N, Acid Hydrochloride</td>
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<td>BI ONEDCAL RES FDN</td>
<td>Ammonia A N 13, Ammonia A N-13, Fluodeoxyglucose F18, Fluodeoxyglucose F-18, Sodium Fluoride F-18</td>
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<tr>
<td>BI ONPHARMA INC</td>
<td>Amantadine, Amantadine, Azithromycin, Azithromycin, Azithromycin N, Benzonatate, Benzonatate, Bexarotene, Bexarotene, Calci Triol, Calci Triol,</td>
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</tbody>
</table>
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**B**

| BIONPHARMA INC | Cetirizine Hydrochloride (Hives Relief), Cetirizine Hydrochloride (OTC) |
| CLOBAZAM | Clonazepam |
| DI CLOFENAC POTASSIUM UM | Di Clofenac Potassium Um |
| DOFETILI DE | Dofetilide |
| ETHOSUXIUM DE | Ethosuximide |
| I BUROFEN AND I PHENYDRAM NE HYDROCHLORI DE | Ibuprofen and Phenylhydramine Hydrochloride (OTC) |
| LOPERAM DE HYDROCHLORI DE | Loperamide Hydrochloride |
| M DOL LI QUI D GELS | Midol Liquid Gels, Ibuprofen (OTC) |
| NAPROXEN SODIUM | Naproxen Sodium (OTC) |
| NIMODIPINE | Nimodipine |
| PARICALCITOL | Paricalcitol |
| PROGESTERONE | Progesterone |
| TETRABENAZINE | Tetrabenazine |
| VALPROIC ACID | Valproic Acid |
| VITAMIN D | Ergocalciferol |

| BLAIREX LABORATORIES INC | Broncho Saline, Sodium Chloride (OTC) |
| BLUE EARTH DIAGNOSTICS LTD | Axumin, Fluciclovine F-18 |
| BLUEPHARMA US INC | Granisetron Hydrochloride Preservative Free, Granisetron Hydrochloride |
| BOEHRINGER INGELHEIM PHARMACEUTICALS INC | Aggrenox, Aspirin |
| BOEHRINGER INGELHEIM M | Catapres, Clonidine Hydrochloride |
| BOEHRINGER INGELHEIM M | Catapres-Tts-1, Clonidine |
| BOEHRINGER INGELHEIM M | Catapres-Tts-2, Clonidine |
| BOEHRINGER INGELHEIM M | Catapres-Tts-3, Clonidine |
| BOEHRINGER INGELHEIM M | Glotri, Empagliflozin |
| BOEHRINGER INGELHEIM M | Mobic, Meloxicam |
| BOEHRINGER INGELHEIM M | Ofev, Nintedanib Elylolate |
| BOEHRINGER INGELHEIM M | Persantin, Dipyridamole |
| BOEHRINGER INGELHEIM M | Pradaxa, Dabigatran Etxilate |
| BOEHRINGER INGELHEIM M | Spiriva, Tiotropium Bromide |
| BOEHRINGER INGELHEIM M | Striverdi, Olodaterol Hydrochloride |
| BOEHRINGER INGELHEIM M | Syjardy, Empagliflozin |
| BOEHRINGER INGELHEIM M | Trajenta, Linagliptin |
| BOEHRINGER INGELHEIM M | Viramune, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune XR, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune XR, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune, Nevirapine |

| BIONPHARMA | Clonazepam |
| CLOBAZAM | Clonazepam |
| DI CLOFENAC POTASSIUM UM | Di Clofenac Potassium Um |
| DOFETILI DE | Dofetilide |
| ETHOSUXIUM DE | Ethosuximide |
| I BUROFEN AND I PHENYDRAM NE HYDROCHLORI DE | Ibuprofen and Phenylhydramine Hydrochloride (OTC) |
| LOPERAM DE HYDROCHLORI DE | Loperamide Hydrochloride |
| M DOL LI QUI D GELS | Midol Liquid Gels, Ibuprofen (OTC) |
| NAPROXEN SODIUM | Naproxen Sodium (OTC) |
| NIMODIPINE | Nimodipine |
| PARICALCITOL | Paricalcitol |
| PROGESTERONE | Progesterone |
| TETRABENAZINE | Tetrabenazine |
| VALPROIC ACID | Valproic Acid |
| VITAMIN D | Ergocalciferol |

| BLAIREX LABORATORIES INC | Broncho Saline, Sodium Chloride (OTC) |
| BLUE EARTH DIAGNOSTICS LTD | Axumin, Fluciclovine F-18 |
| BLUEPHARMA US INC | Granisetron Hydrochloride Preservative Free, Granisetron Hydrochloride |
| BOEHRINGER INGELHEIM PHARMACEUTICALS INC | Aggrenox, Aspirin |
| BOEHRINGER INGELHEIM M | Catapres, Clonidine Hydrochloride |
| BOEHRINGER INGELHEIM M | Catapres-Tts-1, Clonidine |
| BOEHRINGER INGELHEIM M | Catapres-Tts-2, Clonidine |
| BOEHRINGER INGELHEIM M | Catapres-Tts-3, Clonidine |
| BOEHRINGER INGELHEIM M | Glotri, Empagliflozin |
| BOEHRINGER INGELHEIM M | Mobic, Meloxicam |
| BOEHRINGER INGELHEIM M | Ofev, Nintedanib Elylolate |
| BOEHRINGER INGELHEIM M | Persantin, Dipyridamole |
| BOEHRINGER INGELHEIM M | Pradaxa, Dabigatran Etxilate |
| BOEHRINGER INGELHEIM M | Spiriva, Tiotropium Bromide |
| BOEHRINGER INGELHEIM M | Striverdi, Olodaterol Hydrochloride |
| BOEHRINGER INGELHEIM M | Syjardy, Empagliflozin |
| BOEHRINGER INGELHEIM M | Trajenta, Linagliptin |
| BOEHRINGER INGELHEIM M | Viramune, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune XR, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune XR, Nevirapine |
| BOEHRINGER INGELHEIM M | Viramune, Nevirapine |

| BIONPHARMA | Clonazepam |
| CLOBAZAM | Clonazepam |
| DI CLOFENAC POTASSIUM UM | Di Clofenac Potassium Um |
| DOFETILI DE | Dofetilide |
| ETHOSUXIUM DE | Ethosuximide |
| I BUROFEN AND I PHENYDRAM NE HYDROCHLORI DE | Ibuprofen and Phenylhydramine Hydrochloride (OTC) |
| LOPERAM DE HYDROCHLORI DE | Loperamide Hydrochloride |
| M DOL LI QUI D GELS | Midol Liquid Gels, Ibuprofen (OTC) |
| NAPROXEN SODIUM | Naproxen Sodium (OTC) |
| NIMODIPINE | Nimodipine |
| PARICALCITOL | Paricalcitol |
| PROGESTERONE | Progesterone |
| TETRABENAZINE | Tetrabenazine |
| VALPROIC ACID | Valproic Acid |
| VITAMIN D | Ergocalciferol |
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

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<td>CYPROHEPTADINE HYDROCHLORIDE, CYPROHEPTADINE HYDROCHLORIDE DE</td>
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** B **

* BRECKENRIDGE PHARMACEUTICAL INC
  LEVETIRACETAM, LEVETIRACETAM
  MEFENAMIC ACID, MEFENAMIC ACID
  MEGESTROL ACETATE, MEGESTROL ACETATE
  MELOXICAM, MELOXICAM
  METHSCOPOLAMINE BROMIDE, METHSCOPOLAMINE BROMIDE
  METHYLERGONOVINE MALEATE, METHYLERGONOVINE MALEATE
  METHYLPHENIDATE HYDROCHLORIDE, METHYLPHENIDATE HYDROCHLORIDE
  NEOMYCIN SULFATE, NEOMYCIN SULFATE
  OMEPRAZOLE, OMEPRAZOLE
  OXCARBAZEPINE, OXCARBAZEPINE
  PEG-3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE, POLYETHYLENE GLYCOL
  PI OGLI TAZONE HYDROCHLORIDE, PI OGLI TAZONE HYDROCHLORIDE
  PI ROKI CAM, PI ROKI CAM
  PRAM PEXOLE, PRAM PEXOLE
  RABEPRAZOLE, RABEPRAZOLE
  RANITIDINE HYDROCHLORIDE, RANITIDINE HYDROCHLORIDE
  ROFLUMILAST, ROFLUMILAST
  TETRACYCLINE HYDROCHLORIDE, TETRACYCLINE HYDROCHLORIDE
  ZOLEDRONIC ACID, ZOLEDRONIC ACID

BRI GHAM WOMENS
* BRI GHAM AND WOMENS HOSP
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18

BRI GHAM WOMENS HOSP
* BRI GHAM AND WOMENS HOSP I NC
  AMMONIA N 13, AMMONIA A N-13

BRI STOL MYERS SQUI BB
* BRI STOL MYERS SQUI BB
  AZACTAM, AZTREONAM
  BARACLEUD, ENTECAVIR R
  PRAVACHOL, PRAVASTATIN N SODIUM
* BRI STOL MYERS SQUI BB CO
  AZACTAM I N PLASTIC CONTAINER, AZTREONAM
  DROXIA, HYDROXYUREA
  GLUCOPHAGE XR, METFORM IN HYDROCHLORIDE
  HYDREA, HYDROXYUREA
  REYATAZ, ATAZANAVIR SULFATE
  SPRYCEL, DASATI N B
  SUSTIVA, EFAVIRENZ
  VI DEX EC, DI DANOSI NE
* BRI STOL MYERS SQUI BB CO PHARMACEUTICAL CAL RESEARCH IN NSTI TUTE
  ELIQUI S, API XABAN
  ETOPOPHOS PRESERVATIVI VE FREE, ETOPOSI DE PHOSPHATE
  GLUCOPHAGE, METFORM IN HYDROCHLORIDE
  ZERIT T, STAVUDINE NE
* BRI STOL MYERS SQUI BB PHARMA CO
  COUMADIN, WARFARIN SODIUM

BRI STOL- MYERS SQUI BB
* BRI STOL- MYERS SQUI BB CO
  DAKIL NZA, DACLATASVIR R DI HYDROCHLORIDE
  EVOTAZ, ATAZANAVIR SULFATE
  VI DEX, DI DANOSI NE
  ZERIT T, STAVUDINE NE

** C **

CADILA PHARMACEUTICALS LTD
* CADILA PHARMACEUTICALS LTD
  ACYCLOVIR, ACYCLOVIR
  DONEPEZI L HYDROCHLORIDE, DONEPEZI L HYDROCHLORIDE
  FOLIC ACID, FOLIC ACID
  GEMFI BROZIL, GEMFI BROZIL
  GLYBURIDE, GLYBURIDE
  HYDRAZAZI LE HYDROCHLORIDE, HYDRAZAZI LE HYDROCHLORIDE
  METRONIDAZOLE, METRONIDAZOLE
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<td>CADILA PHARMACEUTICS LTD</td>
<td>OFLOXACIN, OFLOXACIN</td>
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<td>RIVASTIGMINE TARTRATE, RIVASTIGMINE TARTRATE</td>
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<td>ROSUVASTATIN CALCI UM, ROSUVASTATI N CALCI UM</td>
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<td>TELM SARTAN, TELM SARTAN</td>
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<td>VENLAFAXI NE HYDROCHLORI DE, VENLAFAXI NE HYDROCHLORI DE</td>
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<td>VERAPAM L HYDROCHLORI DE, VERAPAM L HYDROCHLORI DE</td>
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<td>CADISTA PHARMACEUTICALS INC</td>
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<td>CALL INC</td>
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<td>CAPELLON PHARMACEUTICALS LLC</td>
<td>POLMON, DEXCHLORPHENI RAM NE MALEATE</td>
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<td>CARDINAL HEALTH 414</td>
<td>AMMONI A N 13, AMMONI A N-13</td>
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<td>FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18</td>
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<td>LYMPHOSEEK KI T, TECHNETI UM TC-99M TI LMANOCEPT</td>
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<td>SODI UM FLUORIDE DE F-18, SODI UM FLUORIDE DE F-18</td>
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** C **

* CASI PHARMACEUTICALS INC
  TENOFOVIR DISOPROXIL FUMARATE, TENOFOVIR DISOPROXIL FUMARATE
  TIZANIDINE HYDROCHLORIDE, TIZANIDINE HYDROCHLORIDE
  TRIAMTERENE AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE

* CASPER PHARMA LLC
  CASPER PHARMA LLC
  AQUASOL A, VITAMIN A PALMITATE
  C M P, VITAMIN A PALMITATE
  CASPOLYN HC, HYDROCORTISONE
  FURADANTIN, NITROFURANTOIN
  NEOSPORIN, BACITRACIN ZINC
  ZYLOPRIM, ALLOPURINOL

* CATALENT
  CATALENT PHARMA SOLUTIONS LLC
  AQUASOL A, VITAMIN A PALMITATE
  FURADANTIN, NITROFURANTOIN
  NEOSPORIN, BACITRACIN ZINC
  ZYLOPRIM, ALLOPURINOL

* CATALYST PHARMS
  CATALYST PHARMACEUTICALS INC
  FIRDAPSE, AMIFAMPRIDINE PHOSPHATE

* CEDIA PHARMA LLC
  DEXMETHYLPHENIDATE HYDROCHLORIDE, DEXMETHYLPHENIDATE HYDROCHLORIDE
  LEVO T, LEVOTHYROXINE SODIUM

* CELATOR PHARMS
  CELATOR PHARMACEUTICALS INC
  VYXEOS, CYTARABINE

* CELERITY PHARMS
  CELERITY PHARMACEUTICALS LLC
  EPTIFIBATIDE

* CELGENE
  CELGENE CORP
  INOSINON, INOSINON
  LEUKERAN, MELPHESI
  REVLIMID, LENALIDOMIDE
  THALOMID, THALIDOMIDE
  VIDAZA, AZACITIDINE

* CELGENE CORP
  IDHIFA, ENASIDENIB MESYLATE
  OTEZLA, APREMILAST

* CELLTRION
  CELLTRION INC
  ACIPHEX SPRINKLE, RABEPRAZOLE SODIUM
  CEYONE
  CHANGZHOU PHARMA
  CEPHALON
  CERECOR INC
  CHARTWELL LIFE SCIENCES LLC
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<td>CHIESI USA INC</td>
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<td>Zyflo CR, Zyloprim, Zyloprim, Zyloprim</td>
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<td>Zitromox, Zitromox, Zitromox, Zitromox</td>
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### CHILDREN'S HOSP M

** CHI LDRENS HOSP M CHI GAN
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18

### CHI NA RESOURCES

** CHI NA RESOURCES SAI KE PHARMACEUTICAL CO LTD
  AMLODI PI NE BESYLATE, AMLODI PI NE BESYLATE

### CHI RHOSI N

** CHI RHOSI M "SECRET HUMAN"

### CI NTEX SVCS

** CI NTEX SERVICES LLC
  FLURANDRENOL DE, FLURANDRENOL DE

### CI PHR PHARMS INC

** CI PHR PHARMAUTICS CALS INC
  CONZI P, TRAMADOL HYDROCHLORIDE DE
  LI POFEN, FENOFIBRATE

### C PL A

** C PL A LTD
  ABACAVIR SULFATE AND LAMIVUDINE, ABACAVIR SULFATE
  ABACAVIR SULFATE, ABACAVIR SULFATE
  ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE, ALBUTEROL SULFATE
  ALENDRONATE SODIUM, ALENDRONATE SODIUM
  ALOSETRON HYDROCHLORIDE DE, ALOSETRON HYDROCHLORIDE DE
  AMLODI PI NE BESYLATE AND BENAZEPRI L HYDROCHLORIDE DE, AMLODI PI NE BESYLATE
  AMLODI PI NE BESYLATE, AMLODI PI NE BESYLATE
  ANASTROZOLE, ANASTROZOLE
  ATAZANAVIR SULFATE, ATAZANAVIR SULFATE
  AZACI TI DI NE, AZACI TI DI NE
  BI VALI RUDI N, BI VALI RUDI N
  BUDESONIDE DE, BUDESONIDE DE
  CASPOFUNGIN ACETATE, CASPOFUNGIN ACETATE
  CELECOXIB, CELECOXIB
  CI NACALCET HYDROCHLORIDE DE, CI NACALCET HYDROCHLORIDE DE
  DARI FENACI N HYDROBROMIDE DE, DARI FENACI N HYDROBROMIDE DE
  DECI TABI NE, DECI TABI NE
  DI CLOFENAC SODIUM DE, DI CLOFENAC SODIUM DE
  DOCETAXEL, DOCETAXEL
  EFAVIR RENZ, EFAVIR RENZ
  EMTRI CI TABI NE, EMTRI CI TABI NE
  ENTECAVIR R, ENTECAVIR R
  EXEMESTANE, EXEMESTANE
  FAMICI CLOMI R, FAMICI CLOMI R
  FENOFIBRATE, FENOFIBRATE
  FI NASTERI DE, FI NASTERI DE
  FLUTAM DE, FLUTAM DE
  GEMICI TABI NE HYDROCHLORIDE DE, GEMICI TABI NE HYDROCHLORIDE DE
  GRI SEFULVU N, GRI SEFULVU N, M CROSI ZE
  I SROPERENOL HYDROCHLORIDE DE, I SROPERENOL HYDROCHLORIDE DE
  LAM VUDI NE AND ZI DUVUDE DE, LAM VUDI NE
  LAM VUDI NE, LAM VUDI NE
  LAMOTRI GI NE, LAMOTRI GI NE
  LEVALBUTEROL HYDROCHLORIDE DE, LEVALBUTEROL HYDROCHLORIDE DE
  MELOXICAM, MELOXICAM
  METOPROLOL SUCCHI NATE, METOPROLOL SUCCHI NATE
  MONTELUKAST SODIUM DE, MONTELUKAST SODIUM DE
  NEVI RAPI NE, NEVI RAPI NE
  OLOPATADI NE HYDROCHLORIDE DE, OLOPATADI NE HYDROCHLORIDE DE
  OXALI PLATI N, OXALI PLATI N
  PALONOSETRON HYDROCHLORIDE DE, PALONOSETRON HYDROCHLORIDE DE
  PHENYLEPHRINE NE HYDROCHLORIDE DE, PHENYLEPHRINE NE HYDROCHLORIDE DE
  PRAVASTATIN SODIUM DE, PRAVASTATIN SODIUM DE
  SODIUM DE NI TROPRIUS DE, SODIUM DE NI TROPRIUS DE
  TENOFOVIR R DI SORPRISTI L FUMARATE, TENOFOVIR R DI SORPRISTI L FUMARATE
  TERBI NAFI NE HYDROCHLORIDE DE, TERBI NAFI NE HYDROCHLORIDE DE
  TESTOSTERONE CYPIONATE, TESTOSTERONE CYPIONATE
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## APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** C **

* CRANE PHARMACEUTICALS LLC
  DAPTOMYCIN
  DAPTOMYCIN

CROSSMEDICA SA

* CROSSMEDICA SA
  MDXI FLOXACIN H HYDROCHLORIDE
  MDXI FLOXACIN H HYDROCHLORIDE
  TRIMI PRAM NE MALEATE
  TRIMI PRAM NE MALEATE
  VARDENAFI L HYDROCHLORIDE

CROWN LABS

* CROWN LABORATORIES INC
  ALA-CORT, HYDROCORTISONE
  ALA-SCALP, HYDROCORTISONE
  TRI DERM

CROWN LABS INC

* CROWN LABORATORIES INC
  ALA-CORT, HYDROCORTISONE
  ALA-SCALP, HYDROCORTISONE
  TRIDERM, TRIAMCINOLONE ACETONIDE

CSPC NBP PHARM CO

* CSPC NBP PHARMACEUTICALS LTD
  BENZONATATE
  BENZONATATE

CSPC OUYI PHARM CO

* CSPC OUYI PHARMACEUTICALS LTD
  AZITHROMYCIN
  AZITHROMYCIN
  CELECOXIB
  CELECOXIB
  CLOPIDOGREL BI SULFATE
  CLOPIDOGREL BI SULFATE
  DONEPEZI L HYDROCHLORIDE
  DONEPEZI L HYDROCHLORIDE
  DULOXETI NE HYDROCHLORIDE
  DULOXETI NE HYDROCHLORIDE
  GABAPENTI N
  GABAPENTI N
  MEMANTI NE HYDROCHLORIDE
  MEMANTI NE HYDROCHLORIDE
  METFORMI N HYDROCHLORIDE
  METFORMI N HYDROCHLORIDE
  MONTELUKAST SODIUM
  MONTELUKAST SODIUM
  NYSTATI N AND TRI AMCI NOLONE ACETONIDE
  NYSTATI N

CUBIST PHARMACOS LLC

* CUBIST PHARMACEUTICALS INC
  ENTEREG
  ALVIMOPAN

CUBIST PHARMACOS INC

* CUBIST PHARMACEUTICAL INC
  ENTEREG
  ALVIMOPAN

CUMBERLAND PHARMACEUTICALS INC

* CUMBERLAND PHARMACEUTICAL INC
  ACETAMOXONE
  ACETAMOXONE
  CALDOLOXONE
  CALDOLOXONE
  LACTULOZOLE
  LACTULOZOLE
  TELAVANCOL
  TELAVANCOL

CUSTOPHARM INC

* CUSTOPHARM INC
  ACETAMONACETAMON
  ACETAMONACETAMON
  FLUDARABINE PHOSPHATE
  FLUDARABINE PHOSPHATE
  PENTOBARBITAL SODIUM
  PENTOBARBITAL SODIUM

CUTANEA

* CUSTOPHARM INC
  ACETAMONACETAMON
  ACETAMONACETAMON
  FLUDARABINE PHOSPHATE
  FLUDARABINE PHOSPHATE
  PENTOBARBITAL SODIUM
  PENTOBARBITAL SODIUM

CYCLE PHARMAUS LTD

* CYCLE PHARMACEUTICALS LTD
  KETOROLAC TROMETHAMINE
  KETOROLAC TROMETHAMINE

CYPRESS PHARMACOS LLC

* CYPRESS PHARMACEUTICAL INC
  CYPRESS PHARMACEUTICAL INC
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   VI TUIZ, CHLORPHENIRAMINE Maleate  
   ZUTRI PRO, CHLORPHENIRAMINE Maleate | DAEWOONG PHARMACEUTICAL CO LTD  
   MEROPENEM, MEROPENEM  
   DAICHI SANKYO INC  
   AZOR, AMLODIPINE BESYLATE  
   BENICAR HCT, HYDROCHLOROTHI AZI DE  
   BENICAR, OLMESARTAN MEDOXOMIL  
   TRIP BENZOR, AMLODIPINE BESYLATE  
   VELCHOL, COLESEVELAM HYDROCHLORIDE |
| DAI L CHI SANKYO  
   AZOR, AMLODIPINE BESYLATE  
   BENICAR HCT, HYDROCHLOROTHI AZI DE  
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   TRIP BENZOR, AMLODIPINE BESYLATE  
   VELCHOL, COLESEVELAM HYDROCHLORIDE | DAI L CHI SANKYO INC  
   EVOXAC, CEVIMELINE HYDROCHLORIDE  
   MORPHABOND ER, MORPHINE SULFATE  
   SAVAYSAA, EDOXABAN TOSYLATE |
| DAI TO PHARMA CO LTD  
   RI LUZOLE, RI LUZOLE | DAVCO LABS LLC  
   M FEPREX, M FEPRI STONE |
| DAVA INTL INC  
   ALPRAZOLAM, ALPRAZOLAM | DAVA PHARMS INC  
   ACYCLOVIR, ACYCLOVIR  
   AMOXICILLIN, AMOXICILLIN  
   AMPICILLIN TRIHYDRATE, AMPICILLIN/AMPICILLIN TRIHYDRATE  
   ATENOLOL, ATENOLOL  
   CI METI DI NE HYDROCHLORIDE, CI METI DI NE HYDROCHLORIDE  
   DOXAZOSIN, DOXAZOSIN N MESYLATE  
   GLYBURIDE, (M CRONI ZED), GLYBURIDE DE  
   METHOTREXATE SODIUM, METHOTREXATE SODIUM  
   MORPHINE SULFATE, MORPHINE SULFATE  
   PENI CI LII N V. POTASSIUM, PENI CI LII N V. POTASSIUM  
   PROPYLTHIORACIL, PROPYLTHIORACIL  
   PYRAZINAMIDE, PYRAZINAMIDE  
   SELEGILNE HYDROCHLORIDE, SELEGILNE HYDROCHLORIDE  
   VOSPI RE ER, ALBUTEROL SULFATE |
| DAVIS AND GECK  
   PRE-OP II, HEXACHLOROPHENE  
   PRE-OP, HEXACHLOROPHENE | DBL PHARMA  
   METHOCARBAMOL, METHOCARBAMOL |
| DENTSPLY PHARM  
   PRE-OP II, HEXACHLOROPHENE  
   PRE-OP, HEXACHLOROPHENE | DEPO NF  
   NUENTYNA ER, TAPENTADOL HYDROCHLORIDE  
   NUENTYNA, TAPENTADOL HYDROCHLORIDE |
| DEPROCO  
   LI GNIOSPAN FORTE, EPI NEPHRI NE BI TARTRATE | DENTSPLY PHARMACEUTICAL INC  
   CI TANEST FORTE DENTAL, EPI NEPHRI NE BI TARTRATE  
   ORA Q X, LI DOCAI NE |
| DEPROCO INC  
   LI GNIOSPAN FORTE, EPI NEPHRI NE BI TARTRATE | DENTSPLY PHARMACEUTICAL INC  
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** D **

* DR REDDYS LABORATORIES ES I NC

  IBUPROFEN, IBUPROFEN
  LEVOFLOXACIN, LEVOFLOXACIN
  MELOXI CAM, MELOXI CAM
  METFORM N HYDROCHLORIDE, METFORM N HYDROCHLORIDE
  NAPROXEN SODIUM AND PSEUDOEPHEDRINE HCL HYDROCHLORIDE, NAPROXEN SODIUM (OTC)
  NAPROXEN SODIUM, NAPROXEN SODIUM (OTC)
  NI TROGLYCELI N, NI TROGLYCELI N
  PRAVASTATIN SODIUM, PRAVASTATIN SODIUM
  PROGESTERONE, PROGESTERONE
  PROPOFOL
  RANITIDINE HYDROCHLORIDE, RANITIDINE HYDROCHLORIDE
  RIVASTIGMINE TARTRATE, RIVASTIGMINE TARTRATE
  SIMVASTATIN, SIMVASTATIN
  SUMATRIPTAN SUCCINATE, SUMATRIPTAN SUCCINATE
  TERBINAFINE HYDROCHLORIDE, TERBINAFINE HYDROCHLORIDE
  TIZANIDINE HYDROCHLORIDE, TIZANIDINE HYDROCHLORIDE
  ZIPRASIDONE HYDROCHLORIDE, ZIPRASIDONE HYDROCHLORIDE
  ZOLPIDEM TARTRATE, ZOLPIDEM TARTRATE

* DR REDDYS LABS LTD

  LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE DIHYDROCHLORIDE
  AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM, AMLODIPINE BESYLATE
  ASPIRIN AND DIPYRIDAMOLE, ASPIRIN
  ATOMOXETINE HYDROCHLORIDE, ATOMOXETINE HYDROCHLORIDE
  ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM
  AZACITIDINE
  BIVALIRUDIN
  CANDESARTAN CI LEXETI L AND HYDROCHLOROTHY AZI DE, Candesartan CI Lexetil
  CARVEDIOL, CARVEDIOL
  CETIRIZINE HYDROCHLORIDE ALLERGY, CETIRIZINE HYDROCHLORIDE (OTC)
  CETIRIZINE HYDROCHLORIDE HIVES, CETIRIZINE HYDROCHLORIDE (OTC)
  CIPROFLOXACIN EXTENDED RELEASE, Ciprofloxacin
  CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE
  CITALOPRAM HYDROBROMIDE, Citalopram Hydrobromide
  CLOFARABI N, Clofarabine
  COLESEVELAM HYDROCHLORIDE, Colesevelam Hydrochloride
  DECITABINE
  DESLOMATADI NE AND PSEUDOEPHEDRINE SULFATE 24 HOUR, Deslormatadine
  DI VALPROEX SODIUM, Di Valproex Sodium
  DOXORUBICIN HYDROCHLORIDE, Doxorubicin Hydrochloride
  ENALAPRIL MALEATE AND HYDCHLOROTHY, Enalapril Maleate
  ESZOPICLONE
  FAMOTIDINE, FAMOTIDINE (OTC)
  FENIXFENADINO HYDROCHLORIDE, Fexofenadine
  FI NASTERI DE, Fi Nasterid E
  FLUOXETIN HYDROCHLORIDE, Fluoxetine Hydrochloride
  GALANTAMINE HYDROBROMIDE, Galantamine Hydrobromide
  GEMCI TABI N HYDROCHLORIDE, Gemic Tabine Hydrochloride
  GLI MEPI RY DE, GLI Mepti Ryde
** B **

**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

- **D**

- **DR REDDYS LABORATORIES LTD**
  - Glycopyrrolate
  - Glycopyrrolate
  - Granisetron Hydrochloride De, Granisetron Hydrochloride De
  - Guaiifenesin N and Pseudoephedrine Ne Hydrochloride De, Guaiifenesin N (OTC)
  - Ibandronate Sodi Um, Ibandronate Sodi Um
  - Ibuprofen and Pheniramine HCl OTC, Ibuprofen and Pheniramine HCl OTC
  - Ibuprofen and Pseudoephedrine Ne Hydrochloride De, Ibuprofen (OTC)
  - Lamotrigine
  - Lansoprazole, Lansoprazole
  - Lansoprazole, Lansoprazole (OTC)
  - Letrozole, Letrozole
  - Levchetram, Levchetram
  - Levocetirizin Dihydrochlorid, Levocetirizin Dihydrochlorid (OTC)
  - Lnciplit N, Lnciplit N
  - Omeprazole and Sodi Um, Omeprazole Magnesi Um (OTC)
  - Omeprazole, Omeprazole
  - Onandizzon HCl, Onandizzon HCl
  - Oxaprin, Oxaprin
  - Palonosetron HCl, Palonosetron HCl
  - Pantoprazole Sodi Um, Pantoprazole Sodi Um
  - Panadol, Panadol
  - Paracetamol, Paracetamol
  - Paricalcitol
  - Pramipexole Dihydrochlorid, Pramipexole Dihydrochlorid
  - Quetiapine Fumarate
  - Rabeprozol Sodi Um, Rabeprozol Sodi Um
  - Ramipril
  - Ranitidine Hydrochloride, Ranitidine Hydrochloride
  - Risperidone
  - Ropeinitol Hydrochlorid, Ropeinitol Hydrochlorid
  - Sevelamer Carbonat, Sevelamer Carbonat
  - Tetrabenazine
  - Tetrabenazine
  - Zafirlukast
  - Zembrace Sympto, Zembrace Sympto

- **DR REDDYS LABS SA**
  - Buprenorphin Ne Hydrochlorid, Buprenorphin Ne Hydrochlorid De, Buprenorphin Ne Hydrochlorid De
  - Ezetimib M Be and Simvastatin N, Ezetimib M Be
  - Fenofibrate (M Cronic Zed), Fenofibrate

- **DR REDDYS LABORATORIES ES LTD**
  - Moxifloksacin Hydrochlorid, Moxifloksacin Hydrochlorid
  - Nategliptin, Nategliptin
  - Nizatidin, Nizatidin
  - Ofloksacin
  - Olanzapin, Olanzapin
  - Omeprazole Sodi Um, Omeprazole Sodi Um
  - Omeprazole Magnesi Um, Omeprazole Magnesi Um (OTC)
  - Omeprazole, Omeprazole (OTC)
  - Onandezetrin HCl, Onandezetrin HCl
  - Oxazepam, Oxazepam
  - Palomosetron Hydrochlorid, Palomosetron Hydrochlorid
  - Pantoprazole Sodi Um, Pantoprazole Sodi Um
  - Paracetamol, Paracetamol
  - Paroxetine M Be, Paroxetine M Be
  - Quetiapine Fumarate, Quetiapine Fumarate
  - Rabaprazol Sodi Um, Rabaprazol Sodi Um
  - Raloxifin, Raloxifin
  - Ramipril
  - Raloxifin, Raloxifin
  - Ranitidine Hydrochloride, Ranitidine Hydrochloride
  - Risperidone
  - Ropinirole Hydrochlorid, Ropinirole Hydrochlorid
  - Sevelamer Carbonat, Sevelamer Carbonat
  - Tetrabenazines, Tetrabenazines
  - Tetrahydrofuran, Tetrahydrofuran
  - Thiotepa, Thiotepa
  - Topotecan Hydrochlorid, Topotecan Hydrochlorid
  - Valganciclovir Hydrochloride, Valganciclovir Hydrochloride
  - Venlafaxin Hydrochlorid, Venlafaxin Hydrochloride
  - Vi Gabapentin, Vi Gabapentin
  - Vi Norelbin Ne Tartrate, Vi Norelbin Ne Tartrate
  - Zafirlukast, Zafirlukast
  - Zembrase Symptoch, Zembrase Symptoch
  - Zenatane, Zenatane
  - Zoledron C Ac D, Zoledron C Ac D
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

#### ** D **

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<th>Products</th>
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<td>TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT</td>
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<td>DUCHESSNA Y INC</td>
<td>BONI ESTA, DOXYLAMINE SUCCINATE, OSPHENA, OSPHEN FENE</td>
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<td>DURAMED PHARMS BARR</td>
<td>AVIANE-28, ETHINYL ESTRADIOL OL, DESOGESTREL AND ETHYL NYL Estradiol OL, ENPRESSE-28, METHYLPRPRNDI SOLONE, TRIAMTRENE AND HYDROCHLOROTHIAZIDE</td>
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<td>DUSA INC</td>
<td>LEVULAN, AM NOLEVULI NI C ACI D HYDROCHLORIDE</td>
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<td>DOCTOR REDDYS LABORATORIES LTD</td>
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<td>EAGLE PHARMS INC</td>
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** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

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<td>Frova, Frovatri PTan Succinate</td>
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<td>Opana, Oxymorphone Hydrochlori De</td>
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<td>Percodan, Aspirin</td>
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<td>Aveed, Testosterone Undecanoate</td>
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<td>Coly-Mycin S, COLISTIN SULFATE</td>
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<td>Megace ES, Megestrol Acetate</td>
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** E **

- **ENDO PHARMA CEUTIS I NC**
  - NASCOBAL, CYANOCOBALAMIN
  - VALGANCE CLOVIR R HYDROCHLORIDE, VALGANCE CLOVIR R HYDROCHLORIDE

- **EP I HEALTH**
  - CLOCORTOLONE PI VALATE
  - M NOLI RA, M NOCYCLINE HYDROCHLORIDE DE
  - SI TAVI G, ACYCLOVID R

- **EP I PHARMA**
  - MEPERIDINE HYDROCHLORIDE, MEPERIDINE HYDROCHLORIDE
  - NICARDIPINE HYDROCHLORIDE, NICARDIPINE HYDROCHLORIDE

- **EP I PHARMA LLC**
  - BETAXOLOL HYDROCHLORIDE, BETAXOLOL HYDROCHLORIDE
  - CI TALOPRAM HYDROBROMIDE, CI TALOPRAM HYDROBROMIDE
  - FLAVOXATE HYDROCHLORIDE, FLAVOXATE HYDROCHLORIDE
  - SULI NDAC, SULI NDAC
  - TRANDOLAPRI L, TRANDOLAPRI L

- **EP I PHARMA I NC**
  - ESTRADIOL, ESTRADIOL
  - SOTALOL HYDROCHLORIDE, SOTALOL HYDROCHLORIDE

- **EP I PHARMA LLC**
  - AMLODI PI NE BESYLALE, AMLODI PI NE BESYLALE
  - AZI THROMCY N, AZI THROMCY N
  - BENZPHETAMINE HYDROCHLORIDE, BENZPHETAMINE HYDROCHLORIDE
  - BENZTROPINE NE MESYLALE, BENZTROPINE NE MESYLALE
  - CLI NDAMCY N HYDROCHLORIDE, CLI NDAMCY N HYDROCHLORIDE
  - DEMECLOCYCLINE HYDROCHLORIDE, DEMECLOCYCLINE HYDROCHLORIDE
  - DEXTROAMPHETAMINE, AMPHETAMINE, AMPHETAMINE
  - GLIBURIDE, GLIBURIDE
  - HYDROCODONE BITARTRATE AND ACETAMINOPHENE, ACETAMINOPHENE
  - MECLIZINE HYDROCHLORIDE, MECLIZINE HYDROCHLORIDE
  - METHADONE HYDROCHLORIDE, METHADONE HYDROCHLORIDE
  - MOLY NDONE HYDROCHLORIDE, MOLY NDONE HYDROCHLORIDE
  - NYSTATIN, NYSTATIN
  - OXYCODONE AND ACETAMINOPHENE, ACETAMINOPHENE
  - OXYMORPHONE HYDROCHLORIDE, OXYMORPHONE HYDROCHLORIDE
  - PHENYTOIN, PHENYTOIN

- **ESPERO**
  - ESPERO BIO PHARMA I NC
  - DURLAZA, ASPI RIN

- **ESSENTIAL ISOTOPES**
  - ESSENTIAL ISOTOPES LLC
  - AMMONIUM N 13, AMMONIUM N-13
  - FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18
  - SODIUM FLUORIDE F-18, SODIUM FLUORIDE F-18

- **ETHPHARM**
  - BUPRENORPHINE HYDROCHLORIDE DE, BUPRENORPHINE HYDROCHLORIDE DE

- **ETHPHARM USA CORP**
  - BUPRENORPHINE HYDROCHLORIDE DE AND NALOXONE HYDROCHLORIDE DE

- **EURO PHARMA**
  - EUGA PHARMA SPECI ALI TI ES LTD
  - CAPECIC TABI NE, CAPECIC TABI NE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** E **

* EUIGIA PHARMA SPECIA TES LTD
  CARBOPLATIN, CARBOPLATIN
  LETROZOLE, LETROZOLE
  OXALI PLATIN, OXALI PLATIN
  PROGESTERONE, PROGESTERONE

* EUROHEALTH INTNATL SARL
  DROPERIDOL, DROPERIDOL
  HYDROMORPHONE HYDROCHLORIDE, HYDROMORPHONE HYDROCHLORIDE
  MORPHINE SULFATE, MORPHINE SULFATE
  NEOSTIGMINE METHYL SULFATE, NEOSTIGMINE METHYL SULFATE

* EXALENZ BIOSCIENCE
  IDKIT:HP, CITRIC ACID

* EXALENZ BIOSCIENCE LTD
  DROPERIDOL, DROPERIDOL
  HYDROMORPHONE HYDROCHLORIDE, HYDROMORPHONE HYDROCHLORIDE
  MORPHINE SULFATE, MORPHINE SULFATE
  NEOSTIGMINE METHYL SULFATE, NEOSTIGMINE METHYL SULFATE

* EXALENZ BIOSCIENCE LTD
  IDKIT:HP, CITRIC ACID

* EXELA HOLDINGS
  DICLOFENAC SODIUM AND MISOPROSTOL, DICLOFENAC SODIUM

* EXELA HOLDINGS INC
  DICLOFENAC SODIUM AND MISOPROSTOL, DICLOFENAC SODIUM

* EXELA PHARMA SCIENCES
  CAFFEINE CITRATE, CAFFEINE CITRATE
  NICARDIPINE HYDROCHLORIDE, NICARDIPINE HYDROCHLORIDE
  PALONOSETRON HYDROCHLORIDE, PALONOSETRON HYDROCHLORIDE

* EXELA PHARMA SCIENCES LLC
  CAFFEINE CITRATE, CAFFEINE CITRATE
  NICARDIPINE HYDROCHLORIDE, NICARDIPINE HYDROCHLORIDE
  PALONOSETRON HYDROCHLORIDE, PALONOSETRON HYDROCHLORIDE

* EXELI X S
  COMETRIQ, CABOZANTINIB S-MALATE

* EXELI X S INC
  DEXYCU KIT, DEXAMETHASONE
  YUTIQ, FLUOCINOLONE ACETONIDE

* EYEOPI PHARMS
  DEXYCUT KIT, DEXAMETHASONE
  YUTIQ, FLUOCINOLONE ACETONIDE

* EYEVANCE PHARMS
  ZERVIATE, CETIRIZINE HYDROCHLORIDE

* EYEVANCE PHARMA SCIENCES LLC
  ZERVIATE, CETIRIZINE HYDROCHLORIDE

* ELI LILLY
  ALI MTA, PEMETREXED DI SODIUM
  CI ALI S, TADALAFIL
  CYMBALTA, DULOXETIN HYDROCHLORIDE
  ESI STA, RALOXIFENE HYDROCHLORIDE
  FORTEO, TERIPARATHI N HUMAN
  GENZAR, GEMI TIBI N HYDROCHLORIDE
  GLUCAGON, GLUCAGON
  HUMATROPE, SOMATROPIN RECOMBI NANT
  HUMALOG KWP KEN, INSULI N LI SPRO RECOMBI NANT
  HUMALOG M X 50/50 KWP KEN, INSULI N LI SPRO PROTAMINE RECOMBI NANT
  HUMALOG M X 50/50, INSULI N LI SPRO PROTAMINE RECOMBI NANT
  HUMALOG M X 75/25 KWP KEN, INSULI N LI SPRO PROTAMINE RECOMBI NANT
  HUMALOG M X 75/25, INSULI N LI SPRO PROTAMINE RECOMBI NANT
  HUMALOG, INSULI N LI SPRO RECOMBI NANT
  HUMATROPE, SOMATROPIN RECOMBI NANT
  HUMALOG M X 70/30 PEN, INSULI N LI SPRO RECOMBI NANT HUMAN (OTC)
  HUMALOG M X 70/30 PEN, INSUR N RECOMBI NANT HUMAN (OTC)
  HUMALOG M X 70/30, INSULI N LI SPRO RECOMBI NANT HUMAN (OTC)
  HUMALOG M X 70/30, INSULI N SUSP I SOPHANE RECOMBI NANT HUMAN (OTC)
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

#### **E**

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<td>HUMULIN R KIWIPEN, INSULIN HUMAN</td>
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#### **F**

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<td>PI ROKI CAM, PI ROKI CAM</td>
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# Appendix B - Product Name Sorted by Applicant

**F**

### Forest Labs Inc

- **VIOKACE, PANCRELIASE (AMYLASE**
- **ZENPEP, PANCRELIASE (AMYLASE**

### Forest Labs LLC

- **NAMENDA XR, MEMANTINE HYDROCHLORIDE**
- **SAPHRIS, ASENAPINE MALEATE**

### Fougera Pharmas

- **FOUGERA PHARMACEUTICALS CALS INC**
  - **ADAPALENE, ADAPALENE**
  - **ALCLOMETASONE DI PROPIONATE, ALCLOMETASONE DI PROPIONATE**
  - **AMCI NONI DE, AMCI NONI DE**
  - **BETAMETHASONE DI PROPIONATE, BETAMETHASONE DI PROPIONATE**
  - **CALCIPOTRIENE, CALCIPOTRIENE**
  - **CICLOPIROX, CICLOPIROX**
  - **CLINDAMYCIN PHOSPHATE, CLINDAMYCIN PHOSPHATE**
  - **CLOBETASOL PROPIONATE, CLOBETASOL PROPIONATE**
  - **CLOBETASOL PROPIONATE (EMOLLIENT), CLOBETASOL PROPIONATE**
  - **CLOTRIMAZOLE AND BETAMETHASONE DI PROPIONATE, BETAMETHASONE DI PROPIONATE**
  - **CLOTRIMAZOLE, CLOTRIMAZOLE**
  - **CUTIVATE, FLUTICASONE PROPIONATE**
  - **DESONI DE, DESONI DE**
  - **DESOKI METASONE, DESOKI METASONE**
  - **DI FLORASONE DI ACETATE, DI FLORASONE DI ACETATE**
  - **ERYTHROMYCIN N, ERYTHROMYCIN N**
  - **FLUCI NONI DE EMULSI FI ED BASE, FLUCI NONI DE**
  - **FLUCI NONI DE, FLUCI NONI DE**
  - **FLUTI CASONE PROPIONATE, FLUTI CASONE PROPIONATE**
  - **HALOBETASOL PROPIONATE, HALOBETASOL PROPIONATE**
  - **HYDROCORTISONE, HYDROCORTISONE**
  - **IMIQUIMOD, IMIQUIMOD**
  - **KETOCONAZOLE, KETOCONAZOLE**
  - **LI DOCAI NE AND PRI LOCALI NE, LI DOCAI NE**
  - **METRONI DAZOLE, METRONI DAZOLE**
  - **MOMETASONE FURATE, MOMETASONE FURATE**
  - **MUPI ROCI N, MUPI ROCI N**
  - **NYSTATI N, NYSTATI N**
  - **OXY STAT, OXY CONAZOLE NI TRATE**
  - **PANDEL, HYDROCORTISONE PROPIONATE**
  - **PREDNI CARBATE, PREDNI CARBATE**
  - **SOLARAZE, DI CLOFENAC SODIUM**
  - **SULFACETAM DE SODIUM, SULFACETAM DE SODIUM**
  - **TERNAZOLE, TERNAZOLE**
  - **TYZIDE, TETRAHYDROZOLI NE HYDROCHLORIDE**

### Fougera Pharmas Inc

- **ACYCLOVIR, ACYCLOVIR**
- **BETAMETHASONE DI PROPIONATE, BETAMETHASONE DI PROPIONATE**
- **BETAMETHASONE VALERATE, BETAMETHASONE VALERATE**
- **CLINDAMYCIN PHOSPHATE, CLINDAMYCIN PHOSPHATE**
- **CLOBETASOL PROPIONATE, CLOBETASOL PROPIONATE**
- **FLUCI NONI DE ACETONI DE, FLUCI NONI DE ACETONI DE**
- **NYSTATI N AND YZIDE ACETONI DE, NYSTATI N**
- **TACROLIMUS, TACROLIMUS**
- **VEREGEN, SI NECATECHI NS**

### Fresenius

- **FRESENIUS KABI DEUTSCHLAND GMBH**
### Appendix B - Product Name Sorted by Applicant

**F**

* **Fresenius Kabi Deutschland Gmbh**
  - Intralipid 10%, Soybean Oil
  - Intralipid 20%, Soybean Oil
  - Intralipid 30%, Soybean Oil

* **Fresenius Kabi**
  - Intralipid 50%, Soybean Oil

* **Fresenius Kabi Anti Infectives Srl**
  - Piperacillin and Tazobactam, Piperacillin Sodium

* **Fresenius Kabi Austria Gmbh**
  - Lactulose, Lactulose

* **Fresenius Kabi Oncology Plc**
  - Anastrozole, Anastrozole
  - Bicalutamide, Bicalutamide
  -Gemcitabine Hydrochloride, Gemcitabine Hydrochloride
  -Irinotecan Hydrochloride, Irinotecan Hydrochloride
  -Letrozole, Letrozole

* **Fresenius Kabi Oncology Plc**
  - Anastrozole, Anastrozole
  -Bicalutamide, Bicalutamide
  -Gemcitabine Hydrochloride, Gemcitabine Hydrochloride
  -Irinotecan Hydrochloride, Irinotecan Hydrochloride
  -Letrozole, Letrozole

* **Fresenius Kabi Usa**
  - Acetaminophen, Acetaminophen
  -Acetylcysteine, Acetylcysteine
  -Acyclovir Sodium, Acyclovir Sodium
  -Adenosine, Adenosine
  -Amikacin Sulfate, Amikacin Sulfate
  -Amiodarone Hydrochloride, Amiodarone Hydrochloride
  -Argatroban, Argatroban
  -Arsenii C Tri Oxide, Arsenii C Tri Oxide
  -Astramorphp, Morphine Sulfate
  -Atropine Sulfate, Atropine Sulfate
  -Azi Thromycins, Azi Thromycins
  -Aztreonam, Aztreonam
  -Baci Trai N, Baci Trai N
  -Bacteriosis C Sodi Um Chloro De 0.9% In Plasti C Contai Ner, Sodi Um Chloro De
  -Benztropine Ne Mesylate, Benztropine Ne Mesylate
  -Bleomycin C Sodi Um, Bleomycin C Sodi Um
  -Bortezom B, Bortezom B
  -Caffeine Ne Ci Trate, Caffeine Ne Ci Trate
  -Calcium Gluconate, Calcium Gluconate
  -Carbolipats, Carbolipats
  -Caspofungins In Acetate, Caspofungins In Acetate
  -Cefotetan, Cefotetan In Sodi Um
  -Chloramphenicol Sodi Um Succinate, Chloramphenicol Sodi Um Succinate
  -Chlorothiazide Azi De Sodi Um, Chlorothiazide Azi De Sodi Um
  -Chori Oni C, Gonadotropins Gonadotropins
  -Clarin C, Clarin C
  -Clarithrion C, Clarithromycin
  -Colistimethate Sodi Um, Colistimethate Sodium
  -Cytochrome A, Cytochrome A
  -Cytarabine Ne, Cytarabine Ne
  -Dacarbazine Ne, Dacarbazine Ne
  -Daptomycin C, Daptomycin C
  -Daunorubicin C Sodi Um, Daunorubicin Sodium
  -Dexamethasone Sodium P, Dexamethasone Sodium Phosphate
  -Dextrase 10% In Plasti C Contai Ner, Dextrase
  -Dextrase 5% In Plasti C Contai Ner, Dextrase
  -Diazepam, Diazepam
  -Di Menhydrin N, Di Menhydrin N
  -Di Phenhydramine, Di Phenhydramine
  -Di Pri Van, Propofol
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** F **

FRESENIUS KABI USA LLC

DI PYRI DYNOLE, DI PYRI DYNOLE
DOKRUBI CI N HYDROCHLORI DE, DOKRUBI CI N HYDROCHLORI DE
DOKY 100, DOXYCYCLINE HYCLATE
DOKY 200, DOXYCYCLINE HYCLATE
EPI RUBI CI N HYDROCHLORI DE, EPI RUBI CI N HYDROCHLORI DE
ESMOLOL HYDROCHLORI DE, ESMOLOL HYDROCHLORI DE
ETOPOSI DE, ETOPOSI DE
FAMOTI DI NE PRESERVATI VE FREE, FAMOTI DI NE
FAMOTI DI NE, FAMOTI DI NE
FLOKURI DI NE, FLOKURI DI NE
FLUCONAZOLE I N SODI UM CHLORI DE 0.9% FLUCONAZOLE
FLUDARABI NE PHOSPHATE, FLUDARABI NE PHOSPHATE
FLUMAZENI L, FLUMAZENI L
FLUOROURACIL, FLUOROURACIL
FLUPHENAZI NE DECANOATE, FLUPHENAZI NE DECANOATE
FLUPHENAZI NE HYDROCHLORI DE, FLUPHENAZI NE HYDROCHLORI DE
FOLI C AO D, FOLI C AO D
FOSAPREPI TANT DI MEGLUM NE, FOSAPREPI TANT DI MEGLUM NE
FOSPHENYTOI N SODI UM, FOSPHENYTOI N SODI UM
FUROSEM DE, FUROSEM DE
GANGI CLOVI R, GANGI CLOVI R SODI UM
GEMI TABI NE HYDROCHLORI DE, GEMI TABI NE HYDROCHLORI DE
GENTAM CI N SULFATE, GENTAM CI N SULFATE
GLUCAGON, GLUCAGON HYDROCHLORI DE
GLYCOPPIRROLATE, GLYCOPPIRROLATE
GRAN SETRON HYDROCHLORI DE PRESERVATI VE FREE, GRAN SETRON HYDROCHLORI DE
GRAN SETRON HYDROCHLORI DE, GRAN SETRON HYDROCHLORI DE
HALOPERI DOL DECANOATE, HALOPERI DOL DECANOATE
HALOPERI DOL, HALOPERI DOL LACTATE
HEPARI N SODI UM I N PLASTI CI N PLASTIC CONTAIN, HEPARI N SODI UM
HEPARI N SODI UM PRESERVATI VE FREE, HEPARI N SODI UM
HEPARI N SODI UM, HEPARI N SODI UM
HYDRAZI NE HYDROCHLORI DE, HYDRAZI NE HYDROCHLORI DE
I DARUBI CI N HYDROCHLORI DE, I DARUBI CI N HYDROCHLORI DE
I FOSFAM DE, I FOSFAM DE
I NDOETHACI N, I NDOETHACI N
I RI NOTECAN HYDROCHLORI DE, I RI NOTECAN HYDROCHLORI DE
KABI VEN I N PLASTI CI N PLASTIC CONTAIN, AM NO ACI D5
KETOROLAC TROMETAM NE, KETOROLAC TROMETHAM NE
LEUCOVORI N CALCI UM PRESERVATI VE FREE, LEUCOVORI N CALCI UM
LEUCOVORI N CALCI UM, LEUCOVORI N CALCI UM
LEVETI RACETAM, LEVETI RACETAM
LEVOFLOXACI N I N DEXTROSE 5% I N PLASTI CI N PLASTIC CONTAIN, LEVOFLOXACI N
LEVOTHYROXI NE N SODI UM LEVOTHYROXI NE N SODI UM
LI DOCAI NE HYDROCHLORI DE I N PLASTI CI N PLASTIC CONTAIN, LI DOCAI NE HYDROCHLORI DE
LI DOCAI NE HYDROCHLORI DE PRESERVATI VE FREE, LI DOCAI NE HYDROCHLORI DE
LI NEZOLI D, LI NEZOLI D
MAGNESI UM SULFATE I N DEXTROSE 5% I N PLASTI CI N PLASTIC CONTAIN, MAGNESI UM SULFATE
MAGNESI UM SULFATE I N PLASTI CI N PLASTIC CONTAIN, MAGNESI UM SULFATE
MAGNESI UM SULFATE, MAGNESI UM SULFATE
MAGNESI UM SULFATE, MAGNESI UM SULFATE
MANNI TOL 25%, MANNI TOL
MELPHALAN HYDROCHLORI DE, MELPHALAN HYDROCHLORI DE
MESNA, MESNA
METHOCARBAMOL, METHOCARBAMOL
METHOTREXATE PRESERVATI VE FREE, METHOTREXATE SODI UM
METHOTREXATE SODI UM, METHOTREXATE SODI UM
METHYLPRIDINOL SODI UM SUCCI NATE, METHYLPRIDINOL SODI UM SUCCI NATE
METOCLOPROMA DE HYDROCHLORI DE, METOCLOPROMA DE HYDROCHLORI DE
METOPROLOL TARTRATE, METOPROLOL TARTRATE
M DAZOLAM HYDROCHLORI DE PRESERVATI VE FREE, M DAZOLAM HYDROCHLORI DE
M DAZOLAM HYDROCHLORI DE, M DAZOLAM HYDROCHLORI DE
M LRI NONE LACTATE, M LRI NONE LACTATE
M TOKANTRONE HYDROCHLORI DE, M TOKANTRONE HYDROCHLORI DE
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine Sulfate</td>
<td>Fresenius Kabi USA LLC</td>
</tr>
<tr>
<td>Moxifloxacin Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
</tr>
<tr>
<td>Naropin, Ropivacaaine Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Nesacaine, Chloroprocaine Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
</tr>
<tr>
<td>Nesacaine-MPF, Chloroprocaine Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
</tr>
<tr>
<td>Octreotide De Acetate (Preservative Free)</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Octreotide De Acetate</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Omevagen, FISH OIL TRI GLYCERIDES</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Ondansetron Hydrochloride Preservative Free</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Ondansetron Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Oxaliplatin</td>
<td>Fresenius Medcl</td>
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<tr>
<td>Oxytocin</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Paclitaxel</td>
<td>Fresenius Medcl</td>
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<tr>
<td>Palonosetron Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<td>Pamronate Di Sodi UM</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Pentam, Pentam Di NE I SETHI QNATE</td>
<td>Fresenius Kabi USA LLC</td>
</tr>
<tr>
<td>Percabiven In Plastic Container, Amino Acids</td>
<td>Fresenius Medcl</td>
</tr>
<tr>
<td>Piperacillin And Tazobactam, Piperacillin Sodium</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Polocaine, Mepivacaine Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<td>Polocaine-MPF, Mepivacaine Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Polymyxin N B Sulfate, Polymyxin N B Sulfate</td>
<td>Fresenius Kabi USA LLC</td>
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<td>Potassium Chloride In Plastic Container</td>
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<tr>
<td>Progesterone, Progesterone</td>
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<td>Propranolol Hydrochloride, Propranolol Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<td>Protonom Sulfate, Protonom Sulfate</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Pyridoxine Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Remifentanil De Acetate (Preservative Free)</td>
<td>Fresenius Kabi USA LLC</td>
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<td>Remifentanil De Acetate</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Rocuronium Um Brom De, Rocuronium Um Brom De</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Sensorcal, Bupivacaine Hydrochloride</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Sensorcal N, Bupivacaine Hydrochloride</td>
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<tr>
<td>Smflpi D 20% FISH OIL</td>
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<tr>
<td>Sodium Acetate</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Sodium Chloride 0.45% In Plastic Container</td>
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<tr>
<td>Sodium Chloride 0.9% In Plastic Container</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Sterile Water For Injection In Plastic Container</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Sumatriptan Succinate, Sumatriptan Succinate</td>
<td>Fresenius Kabi USA LLC</td>
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<tr>
<td>Tranexamic Caci D, Tranexamic Caci D</td>
<td>Fresenius Kabi USA LLC</td>
</tr>
<tr>
<td>Zolestron Caci D, Zolestron Caci D</td>
<td>Fresenius Kabi USA LLC</td>
</tr>
</tbody>
</table>
** F **

- FRESENIUS MEDICAL CARE NORTH AMERICA
  - DELFLEX W DEXTROSE 2.5% LOW MAGNESIUM LOW CALCI UM IN PLASTIC CONTAINER, CALCI UM
  - DELFLEX W DEXTROSE 4.25% IN PLASTIC CONTAINER, CALCI UM CHLORIDE
  - DELFLEX W DEXTROSE 4.25% LOW MAGNESIUM LOW CALCI UM IN PLASTIC CONTAINER, CALCI UM
  - PHOSLO GELCAPS, CALCI UM ACETATE
  - PHOSLYRA, CALCI UM ACETATE

- FRONTIDA BIOPHARM
  - CI LOSTAZOL, CI LOSTAZOL
  - CYCLOBENZAPRI NE HYDROCHLORIDE DE, CYCLOBENZAPRI NE HYDROCHLORIDE DE

** G **

- G AND W LABS
  - ACEPHEN, ACETAMINOPHEN (OTC)
  - CALCIUM PHOSPHATE, CALCIUM PHOSPHATE
  - FLUCNIZO SULFATE, FLUCNIZO SULFATE
  - FLUTICASONE PROPIONATE, FLUTICASONE PROPIONATE
  - ALBUTEROL SULFATE, ALBUTEROL SULFATE
  - BETA-VAL, BETAMETHASONE VALerate
  - BETAMETHASONE DI PROPIONATE, BETAMETHASONE DI PROPIONATE
  - CI CLOPI ROX, CI CLOPI ROX
  - CLINAMICIN N PHOSPHATE, CLINAMICIN N PHOSPHATE

- G AND W LABS INC
  - ACAZOLAMIDE, ACAZOLAMIDE
  - ACYCLOVIR, ACYCLOVIR
  - ACYCLOVIR, ACYCLOVIR
  - ALBUTEROL SULFATE, ALBUTEROL SULFATE
  - BETA-VAL, BETAMETHASONE VALerate
  - BETA-VAL, BETAMETHASONE VALerate
  - BETAMETHASONE DI PROPIONATE, BETAMETHASONE DI PROPIONATE
  - CALCIUM PHOSPHATE, CALCIUM PHOSPHATE
  - CI CLOPI ROX, CI CLOPI ROX
  - CLINAMICIN N PHOSPHATE, CLINAMICIN N PHOSPHATE
  - CLINAMICIN N PHOSPHATE, CLINAMICIN N PHOSPHATE

- GAND W LABS LP
  - ACYCLOMycin, ACYCLOMycin
  - ACYCLOMycin, ACYCLOMycin
  - ACYCLOMycin, ACYCLOMycin
  - ACYCLOMycin, ACYCLOMycin
  - ACYCLOMycin, ACYCLOMycin
  - ACYCLOMycin, ACYCLOMycin

- GALDERMA LABS
  - CLOBEX, CLOBETASOL PROPIONATE
  - EPI DUO FORTE, ADAPALENE

- GALDERMA LABS LP
  - CLOBEX, CLOBETASOL PROPIONATE
** G **

* GALDERMA LABORATORIES LP
  CAPEX, FLUCINOLONE ACETONIDE DE
  CLOBEX, CLOBETASOL PROPIONATE
  DESOVIEN, DESONI DE
  DIFFEREN N, ADAPALENE
  DIFFEREN N, ADAPALENE (OTC)
  EPI DUO, ADAPALENE
  METROCREAM, METRONIDAZOLE
  METROGEL, METRONIDAZOLE
  METROLID OX, METRONIDAZOLE
  MIVASO, BRI MINI DINE TARTRATE
  ORACEA, DOXYCYCLINE
  SOOANTRA, IVERMECTIN N
  TRIP-LUMA, FLUCINOLONE ACETONIDE DE
  VECTICAL, CALCITRIOL

GALEN SPEC ALTY
* GALEN SPEC ALTY PHARMA US LLC
  SYNERA, LI DOCAI NE

GALEN UK
* GALEN LTD
  ADASUVE, LOKAPI NE

GALT PHARMS
* GALT PHARMAEUITS CALS LLC
  DORAL, QUAZEPAM

GATE PHARMS
* GATE PHARMAEUITS CALS
  CLOPI DOGREL BI SULFATE, CLOPI DOGREL II SULFATE
  LI NEZOLI D, LI NEZOLI D

GATOR PHARMS
* GATOR PHARMAEUITS CALS I NC
  COLPREP KIT T, MAGNESIUM SULFATE

GAVI S PHARMS
* GAVI S PHARMAEUITS CALS LLC
  NALOXONE HYDROCHLORIDE DE AND PENTAZOCINE G HYDROCHLORIDE DE, NALOXONE HYDROCHLORIDE DE
  NYSATI N, NYSATI N
  ORPHENADRI NE CI TRATE, ORPHENADRI NE CI TRATE
  QUI NARETI C, HYDROCHLOROTHI AZI DE
  TRI METHOBENZAM DE HYDROCHLORIDE DE, TRI METHOBENZAM DE HYDROCHLORIDE DE

GAVI S PHARMS LLC
* GAVI S PHARMAEUITS CALS LLC
  FLUCINOLONE ACETONIDE DE, FLUCINOLONE ACETONIDE DE

GD SEARLE
* GD SEARLE LLC
  CELEBREX, CELECOXIB
  DAYPRO, OKAPROZI N

GD SEARLE LLC
* GD SEARLE LLC
  ALDACTAZI DE, HYDROCHLOROTHI AZI DE
  ALDACTONE, SPI RONLACTONE
  ARTHROTEC, DI CLOFENAC SODI UM
  CALAN, VERAPAMIL I-123 HYDROCHLORIDE DE
  CYTOTEC, M SORPRESTOL
  FLAGYL, METRONIDAZOLE
  I NSPRA, EPLERENONE
  LOMOTI L, ATROPIN INE SULFATE
  NORPACE CR, DI SORPRESTOL DE PHOSPHATE
  NORPACE, DI SORPRESTOL DE PHOSPHATE
  SYNAREL, NAFAREL IN ACETATE

GE HEALTHCARE
* GE HEALTHCARE
  ADREVIEW, IOBENGUANE SULFATE I-123
  CERETEC, TECHNETIUM TC-99M EXAMETAZI ME KIT
  I NDI CLOR, I NDI UM I N-111 CHLORIDE DE
  I NDI UM I N-111 OXYQUI NOLI NE, I NDI UM I N-111 OXYQUI NOLI NE
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

* GE HEALTHCARE
  ** G **
  METASTRON, STRONTIUM CHLORIDE SR-89
  MPI I ND1 UM DTPA I N 111, I ND1 UM I N 111 PENTETATE DI SODI UM
  NIOVI EW 30ML, TECHNETIUM T-99M TETROFOSM N KIT
  OMNI PAQUE 12, IOHEXOL
  OMNI PAQUE 140, IOHEXOL
  OMNI PAQUE 180, IOHEXOL
  OMNI PAQUE 240, IOHEXOL
  OMNI PAQUE 300, IOHEXOL
  OMNI PAQUE 350, IOHEXOL
  OMNI PAQUE 9, IOHEXOL
  OMNI SCAN, GADODI AM DE
  OPTI SON, ALBUM N HUMAN
  TECHNETIUM T-99M GENERATOR, TECHNETIUM T-99M SODIUM PERTECHNETATE GENERATOR
  THALLIUM CHLORIDE TL 201, THALLIUM CHLORIDE DE TL-201
  VI SI PAQUE 270, IOXI XANOL
  VI SI PAQUE 320, IOXI XANOL
  VI ZAMYL, FLUTEMETAMOL F-18

GE HEALTHCARE I NC
  * GE HEALTHCARE I NC
  DATSCN, I OFLUPANE I-123

GEMINI LABS LLC
  * GEMINI LABORATORIES ES LLC
  PRANDI N, REPAGLI NI DE

GENENTECH
  * GENENTECH I NC
  ERI VEGE, VI SMODEG B
  NUTROPI N AQ NUSPI N, SOMATROPI N RECOMBI NANT

GENENTECH I NC
  * GENENTECH I NC
  COTELLI C, COBI METI NI B FUMARATE
  ESBI ET, PI RFENI DONE
  XOFLUZA, BALOKAVI R MARBOXI L

GENERICS
  * GENERICS INTERNAZIONAL VENTURES ENTERPRISES LLC
  DI CYCLOM NE HYDROCHLORI DE, DI CYCLOM NE HYDROCHLORI DE

GENEYORK PHARMS
  * GENEYORK PHARMACEUTICALS GROUP LLC
  PREDNI SONE, PREDNI SONE

GENUS LI FESCI ENCES
  * GENUS LI FE SCI ENCES I NC
  GORELTO, COCAI NE HYDROCHLORI DE
  OXYCODONE, OXYCODONE HYDROCHLORI DE
  POTASSI UM CHLORI DE, POTASSI UM CHLORI DE
  YOSPRALA, ASPI RI N
  * GENUS LI FESCI ENCES I NC
  HYDROCODONE BI TARTRATE AND ACETAM NOPHEN, ACETAM NOPHEN

GENZYME
  * GENZYME CORP
  CEREZYME, I M GLUCERASE
  CLOLAR, CLOFARABI NE
  MOZI OBI L, PLERI XAFOR
  RENAGEL, SEVELAMER HYDROCHLORI DE
  RENVELA, SEVELAMER CARBONATE
  THYROGEN, THYROTROPI N ALFA

GENZYME CORP
  * GENZYME CORP
  CAPRELSA, VANDETANI B
  CERDELGA, ELI GLUSTAT TARTRATE

G LEAD
  * G LEAD SCI ENCES I NC
  CAYSTON, AZTREONAM
  EMTRI VA, EMTRI CI TABI NE
  HEPSENA, ADEFOMV R DI PI VOXI L
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** G **

* GILEAD SCIENCES INC
  LETAIRIS, AMBRISENTAN
  RANEXA, RANOLAZINE
  TRUVADA, EMTRICITABINE

* GILEAD SCIENCES LLC
  ATRIPLA, EFAVIRENZ

* GILEAD SCIENCES INC
  BIKTARVY, BICTEGRAVIR SODIUM
  COMPLERA, EMTRICITABINE
  DESCovy, EMTRICITABINE
  EPCLUSA, SOFOSBUVIR R
  GENVOYA, COBI CI STAT
  HARVONI, LEDI PASVI R
  ODEFSEY, EMTRICITABINE
  SOVALDI, SOFOSBUVIR R
  STRI BI LD, COBI CI STAT
  TYBOST, COBI CI STAT
  VEMLIDY, TENOFOS R ALAFENAM DE FUMARATE
  VI READ, TENOFOS R DI SORPH L FUMARATE
  VOSEVI, SOFOSBUVIR R
  ZYDELIG, I DELALI SI B

* GLAND PHARMA LTD
  ADENOSI NE, ADENOSI NE
  AM ODARONE HYDROCHLORI DE, AM ODARONE HYDROCHLORI DE
  ARGATROBAN I N SODI UM CHLORI DE, ARGATROBAN
  AZI THIMYCI N, AZI THIMYCI N
  CARBOPLATI N, CARBOPLATI N
  CASPOFUNGIN ACETATE, CASPOFUNGIN ACETATE
  CI SPLATI N, CI SPLATI N
  CLOFARABI NE, CLOFARABI NE
  DEFEROXAM NE MESYALTE, DEFEROXAM NE MESYALTE
  DEXRAZOKANE HYDROCHLORI DE, DEXRAZOKANE HYDROCHLORI DE
  DOXORUBI CI N HYDROCHLORI DE, DOXORUBI CI N HYDROCHLORI DE
  ETOM DATE, ETOM DATE
  FLUOROURACI L, FLUOROURACI L
  GEMI TABI NE HYDROCHLORI DE, GEMI TABI NE HYDROCHLORI DE
  HALOPERI DOL DECANOATE, HALOPERI DOL DECANOATE
  HALOPERI DOL, HALOPERI DOL LACTATE
  HEPARI N SODI UM, HEPARI N SODI UM
  KETOROLAC TROMETHAM NE, KETOROLAC TROMETHAM NE
  LABETALOL HYDROCHLORI DE, LABETALOL HYDROCHLORI DE
  LEVETI RACETAM I N SODI UM CHLORI DE, LEVETI RACETAM
  LEVOLEUCOVORI N CALCI UM, LEVOLEUCOVORI N CALCI UM
  MESNA, MESNA
  METHOCARBAMOL, METHOCARBAMOL
  METOPROL TARTRATE, METOPROL TARTRATE
  M DAZOLAM HYDROCHLORI DE, M DAZOLAM HYDROCHLORI DE
  M LRI NONE LACTATE, M LRI NONE LACTATE
  ONDANSETRONE HYDROCHLORI DE, ONDANSETRONE HYDROCHLORI DE
  OKALI PLATI N, OKALI PLATI N
  PACI TAXEL, PACI TAXEL
  POLYM/XI N B SULFATE, POLYM/XI N B SULFATE
  ROCRURONI UMBROM DE, ROCRURONI UMBROM DE
  TRANEXAM C ACI D, TRANEXAM C ACI D
  VANCOMCYI N HYDROCHLORI DE, VANCOMCYI N HYDROCHLORI DE
  VECURONI UMBROM DE, VECURONI UMBROM DE
  ZOLEDRONI C ACI D, ZOLEDRONI C ACI D
  ZOLEDRONI C, ZOLEDRONI C ACI D

* GLASSHOUSE PHARMA LTD
  CLINDAMYCIN PHOSPHATE, CLINDAMYCIN PHOSPHATE
** **

** GLASSHOUSE PHARMACEUTICALS LTD CANADA
FLUCONAZOLE DE, FLUCONAZOLE DE

** GLAXO GRP ENGLAND
* GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
INCRUSE ELLIPTA, UMECLIDINIUM BROMIDE

* GLAXO GROUP LTD DBA GLAXOSMITHKLINE
FLOVENT HFA, FLUTICASONE PROPIONATE

* GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
ADVAIR DRI SKUS 100/50, FLUTICASONE PROPIONATE
ADVAIR DRI SKUS 250/50, FLUTICASONE PROPIONATE
ADVAIR DRI SKUS 500/50, FLUTICASONE PROPIONATE
ADVAIR R HFA, FLUTICASONE PROPIONATE
BREO ELLIPTA, FLUTICASONE FURUATE
FLOVENT DI SKUS 100, FLUTICASONE PROPIONATE
FLOVENT DI SKUS 250, FLUTICASONE PROPIONATE
FLOVENT DI SKUS 50, FLUTICASONE PROPIONATE

** GLAXOSMITHKLINE
* GLAXOSMITHKLINE
ABREVA, DOCOSANOL (OTC)
AVODART, DUTASTERIDE DE
BECOMASE AQ, BECLOMETHASONE PAMPONATE MONOHYDRATE
EPIVI R-HBV, LAMIVUDINE NE
I M TREX STATDOSE, SUMATRIPTAN SUICIDES NATE
I M TREX, SUMATRIPTAN PTAN
I M TREX, SUMATRIPTAN SUICIDES NATE
J ALYN, DUTASTERIDE DE
MALARONE PEDIATRIC C, ATOVACQUONE
MALARONE, ATOVACQUONE
NI CORETTE (MNT), NI COTI NE POLACRILEX (OTC)
NI CORETTE, NI COTI NE POLACRILEX (OTC)
RELENZA, ZANAMIVIR V R
VALTREX, VALACYCLOVIR R HYDROCHLORIDE DE
WELLBUTRIN SR, BUPROPION ON HYDROCHLORIDE DE
ZYBAN, BUPROPION ON HYDROCHLORIDE DE

* GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDING INC (US) LLC
LAMISOL, TERBINAfine HYDROCHLORIDE (OTC)

* GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND
ANORO ELLIPTA, UMECLIDINIUM BROMIDE DE
ARNALTY ELLIPTA, FLUTICASONE FURUATE
KRI NTAFEL, TAFENOQUE SUICIDES NATE
TRELEGY ELLIPTA, FLUTICASONE FURUATE

* GLAXOSMITHKLINE INTELLECTUAL PROPERTY LTD ENGLAND
SEREVENT, SALMETEROL XI NAFOATE
VENTOLI N HFA, ALBUTEROL SULFATE

** GLAXOSMITHKLINE CONSUMER HEALTHCARE

** GLAXOSMITHKLINE CONSUMER HEALTHCARE
ALLI, ORLI STAT (OTC)
EXCEDRIN P (MGR (NE)), ACETAMINOPHEN (OTC)
FLONASE ALLERGY RELIS ARE, FLUTICASONE PROPIONATE (OTC)
FLONASE SENSITIVE RELIS ARE, FLUTICASONE FURUATE (OTC)
LAMISOL, TERBINAfine NE HYDROCHLORIDE (OTC)
LAMISOL, TERBINAfine NE HYDROCHLORIDE (OTC)
NI CORETTE, NI COTI NE POLACRILEX (OTC)
PREVACID 24 HR, LANSOPRAZOLE (OTC)
VOLTAREN, DICLOFENAC SODIUM

** GLAXOSMITHKLINE CONSUMER HEALTHCARE

** GLAXOSMITHKLINE CONSUMER HEALTHCARE
AMERGE, NARATRIPTAN HYDROCHLORIDE DE
DYAZIDE, HYDROCHLOROTHIAZIDE (OTC)
FLOLAN, EPoprostenol SODIUM (OTC)
LAMICTAL CD, LAMOTRIGINE
** GLAXOSMITHKLINE LLC **

- LAMICTAL ODT, LAMOTRIGINE
- LAMICTAL XR, LAMOTRIGINE
- LAMICTAL, LAMOTRIGINE
- MEPRON, ATOVACUONE
- RENOFLY, PROPILOLE HYDROCHLORIDE
- RENOFLY, PROPILOLE HYDROCHLORIDE

** GLENMARK **

- GLENMARK THERAPEUTICS CS INC USA
  - ECOZA, ECONAZOLE NITRATE
- GLENMARK GENERICS INC USA
  - ADAPALENE, ADAPALENE
  - BETADEMETHASONE DI PROPIONATE, BETADEMETHASONE DI PROPIONATE
  - CM QUI MOD, CM QUI MOD
  - DEXAMETHASONE FURATE, DEXAMETHASONE FURATE
  - NI ZATI DI NE, NI ZATI DI NE
  - ZONI SAM DE, ZONI SAM DE
- GLENMARK GENERICS LIMITED
  - ACAMPROSATE CALCIUM, ACAMPROSATE CALCIUM
  - ALCLOPIROX, ALCLOPIROX
  - CARVEDILOL, CARVEDILOL
  - CI CLOPIROX, CI CLOPIROX
  - CI TALOFLOXIC ACID, CI TALOFLOXIC ACID
  - DEZOPICLONE, DEZOPICLONE
  - EDICINE, EDDICINE
  - HEATHER, NORETHINDRONE
  - HYDROCORTISONE BUTYRATE, HYDROCORTISONE BUTYRATE
  - LAMOTRI NE, LAMOTRI NE
  - LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE DIHYDROCHLORIDE
  - LEVONORGESTREL AND ETHINYL Estradiol, ETHINYL Estradiol
  - LEVONORGESTREL AND ETHINYL Estradiol, ETHINYL Estradiol
  - MONTELUKAST SODIUM, MONTELUKAST SODIUM
  - NAPROXEN, NAPROXEN
  - NAPROXEN, NAPROXEN
  - ORAL, ORAL
  - ORAL, ORAL
  - ORAL, ORAL
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  - ORAL, ORAL
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** G **

* GLENMARK GENERICS LTD
  TROPIUM CHLORIDE, TROPIUM CHLORIDE
  URSDIOL, URSDIOL
  VERAPAM L HYDROCHLORIDE DE, VERAPAM L HYDROCHLORIDE DE
  VI CRELE, DESOGESTREL
  ZOLM TRI PTAN, ZOLM TRI PTAN

* GLENMARK GENERICS LTD I NDIA
  I NDOMETHACI N, I NDOMETHACI N
  NORETH NDRONE ACETATE, NORETH NDRONE ACETATE
  PRAM PEXOLE DI HYDROCHLORI DE, PRAM PEXOLE DI HYDROCHLORI DE

GLENMARK PHARMS

* GLENMARK PHARMEUTICS CALS I NC
  CLOBETASOL PROPI ONATE, CLOBETASOL PROPI ONATE
  TERIC FLUNUM DE, TERIC FLUNUM DE

* GLENMARK PHARMEUTICS CALS I NC USA
  CI CLOPI ROX, CI CLOPI ROX
  CLOTRI MAZOLE, CLOTRI MAZOLE
  MUPI ROCI N, MUPI ROCI N

* GLENMARK PHARMEUTICS CALS LTD
  MDEXI PRI L HYDROCHLORI DE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE

* GLENMARK PHARMEUTICS CALS SA
  ATOVAQUONE, ATOVAQUONE
  AZELAI C ACI D, AZELAI C ACI D
  CALCI POTRI ENE, CALCI POTRI ENE
  CLOBETASOL PROPI ONATE, CLOBETASOL PROPI ONATE
  CLOTRI MAZOLE AND BETAMETHASONE DI PROPI ONATE, BETAMETHASONE DI PROPI ONATE
  DESONI DE, DESONI DE
  HA LEY 1.5/30, ETHI NYL ESTRADI OL
  HA LEY FE 1.5/30, ETHI NYL ESTRADI OL
  LI NEZOLI D, LI NEZOLI D
  NORGESTI MATE AND ETHI NYL ESTRADI OL, ETHI NYL ESTRADI OL
  ROSUVA STATI N CALCI UM, ROSUVA STATI N, CALCI UM
  TRI AMI NOLONE ACETONI DE, TRI AMI NOLONE ACETONI DE

GLENMARK PHARMS I NC

* GLENMARK PHARMEUTICS CALS I NC USA
  CALCI POTRI ENE, CALCI POTRI ENE
  LI THI UM CARBONATE, LI THI UM CARBONATE
  MUPI ROCI N, MUPI ROCI N, CALCI UM
  RANI TI DI NE, HYDROCHLORI DE, RANI TI DI NE, HYDROCHLORI DE

GLENMARK PHARMS LTD

* GLENMARK PHARMEUTICS CALS LTD
  ACYLCLOM R, ACYLCLOM R
  AMLODI PI NE AND OLMESARTAN MEDOXOM L, AMLODI PI NE BESYLATE
  ATOMOXTI NE HYDROCHLORI DE, ATOMOXTI NE HYDROCHLORI DE
  BENDAMUSTI NE HYDROCHLORI DE, BENDAMUSTI NE HYDROCHLORI DE
  CLOBETASOL PROPI ONATE, CLOBETASOL PROPI ONATE
  COLESEVELAM HYDROCHLORI DE, COLESEVELAM HYDROCHLORI DE
  DESMOPRESSI N ACETATE, DESMOPRESSI N ACETATE
  DESONI DE, DESONI DE
  DI CLOFENAC SODI UM, DI CLOFENAC SODI UM
  DROPI RONE AND ETHI NYL ESTRADI OL, DROPI RONE
  ESTRADI OL, ESTRADI OL
  EZETI M BE, EZETI M BE
  FENOFI BRATE (M CRONI ZED), FENOFI BRATE
  FLUCI NOLONE ACETONI DE, FLUCI NOLONE ACETONI DE
  FLUCI NONI DE ACETONI DE, FLUCI NOLONE ACETONI DE
  FROVATI PTAN SUCCI NATE, FROVATI PTAN SUCCI NATE
  GABAPENTI N, GABAPENTI N
  HA LEY FE 1/20, ETHI NYL ESTRADI OL
  HYDRAZAE NE HYDROCHLORI DE, HYDRAZAE NE HYDROCHLORI DE
  HYDROCRITI SONE VALERATE, HYDROCRITI SONE VALERATE
  I NDOMETHACI N, I NDOMETHACI N
  LAMOTRI GI NE, LAMOTRI GI NE
  LEVONORGESTREL AND ETHI NYL ESTRADI OL, ETHI NYL ESTRADI OL
  LEVONORGESTREL, LEVONORGESTREL (OTC)
** G **

* GLENMARK PHARMACEUTICALS LTD
  LIDOCAINE, LIDOCAINE
  NAPROXEN SODIUM, NAPROXEN SODIUM
  NORLEINE ACETATE AND ETHYL ESTRADIOL AND FERROUS FUMARATE, ETHYL ESTRADIOL
  NORLEINE ACETATE AND ETHYL ESTRADIOL, ETHYL ESTRADIOL
  NYSTATIN AND TRIAMCINOLONE ACETONIDE, NYSTATIN
  OLMESARTAN MEDOXOMIL, OLMESARTAN MEDOXOMIL
  OXCARBAZEPINE, OXCARBAZEPINE
  POTASSIUM CHLORIDE, POTASSIUM CHLORIDE
  PROPAFENONE HYDROCHLORIDE, PROPAFENONE HYDROCHLORIDE
  RALOXIFENE HYDROCHLORIDE, RALOXIFENE HYDROCHLORIDE
  RILUZOLE, RILUZOLE
  RIZATRIPTAN BENZOATE, RIZATRIPTAN BENZOATE
  RUFINAMIDE, RUFINAMIDE
  TACROLIMUS, TACROLIMUS
  TEMLISARTAN, TEMLISARTAN
  TRIAMCINOLONE ACETONIDE, TRIAMCINOLONE ACETONIDE
  VORICONAZOLE, VORICONAZOLE

GLENMARK PHARMS SA
* GLENMARK PHARMACEUTICALS LTD SA SWITZERLAND
  APREPITANT, APREPITANT
  NITROGLYCERIN, NITROGLYCERIN

GLOBAL ISOTOPES LLC
* GLOBAL ISOTOPES LLC DBA ZEVACOR MOLECULAR
  AMMONIA N-13, AMMONIA N 13
  CHOLINE C-11, CHOLINE C-11
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18
  SODIUM FLUORIDE F-18, SODIUM FLUORIDE F-18

GP PHARM SA
* GP PHARM SA
  LUTRACYTE DEPOT KIT, LEUPROLIDE DE ACETATE

GRANULES INDIA
* GRANULES INDIA LTD
  IBUPROFEN, IBUPROFEN (OTC)
  METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE
  NAPROXEN SODIUM, NAPROXEN SODIUM (OTC)

GRANULES INDIA LTD
* GRANULES INDIA LTD
  CETIRIZINE HYDROCHLORIDE ALLERGY, CETIRIZINE HYDROCHLORIDE (OTC)
  IBUPROFEN, IBUPROFEN
  METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE
  METHOCARBAMOL, METHOCARBAMOL
  RANITIDINE HYDROCHLORIDE, RANITIDINE HYDROCHLORIDE (OTC)

GRANULES PHARMAS
* GRANULES PHARMACEUTICALS CALS INC
  METHYLGERONONI NE MALEATE, METHYLGERONONI NE MALEATE
  METHYLPHENI DATE HYDROCHLORIDE, METHYLPHENI DATE HYDROCHLORIDE

GRAM PHARMS
* GRAM PHARMACEUTICALS CALS PRI VATE LTD
  AMATANDI NE HYDROCHLORIDE DE, AMATANDI NE HYDROCHLORIDE DE
  ATORVASTATIN CALCI UM, ATORVASTATIN CALCI UM
  FENOFIBRATE, FENOFIBRATE

GUARDIAN DRUG
* GUARDIAN DRUG CO
  GUAI FENESI N, GUAI FENESI N (OTC)
  IBUPROFEN, IBUPROFEN (OTC)

GUERBET
* GUERBET LLC
  DOTAREM, DOTAREM GADOTERATE MEGLUM NE
  LI PI ODOL, LI PI ODOL

GW RES LTD
* GW RESEARCH LTD
### Appendix B - Product Name Sorted by Applicant

#### **G**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPIDIOLEX, CANNABIDIOL</td>
<td>GW RESEARCH LTD</td>
</tr>
<tr>
<td>AMPICILLIN AND SULBACTAM</td>
<td>GC HANFORD MANUFACTURING CO</td>
</tr>
<tr>
<td>AMPICILLIN SODIUM</td>
<td>GC HANFORD MANUFACTURING CO</td>
</tr>
<tr>
<td>PENICILLIN G POTASSIUM</td>
<td>GC HANFORD MANUFACTURING CO</td>
</tr>
<tr>
<td>GONI TRO, NITROGLYCERIN</td>
<td>G POHL BOSKAMP GMBH AND CO KG</td>
</tr>
</tbody>
</table>

#### **H**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM CHLORIDE 0.9%</td>
<td>HAEMONETICS CORP</td>
</tr>
<tr>
<td>AZITHROMYCIN</td>
<td>HALOCARBON PRODUCTS CORP</td>
</tr>
<tr>
<td>GANCICLOVIR SODIUM</td>
<td>HALOZYME THERAPEUTICS CS INC</td>
</tr>
<tr>
<td>LEVETIRACETAM</td>
<td>HALOZYME THERAPEUTICS CS INC</td>
</tr>
<tr>
<td>VORI CONAZOLE</td>
<td>HALOZYME THERAPEUTICS CS INC</td>
</tr>
<tr>
<td>ISOFLURANE</td>
<td>HANGZHOU BI N J IANG</td>
</tr>
<tr>
<td>SEVOFLURANE</td>
<td>HANGZHOU BI N J IANG</td>
</tr>
<tr>
<td>PENTETATE CALCIUM TRISODIUM</td>
<td>HANSAMED I NC</td>
</tr>
<tr>
<td>PENTETATE CALCIUM TRISODIUM</td>
<td>HARRI S PHARM</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HEBEI CHANGSHAN</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HEELS NI</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HEC PHARM</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HELSI NI</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HELSI NI HEALTHCARE SA</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HELSI NI</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HELSI NI HEALTHCARE SA</td>
</tr>
<tr>
<td>PENTETATE ZI NC TRISODIUM</td>
<td>HELSI NI HEALTHCARE SA</td>
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</tbody>
</table>

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*Abbreviations: GA = GABA, GLS = GABAergic ligand site.*
# APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

**H**

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>HELSINN HEALTHCARE SA</td>
<td>ALOXI, PALONOSETRON HYDROCHLORIDE</td>
</tr>
<tr>
<td>HERCON PHARM  LLC</td>
<td>NI TROGLYCRENI N, NI TROGLYCERI N</td>
</tr>
<tr>
<td>HERITAGE LI FE</td>
<td>CLOZAPI L, CLOZARI L</td>
</tr>
<tr>
<td>HERITAGE PHARMA LABS INC</td>
<td>ACETAM NOPHEN, ACETAM NOPHEN (OTC), ACETAZOLAM DE, ACETAZOLAM DE</td>
</tr>
<tr>
<td>HERITAGE PHARMA LABS INC</td>
<td>AMANTADI NE HYDROCHLORIDE DE, AMANTADI NE HYDROCHLORIDE DE BETHANECHOL CHLORIDE DE, BETHANECHOL CHLORIDE DE BUSPI RONE HYDROCHLORIDE DE, BUSPI RONE HYDROCHLORIDE DE DESMOPIRESSI N ACETATE, DESMOPIRESSI N ACETATE DI FLUNI SAL, DI FLUNI SAL DOKAZOSI N MESYLATE, DOKAZOSI N MESYLATE HYDROXYZI NE HYDROCHLORIDE DE, HYDROXYZI NE HYDROCHLORIDE DE HYDROXYZI NE PAMDATE, HYDROXYZI NE PAMDATE LI THI UM CARBONATE, LI THI UM CARBONATE METH MAZOLE, METH MAZOLE NI FEDI PI NE, NI FEDI PI NE</td>
</tr>
<tr>
<td>HERON THERAPEUTIS INC</td>
<td>CI NIVANTI, APRIPIT AN T, SUSTOL, GRANIT, T ETRON</td>
</tr>
<tr>
<td>HETERO LABS LTD III</td>
<td>HETERO LABS LTD UNI T III I I</td>
</tr>
</tbody>
</table>

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- **H** represents the start of the list of products sorted alphabetically by applicant name starting with 'H'.
- Each applicant is followed by a list of product names they are associated with.
- The format is consistent throughout, listing both generic and, where applicable, trade names.

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The table provides a structured overview of the products listed under the Applicant column, offering a clear and concise representation of the approved drug products in 39th edition of the Approved Drug Product List.
** H **

* HETERO LABS LTD UNIT III
  ABACAVIR SULFATE, ABACAVIR SULFATE
  ATOVACUONE, ATOVACUONE
  CI TALOPRAM HYDROBROM DE, CI TALOPRAM HYDROBROM DE
  CLOBAZAM, CLOBAZAM
  DULOXETIN NE HYDROCHLORI DE, DULOXETIN NE HYDROCHLORI DE
  EFAVIRAN, EFAVIRAN
  ESCI TALOPRAM OKALE, ESCI TALOPRAM OKALE
  ESCIMEPRAZOLE MAGNESIUM, ESCIMEPRAZOLE MAGNESIUM
  FENOFIBRATE, FENOFIBRATE
  FI NASTERI DE, FI NASTERI DE
  HYDRALAZIN NE HYDROCHLORI DE, HYDRALAZIN NE HYDROCHLORI DE
  HYDROXYZI NE HYDROCHLORI DE, HYDROXYZI NE HYDROCHLORI DE
  I NDOMETHACI N, I NDOMETHACI N
  LAM VUDI NE AND ZI DOVUDI NE, LAM VUDI NE
  LEVETI RACETAM, LEVETI RACETAM
  LEVOCETI R ZI NE DI HYDROCHLORI DE, LEVOCETI R ZI NE DI HYDROCHLORI DE
  LI THIUM CARBONATE, LI THIUM CARBONATE
  METHOCARBAMOL, METHOCARBAMOL
  NEVI RAPID DE, NEVI RAPID DE
  OSELTAM VI R PHOSPHATE, OSELTAM VI R PHOSPHATE
  RI TONAVI R, RI TONAVI R
  ROFLUM LAST, ROFLUM LAST
  SI MASTATI N, SI MASTATI N
  STAVUDI NE, STAVUDI NE
  TENOFORI R DI SOPROXI L FUMARATE, TENOFORI R DI SOPROXI L FUMARATE
  TOLERODI NE TARTRATE, TOLERODI NE TARTRATE
  TORSEM DE, TORSEM DE
  ZI DOVUDI NE, ZI DOVUDI NE

HETERO LABS LTD UNIT V
  ACMCYLO R, ACMCYLO R
  AMI PRAZOLO, AMI PRAZOLO
  CHI LDREN S FEXOFENADI NE HYDROCHLORI DE ALLERGY, FEXOFENADI NE HYDROCHLORI DE (OTC)
  DONPEZI L HYDROCHLORI DE, DONPEZI L HYDROCHLORI DE
  ENTECPAVI R, ENTECPAVI R
  FAMO CLOFI R, FAMO CLOFI R
  FEXOFENADI NE HYDROCHLORI DE ALLERGY, FEXOFENADI NE HYDROCHLORI DE (OTC)
  I RBESARTAN, I RBESARTAN
  LAM VUDI NE AND ZI DOVUDI NE, LAM VUDI NE
  LAM VUDI NE, LAM VUDI NE
  LEVOFLOXIACI N, LEVOFLOXIACI N
  LI NEZOLI D, LI NEZOLI D
  LOSARTAN POTASSIUM, LOSARTAN POTASSIUM
  MONTIELIUSK SODIUM, MONTIELIUSK SODIUM
  PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM
  ROUVASTATINA CALCIUM, ROUVASTATINA CALCIUM
  SI LLDAFI L DI TRATE, SI LLDAFI L DI TRATE
  TELM SARTAN, TELM SARTAN
  TETRABENAZI NE, TETRABENAZI NE
  VAFCYCLO R HYDROCHLORI DE, VAFCYCLO R HYDROCHLORI DE
  VAGIANI CLOFI R HYDROCHLORI DE, VAGIANI CLOFI R HYDROCHLORI DE
  VALSARTAN, VALSARTAN

HEYL CHEM SCH
  HEYL CHEM SCH PHARMACEUTIS S FABRI K
  RADIOGARASE (PRUSSI AN BLU), FERRIC HEXACYANOFERRATE(III)

HI TECH PHARMA
  H1 TECH PHARMA C P NP
  ACETAMINOPHEN AND CODEINE NE PHOSPHATE, ACETAMINOPHEN
  ACMCYLO R, ACMCYLO R
  ALBUTEROL SULFATE, ALBUTEROL SULFATE
  AMI PRAZOLO NE HYDROCHLORI DE, AMI PRAZOLO NE HYDROCHLORI DE
  CALCI POTRI ENE, CALCI POTRI ENE
  CHLORHEXI DI NE GLUCONATE, CHLORHEXI DI NE GLUCONATE
  CI CLOPI ROX, CI CLOPI ROX
** H **

HI TECH PHARMACAL CO INC
- CI METI DI NE HYDROCHLORIDE DE, CI METI DI NE HYDROCHLORIDE DE
- CORAX, CLOBETASOL PROPI ONATE
- DORZOLAM DE HYDROCHLORIDE DE AND TI MOLOL MALEATE, DORZOLAM DE HYDROCHLORIDE DE
- DORZOLAM DE HYDROCHLORIDE DE, DORZOLAM DE HYDROCHLORIDE DE
- EMBELINE E, CLOBETASOL PROPI ONATE
- EMBELINE, CLOBETASOL PROPI ONATE
- FLUTI CASONE PROPI ONATE, FLUTI CASONE PROPI ONATE
- GABAPENTI N, GABAPENTI N
- HYDROCODONE BI TARTRATE AND HOMATROPI NE METHYLBRONDE, HOMATROPI NE METHYLBRONDE
- HYDROXYZI NE HYDROCHLORIDE DE, HYDROXYZI NE HYDROCHLORIDE DE
- LACTULOSE, LACTULOSE
- LEVOCARNI TI NE, LEVOCARNI TI NE
- LEVOLOXACI N, LEVOLOXACI N
- LI DOCAI NE AND PRI LOCAI NE, LI DOCAI NE
- LI DOCAI NE HYDROCHLORIDE DE, LI DOCAI NE HYDROCHLORIDE DE
- LOPERAM DE HYDROCHLORIDE DE, LOPERAM DE HYDROCHLORIDE DE (OTC)
- M DAZOLAM HYDROCHLORIDE DE, M DAZOLAM HYDROCHLORIDE DE
- M NOXI DI L (FOR MEN), M NOXI DI L (OTC)
- M NOXI DI L (FOR WOMEN), M NOXI DI L (OTC)
- NYSTATI N, NYSTATI N
- OFLOXACI N, OFLOXACI N
- PREDNI SOLONE SODIUM PHOSPHATE, PREDNI SOLONE SODIUM PHOSPHATE
- PROMETHAZI NE HYDROCHLORIDE DE AND CODEI NE PHOSPHATE, CODEI NE PHOSPHATE
- PROMETHAZI NE HYDROCHLORIDE DE AND DEXTROMETHORPHAN HYDROBROM DE, DEXTROMETHORPHAN
- PROMETHAZI NE HYDROCHLORIDE DE, PROMETHAZI NE HYDROCHLORIDE DE
- RANITI DI NE HYDROCHLORIDE DE, RANITI DI NE HYDROCHLORIDE DE
- SULFAMETHOXAZOLE AND TRI M ETHOPHRI M, SULFAMETHOXAZOLE
- TI MOLOL MALEATE, TI MOLOL MALEATE
- VOSOL HC, ACETI C ACI D, GLACI AL
- VOSOL, ACETI C ACI D, GLACI AL

HI TECH PHARMA CO
- HI TECH PHARMACAL CO INC
- FLUNI SOLI DE, FLUNI SOLI DE
- PREDNI SOLONE, PREDNI SOLONE

HI - TECH PHARMA CO
- HI - TECH PHARMACAL CO INC
- BI MATOPROST, BI MATOPROST
- FAMOTI DI NE, FAMOTI DI NE
- GATI FLOXACI N, GATI FLOXACI N
- LORAZEPAM, LORAZEPAM
- PROMETHAZI NE HYDROCHLORIDE DE, PHENYLEPHRI NE HYDROCHLORIDE DE W CODEI NE PHOSPHATE, CODEI NE

HI - TECH PHARMACAL
- HI - TECH PHARMACAL CO INC
- BETAMETHASONE DI PROPONATE, BETAMETHASONE DI PROPONATE
- BI MATOPROST, BI MATOPROST
- BROMFENAC SODIUM, BROMFENAC SODIUM
- CLOBETASOL PROPI ONATE, CLOBETASOL PROPI ONATE
- DESONI DE, DESONI DE
- DI CLOFENAC SODIUM, DI CLOFENAC SODIUM
- I BUROPHEN I, BUROPHEN I
- LEVETI RACETAM, LEVETI RACETAM
- MEGESTROL ACETATE, MEGESTROL ACETATE
- MORPHI NE SULFATE, MORPHI NE SULFATE
- OXYCODONE HYDROCHLORIDE DE, OXYCODONE HYDROCHLORIDE DE
- PHENYLEPHRI NE HYDROCHLORIDE DE AND PROMETHAZI NE HYDROCHLORIDE DE, PHENYLEPHRI NE
- TRI FLURI DI NE, TRI FLURI DI NE

H GH TECH PHARMA
- H GH TECHNOLOGY PHARMACAL CO INC
- VALPROI C ACI D, VALPROI C ACI D

HI KMA
- HI KMA FARMACEUTI CA LDA
- CEFOTAXI ME, CEFOTAXI ME SODIUM
- HI KMA PHARMACEUTI CALS
- AMOXI CI LLI N, AMOXI CI LLI N
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

** H **

- **HI KMA PHARMAEUUTICALS LLC**
  - CEFACLOR, CEFACLOR
  - CEFADROXI L, CEFADROXI L/CEFADROXI L HEMI HYDRATE
  - CEPHALEXI N, CEPHALEXI N
  - CI PROFLOXACIN HYDROCHLORIDE DE, CI PROFLOXACIN HYDROCHLORIDE DE
  - GLYBURIDE (M CRONI ZED), GLYBURIDE

- **HI KMA FARMACEUTICA CA (PORTUGAL) SA**
  - AMIODARONE HYDROCHLORIDE, AMIODARONE HYDROCHLORIDE
  - BENZTROPI NE MESYLATE, BENZTROPI NE MESYLATE
  - BUTORPHANOL TARTRATE, BUTORPHANOL TARTRATE
  - CEFOKI TI N, CEFOKI TI N SODI UM
  - CEFTRIAXON AXONE, CEFTRI AXONE SODI UM
  - CI PROFLOXACIN I N DEXTROSE 5% I N PLASTIC CONTAINER, CI PROFLOXACIN I N
  - CI PROFLOXACIN N, CI PROFLOXACIN N
  - CLONIDINE HYDROCHLORIDE, CLONIDINE HYDROCHLORIDE
  - LEVETIRACETAM, LEVETIRACETAM
  - LEVOFLOXACIN I N DEXTROSE 5% I N PLASTIC CONTAINER, LEVOFLOXACIN I N
  - METOPROLOL TARTRATE, METOPROLOL TARTRATE
  - M LRI NONE LACTATE I N PLASTIC CONTAINER, M LRI NONE LACTATE
  - ONDANSETRON HYDROCHLORIDE DE, ONDANSETRON HYDROCHLORIDE

- **HI KMA FARMACEUTICA CA PORTUGAL LDA**
  - CEFAZOLIN SODIUM, CEFAZOLIN SODIUM
  - CEFUROXIME SODIUM, CEFUROXIME SODIUM
  - FLUCONAZOLE IN SODIUM CHLORIDE 0.9%, FLUCONAZOLE

- **HI KMA FARMACEUTICA CA PORTUGAL SA**
  - CIFOTETAN, CIFOTETAN IN SODI UM
  - CIFUROXIM SODI UM, CIFUROXIM SODI UM
  - DI LTI AZEM HYDROCHLORIDE DE, DI LTI AZEM HYDROCHLORIDE DE
  - ETOM DATE, ETOM DATE
  - METHYLPRIDNI SOLONE SODI UM SUCCI NATE, METHYLPRIDNI SOLONE SODI UM SUCCI NATE
  - NOREPI NEPHRI NE BI TARTRATE, NOREPI NEPHRI NE BI TARTRATE
  - OXYTOCIN N, OXYTOCIN N
  - SUMATRIPTAN SUCCI NATE, SUMATRIPTAN SUCCI NATE
  - TESTOSTERONE ENANTHATE, TESTOSTERONE ENANTHATE
  - VANCOMYCIN HYDROCHLORIDE DE, VANCOMYCIN HYDROCHLORIDE DE

- **HI KMA FARMACEUTICA CA SA**
  - ZOLEDRON C ACI D, ZOLEDRON C ACI D

- **HI KMA INTERNATIONAL PHARMA LLC**
  - BUTALBITAL, ASPIRIN AND CAFFEINE, ASPIRIN
  - CARISOPRODOL, CARISOPRODOL
  - CORTISONE ACETATE, CORTISONE ACETATE
  - DIGOXIN, DIGOXIN
  - HYDROCORTISONE, HYDROCORTISONE
  - DOXYCYCLINE HYCLATE, DOXYCYCLINE HYCLATE
  - ERGOTAMINE TARTRATE AND CAFFEINE, CAFFEINE
  - DOPAMINE HYDROCHLORIDE DE, DOPAMINE HYDROCHLORIDE DE
  - DOXYCYCLINE HYCLATE, DOXYCYCLINE HYCLATE
  - HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  - HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  - HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** H **

* HI KMA INTERNATI ONAL PHARMACEUTI CALS LLC
  - ISOSORBIDE DINITRATE, ISOSORBIDE DINITRATE
  - LISINOPRIL AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  - LISINOPRIL, LISINOPRIL
  - METHOCARBAMOL, METHOCARBAMOL
  - M T GARE, COLCHIC IN
  - PRI M DONE, PRI M DONE

* HI KMA PHARMACY LTD
  - HIKMA INTERNATIONAL PHARMACEUTICALS LLC
  - AMLODI PI N AND CLAVULANATE POTASSI UM, AMLODI PI N
  - AMLODI PI N, AMLODI PI N
  - CEFA DROXI L, CEFA DROXI L HEMI HYDRATE
  - DI CYCLOM NE HYDROCHLORI DE, DI CYCLOM NE HYDROCHLORI DE
  - DI HYDROERGOTAM NE MESYLA TE, DI HYDROERGOTAM NE MESYLA TE
  - ESCI TALOPRAM OKALATE, ESCI TALOPRAM OKALATE
  - FLUDROCORTI SONE ACETATE, FLUDROCORTI SONE ACETATE
  - GENFI BROZI L, GENFI BROZI L
  - I SOSORBI DE MONONI TRATE, I SOSORBI DE MONONI TRATE
  - LETROZOLE, LETROZOLE
  - MODAFI NI L, MODAFI NI L
  - PENI CI LLI N V POTASSI UM, PENI CI LLI N V POTASSI UM
  - RI FAMPI N, RI FAMPI N
  - VANCOMYCIN HYDROCHLORIDE, VANCOMYCIN HYDROCHLORIDE

* HI KMA PHARMACEUTICALS CO LTD
  - PARICALCITOL

* HI KMA PHARMACEUTICALS LLC
  - AMLODI PI N BESYLA TE, AMLODI PI N BESYLA TE
  - AMOXI CI LLI N AND CLAVULANATE POTASSI UM, AMOXI CI LLI N
  - DI CYCLOM NE HYDROCHLORI DE, DI CYCLOM NE HYDROCHLORI DE
  - ESCI TALOPRAM OKALATE, ESCI TALOPRAM OKALATE
  - FLUDROCORTI SONE ACETATE, FLUDROCORTI SONE ACETATE
  - GENFI BROZI L, GENFI BROZI L
  - I SOSORBI DE MONONI TRATE, I SOSORBI DE MONONI TRATE
  - LETROZOLE, LETROZOLE
  - MODAFI NI L, MODAFI NI L
  - PENI CI LLI N V POTASSI UM, PENI CI LLI N V POTASSI UM
  - RI FAMPI N, RI FAMPI N
  - VANCOMYCIN HYDROCHLORIDE, VANCOMYCIN HYDROCHLORIDE

* HI L DERMAC
  - AB I RATERONE ACETATE, AB I RATERONE ACETATE
  - BUTALBI TAL, ACETAM NPHEN AND CAFFE I N, ACETAM NPHEN
  - CHLOROQUINE NE PHOSPHATE, CHLOROQUINE NE PHOSPHATE
  - DANTROLENE SODI UM, DANTROLENE SODI UM
  - DOKERCALCI FEROL, DOKERCALCI FEROL
  - FOLI C ACI D, FOLI C ACI D
  - HYDROXYCHLOROQUINE NE SULFATE, HYDROXYCHLOROQUINE NE SULFATE
  - I SOSORBI DE MONONI TRATE, I SOSORBI DE MONONI TRATE
  - OLANZAPI NE, OLANZAPI NE
  - PI ROXI CAM, PI ROXI CAM
  - PREDNI SONE, PREDNI SONE
  - ZALEPLON

* HI L DER MAC TEUTI CALS
  - DERMAC-SMOOTH/FS, FLUCI NOLONE ACETONI DE
  - DERMAC TEUTI CALS

* HI L DER MAC TEUTI CALS I NC
  - TOLAK, FLUCI NOLONE ACETONI DE

* HI SAM TSU PHARM CO
  - SAM TSU PHARMACEUTICALS CAL CO I NC
  - SALONPAS, MENTHOL (OTC)

* HI SUN PHARM HANGZHOU
  - SUN PHARMACEUTICALS CAL (HANGZHOU) CO LTD
  - IRBESARTAN AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  - IRBESARTAN, IRBESARTAN
  - RI NOTECAN HYDROCHLORI DE, RI NOTECAN HYDROCHLORI DE

* HI SUN PHARMACEUTICALS CAL HANGZHOU CO LTD
  - CAPREOMYCIN SULFATE, CAPREOMYCIN SULFATE
  - DIONEPEZI L HYDROCHLORI DE, DIONEPEZI L HYDROCHLORI DE
  - PRAVASTATI N SODI UM, PRAVASTATI N SODI UM

HOFMANN LA ROCHE
  - HOFMANN LA ROCHE I NC
  - BONI VA, BANDRONATE SODI UM
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DEXTROSE 25% DEXTROSE
DEXTROSE 5% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 50% IN PLASTIC CONTAINER, DEXTROSE
DEXTROSE 50% DEXTROSE
DI AZEPAM, DI AZEPAM
DI LTI AZEM HYDROCHLORIDE DE, DI LTI AZEM HYDROCHLORIDE DE
DI PHENHYDRAM NE HYDROCHLORIDE DE, DI PHENHYDRAM NE HYDROCHLORIDE DE
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DOBAMNE HYDROCHLORIDE DE, DOBAMNE HYDROCHLORIDE DE
DROPERIDOL, DROPERIDOL
ENAPRI LAT, ENAPRI LAT
EPI RUBI CI N HYDROCHLORIDE DE, EPI RUBI CI N HYDROCHLORIDE DE
ERYTHROCI N, ERYTHROMYCI N LACTOBI CNATE
FENTANYL CI TRATE PRESERVATIVE FREE, FENTANYL CI TRATE
FENTANYL CI TRATE, FENTANYL CI TRATE
FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER, FLUCONAZOLE
FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, FLUCONAZOLE
FUROSEMIDE, FUROSEMIDE
GENTAM CI N SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, GENTAM CI N SULFATE
GENTAM CI N SULFATE, GENTAM CI N SULFATE
HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, HEPARI N
HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER, HEPARI N SODIUM
HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER, HEPARI N SODIUM
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KETAM NE HYDROCHLORIDE DE, KETAM NE HYDROCHLORIDE DE
KETOROLAC TROMETHAM NE, KETOROLAC TROMETHAM NE
LABETALOL HYDROCHLORIDE DE, LABETALOL HYDROCHLORIDE DE
LEVOPHED, NOREPI NEPHRI NE BI TARTRATE
LI DOCAI NE HYDROCHLORIDE DE 5% AND DEXTROSE 7.5%, LI DOCAI NE HYDROCHLORIDE DE
LI DOCAI NE HYDROCHLORIDE DE AND EPI NEPHRI NE, EPI NEPHRI NE
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LI DOCAI NE HYDROCHLORIDE DE, LI DOCAI NE HYDROCHLORIDE DE
LORAZEPAM, LORAZEPAM
M.V.I. ADULT (PHARMACY BULK PACKAGE), ASCORB C ACI D
M.V.I. ADULT, ASCORB C ACI D
M.V.I. PEDI ATRI C, ASCORB C ACI D
MAGNESIUM SULFATE IN DEXTROSE 5% IN PLASTIC CONTAINER, MAGNESIUM SULFATE
MAGNESIUM SULFATE IN PLASTIC CONTAINER, MAGNESIUM SULFATE
MAGNESIUM SULFATE, MAGNESIUM SULFATE
MANGANESE CHLORIDE IN PLASTIC CONTAINER, MANGANESE CHLORIDE IN PLASTIC CONTAINER
MANN TOL 25%, MANN TOL
MARCAI NE HYDROCHLORIDE DE PRESERVATIVE FREE, BUPI VACAI NE HYDROCHLORIDE DE
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METOPROLOL TARTRATE, METOPROLOL TARTRATE
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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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| HOSPIRA INC | CEFTRIAXONE, CEFTRIAXONE SODIUM |
| HOSPIRA INC | CEFUROXIME SODIUM, CEFUROXIME SODIUM |
| HOSPIRA INC | CLOFARABINE, CLOFARABINE |
| HOSPIRA INC | DAPTOMYCIN, DAPTOMYCIN |
| HOSPIRA INC | DOCETAXEL, DOCETAXEL |
| HOSPIRA INC | DOKERCALCI FERL, DOKERCALCI FEROL |
| HOSPIRA INC | GEMC TABI NE HYDROCHLORI DE, GEMC TABI NE HYDROCHLORI DE |
| HOSPIRA INC | HEPARI N SODI UM, HEPARI N SODI UM |
| HOSPIRA INC | HYDROMORPHONE HYDROCHLORI DE, HYDROMORPHONE HYDROCHLORI DE |
| HOSPIRA INC | I M PENEM AND CI LASTATI N, CI LASTATI N SODI UM |
| HOSPIRA INC | I NDOMETHACI N SODI UM, I NDOMETHACI N SODI UM |
| HOSPIRA INC | LEVETI RACETAM, LEVETI RACETAM |
| HOSPIRA WORLDWIDE | LEVOFLOXACI N I N DEXTROSE 5% I N PLASTI C CONTAI NER, LEVOFLOXACI N |
| HOSPIRA WORLDWIDE | LI NEZOLI D I N SODI UM CHLORI DE 0.9% I N PLASTI C CONTAI NER, LI NEZOLI D |
| HOSPIRA WORLDWIDE | LI NEZOLI D, LI NEZOLI D |
| HOSPIRA WORLDWIDE | MAGNESI UM SULFATE, MAGNESI UM SULFATE |
| HOSPIRA WORLDWIDE | MAXI PI ME, CEFEPIMI HYDROCHLORI DE |
| HOSPIRA WORLDWIDE | MEROPENEM, MEROPENEM |
| HOSPIRA WORLDWIDE | M I LRI NONE LACTATE, M I LRI NONE LACTATE |
| HOSPIRA WORLDWIDE | MORPHI NE SULFATE, MORPHI NE SULFATE |
| HOSPIRA WORLDWIDE | NI PENT, PENTOSTATI N |
| HOSPIRA WORLDWIDE | OKACI LLI N SODI UM, OKACI LLI N SODI UM |
| HOSPIRA WORLDWIDE | OKALI PLATI N, OKALI PLATI N |
| HOT SHOTS NM LLC | PALONOSETRON HYDROCHLORI DE, PALONOSETRON HYDROCHLORI DE |
| HOT SHOTS NM LLC | PARI CALCI TOL, PARI CALCI TOL |
| HOT SHOTS NM LLC | PI PERACI LLI N AND TAZOBACTAM, PI PERACI LLI N SODI UM |
| HOT SHOTS NM LLC | SODI UM BI CARBONATE, SODI UM BI CARBONATE |
| HOT SHOTS NM LLC | TACROLI MUS, TACROLI MUS |
| HOT SHOTS NM LLC | TOPOTECAN HYDROCHLORI DE, TOPOTECAN HYDROCHLORI DE |
| HOT SHOTS NM LLC | VANCOMYCIN N HYDROCHLORI DE, VANCOMYCIN N HYDROCHLORI DE |
| HOT SHOTS NM LLC | ZOLEDRONI C ACI D, ZOLEDRONI C ACI D |

** HOSPIRA WORLDWIDE DE **

| HOSPIRA WORLDWIDE DE | OXALI PLATI N, OXALI PLATI N |

** HOT SHOTS NM LLC **

| HOT SHOTS NM LLC | FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18 |
| HOT SHOTS NM LLC | SODI UM FLUORI DE F-18, SODI UM FLUORI DE F-18 |

** HOUSTON CYCLOTRON **

| HOUSTON CYCLOTRON PARTNERS LP | AMMONI A N 13, AMMONI A N-13 |
| HOUSTON CYCLOTRON PARTNERS LP | FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18 |
| HOUSTON CYCLOTRON PARTNERS LP | SODI UM FLUORI DE F-18, SODI UM FLUORI DE F-18 |

** HQ SPECI ALTY PHARMA **

| HQ SPECI ALTY PHARMA CORP | CALCI UM GLUCONATE I N SODI UM CHLORI DE, CALCI UM GLUCONATE |
| HQ SPECI ALTY PHARMA CORP | CI SPLATI N, CI SPLATI N |
| HQ SPECI ALTY PHARMA CORP | DEXMEDETOM DI NE HYDROCHLORI DE, DEXMEDETOM DI NE HYDROCHLORI DE |
| HQ SPECI ALTY PHARMA CORP | ESMOLOL HYDROCHLORI DE DOUBLE STRENGTH I N PLASTI C CONTAI NER, ESMOLOL HYDROCHLORI DE |
| HQ SPECI ALTY PHARMA CORP | ESMOLOL HYDROCHLORI DE I N PLASTI C CONTAI NER, ESMOLOL HYDROCHLORI DE |
| HQ SPECI ALTY PHARMA CORP | LI NEZOLI D, LI NEZOLI D |
| HQ SPECI ALTY PHARMA CORP | MAGNESI UM SULFATE I N DEXTROSE 5% I N PLASTI C CONTAI NER, MAGNESI UM SULFATE |
| HQ SPECI ALTY PHARMA CORP | MAGNESI UM SULFATE I N PLASTI C CONTAI NER, MAGNESI UM SULFATE |
| HQ SPECI ALTY PHARMA CORP | TAXOL, PACLI TAXEL |

** HQ SPECI ALTY PHARMA **

| HQ SPECI ALTY PHARMA LLCC | LEVETI RACETAM I N SODI UM CHLORI DE, LEVETI RACETAM |

** HUMANWELL PURACAP **

| HUMANWELL PURACAP PHARMAECUTI CAL VIWHAN CO LTD | DUTASTERI DE, DUTASTERI DE |
| HUMANWELL PURACAP PHARMAECUTI CAL VIWHAN CO LTD | I BUPROFEN, I BUPROFEN (OTC) |

** HZNP **

| HZNP MEDI CI NES LLC | M GERGOT, CAFFEIN |
| HZNP MEDI CI NES LLC | M GERGOT, CAFFEIN |
** H **

- ** HZNP MEDICINES LLC **
  - PENNSAID, DICLOFENAC SODIUM

- ** ROCHE **
  - BONIVA, IBANDRONATE SODIUM
  - FUZEON, ENFUVIRTIDE
  - KLONOPIN, CLONAZEPAM
  - TAM FLU, OSELTAMIVIR VI R PHOSPHATE
  - VALI UM, DI AZEPAM

** I **

- ** IBSA INST BIO **
  - IBSA INSTITUT BIOCHIMIQUE SA
  - LICART, DICLOFENAC EPOLAMINE

- ** I CU MEDI CAL INC **
  - I CU MEDI CAL INC
    - ACETI C ACI D 0.25% I N PLASTI C CONTAI NER
    - ACETI C ACI D, GLACIAL
    - AM NOSYN 10% AM NO ACI DS
    - AM NOSYN 3.5% M AM NO ACI DS
    - AM NOSYN 8.5% W ELECTROLYTES AM NO ACI DS
    - AM NOSYN 8.5% AM NO ACI DS
    - AM NOSYN 11 10% I N PLASTI C CONTAI NER AM NO ACI DS
    - AM NOSYN 11 15% I N PLASTI C CONTAI NER AM NO ACI DS
    - AM NOSYN PF 10% AM NO ACI DS
    - AM NOSYN PF 7% AM NO ACI DS
    - DEXTROSE 10% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 20% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 30% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 40% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 5% AND LACTATED RINGER'S I N PLASTI C CONTAI NER CALCI UM CHLORI DE
    - DEXTROSE 5% AND SODI UM CHLORI DE 0.225% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 5% AND SODI UM CHLORI DE 0.3% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 5% AND SODI UM CHLORI DE 0.45% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 5% AND SODI UM CHLORI DE 0.9% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 5% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 50% I N PLASTI C CONTAI NER DEXTROSE
    - DEXTROSE 70% I N PLASTI C CONTAI NER DEXTROSE
    - GLYCI NE 1.5% I N PLASTI C CONTAI NER GLYCI NE
    - IONSOL MB AND DEXTROSE 5% I N PLASTI C CONTAI NER DEXTROSE
    - LACTATED RINGER'S I N PLASTI C CONTAI NER CALCI UM CHLORI DE
    - MANNI TOL 20% I N PLASTI C CONTAI NER MANNI TOL
    - MORPHI NE SULFATE MORPHI NE SULFATE
    - NORMOSOL-M AND DEXTROSE 5% I N PLASTI C CONTAI NER DEXTROSE
    - NORMOSOL-M AND DEXTROSE 5% I N PLASTI C CONTAI NER DEXTROSE
    - NORMOSOL-R AND DEXTROSE 5% I N PLASTI C CONTAI NER DEXTROSE
    - PHYSI OL SOL I N PLASTI C CONTAI NER MAGNESI UM CHLORI DE
    - POTASSI UM CHLORI DE 0.149% I N SODI UM CHLORI DE 0.45% I N PLASTI C CONTAI NER POTASSI UM
    - POTASSI UM CHLORI DE 10MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.225% I N PLASTI C
    - POTASSI UM CHLORI DE 10MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.3% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 10MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.45% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 10MEQ I N PLASTI C CONTAI NER POTASSI UM CHLORI DE
    - POTASSI UM CHLORI DE 15MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.225% I N PLASTI C
    - POTASSI UM CHLORI DE 15MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.3% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.225% I N PLASTI C
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.3% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.45% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.9% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% I N PLASTI C CONTAI NER DEXTROSE
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% I N SODI UM CHLORI DE 0.3% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.225% I N PLASTI C
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.3% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.45% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.9% I N PLASTI C CONTAI NER
    - POTASSI UM CHLORI DE 20MEQ I N DEXTROSE 5% AND SODI UM CHLORI DE 0.45% I N PLASTI C CONTAI NER,
## Appendix B - Product Name Sorted by Applicant

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU Medical Inc</td>
<td>* Potassium Chloride 30mEq in Dextrose 5% in Plastic Container, Dextrose</td>
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<tr>
<td></td>
<td>* Potassium Chloride 40mEq in Dextrose 5% and Sodium Chloride 0.225% in Plastic Container</td>
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<tr>
<td></td>
<td>* Potassium Chloride 40mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container</td>
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<td>* Potassium Chloride 40mEq in Dextrose 5% and Sodium Chloride 0.45% in Plastic Container</td>
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<tr>
<td></td>
<td>* Potassium Chloride 40mEq in Dextrose 5% in Plastic Container, Dextrose</td>
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<tr>
<td></td>
<td>* Potassium Chloride 40mEq in Plastic Container, Potassium Chloride 5mEq in Dextrose 5% and Sodium Chloride 0.225% in Plastic Container</td>
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<tr>
<td></td>
<td>* Potassium Chloride 5mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container</td>
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<tr>
<td></td>
<td>* Ringer’s in Plastic Container, Calcium Chloride</td>
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<td></td>
<td>* Sodium Chloride 0.45% in Plastic Container, Sodium Chloride 0.9% in Plastic Container</td>
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<tr>
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<td>* Sorbitol-Mannitol in Plastic Container, Mannitol</td>
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<td>* Sterile Water for Injection in Plastic Container, Sterile Water for Injection</td>
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<td></td>
<td>* Sterile Water in Plastic Container, Sterile Water for Irrigation</td>
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<td>Ident Pharm Inc</td>
<td>* Fluocinolone Acetonide De, Fluocinolone Acetonide De</td>
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<td>IDT Australis Ltd</td>
<td>* Temozolomide De, Temozolomide De</td>
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<td>Impax</td>
<td>* Adrenacli CK, Epi Nephrine Ne</td>
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<td>Impax Labs</td>
<td>* Acarbose, Acarbose, Anagrelide De Hydrochloride De, Anagrelide De Hydrochloride De, Baclofen, Baclofen</td>
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<td>* Carboli Dopa and Levodopa, Carboli Dopa</td>
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<td>* Clonidine Hydrochloride De, Clonidine Hydrochloride De, Colestil Pol Hydrochloride De, Colestil Pol Hydrochloride De</td>
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<td>* Dantrolene Sodi De, Dantrolene Sodi De</td>
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<tr>
<td></td>
<td>* Dextroamp Saccharate, Amp Aspartate, Dextroamp Sulfate and Amp Sulfate, Amphetamine Ne</td>
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<td>* Di Goki N, Di Goki N, Di Pyri Damole, Di Pyri Damole</td>
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<td>* Di Valproex Sodi Um, Di Valproex Sodi Um</td>
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<tr>
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<td>* Fenofipi Brate (M Cironi Zedi), Fenofipi Brate</td>
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<td>* Fenofipi Brate, Fenofipi Brate</td>
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<td></td>
<td>* Fluocortic Sone Acetate, Fluocortic Sone Acetate</td>
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<td></td>
<td>* Methyltestosterone, Methyln-testosterone</td>
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<td>* M Necycli Ne Hydrochloride De, M Necycli Ne Hydrochloride De, Nadelol And Bendrofluimeth Azide De, Bendrofluimeth Azide De, Oemprazole, Oemprazole</td>
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<td>* Oxymorphone Hydrochloride De, Oxymorphone Hydrochloride De</td>
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<td>* Pi Locarpine Hydrochloride De, Pi Locarpine Hydrochloride De, Promethazin Ne Hydrochloride De, Promethazin Ne Hydrochloride De</td>
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<td>* Pyri Dosti GM Ne Brom De, Pyri Dosti GM Ne Brom De</td>
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<td>* R Liuzole, R Liuzole</td>
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<td>* R Mantiad Ne Hydrochloride De, R Mantiad Ne Hydrochloride De</td>
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<td>* Tamulosin N Hydrochloride De, Tamulosin N Hydrochloride De</td>
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<td>* Terbutaline Ne Sulfate, Terbutaline Ne Sulfate</td>
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<td>Impax Labs Inc</td>
<td>* Aci Treti N, Aci Treti N</td>
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<td>* Albenza, Albenazole</td>
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<td>* Aenadrone Sodi Um, Aenadrone Sodi Um</td>
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<td>* Budesonide, Budesonide De</td>
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<td>* Buspiron Hydrochloride De, Buspiron Hydrochloride De</td>
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<td>* Carded Lol Phosphate, Cardedi Lol Phosphate</td>
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<td>* Colesevelam Hydrochloride De, Colesevelam Hydrochloride De</td>
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<td>* Desmopressin N Acetate, Desmopressin N Acetate</td>
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<td>Product Name</td>
<td>Applicant</td>
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<td>DEXEDRINE, DEXTROAMPHETAMINE SULFATE</td>
<td>IMPAX LABORATORIES INC</td>
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<td>DOXYCYCLINE INC, DOXYCYCLINE INC</td>
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<td>EPI RUBI C N HYDROCHLORIDE DE, EPI RUBI C N HYDROCHLORIDE DE</td>
<td>FENOFI BRI C ACI D, CHOLINE FENOFI BRATE</td>
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<td>GLYBURI DE, GLYBURI DE</td>
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<td>MORPHINE SULFATE, MORPHINE SULFATE</td>
<td>NABUMETONE, NABUMETONE</td>
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<td>** IMPAX PHARMA **</td>
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<td>M DODR I NE HYDROCHLORIDE DE, M DODR I NE HYDROCHLORIDE DE</td>
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<td>ORPHENADRI NE CI TRATE, ORPHENADRI NE CI TRATE</td>
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<td>OKYBUTYNI N CHLORI DE, OKYBUTYNI N CHLORI DE</td>
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<td>** INCYTE CORP **</td>
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<td>** INCYTE CORP **</td>
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<td>J AKAFLI, RUXOLI T N I B PHOSPHATE</td>
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<td>** INDICUS PHARMA **</td>
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<td>BUPRENEX, BUPRENORPHI NE HYDROCHLORIDE DE</td>
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<td>** INFORLIFE **</td>
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<td>CI PROFLOXACI N I N DEXTROSE 5% I N PLASTI C CONTAI NER, CI PROFLOXACI N</td>
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<td>FLUCONAZOLE IN SODIUM CHLORIDE AND DEXTROSE 5% I N PLASTI C CONTAI NER, FLUCONAZOLE</td>
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<td>ROPI VACAI NE HYDROCHLORIDE DE, ROPI VACAI NE HYDROCHLORIDE DE</td>
<td>ZOLEDRONI C ACI D, ZOLEDRONI C ACI D</td>
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<td>** INGENUS PHARMA LLC **</td>
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<td>** INGENUS PHARMA LLC **</td>
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<tr>
<td>ARSENIC I N DEXTROSE 5% I N PLASTI C CONTAI NER, ARSENIC I N DEXTROSE 5% I N PLASTI C CONTAI NER</td>
<td></td>
</tr>
<tr>
<td>CABERCOLI NE, CABERCOLI NE</td>
<td></td>
</tr>
<tr>
<td>CARBOPLATI N, CARBOPLATI N</td>
<td></td>
</tr>
<tr>
<td>CI CLOP ROK, CLOP ROK</td>
<td></td>
</tr>
<tr>
<td>CLOBETASOL PROPI OATE, CLOBETASOL PROPI OATE</td>
<td>ZOLEDRONI C ACI D, ZOLEDRONI C ACI D</td>
</tr>
</tbody>
</table>
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** I **

INGENUS PHARMACEUTICALS LLC
CLOFARABINE, CLOFARABINE
DESIPRAMINE HYDROCHLORIDE, DESIPRAMINE HYDROCHLORIDE
DOCETAXEL, DOCETAXEL
IRINOTECAN HYDROCHLORIDE, IRINOTECAN HYDROCHLORIDE
LEUCOVORIN CALCIUM, LEUCOVORIN CALCIUM
LEVOLEUCOVORIN N CALCIUM, LEVOLEUCOVORIN N CALCIUM
OXALI PLATI N, OXALI PLATI N
TOLCAPONE, TOLCAPONE

INGENUS PHARMS NJ
* I NGENUS PHARMACEUTICALS CALS NJ LLC
CARI SOPRODOL, ASPIRIN AND CODEINE PHOSPHATE, ASPIRIN R

INNOGEN X
* I INNOGEN X LLC
LABETALOL HYDROCHLORIDE, LABETALOL HYDROCHLORIDE
METRONIDAZOLE, METRONIDAZOLE
PILOCARPINE HYDROCHLORIDE, PILOCARPINE HYDROCHLORIDE

INSMED INC
* I INSMED INC
ARI KAYCE KI T, AM KACI N SULFATE

INSTIT BI CHEM
* I INSTI TUT BI OCHEM QUE SA
FLIBECTO, DI CLOFENAC EPOLAM NE

INSTIT TUT BI OCHI M QUE
* I INSTI TUT BI OCHI M QUE SA (IBSA)
TI ROSI NT, LEVOTHYROXI N SODI UM

INSYS DEV CO I NC
* I INSYS DEVELOPMENT CO INC
SUBSYS, FENTANYL
SYNDROS, DRONABNI NOL

INTAS PHARM USA
* I INTAS PHARMACEUTICALS USA INC
IRINOTECAN HYDROCHLORIDE, IRINOTECAN HYDROCHLORIDE

INTELL PHARMACEUTICALS INC
* I INTELL PHARMACEUTICALS CS CORP
DEXMETHYLPHENI DATE HYDROCHLORIDE DE, DEXMETHYLPHENI DATE HYDROCHLORIDE DE
METFORM N HYDROCHLORIDE DE, METFORM N HYDROCHLORIDE DE
QUETI API NE FUMARATE, QUETI API NE FUMARATE
VENLAFAXI NE HYDROCHLORIDE DE, VENLAFAXI NE HYDROCHLORIDE DE

INTERCEPT PHARMS INC
* I INTERCEPT PHARMACEUTICALS LLC INC
OCALI VA, OBETI CHOLI C ACI D

INTERGEL PHARM
* I INTERGEL PHARMACEUTICALS CALS INC
NI FED INE, NI FED INE

INTERGEL PHARMS INC
* I INTERGEL PHARMACEUTICALS INC
DUTASTERI DE, DUTASTERI DE

INTERPHARMA PRAHA AS
* I INTERPHARMA PRAHA AS
ORALTAG, I CHEXOL

INTERSECT ENT INC
* I INTERSECT ENT INC
SI NUVA, MOMETASONE FURerate

INTL MEDI CATED
* I INTERNATI ONAL MEDI CATED SYSTEMS LTD
M R LI NONE LACTATE, M R LI NONE LACTATE

INTL MEDI CATI ON
* I INTERNATI ONAL MEDI CATI ON SYSTEM
LARYNG O J ET KI T, LI DOCAI NE HYDROCHLORIDE DE
LI DOCAI NE HYDROCHLORIDE DE, LI DOCAI NE HYDROCHLORIDE DE
MANNI TOL 25%, MANNI TOL
NALOXONE HYDROCHLORIDE DE, NALOXONE HYDROCHLORIDE DE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** I **

INTERNATIONAL MEDICATION SYSTEM

PHYTONADIONE, PHYTONADIONE

INTERNATIONAL MEDICATION SYSTEMS LTD

LORAZEPAM, LORAZEPAM

SODIUM BICARBONATE, SODIUM BICARBONATE

INVAGEN PHARMA

ALFUZOSIN HYDROCHLORIDE, ALFUZOSIN HYDROCHLORIDE

AMLODIPINE BESYLATE AND VALSARTAN, AMLODIPINE BESYLATE

AMLODIPINE BESYLATE, AMLODIPINE BESYLATE

BENZTROPINE MESYLATE, BENZTROPINE MESYLATE

BUPROPION HYDROCHLORIDE, BUPROPION HYDROCHLORIDE

CALCIUM ACETATE, CALCIUM ACETATE

CALCIUM CHLORIDE 10%, CALCIUM CHLORIDE

CARBINOXAMINE MALEATE, CARBINOXAMINE MALEATE

CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROBROMIDE

CYCLOBENZAPRINE HYDROCHLORIDE, CYCLOBENZAPRINE HYDROCHLORIDE

ESCITALOPRAM OXALATE, ESCITALOPRAM OXALATE

FENOFIBRATE (M CRONI ZED), FENOFIBRATE

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE

FOSINOPRIL SODIUM, FOSINOPRIL SODIUM

GABAPENTIN, GABAPENTIN

GEMFI BROZI L, GEMFI BROZI L

GLI MEPI RI DE, GLI MEPI RI DE

HYDRAZI NE HYDROCHLORIDI DE, HYDRAZI NE HYDROCHLORIDI DE

HYDROXYZI NE HYDROCHLORIDI DE, HYDROXYZI NE HYDROCHLORIDI DE

LEVE TI RACETAM, LEVE TI RACETAM

LI SI NAPI L AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE

LURASI DONE HYDROCHLORIDI DE, LURASI DONE HYDROCHLORIDI DE

MEPROBAMATE, MEPROBAMATE

NAPROXI N, NAPROXI N

OLANZAPI NE, OLANZAPI NE

ORPHENADRI NE CI TRATE, ORPHENADRI NE CI TRATE

PHENTERM NE HYDROCHLORIDI DE, PHENTERM NE HYDROCHLORIDI DE

QUI NAPI L HYDROCHLORIDI DE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE

QUI NAPI L HYDROCHLORIDI DE, QUI NAPI L HYDROCHLORIDI DE

RALOXI FENE HYDROCHLORIDI DE, RALOXI FENE HYDROCHLORIDI DE

SERTRALI NE HYDROCHLORIDI DE, SERTRALI NE HYDROCHLORIDI DE

SEVELAMER CARBONATE, SEVELAMER CARBONATE

TERBI NAFI NE HYDROCHLORIDI DE, TERBI NAFI NE HYDROCHLORIDI DE

TOPI RAMATA, TOPI RAMATA

TROXIUM CHLORI DE, TROXIUM CHLORI DE

WARFARI N SODI UM, WARFARI N SODI UM

ZOLM TRI PTAN, ZOLM TRI PTAN

ZOLPI DEM TARTRATE, ZOLPI DEM TARTRATE

ZONI SAM DE, ZONI SAM DE

INVATECH PHARMA

CALCI TRI OL, CALCI TRI OL

CYPROHEPTADI NE HYDROCHLORIDI DE, CYPROHEPTADI NE HYDROCHLORIDI DE

INVENTIA HEALTHCARE

BUSPI RONE HYDROCHLORIDI DE, BUSPI RONE HYDROCHLORIDI DE

DULOXETI NE HYDROCHLORIDI DE, DULOXETI NE HYDROCHLORIDI DE

FLUOXETI NE HYDROCHLORIDI DE, FLUOXETI NE HYDROCHLORIDI DE

ILOPERI DONE, ILOPERI DONE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** | **

* I NVENTIA HEALTHCARE PRIVATE LTD
  LANSOPRAZOLE, LANSOPRAZOLE
  METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE
  TELMISARTAN, TELMISARTAN

I ONETIX
* I ONETIX CORP
  AMMONIUM N 13, AMMONIUM N-13

I PCA LABS LTD
* I PCA LABORATORI ES LTD
  ALLOPURINOL, ALLOPURINOL
  ATENOLOL, ATENOLOL
  CETIRIZINE HYDROCHLORIDE ALLERGY, CETIRIZINE HYDROCHLORIDE (OTC)
  CETIRIZINE HYDROCHLORIDE HIVES, CETIRIZINE HYDROCHLORIDE (OTC)
  CHLOROQUINE NE PHOSPHATE, CHLOROQUINE NE PHOSPHATE
  FUROSEMIDE, FUROSEMIDE
  HYDROCHLOROTHIAZIDE AZI DE, HYDROCHLOROTHIAZIDE AZI DE
  HYDROXYCHLOROQUINE NE SULFATE, HYDROXYCHLOROQUINE NE SULFATE
  LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE AZI DE, HYDROCHLOROTHIAZIDE AZI DE
  LOSARTAN POTASSIUM UM LOSARTAN POTASSIUM UM
  METOCLOPRAM DE HYDROCHLOROTHIAZIDE, METOCLOPRAM DE HYDROCHLOROTHIAZIDE
  METOPROLOL TARTRATE, METOPROLOL TARTRATE
  ONDAZETRON HYDROCHLOROTHIAZIDE, ONDAZETRON HYDROCHLOROTHIAZIDE
  PROPRANOLOL HYDROCHLOROTHIAZIDE, PROPRANOLOL HYDROCHLOROTHIAZIDE
  TRAMADOL HYDROCHLOROTHIAZIDE, TRAMADOL HYDROCHLOROTHIAZIDE
  WARFARIN SODIUM, WARFARIN SODIUM

I PR
* I PR PHARMACEUTICALS LLC
  CRESTRON, ROSUVASTATIN CALCIUM
  ZOLMET, ZOLMET TRIPAN

I PSEN INC
* I PSEN BIOPHARMACEUTICALS LLC
  CREATIN, CREATININE
  IRON PDF, ION PDF

I PSEN PHARMA
* I PSEN PHARMA BIOTECH SAS
  SOMATULIN DEPOT, LANREOTIDE DE ACETATE

I ROKO PHARMS
* I ROKO PHARMACEUTICALS LLC
  I NDOCINUM, I NDMETHACIN

I ROKO PHARMS LLC
* I ROKO PHARMACEUTICALS LLC
  TIVORBEX, I NDMETHACIN
  VLOCLOX, MELOXI CAM
  ZORVLEEX, DI CLOFENAC

I RONSHORE PHARMS
* I RONSHORE PHARMACEUTICALS LLC AND DEVELOPMENT INC
  J CRANAY PM, METHYLMETHANOTRIAZEHYDROCHLOROTHIAZIDE

I RONWOOD PHARMS INC
* I RONWOOD PHARMACEUTICALS LLC
  DUZALLO, ALLOPURINOL
  ZURAMPIC, LESI NURAD

I SO TEX
* I SO TEX DI AGOSTI CI INC
  J ENATROPE, ALBUM IN IODIUM IODINE I-125 SERUM
  MEGATROPE, ALBUM IN IODIUM IODINE I-131 SERUM

I SOTEX
* I SOTEX DI AGOSTI CI
  GLOFIL-125, IOTHALAMATE SODIUM I-125

I STI TUTO BI O I TA SPA
* I STI TUTO BI O I TALI ANY SPA
  AMPI CI LLI N AND SUBACTAM, AMPI CI LLI N SODIUM
  AMPI CI LLI N SODIUM, AMPI CI LLI N SODIUM
  NAFCILLIN SODIUM, NAFCILLIN SODIUM
  PENI CI LLI N G POTASSIUM, PENI CI LLI N G POTASSIUM
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**I **

| ISTITUTO BIOCHIMICO ITALIANO SPA | PIPERACILLIN AND TAZOBACTAM |
| ISTITUTO BIOCHIMICO ITALIANO SPA | PIPERACILLIN, PIPERACILLIN SODIUM |
| ITALFARMACO SPA | TIGLUTIK KIT, RILUZOLE |
| IVAX PHARMS | VALSARTAN, VALSARTAN |
| IVAX PHARMS INC | OLanzAPI, OLanzAPI |
| IVAX PHARMS INC | ANAGRELIDE HYDROCHLORIDE, ANAGRELIDE HYDROCHLORIDE |
| IVAX PHARMS INC | BACLOFEN, BACLOFEN |
| IVAX PHARMS INC | BENAZEPRIL HYDROCHLORIDE, BENAZEPRIL L HYDROCHLORIDE |
| IVAX PHARMS INC | BUMETANIDE, BUMETANIDE |
| IVAX PHARMS INC | CABELGOLI, CABELGOLI |
| IVAX PHARMS INC | CETI R I ZI NE HYDROCHLORIDE DE AND PSEUDOEPHEDRI NE HYDROCHLORIDE DE |
| IVAX PHARMS INC | CEMETI DI DI NE (OTC) |
| IVAX PHARMS INC | CI PROFLOXACI N HYDROCHLORIDE DE, CI PROFLOXACI N HYDROCHLORIDE DE |
| IVAX PHARMS INC | CLOZAPI, CLOZAPI NE |
| IVAX PHARMS INC | CYCLOSPORI NE, CYCLOSPORI NE |
| IVAX PHARMS INC | CYPROHEPTADI NE HYDROCHLORIDE DE, CYPROHEPTADI NE HYDROCHLORIDE DE |
| IVAX PHARMS INC | DIAZEPAM, DIAZEPAM |
| IVAX PHARMS INC | DOXYCYCLI NE HYDRA, DOXYCYCLI NE HYDRALE |
| IVAX PHARMS INC | ESOMEPRAZOLE MAGNESI UM, ESOMEPRAZOLE MAGNESI UM |
| IVAX PHARMS INC | FAMOTI DI DI NE, FAMOTI DI DI NE |
| IVAX PHARMS INC | FLUCONAZOLE, FLUCONAZOLE |
| IVAX PHARMS INC | FLEUXTI NE HYDROCHLORIDE DE, FLEUXTI NE HYDROCHLORIDE DE |
| IVAX PHARMS INC | FUROSEM DE, FUROSEM DE |
| IVAX PHARMS INC | GABAPENTI N, GABAPENTI N |
| IVAX PHARMS INC | HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE |
| IVAX PHARMS INC | I NDOMETHACI N, I NDOMETHACI N |
| IVAX PHARMS INC | LABETALOL HYDROCHLORIDE DE, LABETALOL HYDROCHLORIDE DE |
| IVAX PHARMS INC | LI SI NOPRI L AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE |
| IVAX PHARMS INC | NADOLOL, NADOLOL |
| IVAX PHARMS INC | OXAPROZI N, OXAPROZI N |
| IVAX PHARMS INC | RANITI DI DI NE HYDROCHLORIDE DE, RANITI DI DI NE HYDROCHLORIDE DE |
| IVAX PHARMS INC | TOLTERODI NE TARTRATE, TOLTERODI NE TARTRATE |
| IVAX PHARMS INC | TRAMTERENE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE |
| IVAX PHARMS INC | VERAPAM I HYDROCHLORIDE DE, VERAPAM I HYDROCHLORIDE DE |

**J **

| J AND J CONSUMER INC | CHILDREN'S MOTRIN COLD, IBUPROFEN (OTC) |
| J AND J CONSUMER INC | CHILDREN'S MOTRIN, IBUPROFEN (OTC) |
| J AND J CONSUMER INC | CHILDREN'S ZYRTEC ALLERGY, CETIRIZINE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | CHILDREN'S ZYRTEC HIVES RELIEF, CETIRIZINE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | IMODIUM A-D, LOPERAMIDE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | IMODIUM MULTI-SYMPTOM RELIEF, LOPERAMIDE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | JUNIOR STRENGTH MOTRIN, IBUPROFEN (OTC) |
| J AND J CONSUMER INC | MENTALINE, LOPERAMIDE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | MENTALINE, LOPERAMIDE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | MENTALINE, LOPERAMIDE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | MENTALINE, LOPERAMIDE HYDROCHLORIDE (OTC) |
| J AND J CONSUMER INC | NADOLOL, NADOLOL |
| J AND J CONSUMER INC | OXAPROZI N, OXAPROZI N |
| J AND J CONSUMER INC | RANITI DI DI NE HYDROCHLORIDE DE, RANITI DI DI NE HYDROCHLORIDE DE |
| J AND J CONSUMER INC | TOLTERODI NE TARTRATE, TOLTERODI NE TARTRATE |
| J AND J CONSUMER INC | TRAMTERENE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE |
| J AND J CONSUMER INC | VERAPAM I HYDROCHLORIDE DE, VERAPAM I HYDROCHLORIDE DE |
** J **

* JOHNSON AND JOHNSON CONSUMER INC. MCNEILL CONSUMER HEALTHCARE DIVISION
  TYLENOL, ACETAMINOPHEN (OTC)
  ZYRTEC ALLERGY, CETIRIZINE HYDROCHLORIDE (OTC)
  ZYRTEC-D 12 HOUR, CETIRIZINE HYDROCHLORIDE (OTC)

JACOBIUS
* JACOBIUS PHARMACEUTICAL COMPANY
  DAPSONE, DAPSONE
  PASER, AM NOSAL CYLI C ACI D

JANSSEN BIOTECH
* JANSSEN BIOTECH INC.
  ERELEDA, APALUTAMIDE
  ZYTI GA, ABI RATERONE ACETATE

JANSSEN PHARMA
* JANSSEN PHARMACEUTICALS INC.
  AXERT, ALIMOTRIPTAN MALATE
  CONCERTA, METHYLPHENI DATE HYDROCHLORIDE DE
  DURAGESI C-100, FENTANYL
  DURAGESI C-12, FENTANYL
  DURAGESI C-25, FENTANYL
  DURAGESI C-37, FENTANYL
  DURAGESI C-50, FENTANYL
  DURAGESI C-75, FENTANYL
  ELMIRON, PENTOSAN POLYSULFATE SODIUM
  HALDOL, HALOPERIDOL DECANATE
  HALDOL, HALOPERIDOL LACTATE
  I NVEGA SUSTENNA, PALI PER DONE PALM TATE
  I NVEGA TRI NZA, PALI PER DONE PALM TATE
  I NVEGA, PALI PERI DONE
  I NVOKAME XR, CANAGLIFLOZIN N
  I NVOKAMET, CANAGLIFLOZIN N
  I NVOKANA, CANAGLIFLOZIN N
  M CRONOR, NORETHINDRONE
  NI ZORAL, KETOCONAZOLE
  ORTHO CYCLEN-28, ETHINYL ESTRADIOL
  ORTHO TRI - CYCLEN LQ, ETHINYL ESTRADIOL
  ORTHO TRI - CYCLEN, ETHINYL ESTRADIOL
  ORTHO NOVUM 1/35-28, ETHINYL ESTRADIOL
  ORTHO NOVUM 7/7/7-28, ETHINYL ESTRADIOL
  RAZADYNE ER, GALANTAMINE HYDROBROMIDE
  RAZADYNE, GALANTAMINE HYDROBROMIDE
  RI SPERDAL CONSTA, RI SPERI DONE
  RI SPERDAL, RI SPERI DONE
  SPORANOX, I TRACONAZOLE
  TOPAMAX, TOPI RANATE
  TYLENOL W CODEI NE NO. 3, ACETAMINOPHEN
  TYLENOL W CODEI NE NO. 4, ACETAMINOPHEN
  ULTRACET, ACETAMINOPHEN
  ULTRAM, TRAMADOL HYDROCHLORIDE DE
  XARELTO, RI VAROXABAN

JANSSEN PRODS
* JANSSEN PRODUCTS LP
  EDURANT, RI LPI VI RI NE HYDROCHLORIDE DE
  PREZCODYL, COBI CI STAT
  PREZI STA, DARUNAVI R ETHANOLATE
  SYMITUZA, COBI CI STAT
  YONDIEL S, TRABECTEDIN N

JANSSEN R AND D
* JANSSEN RESEARCH AND DEVELOPMENT LLC
  I NTELENCE, ETRAVI RI NE

JANSSEN RD AND DEVEL
* JANSSEN RESEARCH AND DEVELOPMENT LLC
  DOXI L (LI POSOMAL), DOXORUBICIN N HYDROCHLORIDE DE

JANSSEN THERAP
* JANSSEN THERAPEUTIC DIV. OF JANSSEN PRODUCTS LP
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**J**

**JANSSEN THERAPEUTICS DIV JANSSEN PRODUCTS LP**

SI RTURO, BEDAQUI LI NE FUMARATE

**JAZZ PHARM**

* JAZZ PHARMACEUTI CALS I NC
  XYREM, SODI UM OXYBATE

**JAZZ PHARMS III**

* JAZZ PHARMACEUTI CALS III I INTERNATI ONAL LTD
  FAZACLO OOT, CLOZAPI NE

**JAZZ PHARMS I NC**

* JAZZ PHARMACEUTI CALS I NC
  DEFI TELI O, DEFI BROTI DE SCODI UM

**JIANGSU HANSOH PHARM**

* JIANGSU HANSOH PHARMACEUTI CAL GROUP CO LTD
  GEMI TABI NE HYDROCHLORI DE, GEMI TABI NE HYDROCHLORI DE
  OLANZAPI NE, OLANZAPI NE
  VI NORELBI NE TARTRATE, VI NORELBI NE TARTRATE

**JIANGSU HENGRUI MED**

* JIANGSU HENGRUI I MEDI CI NE CO LTD
  CI SATRACURI UM BESY LatE PRESERVATI VE FREE, CI SATRACURI UM BESY LatE
  CI SATRACURI UM BESY LatE, CI SATRACURI UM BESY LatE
  CYCLOPHOSPHAM DE, CYCLOPHOSPHAM DE
  DEXMEDETEM DI NE HYDROCHLORI DE, DEXMEDETEM DI NE HYDROCHLORI DE
  DOCETAXEL, DOCETAXEL
  FONDAPARI NUX SODI UM, FONDAPARI NUX SODI UM
  GABAPENTI N, GABAPENTI N
  I RI NOTECAN HYDROCHLORI DE, I RI NOTECAN HYDROCHLORI DE
  LETROZOLE, LETROZOLE
  OXALI PLATI N, OXALI PLATI N
  THI OTEPA, THI OTEPA

**JOHNS HOPKINS UNIV**

* JOHNS HOPKI NS UNIV V
  AMMONI A N 13, AMMONI A N-13

**JOHNSON AND JOHNSON**

* JOHNSON AND JOHNSON CONSUMER I NC
  VI SI NE L.R., OKYMETAZOLI NE HYDROCHLORI DE (OTC)
  VI SI NE, NAPHAZOLI NE HYDROCHLORI DE (OTC)

* JOHNSON AND JOHNSON GROUP CONSUMER COMPANI ES
  MNE S ROAI NE, M NOXI DI L (OTC)
  ROAI NE (FOR MEN), M NOXI DI L (OTC)
  ROAI NE (FOR WOMEN), M NOXI DI L (OTC)
  ROAI NE EXTRA STRENGTH (FOR MEN), M NOXI DI L (OTC)
  WOMEN S ROAI NE, M NOXI DI L (OTC)

* JOHNSON AND JOHNSON HEALTHCARE PRODUCTS DI V MNCI E L- PPC I NC
  NI ZORAL A- D, KETOCONAZOLE (OTC)

**JOURNEY**

* JOURNEY MEDIC AL CORP
  EXELDERM, SULCONAZOLE NI TRATE

**JUBILANT CADI STA**

* JUBILANT CADI ST A PHARMACEUTI CALS I NC
  ALENORONATE SODI UM, ALENORONATE SODI UM
  CYCLOBENZAPRI NE HYDROCHLORI DE, CYCLOBENZAPRI NE HYDROCHLORI DE
  DROSPI RENONE AND ETHI NYL ESTRADI OL, DROSPI RENONE
  HYDROCHLOROTHI A ZI DE, HYDROCHLOROTHI A ZI DE
  LAMOTRI GI NE, LAMOTRI GI NE
  MECLI ZI NE HYDROCHLORI DE, MECLI ZI NE HYDROCHLORI DE
  Methylene Predni bolone, Methylene Predni bolone
  PREDNI SONE, PREDNI SONE
  PROCOMP, PROCHELORPERAZI NE MALEATE
  TERAZO S N HYDROCHLORI DE, TERAZO S N HYDROCHLORI DE

**JUBILANT DRA XI MAG**

* JUBILANT DRA XI MAG I NC
  DRA XI EXAMETAZI ME, TECHNETI UM TC- 99M EXAMETAZI ME KI T
  DRA XI MAG MDP- 25, TECHNETI UM TC- 99M MEDRONATE
  DTPA, TECHNETI UM TC- 99M PENTETATE KI T
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** J **

* JUBILANT DRAXIMAGE INC
  HI CON, SODIUM IODIDE I-131
  RUBY-FI LL, RUBIUM CHLORIDE RB-82
  SODIUM IODIDE I-131, SODIUM IODIDE I-131

* JUBILANT DRAXIMAGE RADIOPHARMACIES INC
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18
  SODIUM FLUORIDE F-18, SODIUM FLUORIDE F-18

* JUBILANT DRAXIMAGE USA INC
  TECHNETIUM Tc-99m SPECTRA MABG, TECHNETIUM Tc-99m SPECTRA MABG

* JUBILANT GENERICS LTD
  AMANTADINE HYDROCHLORIDE, AMANTADINE HYDROCHLORIDE
  AMLODIPINE AND OLMESARTAN MEDOXOMIL, AMLODIPINE BESYLATE
  BUPROPION HYDROCHLORIDE, BUPROPION HYDROCHLORIDE
  CELECOXIB, CELECOXIB
  CHI LDREN S, CHI LDREN S
  CETI R I ZI NE HYDROCHLORIDE ALLERGY, CETI R I ZI NE HYDROCHLORIDE (OTC)
  CI TALOPRAM HYDROBROMIDE, CI TALOPRAM HYDROBROMIDE
  CI TALOPRAM HYDROBROMIDE
  CLONI DI NE HYDROCHLORIDE, CLONI DI NE HYDROCHLORIDE
  DARI FENACI N HYDROBROMIDE, DARI FENACI N HYDROBROMIDE
  DONEPEZI L HYDROCHLORIDE, DONEPEZI L HYDROCHLORIDE
  ESCI TALOPRAM OXALATE, ESCI TALOPRAM OXALATE
  FELODI PI NE, FELODI PI NE
  I NDOMETHACI N, I NDOMETHACI N
  I RBESARTAN, I RBESARTAN
  I TRACONAZOLE, I TRACONAZOLE
  LAMOTRI GI NE, LAMOTRI GI NE
  LEVETI RACETAM, LEVETI RACETAM
  LEVOCLOXACI N, LEVOCLOXACI N
  MEM anti NE HYDROCHLORIDE, MEM anti NE HYDROCHLORIDE
  MONTELUKAST SODIUM, MONTELUKAST SODIUM
  NI ACI, NI ACI
  NI ACI
  OLANZAPI NE, OLANZAPI NE
  OLMESARTAN MEDOXOMIL, OLMESARTAN MEDOXOMIL
  PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM
  QUETI API NE FUMARATE, QUETI API NE FUMARATE
  R SPERI DONE, R SPERI DONE
  R SPERI DONE
  R SPERI DONE
  R SPERI DONE
  R SPERI DONE
  RI ZARI PTAN BENZOATE, RI ZARI PTAN BENZOATE
  ROSUVASTATI N CALCI UM, ROSUVASTATI N CALCI UM
  SPI RONOLACTONE, SPI RONOLACTONE
  TELM SARTAN, TELM SARTAN
  TI ZANI DI NE HYDROCHLORIDE, TI ZANI DI NE HYDROCHLORIDE
  VALACYCLOVIR, VALACYCLOVIR

* JUBILANT HOLLI STERSTI ER LLC
  SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

STEVENS I

* JEROME STEVENS PHARMACEUTICALS CALS NC
  BUTALBITAL, ASPIRIN, CAFFEIN, AND CODEINE PHOSPHATE, ASPIRIN
  DI GOXI N, GOXI N
  METHOCARBAMOL AND ASPIRIN, GOXI N
  UNI THROI D, LEVOTHYROXINE SODIUM

** K **

GRIFFEN

* KW GRIFFEN CO
  BI SCRUB, CHLORHEXIDI NE GLUCONATE (OTC)

KADMON PHARMAS LLC

* KADMON PHARMACEUTICALS CALS LLC
  RI BASPHERE, RI BASPHERE
  RI BASPHERE, RI BASPHERE

KAI PHARMS INC
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**K**

* KAI PHARMACEUTICALS INC, A WHOLLY OWNED SUBSIDIARY OF AMGEN INC
  - PARSABIV, ETELCALCETIDE

* KALA PHARMACEUTICALS INC
  - IVELTYS, LOTEPRINOL ETABONATE

* KALEO INC
  - ALUM-Q, EPINEPHRINE
  - EVZI-Q, NALOXONE HYDROCHLORIDE

* KEMPHARM
  - APADAZ, ACETAMINOPHEN

* KERRYX BIOPHARMA INC
  - AURYXIA, FERRIC CITRATE
  - AUVI-Q, EPINEPHRINE
  - EVZIO, NALOXONE HYDROCHLORIDE

* KETTERING MEDCTR
  - FLUDEOXYGLUCOSE F-18, FLUDEOXYGLUCOSE F-18

* KING PHARMS INC
  - SYNERDIO, DALFOPRISTINE

* KING PHARMA RESEARCH AND DEVELOPMENT LLC
  - CYTOMEL, LIOTHYROXINE SODIUM
  - LEVOTHYROXINE SODIUM

* KING PHARMACEUTICALS LLC
  - ALTACE, RAMIPRIL
  - BICILLIN C-R 900/300, PENICILLIN G BENZATHINE
  - BICILLIN C-R, PENICILLIN G BENZATHINE
  - BICILLIN L-A, PENICILLIN G BENZATHINE
  - CORZIDE, BENDROFLUMETIH AZIDE

* KITOV PHARMA LTD
  - CONSENSI, AMLODIPINE BESYLATE

* KNIGHT THERAPPS USA INC
  - IMPAVI DO, MELTZOF SODIUM

* KOMA CO LTD
  - AMMONIA N 13, AMMONIA N-13
  - FLUDEOXYGLUCOSE F-18, FLUDEOXYGLUCOSE F-18
  - LANSOPRAZOLE, LANSOPRAZOLE

* KREITZMAN PET CENTER
  - AMMONIA N 13, AMMONIA N-13
  - FLUDEOXYGLUCOSE F-18, FLUDEOXYGLUCOSE F-18
  - LANSOPRAZOLE, LANSOPRAZOLE

* KRKA TOVARNA ZDRAVLJA
  - LANSOPRAZOLE, LANSOPRAZOLE

* KVK TECH INC
  - PHENERGIC, HYDROCHLORIDE
  - PHENERGIC, HYDROCHLORIDE DE
** K **

- ** KVK TECH I NC **
  - PROMETHAZINE HYDROCHLORIDE, PROMETHAZINE HYDROCHLORIDE

- ** KVK TECH I NC **
  - PHENTERM EN HYDROCHLORIDE DE, PHENTERM EN HYDROCHLORIDE DE

- ** KYMA KI RI N **
  - FARESTON, TOREM FENE CI TRATE
  - SANCUSO, GRANI SETRON

- ** KYTHERA BIOPHARMS **
  - KYTHERA BIOPHARMACEUTI CALS I NC
  - KYBELLA, DEOXCHOLI C ACI D

** L **

- ** L PERRI GO CO **
  - CI METI DI NE, CI METI DI NE ( OTC)
  - CLEMASTI NE FUMARATE, CLEMASTI NE FUMARATE ( OTC)
  - IBUPROFEN, IBUPROFEN ( OTC)
  - NEW STRENGTH IV BUPROFEN, BUPROFEN ( OTC)
  - LEVOCETI RI ZI NI DI HYDROCHLORI DE, LEVOCETI RI ZI NI DI HYDROCHLORI DE
  - LOPERAM DE HYDROCHLORI DE, LOPERAM DE HYDROCHLORI DE ( OTC)
  - M NOXI DI L (FOR MEN), M NOXI DI L ( OTC)
  - M NOXI DI L (FOR WOMEN), M NOXI DI L ( OTC)
  - NI COTI NI POLACRI LEX, NI COTI NI POLACRI LEX ( OTC)

- ** LAB J OLLA PHARMA **
  - GI APREZA, ANGI OTENSIN I I ACETATE

- ** LAB HRA PHARMA **
  - LABRATORIO RE HRA PHARMA
  - ELLA, ULI PRI STAI ACETATE

- ** LABRATORIO RE HRA **
  - LABRATORIO RE HRA PHARMA
  - LYSODREN, M TOTANE

- ** LABRATORIO E HRA **
  - LABRATORIO E HRA PHARMA
  - METOPI RONE, METYRAPONE

- ** LABORATORIOS GRI FOLS **
  - LABORATORIOS GRI FOLS SA
  - SODI UM CHLORI DE 0.9% I N PLASTI C CONTAI NER, SODI UM CHLORI DE

- ** LABORATORIOS SALVAT **
  - LABORATORIOS SALVAT SA
  - OTOVEL, CI PROFLOXACI N HYDROCHLORI DE

- ** LABS LEON FARMA **
  - LABORATORIOS LEON FARMA SA
  - ALTAVERA, ETHI NYL ESTRADI OL
  - ELI FEMME, ETHI NYL ESTRADI OL
  - ESTARYLLA, ETHI NYL ESTRADI OL
  - I NITROVALE, ETHI NYL ESTRADI OL
  - I SI BLOOM, DESOGESTREL
  - J AI M ESS, ETHI NYL ESTRADI OL
  - LEVONORESTREL AND ETHI NYL ESTRADI OL AND ETHI NYL ESTRADI OL, ETHI NYL ESTRADI OL
  - LORYNA, DROPSI RENONE
  - SYEDA, DROPSI RENONE
  - TRI - ESTARYLLA, ETHI NYL ESTRADI OL
  - TRI - LO ESTARYLLA, ETHI NYL ESTRADI OL
  - VI ENNA, ETHI NYL ESTRADI OL
  - VOLNEA, DESOGESTREL

- ** LABS LI CONSA **
  - LABORATORIOS LI CONSA SA
  - LANSOPRAZOLE, LANSOPRAZOLE

- ** LANDELA PHARM **
  - LANDELA PHARMACEUTI CAL
**L**

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<thead>
<tr>
<th>Product Name</th>
<th>Applicant</th>
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<tr>
<td>FLUCETI NE HYDROCHLORIDE, FLUCETI NE HYDROCHLORIDE</td>
<td>LANNETT</td>
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<td>LANNETT CO INC</td>
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### PRODUCT NAME SORTED BY APPLICANT

#### **L**

- **LANNETT CO INC**
  - METADATE ER, METHYLPHENIDATE HYDROCHLORIDE
  - METAPROTERENOL SULFATE, METAPROTERENOL SULFATE
  - METAXALONE, METAXALONE
  - METHYLPHENIDATE HYDROCHLORIDE, METHYLPHENIDATE HYDROCHLORIDE
  - MONOKET, I SOSORBI DE MONONI TRATE
  - MONTELUKAST SODIUM, MONTELUKAST SODIUM
  - MORPHINE SULFATE, MORPHINE SULFATE
  - NEOMYCIN SULFATE, NEOMYCIN SULFATE
  - NIA CI N, NIA CI N
  - NYSTATI N, NYSTATI N
  - OMEPRAZOLE, OMEPRAZOLE
  - ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE
  - OXYBUTYNIN N CHLORIDE DE, OXYBUTYNIN N CHLORIDE DE
  - OXYCODONE AND ACETAM NOPHEN, ACETAM NOPHEN
  - OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE
  - PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM
  - PAROKETI NE HYDROCHLORIDE DE, PAROKETI NE HYDROCHLORIDE DE
  - PHENTERM NE HYDROCHLORIDE DE, PHENTERM NE HYDROCHLORIDE DE
  - PI LOCARPI NE HYDROCHLORIDE DE, PI LOCARPI NE HYDROCHLORIDE DE
  - POTASSI UM CHLORIDE DE, POTASSI UM CHLORIDE DE
  - PREDNI SOLONE, PREDNI SOLONE
  - RABEPRAZOLE SODIUM, RABEPRAZOLE SODIUM
  - RANITI DI NE HYDROCHLORIDE DE, RANITI DI NE HYDROCHLORIDE DE
  - RI FAMPI N, RI FAMPI N
  - RI SPERI DONE, RI SPERI DONE
  - SULFAMETHOKAZOLE AND TRI METHOPR M SULFAMETHOKAZOLE
  - SUMATRI PTAN, SUMATRI PTAN
  - TEMZOLOM DE, TEMZOLOM DE
  - TERBUTALI NE SULFATE, TERBUTALI NE SULFATE
  - THEOPHYLLI NE, THEOPHYLLI NE
  - TRI AMCI NOLONE ACETONI DE, TRI AMCI NOLONE ACETONI DE
  - TRI AMERENE AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  - URSODI OL, URSODI OL
  - VALPROI C ACI D, VALPROI C ACI D
  - ZAROKOLYN, METOLAZONE

- **LANTHEUS MEDICAL IMAGING INC**
  - CARDIOLITE, TECHNETIUM TC-99M SESTAM BI KI T
  - DEFINI TIY, PERFLLUTREN
  - GALLI UM CI TRATE GA 67, GALLI UM CI TRATE GA-67
  - NEUROI TE, TECHNETIUM TC-99M BI CI SATE KI T
  - TECHNELI TE, TECHNETIUM TC-99M SODI UM PERTECHNETATE GENERATOR
  - THALLOUS CHLORIDE TL 201, THALLOUS CHLORIDE DE TL-201
  - XENON XE 133, XENON XE-133

- **LANTHEUS MEDICAL**
  - FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18
  - QUADRAMET, SAMARI UM SM 153 LEXI DRONAM PENTASODI UM

- **LARKEN LABS INC**
  - ACETAM NOPHEN, CAFFEI NE AND DI HYDROCODEI NE BI TARTRATE, ACETAM NOPHEN
  - ALLIZI TAL, ACETAM NOPHEN
  - BUTALBI TAL AND ACETAM NOPHEN, ACETAM NOPHEN
  - DEXAMETHASONE, DEXAMETHASONE

- **LAVIPHARM LABS**
  - FENTANYL-100, FENTANYL
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** L **

* LAVIPHARM LABORATORIES INC
  FENTANYL-25, FENTANYL
  FENTANYL-50, FENTANYL
  FENTANYL-75, FENTANYL

LEADIANT BIOSCI INC
* LEADIANT BIOSCIENCES INC
  ABELCET, AMPHOTERICIN B
  CARNITOR SF, LEVOCARNITINE
  CARNITOR, LEVOCARNITINE
  CYSTARAN, CYSTEAM NE HYDROCHLORIDE
  MATULANE, PROCARBAZI NE HYDROCHLORIDE

LEADING PHARMA LLC
* LEADING PHARMA LLC
  FOLI C ACI D, FOLI C ACI D
  FURASEM DE, FURASEM DE
  GLYCOPYRROLATE, GLYCOPYRROLATE
  HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  LORAZEPAM, LORAZEPAM
  M FEDI PI NE, M FEDI PI NE

LEO LABS
* LEO LABORATORIES LTD
  PI CATO, I NGENIOL MEBUTATE

LEO PHARMA AS
* LEO PHARMA AS
  DESONATE, DESO.NE DE
  DOVONEX, CALCI POTRI ENE
  FI NACE, AZELAI C ACI D
  PROTOPI C, TACROLI MUS
  TCLOPLEX, BETAMETHASONE DI PROPIONATE

LEXI CON PHARMS INC
* LEXI CON PHARMACEUTICALS INC
  XERELMO, TELETRI STAT ETI PRATE

LG CHEM LTD
* LG CHEM LTD
  FACTI VE, GEM FLOXACIN MESYLATE

LI EBELEV-FLARSHI M
* LI EBELEV-FLARSHI M CO LLC
  CONRAY 43, IOTHALAMATE MEGLUM NE
  CONRAY, IOTHALAMATE MEGLUM NE
  CYSTO-CORAY 11, IOTHALAMATE MEGLUM NE
  MD GASTRO E W, DI ATRI ZOATE MEGLUM NE
  OPTI RAY 240, LOVERSOL
  OPTI RAY 300, LOVERSOL
  OPTI RAY 320, LOVERSOL
  OPTI RAY 350, LOVERSOL
  SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, SODIUM CHLORIDE

LIFE MOLECULAR
* LIFE MOLECULAR IMAGING SA
  NEURACEQ, FLORBETABEN F-18

LIFE PHARMA
* LIFE PHARMA FZE
  LACTULOSE, LACTULOSE

LINK
* LINK INTERNATIONAL INC
  DOXYLAM NE SUCCI NATE, DOXYLAM NE SUCCI NATE (OTC)
  I BUPROFEN, I BUPROFEN (OTC)
  LOPERAM DE HYDROCHLORIDE DE, LOPERAM DE HYDROCHLORIDE (OTC)

LINK INTL INC
* LINK INTERNATIONAL INC
  NAPROXEN SODI UM, NAPROXEN SODI UM (OTC)
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** L **

LOREAL USA
* LOREAL USA PRODUCTS INC
  ANTHELIOS 20, AVOBENZONE (OTC)
  ANTHELIOS 40, AVOBENZONE (OTC)
  ANTHELIOS SX, AVOBENZONE (OTC)
  CAPITAL SOLEIL L 15, AVOBENZONE (OTC)

LOTUS PHARM CO LTD
* LOTUS PHARMAEUOTEI CAL CO LTD
  ROWEEPA, LEVETI RACETAM
* LOTUS PHARMAEUOTEI CAL CO LTD NANTOU PLANT
  CALC UI ACETATE, CALCUI ACETATE
  LEVETI RACETAM, LEVETI RACETAM
  LEVONORGESTREL, LEVONORGESTREL
  LEVONORGESTREL, LEVONORGESTREL (OTC)
  PARI CALCI TOL, PARI CALCI TOL

LOXO ONCOLOGY INC
* LOXO ONCOLOGY INC
  VI TRAKVI, LAROTRECTI NI B

LUITPOLD
* LUITPOLD PHARMAEUOTEI CALS INC
  ACETYLCYSTEINE, ACETYLCYSTEINE
  ADENOSINE NE, ADENOSINE NE
  AM NOCAPRO C ACI D, AM NOCAPRO C ACI D
  AM NOPYLHI NE, AM NOPYLHI NE
  BENZTROPINE NE MESYLATE, BENZTROPINE NE MESYLATE
  BETAMETHASONE ACETATE AND BETAMETHASONE SODIUM PHOSPHATE, BETAMETHASONE ACETATE
  BUPRENORPHINE HYDROCHLORIDE, BUPRENORPHINE HYDROCHLORIDE
  BUSULFAN, BUSULFAN
  CAFFEINE NE CI TRATE, CAFFEINE NE CI TRATE
  CALCI UM CHLORIDE DE 10%, CALCI UM CHLORIDE DE
  CHLOROETH A2 DE SODIUM CHLORIDE A2 DE SODIUM
  CLONI DI NE HYDROCHLORIDE DE, CLONI DI NE HYDROCHLORIDE DE
  CYANOCOBALAM N, CYANOCOBALAM N
  CYCLOSPORIN NE, CYCLOSPORINE
  DACTI NOM CI N, DACTI NOM CI N
  DEXAMETHASONE SODIUM PHOSPHATE, DEXAMETHASONE SODIUM PHOSPHATE
  DEXFERRUM ION DEXTRAN
  DEXMEDETOMI DI NE HYDROCHLORIDE DE, DEXMEDETOMI DI NE HYDROCHLORIDE DE
  DI CYCLOM NE HYDROCHLORIDE DE, DI CYCLOM NE HYDROCHLORIDE DE
  DOPAM NE HYDROCHLORIDE DE, DOPAM NE HYDROCHLORIDE DE
  DORZOLAM DE HYDROCHLORIDE DE, DORZOLAM DE HYDROCHLORIDE DE
  DROPERI DOL, DROPERI DOL
  EPINEPHRINE NE, EPINEPHRINE NE
  ESOMOLOL HYDROCHLORIDE DE, ESOMOLOL HYDROCHLORIDE DE
  ESTRADIOL VALERATE, ESTRADIOL VALERATE
  ETPOM DATE, ETPOM DATE
  FLOXURIN NE, FLOXURIN NE
  FOMEPI ZOLE, FOMEPI ZOLE
  FOSPHENYTOIN SODIUM PHOSPHATE, FOSPHENYTOIN SODIUM PHOSPHATE
  GANCI CLOSI R, GANCI CLOSI R SODIUM
  GEMSI TABI NE HYDROCHLORIDE DE, GEMSI TABI NE HYDROCHLORIDE DE
  GLYCOPROPOLATE, GLYCOPROPOLATE
  GRAN SETRON HYDROCHLORIDE DE, GRAN SETRON HYDROCHLORIDE DE
  HYDRAZIN NE HYDROCHLORIDE DE, HYDRAZIN NE HYDROCHLORIDE DE
  HYDROXYPROGESTERONE CAPROATE, HYDROXYPROGESTERONE CAPROATE
  HYDROXYZI NE HYDROCHLORIDE DE, HYDROXYZI NE HYDROCHLORIDE DE
  I BUTI LI DE FUMARATE, I BUTI LI DE FUMARATE
  I N ECTAFER, FERRI CARBOXYMALTOSE
  LEVETI RACETAM, LEVETI RACETAM
  LEVOCARNI TI NE, LEVOCARNI TI NE
  LEVOCARNI TI NE
  LI DOCAI NE HYDROCHLORIDE DE, LI DOCAI NE HYDROCHLORIDE DE
  MANNI TOL 25%, MANNI TOL
  METHOCARBAMOL, METHOCARBAMOL
  METHYLPROPIONATE HYDROCHLORIDE DE, METHYLPROPIONATE HYDROCHLORIDE DE
  METHYLERGONOVY NI MALEATE, METHYLERGONOVY NI MALEATE
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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| Lupin Ltd | * Lupin I Li M Ted |
**L**

* LUPIN LTD

ABACAVIR SULFATE AND LAM VUDI NE, ABACAVIR SULFATE
ABACAVIR SULFATE, LAM VUDI NE AND ZI DOVUDI NE, ABACAVIR SULFATE
AMABELZ, ESTRADIOL
AMLODI PI NE BESYLATE, VALSATAN AND HYDROCHLOROTHI AZI DE, AMLODI PI NE BESYLATE
ARMODAFI N L, ARMODAFI N L
ATOKAQUONE, ATOKAQUONE
AZI THROMCYCI N, AZI THROMCYCI N
BEKYREE, DESOGESTREL
BI MATOPROST, BI MATOPROST
BLI SOVI  24 FE, ETHYL ESTRADIOL
BLI SOVI  3 F, 3/30, ETHYL ESTRADIOL
BLI SOVI  1 F, 1/20, ETHYL ESTRADIOL
BUPROPI ON HYDROCHLORIDE, BUPROPI ON HYDROCHLORIDE
CALCIUM ACETATE, CALCIUM ACETATE
CELECOX B, CELECOX B
CI PROFLOXACI N, CI PROFLOXACI N
CLARI THROMCYCI N, CLARI THROMCYCI N
CLOBAZAM, CLOBAZAM
CLOBETASOL PROPI ONATE, CLOBETASOL PROPI ONATE
CLON PRAM NE HYDROCHLORIDE, CLON PRAM NE HYDROCHLORIDE
CLONDI NE HYDROCHLORIDE, CLONDI NE HYDROCHLORIDE
DAYSEE, ETHYL ESTRADIOL
DECI TABI NE, DECI TABI NE
DESVENLAFAXI NE SUCCI NATE, DESVENLAFAXI NE SUCCI NATE
DI CLOFENAC SODIUM, DI CLOFENAC SODIUM
DONEPEZI L HYDROCHLORIDE, DONEPEZI L HYDROCHLORIDE
DOXERCALCI FEROL, DOXERCALCI FEROL
DOXYCYCLIN NE HYCLATE, DOXYCYCLIN NE HYCLATE
DOXYCYCLIN NE, DOXYCYCLIN NE
DROSPI RENONE AND ETHYL ESTRADIOL, DROSPI RENONE
DROSPI RENONE, ETHYL ESTRADIOL AND LEVOMEFOLATE CALCIUM, DROSPI RENONE
DULOKETI NE HYDROCHLORIDE, DULOKETI NE HYDROCHLORIDE
ENSkyE, DESOGESTREL
ESCI TALOPRAM OXALATE, ESCL TALOPRAM OXALATE
ESZOFI CLONE, ESZOFI CLONE
FALLBACK SOLO, LEVONORGESTREL (OTC)
FAMOTI DI NE, FAMOTI DI NE
FAYOSI M, ETHYL ESTRADIOL
FENOFI BRATE, FENOFI BRATE
FENOFI BRI C ACI D, CHOLINE FENOFI BRATE
FAYOVLV, ETHYL ESTRADIOL
GABAPENTI N, GABAPENTI N
GATI FLOXACI N, GATI FLOXACI N
HYDROCORTISONE BUTYRATE, HYDROCORTISONE BUTYRATE
HYDROXYCHLOROQUINI SODIUM, HYDROXYCHLOROQUINI SODIUM
I M PRAM NE HYDROCHLORIDE, I M PRAM NE HYDROCHLORIDE
I M PRAM NE PAMATE, I M PRAM NE PAMATE
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IRBESARTAN, IRBESARTAN
J ENCyclA, NORETHI NDRONE
KAI TLI B FE, ETHYL ESTRADIOL
KURVELO, ETHYL ESTRADIOL
LAM VUDI NE AND ZI DOVUDI NE, LAM VUDI NE
LAM VUDI NE, LAM VUDI NE
LAMOTRI GNE, LAMOTRI GNE
LEVETI RACETAM, LEVETI RACETAM
LEVONORGESTREL AND ETHYL ESTRADIOL, ETHYL ESTRADIOL
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LOSARTAN POTASSIUM, LOSARTAN POTASSIUM
LURASI DNE HYDROCHLORIDE, LURASI DNE HYDROCHLORIDE
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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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** M **

** MACLEODS PHARMECEUTICALS LTD **
RI VASTI GM NE TARTRATE, RI VASTI GM NE TARTRATE
RI ZATRI PTAN BENZOATE, RI ZATRI PTAN BENZOATE
SI LDENAFI L CI TRATE, SI LDENAFI L CI TRATE
SI LODOSI N, SI LODOSI N
TAMSULOSI N HYDROCHLORIDE, TAMSULOSI N HYDROCHLORIDE
TELMA SARTAN AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
TENOFOVI R DI SOPROXI L FUMARATE, TENOFOVI R DI SOPROXI L FUMARATE
TOLTERODI NE TARTRATE, TOLTERODI NE TARTRATE
TRAMADOL HYDROCHLORIDE DE AND ACETAM NOPHEN, ACETAM NOPHEN
TRAMADOL HYDROCHLORIDE DE, TRAMADOL HYDROCHLORIDE
TRI AMI NOLON ACETATE, TRI AMI NOLON ACETONI DE
TRI AMI NOLON ACETONI DE, TRI AMI NOLON ACETONI DE
VALSARTAN AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
ZOLM TRI PTAN, ZOLM TRI PTAN

** MAGNA PHARMS **
* MAGNA PHARMECEUTICALS CALS I NC
  ZOLP. M ST, ZOLP. DEM TARTRATE

** MAI A PHARMS I NC **
* MAI A PHARMECEUTICALS CALS I NC
  LEVOTHYROXI NE SODI UM LEVOTHYROXI NE SODI UM
  SODI UM PHENYLACETATE AND SODI UM BENZOATE, SODI UM BENZOATE

** MAIPOI NTE **
* MAIPOI NTE PHARMECEUTICALS CALS LLC
  TUXARI N ER, CHLORPHENI RAMI NE MALEATE

** MALLI NOKROOT ARD **
* MALLI NOKROOT ARD I NC
  H.P. ACTHR GEL, CORTI COTROP-I N

** MALLI NOKROOT HOSP **
* MALLI NOKROOT HOSP PRODUCTS I P LTD
  I NOMAX, NI TRI C OXI DE
  OFI RHEV, ACETAM NOPHEN
  UVADEX, METHOKSALEN

** MALLI NOKROOT NUCLEAR **
* MALLI NOKROOT NUCLEAR MEDI C I NE LLC
  GALLI UM CI TRATE GA-67, GALLI UM CI TRATE GA-67
  I NOI UM I N 111 CHLORI DE, I NOI UM I N 111 CHLORI DE
  OCTREOSCAN, I NOI UM I N 111 PENTETREOTI DE KI T
  SODI UM I ODI DE 1-123, SODI UM I ODI DE 1-123
  TECHNESCAN MAG3, TECHNETI UM TC-99M MERTI ATI DE KI T
  TECHNESCAN PYP KI T, TECHNETI UM TC-99M PYROPHOSPHATE KI T
  TECHNESCAN, TECHNETI UM TC-99M OXI DRONATE KI T
  TECHNETI UM TC-99M SESTAM BI KI T, TECHNETI UM TC-99M SESTAM BI KI T
  THALLOUS CHLORI DE TL 201, THALLOUS CHLORI DE TL 201
  ULTRA-TECHNETO FM, TECHNETI UM TC-99M SODI UM PERTECHNETATE GENERATOR
  ULTRATAG, TECHNETI UM TC-99M RED BLOOD CELL KI T
  XENON XE 133, XENON XE-133

** MANNI ND **
* MANNI ND CORP
  AFREZZA, I NSULI N RECOMBI NANT HUMAN

** MARI NA BI OTECH **
* MARI NA BI OTECH I NC
  PRESTALI A, AMLODI PI NE BESYLATE

** MARKSANS PHARMA **
* MARKSANS PHARMA LTD
  CETI RI ZI NE HYDROCHLORI DE ALLERGY, CETI RI ZI NE HYDROCHLORI DE (OTC)
  CETI RI ZI NE HYDROCHLORI DE HI YES, CETI RI ZI NE HYDROCHLORI DE (OTC)
  DULOKETI NE HYDROCHLORI DE, DULOKETI NE HYDROCHLORI DE
  DUTASTERI DE, DUTASTERI DE
  FLUOKETI NE HYDROCHLORI DE, FLUOKETI NE HYDROCHLORI DE
  GABAPENTI N, GABAPENTI N
  I BUPROFEN, I BUPROFEN
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**M**

**MARKSANS PHARMA LTD**
- IBUPROFEN, IBUPROFEN (OTC)
- LORATADINE, LORATADINE (OTC)
- METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE
- NAPROXEN SODIUM, NAPROXEN SODIUM (OTC)
- NAPROXEN, NAPROXEN
- PARICALCITOL, PARICALCITOL

**MARNEL PHARMA**
- MARNEL PHARMA CALS LLC
- CROTAN, CROTAMITON

**MAYER LABS INC**
- MAYER LABORATORIES INC
- TODAY, NONOXYNOL-9 (OTC)

**MAYNE PHARMA**
- MAYNE PHARMA I INTERNATI ONAL PTY LTD
- DORYX MPC, DOXYCYCLINE HYCLATE
- DORYX, DOXYCYCLINE HYCLATE
- ERYC, ERYTHROMYCIN

**MAYNE PHARMA LLC**
- BUDERONIDE, BUDERONIDE DE
- CAM LA, NORETHINDRONE
- CARBI DOPA AND LEVODOPA, CARBI DOPA
- CLARThROMYCIN N, CLARThROMYCIN N
- CLONDI NE, CLONDI NE
- CLOYAPI NE, CLOYAPI NE
- CYCLOSPORIN NE, CYCLOSPORIN NE
- DESOGEESTREL AND ETI NYL ESTRADIOL, DESOGEESTREL
- DEXTROAMPHETAMINE NE SULFATE, DEXTROAMPHETAMINE NE SULFATE
- DI AZEPAM, DI AZEPAM
- DI SOPYRAM DE PHOSPHATE, DI SOPYRAM DE PHOSPHATE
- DROPSI RENONE AND ETI NYL ESTRADIOL, DROPSI RENONE
- ERRIN, NORETHINDRONE
- ESTAZOLAM, ESTAZOLAM
- ESTRADIOL OL, ESTRADIOL OL
- FABIO OR, TAZAROTENE
- FENTANYL-100, FENTANYL
- FENTANYL-25, FENTANYL
- FENTANYL-50, FENTANYL
- FENTANYL-75, FENTANYL
- FLUOROURACIL L, FLUOROURACIL L
- HALOBETASOL PROPI ONATE, HALOBETASOL PROPI ONATE
- LEVONORGESTREL AND ESTRADIOL OLG, LEVONORGESTREL AND ESTRADIOL
- LEVORA 0.15/30-28, ESTRADIOL OL
- LOW OESTREL-28, ESTRADIOL OL
- METHYLPHENIDATE HYDROCHLORIDE, METHYLPHENIDATE HYDROCHLORIDE
- M CROGESTI N 1, 5/30, ESTRADIOL OL
- M CROGESTI N 1/20, ESTRADIOL OL
- M CROGESTI N FE 1/5/30, ESTRADIOL OL
- M CROGESTI N FE 1/20, ESTRADIOL OL
- NORETHINDRONE ACETATE AND ESTRADIOL OL, NORETHINDRONE ACETATE AND ESTRADIOL OL
- NORETHINDRONE AND ESTRADIOL OL, NORETHINDRONE AND ESTRADIOL OL
- NORTRIPTYLINE HYDROCHLORIDE, NORTRIPTYLINE HYDROCHLORIDE
- SORI LUX, CALCI POTRI EN
- TAMOXI FEN CI TRATE, TAMOXI FEN CI TRATE
- TRI-NORINYL 28-DAY, ESTRADIOL OL
- TRIMETHOPRIM, ESTRADIOL OL
- ZOVIA 1/35E-28, ETHINYL ESTRADIOL OL

**MAYNE PHARMA INC**
- AMIODARONE HYDROCHLORIDE, AMIODARONE HYDROCHLORIDE
- BROMPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE AND DEXTROMETHORPHAN
- BUTALBI TAL AND ACETAMINOPHEN, ACETAMINOPHEN
- BUTALBI TAL, ACETAMINOPHEN AND CAFFEINE, ACETAMINOPHEN
** M **

** M **

* MAYNE PHARMA INC
  BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE, ASPIRIN
  CLONIDINE HYDROCHLORIDE, DOXYCYCLINE HYDROCHLORIDE
  DOXYCYCLINE, DOXYCYCLINE HYDROCHLORIDE
  HYDROCODONE BITARTRATE AND PSEUDOEPHEDRINE HYDROCHLORIDE, HYDROCODONE BITARTRATE
  HYDROCODONE, HYDROCODONE HYDROCHLORIDE
  HYDROCODONE BITARTRATE, CHLORPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE HYDROCHLORIDE,
  LIOTHYRONINE SODIUM, LIOTHYRONINE SODIUM
  METHAMPHETAMINE HYDROCHLORIDE, METHAMPHETAMINE HYDROCHLORIDE
  MORPHINE SULFATE, MORPHINE SULFATE
  NYSTATIN, NYSTATIN
  OXYCODONE AND ASPIRIN, ACETAMINOPHEN
  OXYCODONE AND ACETAMINOPHEN, OXYCODONE AND ACETAMINOPHEN
  OXYCODONE, OXYCODONE HYDROCHLORIDE
  OXYCODONE HYDROCHLORIDE, CHLORPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE HYDROCHLORIDE,
  LIOTHYRONINE SODIUM, LIOTHYRONINE SODIUM
  METHAMPHETAMINE HYDROCHLORIDE, METHAMPHETAMINE HYDROCHLORIDE
  MORPHINE SULFATE, MORPHINE SULFATE
  NYSTATIN, NYSTATIN
  OXYCODONE AND ACETAMINOPHEN, ACETAMINOPHEN
  OXYCODONE AND ACETAMINOPHEN, ASPIRIN
  OXYCODONE, OXYCODONE HYDROCHLORIDE
  OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE

* MAYNE PHARMA INTL
  TOLSURA, ITRACONAZOLE

* MCGUFF
  ASCOR, ASCORBIC ACID

* MCNEIL
  I BUPROFEN, BUPROFEN (OTC)

* MCNEIL CONS
  SUDAFED 12 HOUR, PSEUDOEPHEDRINE HYDROCHLORIDE (OTC)

* MCPH
  AMMONIUM N-13, AMMONIUM N-13
  CHOLINE C-11, CHOLINE C-11
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18
  SODIUM FLUORIDE F-18, SODIUM FLUORIDE F-18

* MCHG
  MEDICINES DEVELOPMENT FOR GLOBAL HEALTH
  MEDI NES DECTI N, MEDI NES DECTI N

* MEDAC PHARMA INC
  RASUVO, METHOTREXATE

* MEDI F L INC
  SODIUM CHLORIDE 0.9%, SODIUM CHLORIDE

* MEDIC IN S360
  LILETTA, LEVONORGESTREL

* MEDI CLS
  MEDI CLS PHARMACEUTICAL CORPORATION
  ALDARA, IMiquIMOD
  AMMONUL, SODIUM BENOZOATE
  CALCIUM HISTIDINE 4 MONOHYDRATE, CALCIUM HISTIDINE 4 MONOHYDRATE
  EDETATE CALCIUM DISODIUM
  LOPROX, CLOPROX
  LUXUR, LULICONAZOLE
  METROGEL-VAGINAL, METRONIDAZOLE
  NEOMYCIN SULFATE, NEOMYCIN SULFATE
  NIMICON, NIMICON HCl
  SODIUM CHLORIDE 0.9%

* MEDI CURE
  AGGRASTAT, AGGRASTAT
  TROFIBAN, TROFIBAN
  NI TROPRUSSI DE, NI TROPRUSSI DE

* MEDI METRI KS PHARMA
  ZOFLAS, IMIQUIMOD
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** M **

* MEDIMETRIKS PHARMACEUTICALS INC
  BETAXOLOL HYDROCHLORIDE, BETAXOLOL HYDROCHLORIDE
  LOPROX, CI CLOPI ROX
  NEO SYNALAR, FLUOCI NOLONE ACETONIDE DE
  SYNALAR, FLUOCI NOLONE ACETONIDE DE

* MEDLINE INDUSTRIES INC
  READYPREP CHG, CHLORHEXIDI DI NE GLUCONATE (OTC)

* MEDTECH PRODUCTS INC
  MONISTAT 1 COMBINATION PACK, MICONAZOLE NI TRATE (OTC)
  MONISTAT 3 COMBINATION PACK (PREFILLED), M CONAZOLE NI TRATE (OTC)
  MONISTAT 3, M CONAZOLE NI TRATE
  MONISTAT 7 COMBINATION PACK, M CONAZOLE NI TRATE (OTC)
  MONISTAT 7, M CONAZOLE NI TRATE (OTC)
  NI X, PERMETHRIN N (OTC)
  TAGAMET HB, CI METI DI NE (OTC)

* MELNITA SUBSIDIARY CORP
  BAXDELA, DELAFLOXACIN N MEGLUMINE

* MELNITA THERAPEUTICS INC
  ORBACTI V, ORI TAVANCI N DI PHOSPHATE

* MEM SLOAN-KETTERING CANCER CENTER
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18

* MERCK AND CO INC
  EMEND, APREPI TANT
  FOSAMAX PLUS D, ALENDRONATE SODIUM
  MAXALT, RI ZATRI PTAN BENZOATE
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18
  TRUSOPT, DORZOLAMIDE DE HYDROCHLORIDE DE

* MERCK RESEARCH LABORATORIES DIV MERCK CO INC
  PRI VI LI, LI SI NOPRI L
  PROPECIA, FINASTERIDE
  SI NGULAI R, MONTELUKAST SODIUM
  TRUSOPT, DORZOLAMIDE DE HYDROCHLORIDE DE

* MERCK AND CO INC
  EMEND, FOSAPREPI TANT DI MEGLUMINE
  FOSAMAX, ALENDRONATE SODIUM

* MERCK SHARP & DOHME CORP
  ASMANEX HFA, MOMETASONE FURATE
  ASMANEX TWISTHALER, MOMETASONE FURATE
  CELESTONE SOLUSPAN, BETAMETHASONE ACETATE
  CLARI NEX: D 24 HOUR, DESLORATADI NE
  CLARI NEX: D 12 HOUR, DESLORATADI NE
  DULERA, FORMOTEROL FUMARATE
  ELOCON, MOMETASONE FURATE
  GUANI DI NE HYDROCHLORIDE DE, GUANI DI NE HYDROCHLORIDE DE
  HYZAAR, HYDROCHLOROTHI AZI DE
  I NINZAN, ERTAPENEM SODIUM
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** M **

* MERCK SHARP AND DOHME CORP
  ISENTRESS HD, Raltegravir Potassium
  ISENTRESS, Raltegravir Potassium
  JANUMET XR, Metformin Hydrochloride
  JANUMET, Metformin Hydrochloride
  JANUVIA, Sitagliptin Phosphate
  LOTRISONE, Betamethasone Dipropionate
  NASONEX, Mometasone Furoate
  NOXAFIL, Posaconazole
  PREVYMIS, Liposomal Amphotericin B
  REBETOL, Ribavirin
  SEGLUROMET, Ertugliflozin
  STEGLATRO, Ertugliflozin
  STEGLUJAN, Ertugliflozin
  STROMECTOL, Ivermectin
  TEMODAR, Temozolomide
  ZEPATIER, Elbasvir

* MERIDIAN MEDICAL TECHNOLOGIES INC
  DUODOTE, Atropine

* MERIDIAN MEDICAL TECHNOLOGIES INC
  ATROPEN, Atropine Sulfate
  MORPHINE SULFATE, Morphine Sulfate
  PRALIDOXIME CHLORIDE, Pralidoxime Chloride
  SEIZALAM, Midazolam Hydrochloride

* MERLION PHARMACEUTICALS GMBH
  XTORO, Finafloxacin

* MERRO PHARMACEUTICAL CO LTD
  IBUPROFEN, Ibuprofen (OTC)

* MERZ PHARMAQUENCES LLC
  CUVMOSA, Glycopyrrolate

* METAPHARM INC
  PROVOCOLI NE, Methacholine Chloride

* METUCHEN PHARMACEUTICALS LLC
  STENDRA, Avanafil

* M CRO LABS LTD
  AMLODI PI NE AND OLMESARTAN MEDOXOMIL, Amlodipine Besylate
  CAFFEINE NE CI TRATE, Caffeine Ne Cti Trate
  CELECOXY B, Celecoxib B
  CLI NDAMICI N HYDROCHLORIDE DE, CLIN Damici N Hydrochloride de
  DIPHENHYDRAMINE NE HYDROCHLORIDE DE, Dihyderamine Ne Hydrochloride de
  LEVOSETR NI ZI NE DI HYDROCHLORIDE DE, Levoctet Ni Zi Ne Di Hydrochloride de (OTC)
  PI ROXI CAM, Pi Roxi Cam
  SODIUM NI TROPRUSI DE, Sodium Ni Troprusi De
  VERAPAM L HYDROCHLORIDE DE, Verapamil L Hydrochloride de

* M CRO LABS LTD INDIA
  AMOXI CI LLI N AND CLAVULANATE POTASSI UM, Amoxicillin and Clavulanic Acid
  CROMOLYN SODIUM, Cromolyn Sodium
  NEVI RAPI NE, Nevi Rapi Ne
### Appendix B - Product Name Sorted by Applicant

#### **M**

- **MICRO LABS LTD INDIA**
  - Levocetirizine Dihydrochloride, Levocetirizine Dihydrochloride
  - Tramadol Hydrochloride and Acetaminophen, Acetaminophen

- **MIDATECH PHARMA US**
  - Oravi G, M Conazole
  - Soltamox, Tamoxifen Citrate
  - Ziplenz, Ondansetron

- **MIDWEST MEDICAL ISOTOPES LLC CYCLOTRON DIV**
  - Ammonia N 13, Ammonia N-13
  - Sodium Fluoride F-18, Sodium Fluoride F-18

- **MIKART LLC**
  - Acetaminophen and Codeine Ne Phosphate, Acetaminophen
  - Amantadine Ne Hydrochloride, Amantadine Ne Hydrochloride
  - Benzatonate, Benzatonate
  - Benzhexol Ne Hydrochloride, Benzhexol Ne Hydrochloride
  - Butalbital and Acetaminophen, Acetaminophen
  - Butalbital, Acetaminophen and Caffeine Ne, Acetaminophen
  - Butapap, Acetaminophen
  - Carbamazepine Ne Maleate, Carbamazepine Ne Maleate
  - Chlorzoxazone, Chlorzoxazone
  - Ergotamine Tartrate and Caffeine Ne, Caffeine Ne
  - Ethosuximide, Ethosuximide
  - Hydrocodone Bi Tartrate and Acetaminophen, Acetaminophen
  - Isoniazid, Isoniazid
  - Meperidine Hydrochloride, Meperidine Hydrochloride
  - Methazolam D, Methazolam D
  - Oxycodeone and Acetaminophen, Acetaminophen
  - Phenobarbital Ne Tartrate, Phenobarbital Ne Tartrate
  - Trihexyphenidyl Dyl Hydrochloride, Trihexyphenidyl Dyl Hydrochloride

- **MIKART INC**
  - Oxycodeone and Acetaminophen, Acetaminophen

- **MILLENIUM PHARMS**
  - Ninlaro, Ixazomib Citrate
  - Velcade, Bortezomib

- **MILLICENT HOLDINGS LTD**
  - Femring, Estradiol Acetate

- **MIPS CYCLOTRON AND RADIOCHEMISTRY FACILITY**
  - Ammonia N 13, Ammonia N-13
  - Fluodeoxyglucose F 18, Fluodeoxyglucose F-18
  - Sodium Fluoride F-18, Sodium Fluoride F-18

- **MISSION PHARMA**
  - Binosto, Alendronate Sodium
  - Lithostat, Acetohydroxamic Acid
  - Prednisolone Sodium Phosphate, Prednisolone Sodium Phosphate
  - Texacort, Hydrocortisone
  - Thiola, Thiopronin
  - Tindamax, Tinidazole
  - Urocid-T-K, Potassium Citrate

- **MISSION PHARMACAL CO**
  - Carbamazepine Ne Maleate, Carbamazepine Ne Maleate
  - Potassium Iodide, Potassium Iodide (OTC)

- **MIST PHARMS LLC**
  - Nitromist, Nitroglycerin

- **MITSUBISHI TANABE**

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**Note:** This list is a subset of the complete list available in the document. The full list contains many more products sorted by applicant name.
# APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** M **

* **MITSUBISHI PHARMA CORP**
  - RADICAVA, EDARAVONE

* **MOBERG PHARMA NORTH**
  - CHI LIDREN S ELI XSURE, IBUPROFEN (OTC)

* **MOBI US THERAP**
  - MTO COL, MTOMCY N

* **MOUNLYCKE HLTH**
  - HI BI CLENS, CHLORHEX DI NE GLUCONATE (OTC)
  - HI BI STAT, CHLORHEX DI NE GLUCONATE (OTC)

* **MONARCH PHARMA**
  - MONARCH PHARMACEUTI CALS LLC
    - CORTI SPORI N, BACI TRACI N ZI NC
    - CORTI SPORI N, HYDROCORTISONE ACETATE
  - MENEST, ESTROGENS, ESTERI FI ED
  - NEO SPORI N G U, I RRI GANT, NEO/MCY N SULFATE
  - NEO SPORI N, GRAM CI DI N
  - SEPTRA DS, SULFAMETHOXAZOLE
  - SEPTRA, SULFAMETHOXAZOLE
  - VI ROPT C, TRI FLURI DI NE

* **MONTEREY PHARMS LLC**
  - MONTEREY PHARMACEUTI CALS LLC
    - METHOCARBAMOL, METHOCARBAMOL

* **MOUNTAINE**
  - MOUNTAINE LLC
    - CYPROHEPTADI NE HYDROCHLORIDE DE,
    - CYPROHEPTADI NE HYDROCHLORIDE DE
    - GRI SEOFULVI N, ULTRAM CROSI ZE,
    - GRI SEOFULVI N, ULTRAM CROSI ZE
    - METHALONE, METHALONE
    - METHYLPHENI DATE HYDROCHLORIDE DE,
    - METHYLPHENI DATE HYDROCHLORIDE DE

* **MSD I NTL**
  - MSD I INTERNATI ONAL GMBH
    - VÝTORI N, ÊZETI M BE

* **MSD I NTL GMBH**
  - MSD I INTERNATI ONAL GMBH
    - ZETI A, ÊZETI M BE

* **MSD MERCK CO**
  - MERCK SHARP AND DÓME CORP A SUB OF MERCK AND CO I NC
    - DELSTRI GO, DORAVIRI NE
    - EMEND, APREPI TANT
    - PI FELTRO, DORAVIRI NE
    - SI NGULAI R, MONTENUKAST SODI UM
    - ZOCOR, SI MASTATI N

* **MSN LABS PVT LTD**
  - MSN LABORATORI ES PRI VATE LTD
    - CAPECI TABI NE, CAPECI TABI NE
    - CLOFARABI NE, CLOFARABI NE
    - MDK FLOKACI N HYDROCHLORIDE DE,
    - MDK FLOKACI N HYDROCHLORIDE DE
    - ROSUVASTATI N CALCUM, ROSUVASTATI N CALCUM
    - SI LODOSI N, SI LODOSI N

* **MURTNY PHARMA**
  - MURTNY PHARMACEUTI CALS I NC
    - AM ODARONE HYDROCHLORIDE DE,
    - AM ODARONE HYDROCHLORIDE DE
    - DI PYRI DAMOLX, DI PYRI DAMOLO

* **MUSTAFA NEVZAT I LAC**
  - MUSTAFA NEVZAT I LAC SANAYI I AS (MN PHARMACEUTI CALS)
    - AMPI CI LLI N AND SULBACTAM
    - AMPI CI LLI N SODI UM
    - I RI NOTECAI HYDROCHLORIDE DE,
    - I RI NOTECAI HYDROCHLORIDE DE
    - VANCOMICY N HYDROCHLORIDE DE,
    - VANCOMICY N HYDROCHLORIDE DE

* **MUTUAL PHARM**
  - MUTUAL PHARMACEUTI CAL CO I NC
    - PREDNI SONE, PREDNI SONE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** M **

** MYLAN PHARMACEUTICALS **

FENOFIBRATE, FENOFIBRATE

METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE

TRANEXAMIC ACID, TRANEXAMIC ACID

** MYLAN PHARMACEUTICALS INC **

ACARBOS, ACARBOS

ACEBUTOLOL HYDROCHLORIDE, ACEBUTOLOL HYDROCHLORIDE

ALBUTEROL SULFATE, ALBUTEROL SULFATE

AMLODIPI NE BENZEPRI L HYDROCHLORIDE, AMLODIPI NE BESYLATE

ANASTROZOLE, ANASTROZOLE

ATENOLOL, ATENOLOL

AVITA, TRETINOIN

AZATHIOPRINE, AZATHIOPRINE

AZITHROMYCIN, AZITHROMYCIN

BACLOFEN, BACLOFEN

BALSALAZIDE DE AND HYDROCHLOROTHIAZIDE, BALSALAZIDE DE AND HYDROCHLOROTHIAZIDE

BENAZEPRI L HYDROCHLORIDE, BENAZEPRI L HYDROCHLORIDE

BI CALUTAMI DE, BI CALUTAMI DE

BI SOPROL FUMARATE, BI SOPROL FUMARATE

BROMOCRIPTINE MESYLATE, BROMOCRIPTINE

BUDESONIDE, BUDESONIDE

CETIRIZINE HYDROCHLORIDE HIVES, CETIRIZINE HYDROCHLORIDE (OTC)

CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES, FEXOFENADINE HYDROCHLORIDE (OTC)

CHLOROTHIAZIDE, CHLOROTHIAZIDE

CLOMIPRAMINE HYDROCHLORIDE, CLOMIPRAMINE HYDROCHLORIDE

CLORAZEPATE DI POTASSIUM, CLORAZEPATE DI POTASSIUM

CLORPHENAMINE, CLORPHENAMINE

CLOZAPINE, CYSTAGON

CYPRESIUM, DI FORMICUM

DI AZEPAM, DI AZEPAM

DI CLOFENAC POTASSIUM, DI CLOFENAC POTASSIUM

DI CYCLOM, DI CYCLOM

DI LTI AZEM HYDROCHLORIDE, DI LTI AZEM HYDROCHLORIDE

DI PHENOKYLYATE HYDROCHLORIDE DE AND ATROPI NE SULFATE, ATROPI NE SULFATE

DI VALPROEX SODIUM, DI VALPROEX SODIUM

DOXAZOSIN MESYLATE, DOXAZOSIN MESYLATE

DOXYCYCLIN, DOXYCYCLIN

ENALAPRI L MALEATE AND HYDROCHLOROTHIAZIDE, ENALAPRI L MALEATE

ENALAPRI L MALEATE, ENALAPRI L MALEATE
** M **

* MYLAN PHARMACEUTICALS INC

ESTRA DIOL, ESTRA DIOL

ESTRO PI PATE, ESTRO PI PATE

ETINDRONE DI SODI UM, ETINDRONE DI SODI UM

ETOPOSI DE, ETOPOSI DE

EXTENDED PHENYTO IN SODI UM, PHENYTO IN SODI UM

FAMOTIDI N R, FAMOTIDI N R

FAMOTIDI N NE, FAMOTIDI N NE (OTC)

FENO FIBRATE, FENO FIBRATE

FIBRO KETI NE HYDROCHLORI DE, FIBRO KETI NE HYDROCHLORI DE

FIBRO HENAZI NE HYDROCHLORI DE, FIBRO HENAZI NE HYDROCHLORI DE

FLU CONAZOLE, FLU CONAZOLE

FLUCONAZOLE, FLUCONAZOLE

FLUCONAZOLE, FLUCONAZOLE

FLUOXM E MALEATE, FLUOXM E MALEATE

FURASEM DE, FURASEM DE

GABAPENTI N, GABAPENTI N

GALANTAM NE HYDROBROM DE, GALANTAM NE HYDROBROM DE

GLI MEPI RI DE, GLI MEPI RI DE

GLI PI ZI DE AND METFORMI N HYDROCHLORI DE, GLI PI ZI DE

GLI PI ZI DE, GLI PI ZI DE

GLYBURI DE (M CRONI ZED), GLYBURI DE

GRONI SETRON HYDROCHLORI DE, GRONI SETRON HYDROCHLORI DE

GUANFACI NE HYDROCHLORI DE, GUANFACI NE HYDROCHLORI DE

HALOPERI DOL, HALOPERI DOL

HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE

HYDROXYCHLOROQUINE SULFATE, HYDROXYCHLOROQUINE SULFATE

HYDROXYZINE NE HYDROCHLORI DE, HYDROXYZINE NE HYDROCHLORI DE

I NDAPAM DE, I NDAPAM DE

I NDAPAM DE, I NDAPAM DE

KETOCONAZOLE, KETOCONAZOLE

KETOCONAZOLE, KETOCONAZOLE

KETOPROFEN, KETOPROFEN

KETOROLAC TROMETHAM NE, KETOROLAC TROMETHAM NE

LAMOTRIGINE, LAMOTRIGINE

LATANOPROST, LATANOPROST

LEVE T RACETAM, LEVE T RACETAM

LEVOTHYROXINE SODI UM, LEVOTHYROXINE SODI UM **

LITHI ORONI NE SODI UM, LITHI ORONI NE SODI UM

LITHI ORONI NE SODI UM, LITHI ORONI NE SODI UM

LITHI ORONI NE SODI UM, LITHI ORONI NE SODI UM

LITHI ORONI NE SODI UM, LITHI ORONI NE SODI UM

LITHI ORONI NE SODI UM, LITHI ORONI NE SODI UM

LITHI ORONI NE SODI UM, LITHI ORONI NE SODI UM

LOPRAM DE HYDROCHLORI DE, LOPRAM DE HYDROCHLORI DE

LORATADI NE, LORATADI NE (OTC)

LORAZEPAM, LORAZEPAM

LOSARTAN POTASSIUM, LOSARTAN POTASSIUM

LOVASTATI N, LOVASTATI N

LOXAPI NE SUCCI NATE, LOXAPI NE SUCCI NATE

METHOTREXATE SODI UM, METHOTREXATE SODI UM

METHYLDOPA AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE

METHYLDOPA, METHYLDOPA

METOLAZONE, METOLOAZONE

METOPROLOL TARTRATE, METOPROLOL TARTRATE

MIRTAZAPI NE, MIRTAZAPI NE

MYCOPHENOLATE MOFETI L, MYCOPHENOLATE MOFETI L
**M**

* MYLAN PHARMACEUTICALS INC
  NADOLOL, NADOLOL
  NAPROXEN, NAPROXEN
  NI CARDI PI NE HYDROCHLORIDE, NI CARDI PI NE HYDROCHLORIDE
  NI FEDPI NE, NI FEDPI NE
  NI SOLDI PI NE, NI SOLDI PI NE
  NI TROFURANTOI N (MONOHYDRATE/MACROCRYSTALS), NI TROFURANTOI N
  NI TROFURANTOI N, NI TROFURANTOI N, MACROCRYSTALLI NE
  OMEPRAZOLE, OMEPRAZOLE
  ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE
  ONDANSETRON, ONDANSETRON
  OXYBUTYNIN CHLORIDE, OXYBUTYNIN CHLORIDE
  PENTOXIFYLLINE, PENTOXIFYLLINE
  PERPHENAZINE AND AMITRIPTYLINE HYDROCHLORIDE, AMITRIPTYLINE HYDROCHLORIDE
  PHENYTEK, PHENYTOIN SODIUM
  PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE
  POLYETHYLENE GLYCOL 3350, POLYETHYLENE GLYCOL 3350 (OTC)
  PRAM PEXOLE DI HYDROCHLORIDE DE, PRAM PEXOLE DI HYDROCHLORIDE DE
  PRAZOSIN HYDROCHLORIDE, PRAZOSIN HYDROCHLORIDE
  PROBENCOD D, PROBENECID D
  PROCHLORPERAIZE NA MALEATE, PROCHLORPERAIZE NA MALEATE
  PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE AZI DE, HYDROCHLOROTHIAZIDE AZI DE
  PROPRANOLOL HYDROCHLORIDE, PROPRANOLOL HYDROCHLORIDE
  QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  QUINAPRIL HYDROCHLORIDE, QUINAPRIL HYDROCHLORIDE
  RANITIDINE HYDROCHLORIDE, RANITIDINE HYDROCHLORIDE (OTC)
  RISPERIDONE, RISPERIDONE
  SULINDAC, SULINDAC
  SUMATRIPTAN SUCCINATE, SUMATRIPTAN SUCCINATE
  TACROLIMUS, TACROLIMUS
  TIMOLOL MALEATE, TIMOLOL MALEATE
  TIZANIDINE HYDROCHLORIDE, TIZANIDINE HYDROCHLORIDE
  TOLEMETIN SODIUM, TOLEMETIN SODIUM
  TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN, ACETAMINOPHEN
  TRAMADOL HYDROCHLORIDE, TRAMADOL HYDROCHLORIDE
  VERAPAMIL HYDROCHLORIDE, VERAPAMIL HYDROCHLORIDE
  ZONISAMIDE, ZONISAMIDE

* MYLAN ASI LLC
  ACETAZOLAMIDE SODIUM, ACETAZOLAMIDE SODIUM
  ADENOSI NE, ADENOSI NE
  AZI THROMICI N, AZI THROMICI N
  BUPI VACAI NE HYDROCHLORIDE DE PRESERVATI VE FREE, BUPI VACAI NE HYDROCHLORIDE
  BUPI VACAI NE HYDROCHLORIDE DE, BUPI VACAI NE HYDROCHLORIDE DE
  GRAN SETRON HYDROCHLORIDE DE, GRAN SETRON HYDROCHLORIDE DE
  M DAZOLAM HYDROCHLORIDE DE PRESERVATI VE FREE, M DAZOLAM HYDROCHLORIDE DE
** M **

* MYLAN ASI LLC
POLYMIXI N B SULFATE, POLYMIXI N B SULFATE
ROPI VAQAI NE HYDROCHLORI DE, ROPI VAQAI NE HYDROCHLORI DE
SUMATRI PTAN SUCCI NATE, SUMATRI PTAN SUCCI NATE

* MYLAN I NSTI TUTI ONAL LLC
ACETYLCYSTEINE NE, ACETYLCYSTEINE NE
AM ODARONE HYDROCHLORI DE, AM ODARONE HYDROCHLORI DE
ARGATROBAN, ARGATROBAN
AZAC TI DI NE, AZAC TI DI NE
BI VALI RUDI N, BI VALI RUDI N
CARBOPLATI N, CARBOPLATI N
CHLOROZAI DE SODI UM, CHLOROZAI DE SODI UM
CI DOFOVII R, CI DOFOVII R
COSYNTROPI N, COSYNTROPI N
DANTROLENE SODI UM, DANTROLENE SODI UM
DEXMEDETOM DI NE HYDROCHLORI DE, DEXMEDETOM DI NE HYDROCHLORI DE
DEXRAZOXANE HYDROCHLORI DE, DEXRAZOXANE HYDROCHLORI DE
DI MELPHALAN HYDROCHLORI DE, DI MELPHALAN HYDROCHLORI DE
DI MHETADONE HYDROCHLORI DE, DI MHETADONE HYDROCHLORI DE
FOMEPI ZOLE, FOMEPI ZOLE
HYDRAZI NE HYDROCHLORI DE, HYDRAZI NE HYDROCHLORI DE
I BUTI LI DE FUMARATE, I BUTI LI DE FUMARATE
I SULFAN BLUE, I SULFAN BLUE
KETAM NE HYDROCHLORI DE, KETAM NE HYDROCHLORI DE
MELPHALAN HYDROCHLORI DE, MELPHALAN HYDROCHLORI DE
METHADONE HYDROCHLORI DE, METHADONE HYDROCHLORI DE
METHOCARBAMOL, METHOCARBAMOL
M TOKANTRONE HYDROCHLORI DE, M TOKANTRONE HYDROCHLORI DE
NALOKONE HYDROCHLORI DE, NALOKONE HYDROCHLORI DE
OCTREOTIDE ACETATE (PRESERVATIVE FREE), OCTREOTIDE ACETATE
PALONOSETRON HYDROCHLORI DE, PALONOSETRON HYDROCHLORI DE
PENTOSTATI N, PENTOSTATI N
RHISO-50, DI MELPHALAN HYDROCHLORI DE
ROCURONI UM BROMI DE, ROCURONI UM BROMI DE
SOTRADECOL, SODI UM TETRADECYL SULFATE
TESTOSTERONE CYPIONATE, TESTOSTERONE CYPIONATE
THI AM NE HYDROCHLORI DE, THI AM NE HYDROCHLORI DE
TRANEXAM C ACI D, TRANEXAM C ACI D
ULT VIA, REM FENTANI L HYDROCHLORI DE

* MYLAN I RELAND LTD
ARI XTRA, FONDAPARI NUX SODI UM
CARBAMAZEPINE NE, CARBAMAZEPINE NE
M ACALCI N, CALCITONIN SALMON
PI ROKI CAM, PI ROKI CAM
THEOPHYLLINE NE, THEOPHYLLINE NE
YPEREL, REFEFFENACI N

* MYLAN LABS
RENI RAPI NE, RENI RAPI NE

* MYLAN LABS LTD
ADENOSINE NE, ADENOSINE NE
AM FOSTI NE, AM FOSTI NE
AMPI CI LLI N AND SULBACTAM, AMPI CI LLI N SODI UM
AMPI CI LLI N SODI UM, AMPI CI LLI N SODI UM
ATRACURI UM BESYLATE PRESERVATIVE FREE, ATRACURI UM BESYLATE
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<td>LI NEZOLI D, LI NEZOLI D</td>
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<td>MAGNESIUM SULFATE IN DEXTROSE 5% IN PLASTIC CONTAINER, MAGNESIUM SULFATE</td>
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<td>MDXI FLOKACI N HYDROCHLORIDE DE IN SODIUM CHLORIDE DE 0.8% IN PLASTIC CONTAINER, MDXI FLOKACI N</td>
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* MYLAN LABORATORIES LTD

Mycophenolate Mofetil Hydrochloride, Mycophenolate Mofetil Hydrochloride De

Nafcin Ll Ll Sodium, Nafcin Ll Ll Sodium

Nalbuphine Ne Hydrochloride, Nalbuphine Ne Hydrochloride De

Norepi Nephrine Ne Bi Tarrate, Norepi Nephrine Ne Bi Tarrate

Norethindrone Acetate And Ethyl Nyl Estradiol And Ferrous Fumarate, Ethyl Nyl Estradiol

Norethindrone Acetate And Ethyl Nyl Estradiol, Ethyl Nyl Estradiol

Norethindrone And Ethyl Nyl Estradiol And Ferrous Fumarate, Ethyl Nyl Estradiol

Norethindrone And Ethyl Nyl Estradiol, Ethyl Nyl Estradiol

Norethindrone, Norethindrone

Norgestomet And Ethyl Nyl Estradiol, Ethyl Nyl Estradiol

Ondansetron Hydrochloride, Ondansetron Hydrochloride De

Oxaliplatin, Oxaliplatin

Pamidronate Disodium, Pamidronate Disodium

Pantoprazole Sodium, Pantoprazole Sodium

Paricalcitol, Paricalcitol

Piperacillin And Tazobactam, Piperacillin Sodium

Prochlorperazine Edisylate, Prochlorperazine Edisylate

Ranitidine Hydrochloride, Ranitidine Hydrochloride

Rifampin, Rifampin

Sodium Nitroprusside, Sodium Nitroprusside

Sulfamethoxazole And Trimethoprim, Sulfamethoxazole

Sumatriptan Succinate, Sumatriptan Succinate

Symetrel, Efavirenz

Tobramycin Sulfate, Tobramycin Sulfate

Topotecan Hydrochloride, Topotecan Hydrochloride De

Vancomycin Hydrochloride, Vancomycin Hydrochloride De

Vecuronium Bromide, Vecuronium Bromide De

Zoledronate Calcium, Zoledronate Calcium

MYLAN PHARMA INC

* MYLAN PHARMA INC

Abacavir Sulfate, Abacavir Sulfate

Abiraterone Acetate, Abiraterone Acetate

Acamprosate Calcium, Acamprosate Calcium

Acitretin, Acitretin

Acyclovir, Acyclovir

Almotriptan Malate, Almotriptan Malate

Amlodipine Besylate And Atorvastatin Calcium, Amlodipine Besylate And Atorvastatin Calcium

Amlodipine Besylate And Valsartan, Amlodipine Besylate And Valsartan

Amlodipine Besylate, Amlodipine Besylate

Amnesteem, I Som silence

Armodafinil, Armodafinil

Atazanavir Sulfate, Atazanavir Sulfate

Atorvastatin Calcium, Atorvastatin Calcium

Atovaquone And Proguanil Hydrochloride, Atovaquone

Avi Ta, Trethi Nei

Baclofen, Baclofen

Buprenorphine Ne Hydrochloride, Buprenorphine Ne Hydrochloride De

Cabeceo L, Cabeceo L

Candesartan Cilexetil And Hydrochlorothiazide, Candesartan Cilexetil And Hydrochlorothiazide

Candesartan Cilexetil, Candesartan Cilexetil

Cefuroxime Sodium, Cefuroxime Sodium

Cefuroxime Sodium Extended Release, Cefuroxime Sodium Extended Release

Clarithromycin And Palmitate Hydrochloride De, Clarithromycin And Palmitate Hydrochloride De

Clarithromycin And Palmitate Hydrochloride, Clarithromycin And Palmitate Hydrochloride De

Clobazam, Clobazam

Clobetasol Propionate, Clobetasol Propionate

Clomepsol, Clomepsol

Clop Amp, Clop Amp, Clop Amp

Clop Amp, Clop Amp

Clop Amp, Clop Amp

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* MYLAN PHARMACEUTICALS INC
### Appendix B - Product Name Sorted by Applicant

#### **M**

- MYLAN PHARMACEUTICALS INC
  - MODAFINIL, MODAFINIL
  - MONTELUKAST SODIUM, MONTELUKAST SODIUM
  - MORPHINE SULFATE, MORPHINE SULFATE
  - MOXIFLOXACIN HYDROCHLORIDE, MOXIFLOXACIN HYDROCHLORIDE
  - MYCOPHENOLIC ACID, MYCOPHENOLIC ACID
  - NABUMETONE, NABUMETONE
  - NARATRIPTAN, NARATRIPTAN HYDROCHLORIDE
  - NEVIRAPINE, NEVIRAPINE
  - OLANZAPINE, OLANZAPINE
  - OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  - OLMESARTAN MEDOXOMIL, OLMESARTAN MEDOXOMIL
  - OLOPATADINE HYDROCHLORIDE, OLOPATADINE HYDROCHLORIDE
  - OLUX E, CLOBETASOL PROPIONATE
  - OLUX, CLOBETASOL PROPIONATE
  - OMEPRAZOLE, OMEPRAZOLE
  - PALIPERIDONE, PALIPERIDONE
  - PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM
  - PERPHENAZINE, PERPHENAZINE
  - PHENYTOIN, PHENYTOIN
  - PI NIDOLOL, PI NIDOLOL
  - PI OGLI TAZONE HYDROCHLORIDE, PI OGLI TAZONE HYDROCHLORIDE
  - POTASSIUM CHLORIDE, POTASSIUM CHLORIDE
  - PRASUGREL, PRASUGREL HYDROCHLORIDE
  - PRAVASTATIN SODIUM, PRAVASTATIN SODIUM
  - PREMIZONE SODIUM PHOSPHATE, PREMIZONE SODIUM PHOSPHATE
  - PREDNISOLONE SODIUM PHOSPHATE, PREDNISOLONE SODIUM PHOSPHATE
  - PROPafenone HYDROCHLORIDE, PROPafenone HYDROCHLORIDE
  - QUI NI NE SULFATE, QUI NI NE SULFATE
  - RABEPRAZOLE SODIUM, RABEPRAZOLE SODIUM
  - RASAGILIN MESYLATE, RASAGILIN MESYLATE
  - REPAGI LINI NI DE, REPAGI LINI DE
  - RIZATRIPTAN BENZOATE, RIZATRIPTAN BENZOATE
  - ROSUVASTATIN SODIUM, ROSUVASTATIN SODIUM
  - RUFINAMIDE, RUFINAMIDE
  - SERTRALINE HYDROCHLORIDE, SERTRALINE HYDROCHLORIDE
  - SILDENAFIL CITRATE, SILDENAFIL CITRATE
  - SMATRIPTAN AND NAPROXEN SODIUM, NAPROXEN SODIUM
  - SYMFI LO, EFAVIR RENZ
  - TADALAFI L, TADALAFI L
  - TELM SARTAN AND AMLODI PI NE, AMLODI PI NE BESYLA T
  - TELM SARTAN AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  - TELM SARTAN, TELM SARTAN
  - TENOFI VRI DI SOPRIO X FUMARATE, TENOFI VRI DI SOPRIO X FUMARATE
  - TEREZOSI N HYDROCHLORIDE, TEREZOSI N HYDROCHLORIDE
  - TOBRAMACYI N, TOBRAMACYI N
  - TOLAZAM DE, TOLAZAM DE
  - TOLBUTAM DE, TOLBUTAM DE
  - TOLERODI NE TARTRATE, TOLERODI NE TARTRATE
  - TRAMADOR HYDROCHLORIDE, TRAMADOR HYDROCHLORIDE
  - TRAVOPROPS, TRAVOPROPS
  - TRETIN I NI, TRETIN I NI
  - TRI ACETONI UD DE, TRI ACETONI UD DE
  - TRI AZOLAM, TRI AZOLAM
  - TRI ZYLOCT, POLYETHYLENE GLYCOL 3350
  - VALACYCOV, VALACYCOV
  - VALSARTAN AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  - VALSARTAN, VALSARTAN
  - VORI CONAZOLE, VORI CONAZOLE
  - VUSION, VUSION
  - ZOLPIDEM TARTRATE, ZOLPIDEM TARTRATE
  - ZOLPIDEM TARTRATE
* MYLAN PHARMACEUTICALS INC.
  ZONALON, DOXEPIN HYDROCHLORIDE
  ZOMI RAX, ACYCLOVIR

* MYLAN PHARMACEUTICALS INC.
  FLUVASTATIN SODIUM, FLUVASTATIN SODIUM
  NI ZATI DI NE, NI ZATI DI NE
  OXYBUTYNIN N CHLORIDE DE, OXYBUTYNIN N CHLORIDE DE

MYLAN SPECIALTY LP
* MYLAN SPECIALTY LP
  ACCUNEB, ALBUTEROL SULFATE
  AEROSPAN HFA, FLUNISOLIDE
  ANADROL-50, OXYMETHOLONE
  ASTELI N, AZELASTINE NE HYDROCHLORIDE DE
  ASTEPRO, AZELASTINE NE HYDROCHLORIDE DE
  AVC, SULFANI LAM DE
  BUTI SODIUM, BUTABARBI TAL SODIUM
  CESAMET, NABI LONE
  COLYTE WITH FLAVOR PACKS, POLYETHYLENE GLYCOL 3350
  CORTI FOAM, HYDROCORTISONE ACETATE
  CROMOLYN SODIUM, CROMOLYN SODIUM
  DEMADEX, TORSEM DE
  DEPEN, PENI CI LLAM NE
  DI PENTUM, OLSALAZINE SODIUM
  DYM STA, AZELASTINE NE HYDROCHLORIDE DE
  EDELAR, ZOLOP DERM TARTRATE
  ELESTRI, ESTRA DI OL
  EPI FOAM, HYDROCORTISONE ACETATE
  EPI PEN J R, EPI NEPHRI NE
  EPI PEN, EPI NEPHRI NE
  FELBATOL, FELBAMATE
  GASTROCROM, CROMOLYN SODIUM
  I PRATROP IUM BROM DE, I PRATROP IUM BROM DE
  LEVALBUTEROL HYDROCHLORIDE DE, LEVALBUTEROL HYDROCHLORIDE DE
  MUSE, ALPROSTADI L
  PROCTOFOMA HC, HYDROCORTISONE ACETATE
  ROWASA, MESALAMINE
  SFROWASA, MESALAMINE
  SOMA, CARI SOPRODOL
  TOBI, TOBRAM/CIN

MYLAN SPECIALTY
* MYLAN SPECIALTY LP
  PERFOROMIST, FORMOTEROL FUMARATE

MYLAN TECHNOLOGIES
* MYLAN TECHNOLOGIES INC
  BUPRENORPHINE HYDROCHLORIDE DE AND NALOXONE HYDROCHLORIDE DE,
  BUPRENORPHINE HYDROCHLORIDE DE
  CLONI DI NE, CLONI DI NE
  ESTRADI OL, ESTRADI OL
  FENTANYL-100, FENTANYL
  FENTANYL-12, FENTANYL
  FENTANYL-25, FENTANYL
  FENTANYL-37, FENTANYL
  FENTANYL-50, FENTANYL
  FENTANYL-62, FENTANYL
  FENTANYL-75, FENTANYL
  FENTANYL-87, FENTANYL
  LI DOCAI NE, LI DOCAI NE
  NI TROGLYERI N, NI TROGLYERI N
  NI VASTI GM NE, NI VASTI GM NE
  XULANE, ETHI NYL ESTRADI OL

MYLAN TEORANTA
* MYLAN TEORANTA
  LEVOLEUCOVORIN CALCIUM, LEVOLEUCOVORIN CALCIUM
** NALPROPION **
* NALPROPION PHARMACEUTICALS INC
  CONTRAVE, BUPROPION HYDROCHLORIDE

** NAMGEN LLC **
* NAMGEN LLC
  SODIUM NIROUSU DE, SODIUM NIROUSU DE

** NANG KUANG PHARM CO **
* NANG KUANG PHARMACEUTICALS CAL CO LTD
  LI NEZOLI D, LI NEZOLI D

** NANNING KING-FRIEND **
* NANNING KING-FRIEND BI CHEM CAL. PHARMACEUTICALS CAL CO LTD
  ATRACURIUM BESYLATE, ATRACURIUM BESYLATE
  ATRACURIUM BESYLATE PRESERVATIVE FREE, ATRACURIUM BESYLATE
  CARBOPLATIN N, CARBOPLATIN N
  HEPARI N SODIUM, HEPARI N SODIUM

** NAPO PHARMS INC **
* NAPO PHARMACEUTICALS INC
  CONTRAVERSE, BUPROPION HYDROCHLORIDE

** NATCO PHARMA LTD **
* NATCO PHARMA LTD
  GRANisetron HYDROCHLORIDE DE, GRANisetron HYDROCHLORIDE DE

** NATCO PHARMA LTD **
* NATCO PHARMA LTD
  CHLOROQUINE PHOSPHATE, CHLOROQUINE PHOSPHATE

** NATCO PHARMA LTD **
* NATCO PHARMA LTD
  ALPRAZOLAM, ALPRAZOLAM
  ANASTROZOLE, ANASTROZOLE
  ARMODAFINIL N, ARMODAFINIL N
  AZACITIDINE N, AZACITIDINE N
  CARI SOPRODOLE, CARI SOPRODOLE
  CHLOROQUINE PHOSPHATE, CHLOROQUINE PHOSPHATE
  GLYCOPYRROLATE, GLYCOPYRROLATE
  LANSOPRAZOLE, LANSOPRAZOLE
  LANSOPRAZOLE, LANSOPRAZOLE (OTC)
  LANTHANUM CARBONATE, LANTHANUM CARBONATE
  LETrozole, LETrozole
  ONDANSETRON HYDROCHLORIDE DE, ONDANSETRON HYDROCHLORIDE DE
  OSELTAMIVIR VI R PHOSPHATE, OSELTAMIVIR VI R PHOSPHATE
  RIZATRIPTAN BENZOATE, RIZATRIPTAN BENZOATE
  TRIHEXYTHENYDL HYDROCHLORIDE DE, TRIHEXYTHENYDL HYDROCHLORIDE DE

** NAVI NTA LLC **
* NAVI NTA LLC
  BENZTROPINE NE MESYLATE, BENZTROPINE NE MESYLATE
  CARMUSTINE N, CARMUSTINE N
  FAMOTIDE N, FAMOTIDE N
  FOMEPI ZOLE, FOMEPI ZOLE
  HYDRALAZI N HYDROCHLORIDE DE, HYDRALAZI NE HYDROCHLORIDE DE
  I NDOMETHACIN N SODIUM, I NDOMETHACIN N SODIUM
  METHOCARBAMOL, METHOCARBAMOL
  RIBAVIRIN N, RIBAVIRIN N
  ROPI VACAY HYDROCHLORIDE DE, ROPI VACAY HYDROCHLORIDE DE
  SODIUM PHENYLACETATE AND SODIUM BENZOATE, SODIUM UM BENZOATE
  SODIUM UM BENZOATE, SODIUM UM BENZOATE
  TRINITRIT, TRINITRIT
  TRIENTINE HYDROCHLORIDE

** NCM USA BRONX LLC **
* NCM USA BRONX LLC
  AMMONI A N 13, AMMONI A N 13
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18
  SODIUM FLUORIDE F-18, SODIUM UM FLUORIDE DE F-18

** NEOPHARMA **
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  ALENDRONATE SODIUM, ALENDRONATE SODIUM
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### Appendix B - Product Name Sorted by Applicant

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**NOVARTIS PHARM**

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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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* NOVARTIS PHARMACEUTICALS CORP

Moxeza, Moxifloxacin Hydrochloride
Mydriacyl, Tropicamide
Natacyn, Natamycin
Nevanac, Neopenac
Omni Pred, Predni Solone Acetate
Pataday, Olopatadine HCl
Patanase, Olopatadine HCl
Patanol, Olopatadine HCl
Pazeo, Oclopatadine HCl
Promacta Kit, eltrombopag olamine
Promacta, eltrombopag olamine
Rydapt, M dostaurin N
Si Gln for Lar Kit, pasi reoti de pamdate
Si Mbr Nza, BRI MDNI DI N E TARTRATE
Tafi Nlar, Dabrafeni B Mesylate
Tobralex ST, Dexamethasone
Tobralex, Dexamethasone
Tobrex, Tobralex C
Travatan Z, Travoprost
Tri esence, tri amc nocone acetoni de
Tykerb, Lapati N B DI TOSYLA
e
Vamox, Moxifloxacin HCl
Votri Ent, Pazopanib B Hydrochloride
Zofran Odt, Ondansetron
Zofran, Ondansetron Hydrochloride
Zykadia, Ceri T N B

NOVAST LABS

* NOVAST LABORATORIES ES CH N A LTD

Norethindrone, Norethindrone

* NOVAST LABORATORIES LTD

Acetazolamide, Acetazolamide
Carisoprodol and Aspirin, Aspirin
Carisoprodol, Carisoprodol
Cyproheptadine HCl, Cyproheptadine HCl
Desogestrel and Ethinyl Estradiol, Desogestrel
Her Style, Levonorgestrel (OTC)
I N Dometac HCl, I N Dometac HCl
Larin 1.5/30, Ethinyl Estradiol OL
Larin N 1/20, Ethinyl Estradiol OL
Larin N 24 FE, Ethinyl Estradiol OL
Larin N FE 1.5/30, Ethinyl Estradiol OL
Larin N FE 1/20, Ethinyl Estradiol OL
Leri Bane, Ethinyl Estradiol OL
Mafenide Acetate, Mafenide Acetate
Malmorede, Ethinyl Estradiol OL
Melam Sa, Drospirenone
Mefinorm HCl Hydrochloride, Mefinorm HCl Hydrochloride
Metoprolol Succinate, Metoprolol Succinate
Nadolol, Nadolol
Ni Fedi Pne, Ni Fedi Pne
Norethindrone, Norethindrone
Phentermine Hydrochloride, Phentermine Hydrochloride
Pi Mirea, Desogestrel
Pri Mauke Phosphate, Pri Mauke Phosphate
Probenecid and Colchicin, Colchicin
Queti APi NE Fumarate, Queti APi NE Fumarate
Qui N N Sulfate, Qui N N Sulfate
Setlaki N, Ethinyl Estradiol OL
Topotecan Hydrochloride, Topotecan Hydrochloride
Yaela, Drospirenone

NOVAST LABS LTD

* NOVAST LABORATORIES ES LTD

Dasetta 1/35, Ethinyl Estradiol OL
Dasetta 7/7/7, Ethinyl Estradiol OL
### Appendix B - Product Name Sorted By Applicant

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**NOVI TI UM PHARMA**
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** N **

* NOVITIUM PHARMA LLC
  DAPSONE, DAPSONE
  OXYBUTYNIN CHLORIDE, OXYBUTYNIN CHLORIDE
  PRAZOSIN HYDROCHLORIDE, PRAZOSIN HYDROCHLORIDE
  RANITIDINE, RANITIDINE
  TRIHEXYPHENIDYL HYDROCHLORIDE, TRIHEXYPHENIDYL HYDROCHLORIDE

NOVODRUGS

** O **

* OAK PHARMACEUTICALS INC
  OAK PHARMACEUTICALS INC
** B **

APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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ORCHID HLTHCARE
* ORCHID D HEALTHCARE
 AMLODI PI NE BESYLATE,  AMLODI PI NE BESYLATE
 ARI PI PRAZOLE,  ARI PI PRAZOLE
 CEFADROXI L,  CEFADROXI L/CEFADROXI L HEMI HYDRATE
 CEFDI NI R,  CEFDI NI R
 CEPPOXOZ ME PROKETI L,  CEPPOXOZ ME PROKETI L
 CEPPOXOZ L,  CEPPOXOZ L
 CEFUROI L,  CEPHALEXI N
 CETI RI ZI NE HYDROCHLORI DE ALLERGY,  CETI RI ZI NE HYDROCHLORI DE (OTC)
 CEFUROI L,  CEFUROI L/CEFUROI L HEMI HYDRATE
 CEPFLOXOZ N,  CEPFLOXOZ N
 CEFDINOZ L,  CEFDINOZ L/CEFDINOZ L HEMI HYDRATE
 CEFDINOZ L,  CEFDINOZ L
 CESZOPI CLONE,  CESZOPI CLONE
 CELODI PI NE,  CELODI PI NE
 CEFADROXI N,  CEFADROXI N
 CEFPOXOZ N,  CEFPOXOZ N
 CEFPOXOZ N/CEFPOXOZ N HEMI HYDRATE
 CEFPOXOZ N,  CEFPOXOZ N/CEFPOXOZ N HEMI HYDRATE
 CEFUROI L,  CEFUROI L

OREXO US I NC
* OREXO US I NC
 ZUBSOLV,  BUPRENORPHI NE HYDROCHLORI DE

ORGANON SUB MERCK
* ORGANON USA I NC A SUB OF MERCK AND CO I NC
 BRI DI ON,  SUGAMMADEX SODI UM
 NUNARI NG,  ETHI NYL ESTRADI OL

ORGANON USA I NC
* ORGANON USA I NC
 DESOGEN,  DESOGEN TREL
 SOLLI STI M AQ,  SOLLI TROP I N ALFA BETA
 GANI RELI X ACETATE,  GANI RELI X ACETATE
 EXPLOAN,  ETONOSTREX
 PREGYNYL,  GONADOTROPIN N,  CHORI ONI C
 REMERON SOLTAB,  M RTAZAPI NE
 REMERON,  M RTAZAPI NE

ORI ENT PHARMA CO LTD
* ORI ENT PHARMA CO LTD
 CARI SOPRODOL,  CARI SOPRODOL
 M GLI TOL,  M GLI TOL
 PI TAVASTATI N CALCI UM / PI TAVASTATI N CALCI UM

ORI ON PHARMA
* ORI ON PHARMA
 COMLAN,  ENTACAPONE
 STALEVO 100,  CARBI DOPA
 STALEVO 125,  CARBI DOPA
 STALEVO 150,  CARBI DOPA
 STALEVO 200,  CARBI DOPA
 STALEVO 50,  CARBI DOPA
 STALEVO 75,  CARBI DOPA

ORI T LABS LLC
* ORI T LABORATORIES IES LLC
 BENZONATATE,  BENZONATATE
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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  HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  IMIPRAMINE HYDROCHLORIDE, IMIPRAMINE HYDROCHLORIDE
  LEVETIRACETAM, LEVETIRACETAM
  LORAZEPAM, LORAZEPAM
  METHOCARBAMOL, METHOCARBAMOL
  METHYLPHENI DATE HYDROCHLORI DE, METHYLPHENI DATE HYDROCHLORI DE
  MYCOPHENOLATE MOFETI L, MYCOPHENOLATE MOFETI L
  PAROKETI NE HYDROCHLORI DE, PAROKETI NE HYDROCHLORI DE
  PRI M DONE, PRI M DONE
  RI MACTANE, RI FAMPI N
  RI SPERI DONE, RI SPERI DONE
  SERTRALI NE HYDROCHLORI DE, SERTRALI NE HYDROCHLORI DE
  SI MASTATI N, SI MASTATI N
  SOTALOL HYDROCHLORI DE, SOTALOL HYDROCHLORI DE
  SPI RONOLACTONE, SPI RONOLACTONE
  TI ZANI DI NE HYDROCHLORI DE, TI ZANI DI NE HYDROCHLORI DE
  Trazodone HYDROCHLORI DE, Trazodone HYDROCHLORI DE

** P **

* P AND L DEVELOPMENT LLC DBA PLD DEVELOPMENTS LLC
  IBUPROFEN, IBUPROFEN (OTC)
  PACIF PHARMA
  TI MOLOL MALEATE, TI MOLOL MALEATE
  PACI F C PHARMA I NC
  TI MOLOL MALEATE, TI MOLOL MALEATE

* PACI RA PHARMA I NC
  PACI RA PHARMAEUTI CALS I NC
  EXPAREL, BUPI VACAI NE

* PACK PHARMA LLC
  PACK PHARMAEUTI CALS LLC
  NORETHINDRONE ACETATE, NORETHINDRONE ACETATE

* PADDOCK LLC
  PADDOCK LABORATORIES ES LLC
  ATOVAQUONE, ATOVAQUONE
  BROMOCR PTI NE MESYLATE, BROMOCR PTI NE MESYLATE
  BROMPHENI RAM NE MALEATE, PSEUDEPHEDRINI NE HYDROCHLORI DE AND DEXTROMETHORPHAN
  CALCI UM ACETATE, CALCI UM ACETATE
  CI CLOPI ROX, CI CLOPI ROX
  CLI NDAMICI N PAM TATE HYDROCHLORI DE, CLI NDAMICI N PALM TATE HYDROCHLORI DE
  CLOBETASOL PROPI ONATE, CLOBETASOL PROPI ONATE
  CLOTRI MAZOLE, CLOTRI MAZOLE
  COLOCORT, HYDROCORTI SONE
  COMPO ROCHLORPERAZI NE
  DI HYDROGOTAM NE MESYLATE, DI HYDROGOTAM NE MESYLATE
  FLAVOXATE HYDROCHLORI DE, FLAVOXATE HYDROCHLORI DE
  HYDROCODONE BI TARTRATE AND HOMATROPI NE METHYL BROM DE, HOMATROPI NE METHYL BROM DE
  HYDROCODONE BI TARTRATE AND PSEUDEPHEDRINI NE HYDROCHLORI DE, HYDROCODONE BI TARTRATE
  HYDROCODONE BI TARTRATE, CHLORPHENI RAM NE MALEATE AND PSEUDEPHEDRINI NE HYDROCHLORI DE,
  HYDROMORPHONE HYDROCHLORI DE, HYDROMORPHONE HYDROCHLORI DE
  KI ONEX, SODI UM POLYSTYRENE SULFONATE
  LAX-LYTE WITH FLAVOR PACKS, POLYETHYLENE GLYCOL 3350
  M DAVOR, AM LORI DE HYDROCHLORI DE
  M DAZOLAM HYDROCHLORI DE, M DAZOLAM HYDROCHLORI DE
  MORPHI NE SULFATE, MORPHI NE SULFATE
  NARATRI PTAN, NARATRI PTAN HYDROCHLORI DE
  NYSTOP, NYSTATI N
  PODOFI LOK, PODOFI LOK
  POLYETHYLENE GLYCOL 3350, POLYETHYLENE GLYCOL 3350
  POTASSI UM CHLORI DE, POTASSI UM CHLORI DE
  REPA GLI N DE, REPA GLI N DE
  SODI UM POLYSTYRENE SULFONATE, SODI UM POLYSTYRENE SULFONATE
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

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<td>OMEPRAZOLE AND SODIUM BICARBONATE, OMEPRAZOLE</td>
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<td>OMEPRAZOLE AND SODIUM BICARBONATE, OMEPRAZOLE (OTC)</td>
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<td>OXANDROLONE, OXANDROLONE</td>
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<tr>
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<td>PI MAZI DI, PI MAZI DE</td>
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<td>POMOZI DE, POMOZI DE</td>
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** P **

PAR PHARMACEUTICAL INC

POLYETHYLENE GLYCOL 3350, POLYETHYLENE GLYCOL 3350 (OTC)
QUETI APNE FUMARATE, QUETI APNE FUMARATE
RANITI DI NE HYDROCHLORIDE, RANITI DI NE HYDROCHLORIDE
RI SPERI DONE, RI SPERI DONE
SODIUM PHENYL BUTYRATE, SODIUM PHENYL BUTYRATE
SUMATRIPTAN SUCCINATE, SUMATRIPTAN SUCCINATE
TORSEMIDE, TORSEMIDE
TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN, ACETAMINOPHEN
TRIACYLPROPRANE SULFATE, TRISTACIN ONE SULFATE
TRIACYLPROPRANE SULFATE, TRISTACIN ONE SULFATE
URSODIOL, URSA DIOL
VERAPAM L HYDROCHLORIDE, VERAPAM L HYDROCHLORIDE

PAR PHARM INC

ACCOLATE, ZAFIR LUCAST
ALOSETRON HYDROCHLORIDE, ALOSETRON HYDROCHLORIDE
AMLODI PI NE BESYLATE AND VALSARTAN, AMLODI PI NE BESYLATE
ANTI ZOL, FOMEPI ZOLE
ASPIRIN AND DI PYRI DAMOLE, ASPIRIN
BALSALAZI DE DI SODI UM BALSALAZI DE DI SODI UM
COLCHI CI CI NE, COLCHI CI NE
DEXLANSOPRAZOLE, DEXLANSOPRAZOLE
DEXMETHYLPHENI DATE HYDROCHLORIDE DE, DEXMETHYLPHENI DATE HYDROCHLORIDE DE
DOFETI LI DE, DOFETI LI DE
DOXYLAM NE SUCCI NATE AND PYRI DOXI NE HYDROCHLORIDE DE, DOXYLAM NE SUCCI NATE
ENTECAVI R, ENTECAVIR
ETHACRYNI C ACI D, ETHACRYNI C ACI D
FLUOXETINE HYDROCHLORIDE DE, FLUOXETINE HYDROCHLORIDE DE
I TRACONAZOLE, I TRACONAZOLE
METOCLOPRAZ DE HYDROCHLORIDE DE, METOCLOPRAZ DE HYDROCHLORIDE DE
M DODI DE HYDROCHLORIDE DE, M DODI DE HYDROCHLORIDE DE
MORPHI NE SODIUM, MORPHI NE SODIUM
OMEGA-3 ACI D ETHYL ESTERS, OMEGA-3 ACI D ETHYL ESTERS
OXIBUTYNI N CHLORI DE, OXIBUTYNI N CHLORI DE
PHENOXYPHENAZI NE HYDROCHLORIDE DE, PHENOXYPHENAZI NE HYDROCHLORIDE DE
PRAZI QUANTEL, PRAZI QUANTEL
TI ZANI DI NE HYDROCHLORIDE DE, TI ZANI DI NE HYDROCHLORIDE DE
TOLCAPONE, TOLCAPONE
TRAMADOL HYDROCHLORIDE DE, TRAMADOL HYDROCHLORIDE DE
VI GABATRI N, VI GABATRI N
ZOLPI DEM TARTRATE, ZOLPI DEM TARTRATE

PAR STERILE PRODUCTS LLC

ACETAZOLAMIDE SODIUM, ACETAZOLAMIDE SODIUM
ADRENALI N, EPI NEPHRI NE
ARGATROBAN, ARGATROBAN
BREVI TAL SODI UM METHOHEXI TAL SODI UM
BUPRENORPHI NE HYDROCHLORIDE DE, BUPRENORPHI NE HYDROCHLORIDE DE
COLY-MOCI M COLY-MOCI M COLY-MOCI M COLY-MOCI M COLY-MOCI M
CORPHEDRA, EPHEDRI NE SODIUM
DANTROLI UM DANTRIUM, DANTROLIUM
DELESTROGEN, DELESTROGEN, ESTRADIOL VALERATE
DEXMEDEMETOM DI NE HYDROCHLORIDE DE, DEXMEDEMETOM DI NE HYDROCHLORIDE DE
ETHACRYNATE SODI UM ETHACRYNATE SODI UM
ETOM DATE, ETOM DATE
FLUPHENAZI NE DECANATE, FLUPHENAZI NE DECANATE
GANI CLOVI R, GANI CLOVI R SODI UM
KETAMINI NE HYDROCHLORIDE DE
LEVOTHYROXI NE SODI UM, LEVOTHYROXI NE SODI UM
MELPHALAN HYDROCHLORIDE DE, MELPHALAN HYDROCHLORIDE DE
MCCOPHENOLATE MFINI L HYDROCHLORIDE DE, MCCOPHENOLATE MFINI L HYDROCHLORIDE DE
NEOSTI GM NE METHYL SULFATE, NEOSTI GM NE METHYL SULFATE
PHENYLEPHRINI NE HYDROCHLORIDE DE, PHENYLEPHRINI NE HYDROCHLORIDE DE
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<td>PARATEK PHARMACEUTICALS INC</td>
<td>NUZYRA, OMADACYCLINE TOSYLATE</td>
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<td>PARKE DAVIS</td>
<td>PARKE DAVI S</td>
<td>DI V WARNER LAMBERT CO</td>
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<td>CELONTI N, METHSUXI M DE</td>
<td>CEREBYX, FOSPHENITOYI N SODIUM</td>
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<td>DI LANTI N 125, PHENITOI N</td>
<td>NARDI L, PHENELZINE SULFATE</td>
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<td>ZARONTI N, ETHOSUXI M DE</td>
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<td>PARKE DAVI S</td>
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<td>TREXIX MET, NAPROXEN SODIUM</td>
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<td>PERNIX I RELAND PAIN L</td>
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<td>PERIGO CO</td>
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<td>PERIGO CO</td>
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<td>STI E-CORT, HYDROCORTISONE</td>
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<td>PERIGO CO TENERESE</td>
<td>PERIGO CO TENERESE INC</td>
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<td>NEOMYCIN N AND POLYMIXI N B SULFATES AND BACITRACIN N ZI NC, BACITRACIN N ZI NC</td>
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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

**P**

*PERRIGO ISRAEL PHARMACEUTICALS LTD*

- Clindamycin Phosphate and Benzoyl Peroxide
- Clobetasol Propionate
- Desoximetasone
- Fluocinolone Acetonide
- Fluocinonide
- Fluticasone Propionate
- Gyazole-1
- Butoconazole Nitrate
- Halobetasol Propionate
- I M Qui MD
- Ketocazole
- Ketoconazole
- Mesalamine
- Minoxidil
- Mometasone Furoate
- Nitroglycerin
- Olopatadine Hydrochloride
- Testosterone
- Triamcinolone Acetonide

*PERRIGO NEW YORK*

* PERRIGO NEW YORK INC

- Acetaminophen
- Ammonium Lactate
- Betamethasone Dipropionate
- Centany
- Desonide
- Econazole Nitrate
- Erythromycin
- Fluticasone Propionate
- Gentamycin Sulfate
- Hydrocortisone Valerate
- Ketoconazole
- Minoxidil Extra Strength (for Men)
- Mometasone Furoate
- Mupirolcin
- Nystatin
- Permethrin
- Promethazine
- Selenium Sulfide
- Terconazole
- Triamcinolone

*PERRIGO PHARMA INTL*

* PERRIGO PHARMA INTERNATIONAL DAC

- Clindesse
- Entocort EC
- Evamist
- Loratadine and Pseudoephedrine Sulfate
- Pilocarpine Hydrochloride
- Tretinoin

*PERRIGO PHARMS CO*

* PERRIGO PHARMACEUTICALS CO

- Scopolamine

*PERRIGO R AND D*

* PERRIGO R AND D CO

- Children's Cetirizine Hydrochloride Allergy
- Children's Cetirizine Hydrochloride Hives Relief
- Cetirizine Hydrochloride
- Cetirizine Hydrochloride (OTC)
- Cetirizine Hydrochloride Allergy
- Cetirizine Hydrochloride (OTC)
- Cetirizine Hydrochloride Hives
- Cetirizine Hydrochloride (OTC)
- Cetirizine Hydrochloride Allergy
- Cetirizine Hydrochloride (OTC)
- Cetirizine Hydrochloride Allergy
- Cetirizine Hydrochloride (OTC)
- Cetirizine Hydrochloride Allergy
- Cetirizine Hydrochloride (OTC)
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** P **

1. Applicator: Perrigo R and D Co
   - Desloratadine
   - Desloratadine (OTC)
   - Famotidine
   - Calcium Carbonate, and Magnesi U M Hydroxide, Calcium Carbonate (OTC)
   - Famotidine (OTC)
   - Famotidine (OTC)
   - Guaifenesin and Dextromethorphan Hydrobromide, Dextromethorphan Hydrobromide (OTC)
   - Guaifenesin N and Dextromethorphan Hydrobromide, Dextromethorphan Hydrobromide (OTC)
   - Ibuprofen and Phenylephrine Hydrochloride, Ibuprofen (OTC)
   - Ibuprofen and Diphendrane Citrate, Diphendrane Citrate (OTC)
   - Ibuprofen Sodium, Ibuprofen Sodium (OTC)
   - Ibuprofen (OTC)
   - Lansoprazole, Lansoprazole (OTC)
   - LevoNorgestrel, LevoNorgestrel (OTC)
   - Loperam De Hydrochloride, Loperam De Hydrochloride (OTC)
   - Loperam De Hydrochloride and Simethicone, Loperam De Hydrochloride (OTC)
   - M Conazole Ni Trate, M Conazole Ni Trate (OTC)
   - Montelukast Sodium, Montelukast Sodium (OTC)
   - Naproxen, Naproxen (OTC)
   - Ni Cot Ne Polacrilex, Ni Cot Ne Polacrilex (OTC)
   - Omeprazole and Sodium Bi Carbonate, Omeprazole (OTC)
   - Omeprazole Magnesi U M Sodium, Omeprazole Magnesi U M (OTC)
   - Pantoprazole Sodium, Pantoprazole Sodium (OTC)
   - Polyethylene Glycol 3350, Polyethylene Glycol 3350 (OTC)

2. Applicator: Perrigo UK Finco Ltd Partnership
   - Betamethasone Valerate, Betamethasone Valerate
   - Clindamycin Phosphate, Clindamycin Phosphate
   - Diclofenac Sodium, Diclofenac Sodium
   - Estradiol
   - Flurandrenolide
   - Ingenol Mibutate
   - Ny STATi N and Tri Ami Nolone Acetoni De, Ny STATi N
   - Testosterone, Testosterone
   - Tri Ami Nolone Acetoni De, Tri Ami Nolone Acetoni De

3. Applicator: PetNet Solutions Inc
   - Ammonia N 13, Ammonia N-13
   - Fluodeoxyglucose F18, Fluodeoxyglucose F-18
   - Sodium Fluoride F-18, Sodium Fluoride F-18

4. Applicator: Pfizer
   - Bosphur, Bosphur Ni B Monohydrate
   - Chantix, Varenix
   - I Nlyta, Axit N B Ni B
   - Lyri Ca Cr, Pregabalin N
   - Lyri Ca, Pregabalin N
   - Pri Sti Q, Desvenlafaxine Nic Succinate
   - Rapamune, Si Rol M Js
   - Torisel, Temsi Rol M Js
   - Tygaci L, Ti Gecycl Ne
   - Virend, Vori Conazole
   - Xalkori, Cri Zoti N B
   - Xeljanz, Tofacitinib Ni B Ci Trate

5. Applicator: Pfizer Central Research
   - Diflucan, Fluconazole
   - Zithromax, Azithromycin

6. Applicator: Pfizer Chemicals Division
   - Diflucan, Fluconazole
   - Zithromax, Azithromycin

7. Applicator: Pfizer Inc
   - Diflucan, Fluconazole
   - Zithromax, Azithromycin

- Pfizer Inc
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** P **

* PFIZER INC
  ADVIL ALLERGY AND CONGESTION RELIEF, CHLORPHENIRAMINE MALEATE (OTC)
  ADVIL ALLERGY SI NUS, CHLORPHENIRAMINE MALEATE (OTC)
  ADVIL COLD AND SI NUS, IBUPROFEN (OTC)
  ADVIL CONGESTION RELIEF, IBUPROFEN (OTC)
  ADVIL LI QUI - GELS, IBUPROFEN (OTC)
  ADVIL M GRAI NE LI QUI - GELS, IBUPROFEN (OTC)
  ADVIL MULTI - SYMPTOM COLD & FLU, CHLORPHENIRAMINE MALEATE (OTC)
  ADVIL PM, DI PHENHYDRAMINE CI TRATE (OTC)
  ADVIL PM, DI PHENHYDRAMINE HYDROCHLORIDE (OTC)
  ADVIL, IBUPROFEN (OTC)
  ALAVERT, LORATADINE (OTC)
  AXI D AR, NI ZATI DI NE (OTC)
  CADUET, AMLODI PI NE BESYLATE
  CALAN SR, VERAPAMOL HYDROCHLORIDE
  CARDURA XL, DOXAZOSIN MESYLATE
  CHI LDREN S ADVIL ALLERGY SI NUS, CHLORPHENIRAMINE MALEATE (OTC)
  CHI LDREN S ADVIL COLD, IBUPROFEN (OTC)
  CHI LDREN S ADVIL L - FLAVORED, IBUPROFEN (OTC)
  ELEYSO, TALI GLUCERASE ALFA
  GEODON, ZI PRASI DONE HYDROCHLORIDE
  GEODON, ZI PRASI DONE MESYLATE
  GLUCOTROL XL, GLI PI ZI DE
  GLUCOTROL, GLI PI ZI DE
  HEPARI N SODIUM PRESERVATIVES FREE, HEPARI N SODIUM
  HEPARI N SODIUM, HEPARI N SODIUM
  JUNIOR STRENGTH ADVIL, IBUPROFEN (OTC)
  LI PI TOR, ATORVASTATIN CA LI UM
  LORATADINE, LORATADINE (OTC)
  MERREM, MERREMEN
  NORVASC, AMLODI PI NE BESYLATE
  PEDIATRIC ADVIL, IBUPROFEN (OTC)
  PROCARDIA, NIFEDIPINE
  REVATIO, SILDENAFIL CITRATE
  SONATA, ZALEPLON
  TESSALON, BENZONATATE
  TOBI AZ, FESOTERODINE FU MURATE
  UNASYN, AMPI CI LLI N SODIUM
  ZI THROMAX, AZI THROM/CI N
  * PFIZER LABORATORIES ES DI V PFIZER INC
    CARDURA, DOXAZOSIN MESYLATE
    FELDENE, PI ROXI CAM
    MI NI PRESS, PRAZOSIN HYDROCHLORIDE
    PFI ZER PEN, PENI CI LLI N G POTASSI UM
    PROCARDIA A XL, NI FEDI PI NE
    UNASYN, AMPI CI LLI N SODIUM
    VI BRAMYCI N, DOXYCYCLINE
    VI BRAMYCI N, DOXYCYCLINE CALCI UM
    VI BRAMYCI N, DOXYCYCLINE HYCLATE
    VI STARI L, HYDROXYZINE PAMDATE
  * PFIZER PHARMACEUTICALS CALS INC
    DI LANTI N, PHENYTOIN
    ZOLOFT, SERTRALINE NE HYDROCHLORIDE
  * PFIZER PHARMACEUTICALS PRODUCTION CORP LTD
    TIFFOSYN, DOFETILIDE
  * PFIZER CONSUMER HEALTHCARE
    ADVIL, IBUPROFEN SODIUM (OTC)
  PFIZER INC
  CAMPTOSAR, IRINOTECAN HYDROCHLORIDE
  DAURI SMO, GLASDEGIB
  ELLENCE, EPI RUBICIN HYDROCHLORIDE
  FRAGM N, DALTEPARIN N SODIUM

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<tr>
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** P **

- BACITRACIN
- CLEOCIN HYDROCHLORIDE
- CORTEF
- CYKLOKAPRON
- DEPO-ESTRADIOL
- DEPO-MEDROL
- DETROL LA
- DOXORUBICIN HYDROCHLORIDE
- EMICYT
- ESTRING
- GENOTROPIN
- GLYASET
- HALCION
- HEIMABATE
- IMBRUVICA
- INTRAVENOUS PROPOFOL
- LRECOTRINE
- LINCOMYCIN HYDROCHLORIDE
- MEDIAZOLM
- MEDROL
- NICOTROL
- NSCB-7163 NP
- OGEN 5
- PREPI DI L
- PROSTI N VR
- PROVERA
- R-Gene 10
- SOLU-CORTEF
- SOLU-MEDROL
- SOLYAC Var
- SPECTRUM C
- SYMPLEPTIC
- TADALAFIL
- TELMISARTAN
- THIOPENTAL
- TRILEPTAL
- TRESORAN
- Ultracort
- UR MYCOPHAR
- VESPIRIDE
- XANAX
- XALATAN
- XYLAMINE
- ZINECARD
- ZYVOX

- PHARMACIA AND UPJOHN CO
- PHARMACIA AND UPJOHN SUB PFIZER INC
- PHARMACIA UPJOHN
- PHARMACYCLICS INC
- PHARMADAX INC
- PHARMALUCENCE
| PHARMALUCENCE INC | **P** | PHARMALUCENCE INC |
| HEPATOLITE, TECHNETIUM TC-99M DISOFENIN KIT | | |
| TECHNETIUM TC-99M SESTAMBI, TECHNETIUM TC-99M SESTAMBI KIT | | |
| TECHNETIUM TC-99M MEBROFENIN, TECHNETIUM TC-99M MEBROFENIN KIT | | |

| PHARMA SCIENCE INC | **P** | PHARMA SCIENCE INC |
| BUSULFAN, BUSULFAN | | |
| DECI TABI NE, DECI TABI NE | | |
| GANCI CLOVI R, SODI UM | | |
| GANCI CLOVI R, SODI UM | | |

| PHARMACI LTD | **P** | PHARMACI LTD |
| ARI DOL, KI T | | |
| MANNI TOL | | |

| PHARMACIA ASA | **P** | PHARMACIA ASA |
| CVSI EW KI T | | |
| HEXAM NOLEVULI NATE HYDROCHLORIDE | | |

| PIERRE FABRE | **P** | PIERRE FABRE |
| PI ERRE FABRE MEDI CAMENT | | |
| NADELBI NE, VI NORELBI NE TARTRATE | | |

| PIERRE FABRE DERMA | **P** | PIERRE FABRE DERMA |
| PI ERRE FABRE DERMATOLOGIE | | |
| HEMANGEOL, PROPRANOLOL HYDROCHLORIDE | | |

| PIERREL | **P** | PIERREL |
| PI ERREL S, P, A | | |
| ORABLOC, ARTI CAI NE HYDROCHLORIDE | | |

| PI | **P** | PI |
| PHARMACEUTICALS INC | PI CRITICALLY I NC | |
| BUTALBITAL, ASPIRIN AND COFFEE, ASPRIRIN, DINOSPIRONE, AND ETHYL ESTRADIOL, ETHYL ESTRADIOL, HYDROCOLOGY, HYDROCOLOGY ONE, HYDROCOLOGY ONE | | |
| PI RAMAL CRITICALLY I CAL CARE LTD | | |
| CINACALCET HYDROCHLORIDE, CINACALCET HYDROCHLORIDE | | |
| CLOBAZAM, CLOBAZAM | | |

| PI RAMAL CRITICAL CARE UK | **P** | PI RAMAL CRITICAL CARE UK |
| PI RAMAL CRITICAL CARE LTD | | |
| CICALCIT HYDROCHLORIDE, CICALCIT HYDROCHLORIDE | | |
| CLOBAZAM, CLOBAZAM | | |

| PLD ACQUI SI TIONS LLC | **P** | PLD ACQUI SI TIONS LLC |
| CETIRIZINE HYDROCHLORIDE, CETIRIZINE HYDROCHLORIDE | | |
| CETIRIZINE HYDROCHLORIDE AND PSEUDOPHEDRINE HYDROCHLORIDE, CETIRIZINE HYDROCHLORIDE | | |

| PLD ACQUI SI TIONS LLC | **P** | PLD ACQUI SI TIONS LLC |
| LORATADINE, LORATADINE (OTC) | | |
| ZOLM TRI PTAN, ZOLM TRI PTAN | | |

| PLIVA | **P** | PLIVA |
| A2I THROMCFI I, A2I THROMCFI I N | | |
| BENZTROPINE, BENZTROPINE MESYLATE, BENZTROPINE MESYLATE | | |
| CI METI DI NE, CI METI DI NE | | |
| CI TALOPRAM HYDROBROMIDE, CI TALOPRAM HYDROBROMIDE | | |
** B **

APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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<td>CYCLOBENZAPRINE HYDROCHLORIDE, CYCLOBENZAPRINE HYDROCHLORIDE</td>
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<td>HYDRAZINE HYDROCHLORIDE, HYDRAZINE HYDROCHLORIDE</td>
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<td>ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE</td>
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<td>LOCI D. HYDROCORTISONE BUTYRATE</td>
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** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

** P **

* PRECISION NUCLEAR, LLC
  FLUDEXYLGUCOSE F-18, FLUDEXYLGUCOSE F-18
  SODIUM FLUORIDE F-18, SODIUM FLUORIDE F-18

PRI N STON I NC
  ARI PL PRAZOLE, ARI PL PRAZOLE
  BENZEPRI L HYDROCHLORI DE, BENZEPRI L HYDROCHLORI DE
  BUROPI HYDROCHLORI DE, BUROPI HYDROCHLORI DE
  Candesartan CI Lexeti L and Hydrochlorothi Azide, Candesartan CI Lexeti L
  Captori L, Captori L
  Clonazepam, Clonazepam
  Cloni IN HYDROCHLORI DE, Cloni IN HYDROCHLORI DE
  Clopi Dogrel Bi Sulfate, Clopi Dogrel Bi Sulfate
  Cyclobenzapri Ne Hydrochlori De, Cyclobenzapri Ne Hydrochlori De
  Di Valproex Sodi Um, Di Valproex Sodi Um
  Donepezi L Hydrochlori De, Donepezi L Hydrochlori De
  DoxyCycli Ne Hyclate, DoxyCycli Ne Hyclate
  Dulketi Ne Hydrochlori De, Dulketi Ne Hydrochlori De
  Entecavi R, Entecavi R
  Escl Talopram Okalate, Escl Talopram Okalate
  Fenozi Brate, Fenozi Brate
  Fosi NOPRI L Sodi Um, Fosi NOPRI L Sodi Um
  Furosem De, Furosem De
  Glipi RI De, Glipi RI De
  Glycopyrronate, Glycopyrronate
  Hydrochlorothi Azide, Hydrochlorothi Azide
  Hydroyki Ne Hydrochlori De, Hydroyki Ne Hydrochlori De
  I Rbesartan and Hydrochlorothi Azide, Hydrochlorothi Azide
  I Rbesartan, I Rbesartan
  Leveti Racetam, Leveti Racetam
  Li SI NOPRI L and Hydrochlorothi Azide, Hydrochlorothi Azide
  Li SI NOPRI L, Li SI NOPRI L
  Losartan Potassi Um and Hydrochlorothi Azide, Hydrochlorothi Azide
  Losartan Potassi Um Losartan Potassi Um
  Metform IN Hydrochlori De, Metform IN Hydrochlori De
  Methocarbamol, Methocarbamol
  Nevi Rapi Ne, Nevi Rapi Ne
  Olmesartan Medoxom L and Hydrochlorothi Azide, Hydrochlorothi Azide
  Paroxetine Mesylate, Paroxetine Mesylate
  Paroxetine Ne, Paroxetine Ne Hydrochlori De
  Phenterm IN Hydrochlori De, Phenterm IN Hydrochlori De
  Pi Olgi Tazone Hydrochlori De, Pi Olgi Tazone Hydrochlori De
  Promethazi Ne Hydrochlori De, Promethazi Ne Hydrochlori De
  Qui NOPRI L Hydrochlori De, Qui NOPRI L Hydrochlori De
  Ri Speri Done, Ri Speri Done
  Ropi NI Role Hydrochlori De, Ropi NI Role Hydrochlori De
  Telm Sartan and Hydrochlorothi Azide, Hydrochlorothi Azide
  Telm Sartan, Telm Sartan
  Temazepam, Temazepam
  Valsartan and Hydrochlorothi Azide, Hydrochlorothi Azide
  Valsartan, Valsartan
  Venlafaxine Ne Hydrochlori De, Venlafaxine Ne Hydrochlori De
  Vori Conazole, Vori Conazole

PROF DSPLS
  PROFESSI ONAL DI SPOSABLES I NC
  Prevanti Cs Maxi Swabsti Ck, Chlorhexi Di Ne Gluconate (OTC)
  Prevanti Cs Swab, Chlorhexi Di Ne Gluconate (OTC)
  Prevanti Cs Swabsti Ck, Chlorhexi Di Ne Gluconate (OTC)

PR OGENI CS PHARMS I NC
  PROGENI CS PHARMACEUTI CALS I NC
  Azedra, I Obenguane I-131

PROM US PHARMA, LLC
  PROM US PHARMA LLC
  Sern Vo, Betamethasone Di Propionate

P ROVELL
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

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**P**

- **PROVEL PHARMACEUTICALS LLC**
  - EUTHYROX, LEVOThYROX NE SODIUM

- **PROVENSIS LTD**
  - VARITHENA, POLIDOCANOL

- **PROVEPHARM SAS**
  - PROVAYBLUE, METHYLENE BLUE

- **PTC THERAPEUTICS INC**
  - EMFLAZA, DEFLAZACORT

- **PULMOFLOW INC**
  - KI TABIS PAK, TOBRAMYCIN N

- **PUMA BIOTECH**
  - NERLYNX, NERATINIB MALEATE

- **PURACAP PHARM**
  - MELOXICAM, MELOXICAM

- **PURACAP PHARM LLC**
  - BENZONATATE, BENZONATATE
  - ERGOCALCIUM FEROL, ERGOCALCIUM FEROL
  - MEMANTI NE HYDROCHLORIDE, MEMANTI NE HYDROCHLORIDE
  - NAPROXEN SODIUM, NAPROXEN SODIUM (OTC)
  - PALONOSETRON HYDROCHLORIDE

- **PURDUE GDP**
  - SEROMYCIN, CYCLOSERINE NE

- **PURDUE PHARMA PRODUCTS LP**
  - INTERMEZZO, ZOLPIDEM TARTRATE

- **PURDUE PHARMA LP**
  - BUTRANS, BUPRENORPHINE NE
  - HYSINGLA, HYDROCODONE BI TARTRATE
  - OXYCONTIN, OXYCODONE HYDROCHLORIDE

---

**Q**

- **QILU PHARM CO LTD**
  - CEFAZOLI N SODIUM
  - CEFEPIME ME HYDROCHLORIDE DE, CEFEPIME ME HYDROCHLORIDE
  - CEFTRIAXONE, CEFTRIAXONE SODIUM
  - i rif notecan hydrogen chloride
dei, I RI NOTECAN HYDROCHLORIDE
  - OLANZAPI PE, OLANZAPI PE
  - OLMESARTAN MEDOXOM L, OLMESARTAN MEDOXOM L
  - OLMESARTAN MEDOXOM L
  - ONDANSETRON HYDROCHLORIDE DE, ONDANSETRON HYDROCHLORIDE
  - OXALI PLATI N, OXALI PLATI N
  - PALONOSETRON HYDROCHLORIDE DE, PALONOSETRON HYDROCHLORIDE
  - TENOFOVIR R DI SOPROXI L FUMARATE

- **QILU TI ANHE**
  - PI PERACI LILI N AND TAZOBACTAM, PI PERACI LILI N SODIUM

- **QINGDAO BAHEAL PHARM**
  - METFORM N HYDROCHLORIDE DE, METFORM N HYDROCHLORIDE DE

- **QOL MEDIC**
  - ETHAMOLI N, ETHANOLAM NE OLEATE
  - SUCRAID, SACROSIDASE

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**QUAGEN**
** Q **

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<td>QUAGEN PHARMACEUTICALS LLC</td>
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<td>FLUDEOXYGLUCOSE F18</td>
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** R-PHARM US LLC **

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<td>R2 PHARMA LLC</td>
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** RADIUS HEALTH INC **

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<td>RADIUS HEALTH INC</td>
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** RB HLTH **

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** RECO GAI NESVI LLE LLC **

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** RELYPSA INC **

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** REMPEX PHARMS **

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  OXYTOCIN, OXYTOCIN
  PALONOSETRON HYDROCHLORIDE, PALONOSETRON HYDROCHLORIDE
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  PENTOBARBI TAL SODI UM, PENTOBARBI TAL SODI UM
  PROPOFOL, PROPOFOL
  ROCURONI UM BROM DE, ROCURONI UM BROM DE
  THIAMINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE
  TOPOTECANE HYDROCHLORIDE, TOPOTECANE HYDROCHLORIDE
  VANCOMYCIN HYDROCHLORIDE, VANCOMYCIN HYDROCHLORIDE
  Vecuronium bromide, Vecuronium bromide
  Zoledronate CACI D, Zoledronate CACI D

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* SAGENT STRIDES LLC
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* SALIX PHARMACEUTICALS INC
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  DIURO L, CHLOROTHIAZIDE
  MIDAZOLAM HYDROCHLORIDE, MIDAZOLAM HYDROCHLORIDE
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  OSMOPREP, SODIUM PHOSPHATE, DI BASI CI, ANHYDROUS
  PEPIDON, FAMOTIDE D
  RELISTOR, METHYLALTREXONE BROM DE
  XI FAXAN, RI FAXI M N

SALIX PHARMS INC
* SALIX PHARMACEUTICALS INC
  RELISTOR, METHYLALTREXONE BROM DE

SAMSON MEDICAL TECHNOLOGIES LLC
* SAMSON MEDICAL TECHNOLOGIES LLC
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SANDOZ
* SANDOZ
  DOCETAXEL, DOCETAXEL

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**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

**S**

- **SANDOZ INC**
  - OLanzapine and FluoxetIne HydroChloride, FluoxetIne HydroChloride
  - OmePrazole, OmePrazole
  - Omni Trope, SomatroPii reCombinaNT
  - OndasEtroN, OndasEtroN
  - OrphenAdrine CI trAtE, Aspi ri n, AnC afCei ne, Aspi ri n
  - OrphenAdrine CI trAtE, OrphenAdrine NE CI trAtE
  - Oxali PlaTI n, Oxali PlaTI n
  - Oxaprozi n, Oxoprozi n
  - OkaZePam, okaZePam
  - Penicillin G Potassi um, Penicillin G Potassi um
  - Penicillin G Sodii um, Penicillin G Sodii um
  - Penicillin V Potassi um, Penicillin V Potassi um
  - Perphenazine ne, Perphenazine ne
  - PhenEterm Ne HydroChlori de, PhenEterm Ne HydroChlori de
  - Pi ogli tazone HydroChlori de and gli meP i ri de, Gli meP i ri de
  - Pi ogli tazone HydroChlori de and MeTformi n HydroChlori de, Metformi n HydroChlori de
  - Pi ogli tazone HydroChlori de, Pi ogli tazone HydroChlori de
  - Pi peraci lli n and taZoBactam, pi peraci lli n sodii um
  - PRAVASTATi n sodii um, PRAVASTATi n sodii um
  - ProchloroPerazi ne Maleate, ProchloroPerazi ne Maleate
  - ProMethazi ne HydroChlori de, ProMethazi ne HydroChlori de
  - Queti api ne fumaraTE, Queti api ne fumaraTE
  - Qui ni di ne sulfaTe, qui ni di ne sulfaTe
  - Rani ti di ne HydroChlori de, Rani ti di ne HydroChlori de
  - Ri Bavi ri n, Ri Bavi ri n
  - Ri Fampi n, Ri Fampi n
  - ri Speri done, ri Speri done
  - ri Zatri PTaN Benzoate, ri Zatri PTaN Benzoate
  - sulfaDi aZi ne, sulfaDi aZi ne
  - TacRoli MUs, TacRoli MUs
  - TAMSULOSi n HydroChlori de, TAMSULOSi n HydroChlori de
  - TemAzePam, TemAzePam
  - Terazosi n HydroChlori de, Terazosi n HydroChlori de
  - Tri aMterene and HydroChlorothi aZi de, HydroChlorothi aZi de
  - Tri fluoPerazi Ne HydroChlori de, Tri fluoPerazi Ne HydroChlori de
  - Valacyclovi r HydroChlori de, Valacyclovi r HydroChlori de
  - Vancomyci n HydroChlori de, Vancomyci n HydroChlori de
  - Zolpi Dem tartrate, Zolpi Dem tartrate

- **SANDOZ INC**
  - Acetam i NePheN, ACETam i NePheN
  - Amod i CI lli n and ClaVulanate Potassi um, Amod i CI lli n
  - Anecti ne, suCci nyCholi ne CHlori de
  - AnG i OMax, BI Vali rudi n
  - ARI stoSPAN, TRi AMi noLoNE HeXacetoNi de
  - Aspi ri n and di Pyri daMoLE, Aspi ri n
  - ATorVASTATi n calCi um, ATorVASTATi n calCi um
  - AzelaSti Ne HyDroChlori de, azelaSti Ne HyDroChlori de
  - BETOPTi C, BETAXOLOl HyDroChlori de
  - BI MATOPROSt, BI MATOPROSt
  - Bri mDi di ne TARTrate, Bri mDi di ne TARTrate
  - BromoCri PTi Ne MESylate, BromoCri PTi Ne MESylate
  - BuDESOni de, BuDESOni de
  - BuPROPi on HyDroChlori de, BuPROPi on HyDroChlori de
  - BUSULFAN, BUSULFAN
  - CARBOPlaTI n, CARBOPlaTI n
  - CARTEOLOL HydroChlori de, CARTEOLOL HydroChlori de
  - CasPOfungi N aCetaTE, CasPOfungi N aCetaTE
  - CEf i XI ne, CEf i XI ne
  - CEfTRi AXone, CEfTRi AXone sodii um
  - CLi sATRACuri Um BEsyLATE preservati ve free, CLi sATRACuri Um BEsyLATE
  - CLi sATRACuri Um BEsyLATE, CLi sATRACuri Um BEsyLATE
  - CLi NDAmCi N Phosphate iN 5% Dextrose iN Plasti c Contai ner, CLi NDAmCi N Phosphate
  - CROMOlyN sodi um, CROMOlyN sodi um
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** S **

*SANDOZ INC*

*DECIRAB NE*  *DECIRAB NE*

DEXAMETHASONE SODIUM PHOSPHATE, DEXAMETHASONE SODIUM PHOSPHATE

DEXMEDETOMIDINE HYDROCHLORIDE, DEXMEDETOMIDINE HYDROCHLORIDE

DI CLOFENAC SODIUM, DI CLOFENAC SODIUM

DIGOKIN, DI GOKI N

DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL maleate, DORZOLAM DE HYDROCHLORIDE DE

DORZOLAM DE HYDROCHLORIDE, DORZOLAM DE HYDROCHLORIDE DE

DOXERCALCI FEROL, DOXERCALCI FEROL

ENALAPRIL MALEATE, ENALAPRIL MALEATE

ENOKAPARIN SODIUM, ENOKAPARIN SODIUM

EPHEDRINE SULFATE, EPHEDEI NE SULFATE

EZETI M BE, EZETI M BE

FENOLDOPAM MESYLATE, FENOLDOPAM MESYLATE

FLUMAZENI L, FLUMAZENI L

GATI FLOKACI N, GATI FLOKACI N

GENTAM CI N SULFATE, GENTAM CI N SULFATE

GLATOPA, GLATI RAMEV ACETATE

GRAN SETRON HYDROCHLORIDE DE, GRAN SETRON HYDROCHLORIDE DE

GRI SEOFULVI N, GRI SEOFULVI N, M CROSIE ZE

GRI SEOFULVI N, ULTRAM CROSIE ZE, GRI SEOFULVI N, ULTRAM CROSIE ZE

GUANFACINE HYDROCHLORIDE DE, GUANFACINE HYDROCHLORIDE DE

I NFUM TE ADULT, ALPHA-TOCOPHEROL ACETATE

I NFUM TE PEDI ATRI C (PHARMACY BULK PACKAGE), ASCORBI C ACI D

I NFUM TE PEDI ATRI C, ASCORBI C ACI D

I SONI AZI D, I SONI AZI D

KETOROLAC TROMETAM NE, KETOROLAC TROMETAM NE

LANOSOPRAZOLE, AMDEI CI LLI N AND CLARI THROMOCI N, AMDEI CI LLI N

LATANOPROST, LATANOPROST

LEVOBUNOLYL HYDROCHLORIDE DE, LEVOBUNOLYL HYDROCHLORIDE DE

LEVOLEUCOVORIN CALCIUM, LEVOLEUCOVORIN CALCIUM

LI NEZOLID D, LI NEZOLID D

MAXI TROL, DEXAMETHASONE

METHOTREXATE SODIUM PRESERVATIVE FREE, METHOTREXATE SODIUM

METHYLPRUDINI SOLONE ACETATE, METHYLPRUDINI SOLONE ACETATE

METI PRANOLOL, METI PRANOLOL HYDROCHLORIDE DE

METOPROLOL TARTRATE, METOPROLOL TARTRATE

MONTELUKAST SODIUM, MONTELUKAST SODIUM DE

NEOMYCIN SULFATE AND HYDROCORTISONE SODIUM, HYDROCORTISONE SODIUM

NEVI RAPI NE, NEVI RAPI NE

NOREPI NEPHERI NE BI TARTRATE, NOREPI NEPHERI NE BI TARTRATE

OFLOKACI N, OFLOKACI N

OLANZAPI NE, OLANZAPEI NE

ONDANSETRON HYDROCHLORIDE DE PRESERVATIVE FREE, ONDANSETRON HYDROCHLORIDE DE

ONDANSETRON HYDROCHLORIDE DE, ONDANSETRON HYDROCHLORIDE DE

OACI TACI, OACI TACI

PALONOSETRON HYDROCHLORIDE DE, PALONOSETRON HYDROCHLORIDE DE

PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM DE

PARI CALCI TOL, PARI CALCI TOL

PI PERACI LLI N AND TAZOBACTAM, PI PERACI LLI N SODI DE

PRAZIPEXOLE DE HYDROCHLORIDE DE, PRAZIPEXOLE DE HYDROCHLORIDE DE

PROGESTERONE, PROGESTERONE

QOLI ANA, BRI MONTI DNE TARTRATE

RASAGI LI NE MESYLATE, RASAGI LI NE MESYLATE

REGONOL, PYRI DOSTI GM NE BROM DE

RI BAVI RI N, RI BAVI RI N

ROCURONI SODIUM BROM DE, ROCURONI SODIUM BROM DE

ROPI NI ROLE HYDROCHLORIDE DE, ROPI NI ROLE HYDROCHLORIDE DE

ROSVASTATI N CALCIUM, ROSVASTATI N CALCIUM

SU Lodosi N, SI Lodosi N

SULFACETAM SODIUM PHOSPHATE, SULFACETAM DE SODIUM PHOSPHATE

SULFACETAM SODIUM PHOSPHATE, SULFACETAM SODIUM PHOSPHATE

TELM SARTAN, TELM SARTAN

TERI FLUMONI DE, TERI FLUMONI DE
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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## APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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## Appendix B - Product Name Sorted by Applicant

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- Ammonia N 13, Ammonia N-13
- Fluordeoxyglucose F-18, Fluordeoxyglucose F-18
- Sodium Fluoride F-18, Sodium Fluoride F-18

**SHIONOGI INC**
- Mulpeta, Lusutrombopag
- Ponstel, Mefenamic Acid
- Symproic, Naldeemedine Tosylate
- Ulesfia, Benzyl Alcohol

**SHIRE**
- Adderall XR 10, Amphetamine Aspartate
- Adderall XR 15, Amphetamine Aspartate
- Adderall XR 20, Amphetamine Aspartate
- Adderall XR 25, Amphetamine Aspartate
- Adderall XR 30, Amphetamine Aspartate
- Adderall XR 5, Amphetamine Aspartate
- Carbatrol, Carbamazepine NE
- Intuniv, Guanfacine Hydrochloride DE
- Lidada, Mesalamine
- Pentasa, Mesalamine

**SHIRE DEVELOPMENT LLC**
- Fosrenol, Lanthanum Carbonate
- Motegri Ty, Prucalopride DE Succinate
- Mydayis, Amphetamine Aspartate
- Vyvanse, Lisdexamfetamine Diethylstilbestrol
- Xiidra, Lifitegrast

**SHIRE HUMAN GENETIC THERAPIES INC**
- Vpriv, Velaglucerase Alfa

**SHIRE ORPHAN THERAPIES INC**
- Agrylith, Anagrelide DE Hydrochloride DE
- Fosrenol, Lanthanum Carbonate

**SIGA TECHNOLOGIES INC**
- Tpoxx, Tecovirimat

**SIGMAPHARM LABORATORIES LLC**
- Acitretin, Acitretin
- Adefovir Dipivoxil, Adefovir Dipivoxil DE
- Amiloride Hydrochloride, Amiloride Hydrochloride
- Atenolol, Maleate, Atenolol Maleate
- Citanpost, Di Sulfa Ram
- Defeti, Maleate, Defeti Maleate
- Ergocalciferol, Ergocalciferol
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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* SORCERER THERAPEUTICS LLC
  OLOPATADINE HYDROCHLORIDE, OLOPATADINE HYDROCHLORIDE
  ROPIVACAINE HYDROCHLORIDE, ROPIVACAINE HYDROCHLORIDE
  SODIUM NITROPRUSSIDE, SODIUM NITROPRUSSIDE
  TOBRAMYCIN, TOBRAMYCIN
  VERAPAMIL HYDROCHLORIDE, VERAPAMIL HYDROCHLORIDE

* SOVEREIGN PHARMA INC
  OLOPATADINE HYDROCHLORIDE, OLOPATADINE HYDROCHLORIDE
  ROPIVACAINE HYDROCHLORIDE, ROPIVACAINE HYDROCHLORIDE
  SODIUM NITROPRUSSIDE, SODIUM NITROPRUSSIDE
  TOBRAMYCIN, TOBRAMYCIN
  VERAPAMIL HYDROCHLORIDE, VERAPAMIL HYDROCHLORIDE

* SOVEREIGN PHARMA INC
  OLOPATADINE HYDROCHLORIDE, OLOPATADINE HYDROCHLORIDE
  ROPIVACAINE HYDROCHLORIDE, ROPIVACAINE HYDROCHLORIDE
  SODIUM NITROPRUSSIDE, SODIUM NITROPRUSSIDE
  TOBRAMYCIN, TOBRAMYCIN
  VERAPAMIL HYDROCHLORIDE, VERAPAMIL HYDROCHLORIDE

* SOVEREIGN PHARMACEUTICALS LLC
  OLOPATADINE HYDROCHLORIDE, OLOPATADINE HYDROCHLORIDE
  ROPIVACAINE HYDROCHLORIDE, ROPIVACAINE HYDROCHLORIDE
  SODIUM NITROPRUSSIDE, SODIUM NITROPRUSSIDE
  TOBRAMYCIN, TOBRAMYCIN
  VERAPAMIL HYDROCHLORIDE, VERAPAMIL HYDROCHLORIDE

* SPARC
  OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE
  OXYMORPHONE HYDROCHLORIDE, OXYMORPHONE HYDROCHLORIDE
  PAMELOR, NORTRIPTYLINE HYDROCHLORIDE
  RESTORIL, TEMAZEPAM
  ROXICODONE, OXYCODONE HYDROCHLORIDE
  TOFRANIL, IMIPRAMINE HYDROCHLORIDE
  TRAMADOL HYDROCHLORIDE, TRAMADOL HYDROCHLORIDE

* SPRECGX LLC
  ACETAMINO PHEN AND CODEINE PHOSPHATE, ACETAMINO PHEN
  ANAFRANIL, CLOMIPRAMINE HYDROCHLORIDE
  ANEXSI A 5/325, ACETAMINO PHEN
  ANEXSI A 7.5/325, ACETAMINO PHEN
  BENZEPHTAMINE HYDROCHLORIDE, BENZEPHTAMINE HYDROCHLORIDE
  BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE, BUPRENORPHINE HYDROCHLORIDE
  BUTALBITAL, ACETAMINO PHEN AND CAFFEINE, ACETAMINO PHEN
  DEXTROAMPHETAMINE SULFATE, DEXTROAMPHETAMINE SULFATE
  EXALGO, HYDROMORPHONE HYDROCHLORIDE
  FENTANYL CITRATE, FENTANYL CITRATE
  FENTANYL-100, FENTANYL
  FENTANYL-12, FENTANYL
  FENTANYL-25, FENTANYL
  FENTANYL-50, FENTANYL
  FENTANYL-75, FENTANYL
  FLUCETI NE HYDROCHLORIDE, FLUCETI NE HYDROCHLORIDE
  HYDROCODONE BITARTRATE AND ACETAMINO PHEN, ACETAMINO PHEN
  HYDROMORPHONE HYDROCHLORIDE, HYDROMORPHONE HYDROCHLORIDE
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  RESTORIL, TEMAZEPAM
  TOFRANIL, IMPRAMINE HYDROCHLORIDE
  TRAMADOL HYDROCHLORIDE, TRAMADOL HYDROCHLORIDE

* SPECTRA MDL DEVIC ES
  LI DOCAI NE HYDROCHLORIDE, LI DOCAI NE HYDROCHLORIDE
  SODIUM UM CHLORIDE, SODIUM UM CHLORIDE

* SPECTRUM MRC LLC
  AMMONI A 13, AMMONI A 13
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F18
  SODIUM FLUORIDE F-18, SODIUM FLUORIDE F-18

* SPECTRUM PHARMACEUTICALS LLC
  BELEODAQ, BELI NOSTAT
  EVOMELA, MELPHALAN HYDROCHLORIDE
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**SUN PHARMACEUTICALS INC**

* SUN PHARMACEUTICALS INC * INDUSTRIES LTD

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SUN PHARMACEUTICAL INDUSTRIES LTD

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SUN PHARMACEUTICAL INDUSTRIES LTD

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BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

BUPRENORPHINE HYDROCHLORIDE

CARVEDILOL

CETIRIZINE HYDROCHLORIDE

CLINDAMYCIN HYDROCHLORIDE

CYCLOBENZAPRINE HYDROCHLORIDE

DESMOPRESSIN ACETATE

DILTIAZEM HYDROCHLORIDE

DONEPEZIL HYDROCHLORIDE

DOXYCYCLINE

ESOMEPRAZOLE MAGNESIUM

FAMOTIDINE (OTC)

FENOFO BRATE

FLUCXETI NE HYDROCHLORIDE

GABAPENTI N

GANI RELI X ACETATE

GLYCOPYRROLATE

GUANFACI NE HYDROCHLORIDE

IBANDRONATE SODIUM

INFUGEM GEMCITABINE HYDROCHLORIDE

LANSOPRAZOLE (OTC)

LEVETIRACETAM

LORATADI NE AND PSEUDOEPHEDRI NE SULFATE

LORATADI NE

LORATADI NE LETALI TABI NE HYDROCHLORIDE

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MORPHINE SULFATE

NALOXONE HYDROCHLORIDE AND PENTAZOCINE HYDROCHLORIDE

NALOXONE HYDROCHLORIDE

NAPROXEN SODIUM (OTC)

NARATRIPTAN HYDROCHLORIDE

OPEMRAZOLE

ONDANSETRON

OPCI CON ONE-STEP

OXCARBAZEPINE

PSEUDOEPHEDRI NE HYDROCHLORIDE

RILUZOLE

RIVASTIGMINE TARTRATE

SERTRALINE HYDROCHLORIDE

SODIUM NITROPRUSSIDE

SUMATRIPTAN SUCCINATE

TAMSULOSIN HYDROCHLORIDE

TESTOSTERONE CYPI ONATE

TOPIRAMATE

VALACYCLOVIR HYDROCHLORIDE

VALPROIC ACID

XIMO MINOCYCLINE HYDROCHLORIDE

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SUN PHARMACEUTICAL INDUSTRIES LTD

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BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

BUPRENORPHINE HYDROCHLORIDE

CARVEDILOL

CETIRIZINE HYDROCHLORIDE

CLINDAMYCIN HYDROCHLORIDE

CYCLOBENZAPRINE HYDROCHLORIDE

DESMOPRESSIN ACETATE

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BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

BUPRENORPHINE HYDROCHLORIDE

CARVEDILOL

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CLINDAMYCIN HYDROCHLORIDE

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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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** SUNGEN PHARMA **
SUNGEN PHARMA LLC
DEXTROAMP SACCHARATE AMP ASPARTATE DEXTROAMP SULFATE AND AMP SULFATE AMPHETAM NE

** SUNNY PHARMTECH I NC **
SUNNY PHARMTECH I NC
AM NACAPROI C ACI D AM NACAPROI C ACI D
NI TROFURANTO I (MONOHYDRATE MACROCRYSTALS NI TROFURANTO I

** SUNON OI **
SUNON OI ON PHARMACEUTI CALS I NC
BROVANA ARFORMOTEROL TARTRATE
XOPENEX HFA LEVALBUTEROL TARTRATE

** SUNON ON PHARM I NC **
SUNON ON PHARMACEUTI CALS I NC
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** S **

* SUNOVION PHARMACEUTICALS INC
  APTIOM, ESLICARBAZEPINE ACETATE
  ARCAPTA NEOHALER, I NDACATEROL MALEATE
  LATUDA, LURASI DONE HYDROCHLORIDE DE
  LUNESTA, ESZOPR CLONE
  SEEBRI, GLYCOPRROLATE
  UTIBRON, GLYCOPRROLATE
  ZONEGRAN, ZONISAMIDE

SUNOVION RESP
* SUNOVION RESPI RATORY DEVELOPMENT I NC
  LONHALA MAGNA R KI T, GLYCOPRROLATE

SUNSHINE LAKE
* SUNSHINE LAKE PHARMA CO LTD
  AZI THROMCYI N, AZI THROMCYI N
  CLARI THROMCYI N, CLARI THROMCYI N
  ENTACAPONE, ENTACAPONE
  METFORM N HYDROCHLORIDE DE, METFORM N HYDROCHLORIDE DE
  MXI FLOXAC N HYDROCHLORIDE DE, MXI FLOXACI N HYDROCHLORIDE DE
  OLANZAPI NE, OLANZAPI NE

SUNSTAR AMERI CAS
* SUNSTAR AMERI CAS I NC
  PAROEX, CHLORHEX DI NE GLUCONATE

SUPERNUS PHARMS
* SUPERNUS PHARMACEUTICALS INC
  OXTELLAR XR, OXCARBAZEPINE NE
  TROKENDI XR, TOPI RAMATE

SUVEN LI FE
* SUVEN LI FE SCI ENCES LTD
  MALATHI ON, MALATHI ON

SVC PHARMA
* SVC PHARMA LP
  DRONABI NOL, DRONABI NOL

SWEDI SH ORPHAN
* SWEDI SH ORPHAN BI OVI TRUM AB PUBL
  ORFADI N, NI TI SI NONE

SYNERGY PHARMS
* SYNERGY PHARMACEUTICALS INC
  TRULANCE, PLECANATI DE

SYNTHON PHARMA
* SYNTHON PHARMA INC
  LEVOCETI RI ZI NE DI HYDROCHLORIDE DE, LEVOCETI RI ZI NE DI HYDROCHLORIDE DE
  TAMUSULOSI N HYDROCHLORIDE DE, TAMUSULOSI N HYDROCHLORIDE DE

** T **

ACME LABS
* THE ACME LABORATORIES LTD
  CLOPI DOGREL BI SULFATE, CLOPI DOGREL BI SULFATE
  ZOLPI DEM TARTRATE, ZOLPI DEM TARTRATE

GEN HOSP
* THE GENERAL HOSPITAL CORP
  AMMONI A N 13, AMMONI A N 13

METHODIST HOSP RES
* THE METHODIST HOSP RESEARCH Institute
  FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18

RITEDOSE CORP
* THE RITEDOSE CORP
  ALBUTEROL SULFATE AND I PRATROPI UM BROM DE, ALBUTEROL SULFATE
  ALBUTEROL SULFATE, ALBUTEROL SULFATE
  I PRATROPI UM BROM DE, I PRATROPI UM BROM DE
  LEVALBUTEROL HYDROCHLORIDE DE, LEVALBUTEROL HYDROCHLORIDE DE

TAI HO ONCOLOGY
* TAI HO ONCOLOGY INC
  LONSURF, TI PI RACI L HYDROCHLORIDE DE

TAKEDA PHARM USA
# APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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* TAKEDA PHARMACEUTICALS USA INC |

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| | ACYCLOVIR, ACYCLOVIR |
| | ADAPALENE AND BENZOYL PEROXI DE, ADAPALENE |
| | ADAPALENE, ADAPALENE |
| | ALCLOMETASONE DI PROPI ONATE, ALCLOMETASONE DI PROPI ONATE |
| | AMMONIUM UM LACTATE, AMMONIUM UM LACTATE |
| | BETAMETHASONE DI PROPI ONATE, BETAMETHASONE DI PROPI ONATE |
| | CI CLOPI ROX, CI CLOPI ROX |
| | CI NADAM/Ci N PHOSPHATE AND BENZOYL PEROXI DE, BENZOYL PEROXI DE |
| | CLOMETASOL PROPONATE (EMOLLI ENT), CLOMETASOL PROPONATE |
| | CLOMETASOL PROPONATE, CLOMETASOL PROPONATE |
| | CLOTRIMAZOLE AND BETAMETHASONE DI PROPI ONATE, BETAMETHASONE DI PROPI ONATE |
| | CLOTRIMAZOLE, CLOTRIMAZOLE |
| | CLOTRIMAZOLE, CLOTRIMAZOLE (OTC) |
| | DAPSONE, DAPSONE |
** T **

* TARO PHARMACEUTICALS CALS USA INC
DERMABET, BETAMETHASONE VALERATE
DESONY DE, DESONY DE
DIOCLENAC SODIUM, DIOCLENAC SODIUM
DIFLORASONE DIACETATE, DIFLORASONE DIACETATE
ECONAZOLE, ECONAZOLE
ESCI TALOPRAM OKALATE, ESCI TALOPRAM OKALATE
FLUCCI NONI DE, FLUCCI NONI DE
GENTAM CI N SULFATE, GENTAM CI N SULFATE
HALOBetasol propionate, HALOBetasol propionate
HYDROCORTISONE VALERATE, HYDROCORTISONE VALERATE
HYDROCORTISONE, HYDROCORTISONE
IBUPROFEN, IBUPROFEN
IBUPROFEN, IBUPROFEN (OTC)
KETOZOLE, KETOCONAZOLE
MICONAZOLE 3, MICONAZOLE NITRATE (OTC)
MOMETASONE FURorate, MOMETASONE FURorate
MUPIROCI N, MUPIROCI N
NYSTATIN AND TRI AMO NOLONE ACETONIDE, NYSTATIN
NYSTATIN, NYSTATIN
PHENYTOI N, PHENYTOI N
RANITIDINE, RANITIDINE (OTC)
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, SODIUM CHLORIDE
STERILE WATER FOR INJECTION IN PLASTIC CONTAINER, STERILE WATER FOR INJECTION
SULFAZETAMIDE SODIUM, SULFAZETAMIDE SODIUM
TERBINAFAI NE HYDROCHLORIDE DE, TERBINAFAI NE HYDROCHLORIDE DE (OTC)
TERCONAZOLE, TERCONAZOLE
TRI AMO NOLONE ACETONIDE DE, TRI AMO NOLONE ACETONIDE DE
TRI VAGA ZOLE 3, CLOTRI MAZOLE (OTC)
U-CORT, HYDROCORTISONE ACETATE

TARO PHARM
* TARO PHARMA CEUTICALS CAL INDUSTRIES LTD
AM CINÓNIO HYDROCHLORIDE DE, AM CINÓNIO HYDROCHLORIDE DE
BETAMETHASONE VALERATE, BETAMETHASONE VALERATE
BROMPHENIRAMINE MALEATE, PSEUDOEPHRINE HYDROCHLORIDE AND DEXTROMETHORPHAN
CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE
CLOBAZAM, CLOBAZAM
CLOFLOXACIN HYDROCHLORIDE DE, CLOFLOXACIN HYDROCHLORIDE DE
CLOBETASOL PROPionate, CLOBETASOL PROPionate
CLORAZEPATE DI POTASSIUM, CLORAZEPATE DI POTASSIUM
DESAMOFITI NE, DESAMOFITI NE
DESONY DE, DESONY DE
FELBAMÁTE, FELBAMÁTE
FLUOZURACI L, FLUOZURACI L
GABAPENTI N, GABAPENTI N
GRAN SETRON HYDROCHLORIDE DE, GRAN SETRON HYDROCHLORIDE DE
LORATADINE, LORATADINE (OTC)
METRONIDAZOLE, METRONIDAZOLE
M NOXI DI L (FOR MEN), M NOXI DI L (OTC)
NORTRIPTYLINE HYDROCHLORIDE DE, NORTRIPTYLINE HYDROCHLORIDE DE
NYSTATIN, NYSTATIN
TERI L, CARBAMAZEPINE
WARFARIN SODIUM, WARFARIN SODIUM

TARO PHARM I NDS
* TARO PHARMACEUTICALS CAL INDUSTRIES LTD
AM CINÓNIO HYDROCHLORIDE DE, AM CINÓNIO HYDROCHLORIDE DE
CARBAMAZEPINE, CARBAMAZEPINE
CLOPEX R, CLOPEX R
CLINDAMYCIN PHOSPHATE, CLINDAMYCIN PHOSPHATE
ENALAPRIL MALEATE AND HYDROCHLOROTHI AZI DE, ENALAPRIL MALEATE
ETODOLAC, ETODOLAC
## APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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<thead>
<tr>
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<th>Products</th>
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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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* TEVA PHARMACEUTICALS USA INC

FEXOFENADI NE HYDROCHLORIDE DE HI VES, FEXOFENADI NE HYDROCHLORIDE DE (OTC)
FEXOFENADI NE HYDROCHLORIDE DE, FEXOFENADI NE HYDROCHLORIDE DE
FI NASTERI DE, FI NASTERI DE
FLUCONAZOLE, FLUCONAZOLE
FLUCCI NONI DE EMULSi FI ED BASE, FLUCCI NONI DE
FLUCCI NONI DE, FLUCCI NONI DE
FLUCKETI NE HYDROCHLORIDE DE, FLUCKETI NE HYDROCHLORIDE DE
FLURBI PROFEN, FLURBI PROFEN
FLUVOKAM NE MALEATE, FLUVOKAM NE MALEATE
FOSI NOPRI L SODI UM, FOSI NOPRI L SODI UM
GALZI ZI NC ACETATE
GEMF BROZI L, GEMF BROZI L
GLI MEPI RI DE, GLI MEPI RI DE
GLYBURI DE (M CRONI ZED), GLYBURI DE
GLYBURI DE, GLYBURI DE
HYDROCODEONE BITARTRATE AND I BuproFEN, HYDROCODONE BITARTRATE
I RBE StARTAN AND HYDROCHLOROTHII AZI DE, HYDROCHLOROTHII AZI DE
KETOCONAZOLE, KETOCONAZOLE
KEToproFEN, KEToproFEN
KETOROLAC TROMETHAM NE, KETOROLAC TROMETHAM NE
LAMOTRI GI NE, LAMOTRI GI NE
LEVCOFLOKACI N, LEVCOFLOKACI N
LOPERAM DE HYDROCHLORIDE DE, LOPERAM DE HYDROCHLORIDE DE
LORATADI NE, LORATADI NE (OTC)
LOSARTAN POTASSI UM, LOSARTAN POTASSI UM
LOVASTATI N, LOVASTATI N
METFORMI N HYDROCHLORIDE DE, METFORMI N HYDROCHLORIDE DE
METOCLOPRAM DE HYDROCHLORIDE DE, METOCLOPRAM DE HYDROCHLORIDE DE
METOPROLOL TARTRATE, METOPROLOL TARTRATE
MEXI LETI NE HYDROCHLORIDE DE, MEXI LETI NE HYDROCHLORIDE DE
MI RTAZAPI NE, MI RTAZAPI NE
MOEXI PRI L HYDROCHLORIDE DE AND HYDROCHLOROTHII AZI DE, HYDROCHLOROTHII AZI DE
MOEXI PRI L HYDROCHLORIDE DE, MOEXI PRI L HYDROCHLORIDE DE
MUPI ROCI N, MUPI ROCI N
NAPROKEN SODI UM, NAPROKEN SODI UM
NAPROKEN, NAPROKEN
NEFAZODONE HYDROCHLORIDE DE, NEFAZODONE HYDROCHLORIDE DE
NEOMCI N SULFATE, NEOMCI N SULFATE
NORTRI PTLI NE HYDROCHLORIDE DE, NORTRI PTLI NE HYDROCHLORIDE DE
NYSTATI N, NYSTATI N
OFLOKACI N, OFLOKACI N
ONDANSETRON HYDROCHLORIDE DE PRESERVATI VE FREE, ONDANSETRON HYDROCHLORIDE DE
ONDANSETRON HYDROCHLORIDE DE, ONDANSETRON HYDROCHLORIDE DE
ONDANSETRON, ONDANSETRON
ORAP, PI MOZI DE
OKAPROZI N, OKAPROZI N
OKYMORPHONE HYDROCHLORIDE DE, OKYMORPHONE HYDROCHLORIDE DE
PANTOPRAZOLE SOCI UM, PANTOPRAZOLE SOCI UM
PAROKETI NE HYDROCHLORIDE DE, PAROKETI NE HYDROCHLORIDE DE
PENI CI LLI N V, PENI CI LLI N V POTASSI UM
PI ROCI CAM, PI ROCI CAM
PRAVASTATI N SODI UM, PRAVASTATI N SODI UM
PRELONE, PREDI SOLONE
QUI NAPRI L HYDROCHLORIDE DE, QUI NAPRI L HYDROCHLORIDE DE
RANI TI DI NE HYDROCHLORIDE DE, RANI TI DI NE HYDROCHLORIDE DE
RI BAVI RI N, RI BAVI RI N
RI SPERI DONE, RI SPERI DONE
SERTRALI NE HYDROCHLORIDE DE, SERTRALI NE HYDROCHLORIDE DE
SI LDENAFI L CI TRATI, SI LDENAFI L CI TRATI
SOTALOL HYDROCHLORIDE DE, SOTALOL HYDROCHLORIDE DE
SUCRALFATE, SUCRALFATE
SULFAMETHOXAZOLE AND TRI METHOPRIM DOUBLE STRENGTH, SULFAMETHOXAZOLE
TERBI NAFI NE HYDROCHLORIDE DE, TERBI NAFI NE HYDROCHLORIDE DE
TI CLOP DI NE HYDROCHLORIDE DE, TI CLOP DI NE HYDROCHLORIDE DE
**APPENDIX B - PRODUCT NAME SORTED BY APPLICANT**

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* TEVA PHARMACEUTICALS CALS USA

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ENTECAVI R, ENTECAVI R
EPOPROSTENOL SODIUM, EPOPROSTENOL SODIUM
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ESCI TALOPRAM OKALATE, ESCI TALOPRAM OKALATE
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ETOPOSI DE, ETOPOSI DE
EZETI M BE, EZETI M BE
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FLUVASTATI N SODI UM FLUVASTATI N SODI UM
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GUANFACI NE HYDROCHLORIDE, GUANFACI NE HYDROCHLORIDE
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HALOPERI DOL, HALOPERI DOL LACTATE
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I FOSFAM DE, I FOSFAM DE
I MATI N B MESYLATE, I MATI N B MESYLATE
I RI NOTECAI HYDROCHLORIDE DE, I RI NOTECAI HYDROCHLORIDE DE
LANSOPRAZOLE, LANSOPRAZOLE
LEUCOVOI N CALCI UM LEUCOVORI N CALCI UM
LEUPROLI DE ACETATE, LEUPROLI DE ACETATE
LEVALBUTEROL HYDROCHLORIDE, LEVALBUTEROL HYDROCHLORIDE
LI NEZOLI D, LI NEZOLI D
LOGI LI A, UL PI PRI STAL ACETATE
MESNA, MESNA
METHYLREDI SOLO ACETATE, METHYLREDI SOLO ACETATE
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OLMASERTAN MEDOKOM L, OLMS ARTAN MEDOKOM L
OMEGA-3 ACI D ETHYL ESTERS, OMEGA-3 ACI D ETHYL ESTERS
OMEPRAZOLE, OMEPRAZOLE
PALONOSETRON HYDROCHLORIDE, PALONOSETRON HYDROCHLORIDE
PAM DRONATE DI SODI UM PAM DRONATE DI SODI UM
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PARI CALCI TO, PARI CALCI TO
PI OGLI TAZONE HYDROCHLORIDE DE AND METFORMIN HYDROCHLORIDE DE, METFORMI N HYDROCHLORIDE DE
PI OGLI TAZONE HYDROCHLORIDE DE, PI OGLI TAZONE HYDROCHLORIDE DE
RALOXI FENE HYDROCHLORIDE DE, RALOXI FENE HYDROCHLORIDE DE
RI SEDRONATE SODI UM, RI SEDRONATE SODI UM
ROSUVASTATI N CALCI UM ROSUVASTATI N CALCI UM
SOLI FENACI N SUCCI NATE, SOLI FENACI N SUCCI NATE
SULFAMETHOKAZOLE AND TRI METHOPRIN, SULFAMETHOKAZOLE
SUMATRIPTAN PTAN SUCCI NATE, SUMATRIPTAN PTAN SUCCI NATE
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TENOFOVIR R DI SOPROX L FUMARATE, TENOFOVIR R DI SOPROX L FUMARATE
TOBRAMCY N SULFATE, TOBRAMCY N SULFATE
TOBRAMYCN, TOBRAMYCN
TOLTERODI NE TARTRATE, TOLTERODI NE TARTRATE
TOPOTECAN HYDROCHLORIDE, TOPOTECAN HYDROCHLORIDE
VECURONI UM BROM DE, VECURONI UM BROM DE
VIGABATRIN, VIGABATRIN
VINCRISTINE SULFATE PFS, VINCRISTINE SULFATE
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

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APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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  - CLOBETASOL PROPIONATE, CLOBETASOL PROPIONATE
  - DI CLOFENAC SODIUM, DI CLOFENAC SODIUM
  - ERYTHROMYCIN AND BENZOYL PEROXI DE, BENZOYL PEROXI DE
  - KETOCONAZOLE, KETOCONAZOLE
  - LEVETI RACETAM, LEVETI RACETAM
  - LIDOCAINE AND PRILOCAINE, LIDOCAINE
  - METRONIDAZOLE, METRONIDAZOLE
  - NAFTIFINE HYDROCHLORIDE, NAFTIFINE HYDROCHLORIDE

- ** TOLMAR THERAP **
  - ELI GARD, LEUPROLIDE ACETATE

- ** TORPHARM **
  - CI TALODRAME HYDROBROMIDE, CI TALODRAME HYDROBROMIDE

- ** TORRENT PHARMA INC **
  - M NOCYC I N HYDROCHLORIDE, M NOCYC I N HYDROCHLORIDE

- ** TORRENT PHARMS **
  - LEVOFLXACIN, LEVOFLXACIN
  - LEVOFLXACIN, LEVOFLXACIN

- ** TORRENT PHARMA INC **
  - CI TALODRAME HYDROBROMIDE, CI TALODRAME HYDROBROMIDE
  - DONEPEZI L HYDROCHLORIDE, DONEPEZI L HYDROCHLORIDE
  - LAMOTRI GI NE, LAMOTRI GI NE
  - LAMOTRI GI NE, LAMOTRI GI NE
  - LOSARTAN POTASSIUM AND HYDROCHLOROTHI AZI DE, HYDROCHLOROTHI AZI DE
  - METFORM N HYDROCHLORIDE, METFORM N HYDROCHLORIDE
  - PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM
  - PRAM PEXOLE DI HYDROCHLORIDE, PRAM PEXOLE DI HYDROCHLORIDE
  - SERTRALI NE HYDROCHLORIDE, SERTRALI NE HYDROCHLORIDE
  - ZOLPI DEM TARTRATE, ZOLPI DEM TARTRATE

- ** TORRENT PHARMACEUTICALS LTD **
  - ACYCLOVIR, ACYCLOVIR
  - AMLODIPINE BESYLATE AND VALSARTAN, AMLODIPINE BESYLATE
  - AMLODIPINE BESYLATE, VALSARTAN AND HYDROCHLOROTHI AZI DE, AMLODIPINE BESYLATE
  - ANAGRELIDE HYDROCHLORIDE, ANAGRELIDE HYDROCHLORIDE
  - ARPI PI PRAZOLE, ARPI PI PRAZOLE
  - BUPROPON HYDROCHLORIDE, BUPROPON HYDROCHLORIDE
  - CELECOXIB, CELECOXIB
  - CLOPI DOGREL BI SULFATE, CLOPI DOGREL BI SULFATE
  - DARI FENACI N HYDROBROMIDE, DARI FENACI N HYDROBROMIDE
  - DULOXETI NE HYDROCHLORIDE, DULOXETI NE HYDROCHLORIDE
  - ESI TALODRAME OKALATE, ESI TALODRAME OKALATE
  - ESOMEPAZOLE MAGNESIUM, ESOMEPAZOLE MAGNESIUM
  - FELODI PI NE, FELODI PI NE
  - FENOFI BRATE (M CRONI ZED), FENOFI BRATE
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** T **

| TWI PHARMACEUTICALS INC | HYDROXYCHLOROQUINE SULFATE, HYDROXYCHLOROQUINE SULFATE |
|---------------------------------------------------------------|
| Labetalol Hydrochloride, Labetalol Hydrochloride DE |
| Megestrol Acetate, Megestrol Acetate |
| Metoprolol Succinate, Metoprolol Succinate NE |
| Nifedipine, Nifedipine |
| Sevelamer Carbonate, Sevelamer Carbonate |
| Zolmitriptan, Zolmitriptan |

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| UCI PET IMAGING CENTER | FLUDEOXYGLOUCOSE F18, FLUDEOXYGLOUCOSE F-18 |

| UNIMEDICA LABS PVT LTD | CHLORTHALI DONE, CHLORTHALI DONE |

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<td>MONTIELUKAST SODIUM UM, MONTIELUKAST SODIUM UM</td>
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<td>PI ROXI CAM, PI ROXI CAM</td>
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<th>UNICHEM PHARMAS (USA)</th>
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<td>VALSENTAN, VALSENTAN</td>
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## APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

**U**

- **UNICHEM PHARMACEUTICALS (USA) INC**
  - Bisoprolol Fumarate, Bisoprolol Fumarate

- **UNIMARK REMEDI ES LTD**
  - Montelukast Sodium, Montelukast Sodium

- **UNIQUE PHARM LABS**
  - Atenolol, Atenolol
  - Cetirizine Hydrochloride Allergy, Cetirizine Hydrochloride (OTC)
  - Ciprofloxacin Hydrochloride, Ciprofloxacin Hydrochloride
  - Diclofenac Sodium, Diclofenac Sodium
  - Fexofenadine Hydrochloride Allergy, Fexofenadine Hydrochloride (OTC)
  - Glipizide, Glipizide
  - Lithium Carbonate, Lithium Carbonate
  - Midodrine Hydrochloride, Midodrine Hydrochloride
  - Oxybutynin Chloride, Oxybutynin Chloride
  - Tinidazole, Tinidazole

- **UNITED BIOMEDICAL INC**
  - Terbutaline Sulfate, Terbutaline Sulfate

- **UNITED GUARDIAN INC**
  - Renacidin, Citric Acid

- **UNITED THERAPEUTICS CORP**
  - Orenitram, Treprostinil Diolamine
  - Remodulin, Treprostinil
  - Tyvaso, Treprostinil

- **UNIV MICHIGAN PET RADIOPHARMACEUTICAL PRODUCTION PROGRAM**
  - Fluodeoxyglucose F18, Fluodeoxyglucose F-18

- **UNIV TEXAS MD ANDERSON CANCER CENTER**
  - Choline C-11, Choline C-11
  - Fluodeoxyglucose F18, Fluodeoxyglucose F-18

- **UNIV UTAH CYCLOTRON**
  - Fluodeoxyglucose F18, Fluodeoxyglucose F-18
  - Sodium Fluoride F-18, Sodium Fluoride F-18

- **UPSHER SMITH LABS LLC**
  - Amlodipine Besylate, Amlodipine Besylate
  - Azelastine Hydrochloride, Azelastine Hydrochloride
  - Bethanechol Chloride, Bethanechol Chloride
  - Bexarotene, Bexarotene
  - Bumetanide, Bumetanide
  - Clobazam, Clobazam
  - Clonidine Hydrochloride, Clonidine Hydrochloride
  - Diphenoxylate Hydrochloride and Atropine Sulfate, Atropine Sulfate
  - Doxazosin Mesylate, Doxazosin Mesylate
  - Exemestane, Exemestane
  - Fluvoxamine Maleate, Fluvoxamine Maleate
  - Fosinopril Sodium, Fosinopril Sodium
  - Hydrocodone Bitartrate and Acetaminophen, Acetaminophen
  - Klor-Con M10, Potassium Chloride
  - Klor-Con M15, Potassium Chloride
  - Klor-Con M20, Potassium Chloride
  - Losartan Potassium, Losartan Potassium
  - Memantine Hydrochloride, Memantine Hydrochloride
  - Morphine Sulfate, Morphine Sulfate
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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<th>Product Name</th>
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<td>Nystatin</td>
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** US PHARM HOLDINGS **

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** US PHARMHoldings I **

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** US WORLDMEDS **

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** US WORLDMEDS LLC **

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** USL PHARMA **

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** USV NORTH AMERICA **

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** VALEANT **

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** Mysoline | Pot M Done **
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** V **

VALEANT BERMUDA
* VALEANT INTERNATIONAL BERMUDA
  BENZACLI N, BENZOYL PEROXIDE
  DERMATOP E, EMOLLIENT, PREDNISOLONE
  ELI DEL, PI METROLI MUS
  PENLAC, CI CLOPI REX
  RETI N-A, TRETINOIN N
  XERESE, ACYCLOVIR R
  ZOMI RAX, ACYCLOVIR R

VALEANT INTL
* VALEANT INTERNATIONAL BARBADOS SRL
  ATIVAN, LORAZEPAM
  CARDIZEM CD, DI LTI AZEM HYDROCHLORIDE
  CARDIZEM LA, DI LTI AZEM HYDROCHLORIDE
  CARDIZEM, DI LTI AZEM HYDROCHLORIDE
  RETIN-A M, TRETINOIN
  RETIN-A N-A, TRETINOIN N
  RETIN-A M, TRETINOIN N
  VASERETIC, ENALAPRIL MALEATE
  WELLBUTRIN X, BUPROPION HYDROCHLORIDE
* VALEANT INTERNATIONAL SRL
  BENZAMYCIN, BENZOYL PEROXIDE

VALEANT LUXEMBOURG
* VALEANT PHARMACEUTICALS LUXEMBOURG SARL
  ERTACZO, SERTACONAZOLE N TRATE
  TARGRETIN, BEXAROTENE
  VI SYDUNIES, VERTEPORFIN N

VALEANT PHARM INTL
* VALEANT PHARMACEUTICALS CALS LUXEMBOURG SARL
  ANDROI D 25, METHYLTTESTOSTERONE
  EFUDEX, FLUOROURACIL L
  LIBRI U, CHLORDIAZEPoxide DI HYDROCHLORIDE
  MESTINON, PYRIDOSTIGMINE BROMIDE
  TESTRED, METHYLTTESTOSTERONE
  VI RAZOLE, RI BAVI RI N
  ZELAPAR, SELAG LI NE HYDROCHLORIDE

VALEANT PHARMS
* VALEANT PHARMACEUTICALS CALS NORTH AMERI CA
  MEFHYTON, PHYTONADI ONE
  MESTINON, PYRIDOSTIGMINE BROMIDE
  TIMOPTIC XE, TIMOLOL MALEATE

VALENT PHARMS I NC
* VALENT PHARMACEUTICALS CALS I NTERNATI ONAL I NC
  MESTINON, PYRIDOSTIGMINE BROMIDE
  ULTRAM CROSIE

VALENT PHARMS I NTL
* VALENT PHARMACEUTICALS CALS I NTERNATI ONAL
  APLI SO, MESALAMINE B
  COLAZAL, BALSALAZIDE DI SODIUM
  GI AZO, BALSALAZIDE DI SODIUM
  I LUBL A, EFI NACONAZOLE
  UCEI S, BUDESONIDE

VALENT PHARMS LLC
* VALENT PHARMACEUTICALS CALS NORTH AMERI CA LLC
  MACULGEN, PEGAPTANIB SODIUM
  MESTINON, PYRIDOSTIGMINE BROMIDE
  TASMAR, TOCAPONE
  TI MOPCI C-XE, TI MOL LASTE

VALENT PHARMS NORT
* VALENT PHARMACEUTICALS CALS NORTH AMERI CA LLC
  APLENZI N, BUPROPION HYDROBROMIDE
  CARAC, FLUOROURACIL L
  DERMATOP, PREDNISOLONE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** V **

* VALEANT PHARMACEUTICALS NORTH AMERICA LLC
  DI ASTAT ACUDI AL, DI AZEPAM
  DI ASTAT, DI AZEPAM
  DI LTI AZEM HYDROCHLORIDE DE, DI LTI AZEM HYDROCHLORIDE DE
  FENOFI BRATE, FENOFI BRATE
  I SORDI L, I SOROSI DE DI NI TRATE
  I SUPREL, ISOPTERENOL HYDROCHLORIDE DE
  Klaron, Sulfacetam De Sodi Um
  M NI TRAN, NI TROGLYCOLER N
  NI FEDI PI NE, NI FEDI PI NE
  NORI TATE, METRONI DAZOLE
  PEPO D, FAMOTI DI NE
  RENOVA, Treti Noi N
  RETI N-A, Treti Noi N
  SECONAL SODI UM SECOBARBI TAL SODI UM
  TI AZAC, DI LTI AZEM HYDROCHLORIDE DE
  Vasotec, Enalapril Maleate
  Venlafaxin Ne Hydrochloride De, Venlafaxine Ne Hydrochloride De
  Xenazi Ne, Tetrabenazi Ne

VALIDUS PHARMS
* VALIDUS PHARMACEUTICALS LLC
  BUMEX, BUMETANIDE
  EQUETRO, CARBAMAZEPINE NE
  ROCALTROL, CALCI TRI OL

VALIDUS PHARMACEUTICALS INC
* VALIDUS PHARMACEUTICALS LLC
  MARPLAN, I SOCARBOXAZI D

VANDA PHARMS INC
* VANDA PHARMEUTICALS LLC
  FANAPT, I LOPERI DONE
  HETLI OZ, TASIL MELTEON

VELoki S PHARMS INC
* VELoki S PHARMACEUTICALS LLC
  ENVARSUS XR, TACROLI MUS

VERASTEM INC
* VERASTEM INC
  COPIKTRA, DUVELI S B

VEROSCI ENCE
* VEROSCI ENCE LLC
  CYCLOSET, BROMOCRI PTI NE MESYLALE

VERTEX PHARMS
* VERTEX PHARMACEUTICALS INC
  KALYDECO, I VACAFTOR

VERTEX PHARMACEUTICALS INC
* VERTEX PHARMACEUTICALS INC
  KALYDECO, I VACAFTOR
  ORKambi, I VACAFTOR
  SYMDEKO (COPACKAGED), I VACAFTOR

VERTI CAL PHARMS LLC
* VERTICAL PHARMACEUTICALS LLC
  DI VI GEL, ESTRADE OL

VI B
* VALEANT INTERNATIONAL BERMUDA
  ZOMI RAX, ACYCLOVIR R

VI CURON
* VI CURON PHARMACEUTICALS LLC
  ERAXI S, ANI DULAFUNGI N

VI FOR FRESENIUS US
* VI FOR FRESENIUS US MEDI CAL CARE RENAL PHARMA FRANCE
  VELPHORO, SUCROFERRIC OXYHYDROXY DE

VIIV HLTHCARE
* VIIV HEALTHCARE CO
  COMBI VI R, LAM VUDI NE
  EPI VI R, LAM VUDI NE
** APPENDIX B - PRODUCT NAME SORTED BY APPLICANT **

** V **

* VIIV HEALTHCARE CO *
  EPZI COM, ABACAVIR SULFATE
  J ULUCA, DOLUTEGRAVIR R SODIUM
  LEXI VA, FOSAMPRENAVIR R CALCO UM
  RESCRI PTOR, DELAVIR RDI NE MESYLATE
  RETROVI R, ZI DOVUDI NE
  SELZENTRY, MARAVI ROC
  TI VI CAY, DOLUTEGRAVIR R SODIUM
  TRI UMEQ, ABACAVIR R SULFATE
  TRI ZI VI R, ABACAVIR SULFATE
  ZI AGEN, ABACAVIR R SULFATE

* VI IV PHARMACEUTICALS LLC *
  ACETAM NOPHEN AND CODEI NE PHOSPHATE, ACETAM NOPHEN
  BENZTROPI NE MESYLATE, BENZTROPI NE MESYLATE
  FOLI C ACI D, FOLI C ACI D
  HYDROCORTI SONE AND ACETI C ACI D, ACETI C ACI D GLACI AL
  HYDROCORTI SONE, HYDROCORTI SONE
  NYSTATI N, NYSTATI N
  PHENYLEPHRI NE HYDROCHLORI DE AND PROMETHAZI NE HYDROCHLORI DE, PHENYLEPHRI NE
  PREDN SONE SODI UM PHOSPHATE, PREDN SODE SODI UM PHOSPHATE
  PROMETH HYDROCHLORI DE, PHENYLEPHRI NE HYDROCHLORI DE W CODEI NE PHOSPHATE, CODEI NE
  PROMETHAZI NE DM DEXTROMETHORPHAN HYDRBROM DE
  PROMETHAZI NE HYDROCHLORI DE, PROMETHAZI NE HYDROCHLORI DE
  PROMETHAZI NE WTH CODEI NE, CODEI NE PHOSPHATE
  ZOLPI DEM TARTRATE, ZOLPI DEM TARTRATE

* VI IV PHARMACEUTICALS *
  ACETAM NOPHEN AND CODEI NE PHOSPHATE, ACETAM NOPHEN
  ALPROZOLAM, ALPROZOLAM
  BROMPHENI RAM NE MALEATE, PSEUDOEPHEDRI NE HYDROCHLORI DE AND DEXTROMETHORPHAN
  CARBI NOKAM NE MALEATE, CARBI NOKAM NE MALEATE
  CLI NDAMICI N PHOSPHATE, CLI NDAMICI N PHOSPHATE
  CYCLAFEM 0.5/35, ETHI NYL ESTRADI OL QL
  DEXTROMEPHETAM NE SULFATE, DEXTROMEPHETAM NE SULFATE
  GI LDAGI A, ETHI NYL ESTRADI OL QL
  GI DESST 24 FE, ETHI NYL ESTRADI OL QL
  GRI SEFOULI N, GRI SEFOULI N, M CROSI ZE
  HYDROCODONE BI TARTRATE AND ACETAM NOPHEN, ACETAM NOPHEN
  KI M DES, DESOGESTREL
  METHSCOPOLAM NE BROM DE, METHSCOPOLAM NE BROM DE
  PROPRANOLOL HYDROCHLORI DE, PROPRANOLOL HYDROCHLORI DE

* VI IV PHARMACEUTICALS LLC *
  ACETAM NOPHEN AND CODEI NE PHOSPHATE, ACETAM NOPHEN
  ALLOPURIN NOL, ALLOPURIN NOL
  AM TRI PTYL NE HYDROCHLORI DE, AM TRI PTYL NE HYDROCHLORI DE
  BACLOFEN, BACLOFEN
  BUTALBI TAL, ACETAM NOPHEN AND CAFFEI NE, ACETAM NOPHEN
  BUTALBI TAL, ACETAM NOPHEN, CAFFEI NE AND CODEI NE PHOSPHATE, ACETAM NOPHEN
  CARI SOPRODOL, CARI SOPRODOL
  DI AZEPAM, DI AZEPAM
  HYDROCODONE BI TARTRATE AND ACETAM NOPHEN, ACETAM NOPHEN
  HYDROCODONE BI TARTRATE AND I BUPROFEN, HYDROCODONE BI TARTRATE
  HYDROXYZI NE HYDROCHLORI DE, HYDROXYZI NE HYDROCHLORI DE
  I BUPROFEN, I BUPROFEN
  I BUPROFEN, I BUPROFEN (OTC)
  LEVETI RACETAM, LEVETI RACETAM
  MEPERI DI NE HYDROCHLORI DE, MEPERI DI NE HYDROCHLORI DE
  MYPREDI NE SONE, MYPREDI NE SONE
  METOCLOPRAMDE HYDROCHLORI DE, METOCLOPRAMDE HYDROCHLORI DE
  OXYBUTYNI N CHLORI DE, OXYBUTYNI N CHLORI DE
  OXYCODONE AND ACETAM NOPHEN, ACETAM NOPHEN
  OXYCODONE HYDROCHLORI DE, OXYCODONE HYDROCHLORI DE
  PERPHENAZI NE, PERPHENAZI NE
  PREDN SONE, PREDN SONE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** V **

* VI NTAGE PHARMACEUTICALS INC
  PROPAFENONE HYDROCHLORIDE, SULFASALAZINE, TORSEMIDE
  VINTAGE PHARMACEUTICALS LLC
  CYCLAFEM 1/35, CYCLAFEM 7/7/7, DUTASTERIDE, EMOCQUETTE, FELODON PI NE, GI LDESS 1.5/30, GI LDESS 1/20, GI LDESS FE 1.5/30, GI LDESS FE 1/20, LETROZOLE, MONTELUKAST SODIUM, MORPHINE SULFATE, MYCOPHENOLATE MOFETIL, MYZILRA, ORSYTHIA, PERCOCET, PREVIFEM, TRIPREVIFEM

* VI NTAGE PHARMACEUTICALS LLC
  CYCLAFEM 1/35, CYCLAFEM 7/7/7, DUTASTERIDE, EMOCQUETTE, FELODON PI NE, GI LDESS 1.5/30, GI LDESS 1/20, GI LDESS FE 1.5/30, GI LDESS FE 1/20, LETROZOLE, MONTELUKAST SODIUM, MORPHINE SULFATE, MYCOPHENOLATE MOFETIL, MYZILRA, ORSYTHIA, PERCOCET, PREVIFEM, TRIPREVIFEM

* VI VIRTUS PHARMACEUTICALS INC
  ACARBOSE, ALBUTEROL SULFATE, PALONOSETRON HYDROCHLORIDE
  VIRTUS PHARMS
  DAPSONE, LEVORPHANOL TARTRATE, PHENDIMETRAZINE TARTRATE, PROMETRIUM, TRANEXAMIC ACID

* VI VITRUVIAS THERAPEUTICS LLC
  POTASSIUM CHLORIDE, CYANOCOBALAMIN, LIDOCAINE

* VI VIVA HEALTHCARE FZ LLC
  GLIMEPIRIDE, LOSARTAN POTASSIUM, SIMVASTATIN

* VI VIVIMED GLOBAL

* VI VI MEDICAL GLOBAL
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<td>Vivus, Inc</td>
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** W **

WATSON LABORATORIES INC

NABUMETONE, NABUMETONE

NALOXONE HYDROCHLORIDE DE AND PENTAZOCINE HYDROCHLORIDE DE, NALOXONE HYDROCHLORIDE DE NATEGLI N DE, NATEGLI NI DE

NEOMYCIN N AND POLYMYXIN B SULFATE, NEOMYCIN N SULFATE

NI COTI NE POLACRI LEX, NI COTI NE POLACRI LEX (OTC)

NI ZATI DI NE, NI ZATI DI NE

NORETHINDROXYNE AND ETHINYL ESTRADIOL, ETHINYL ESTRADIOL

OGESTREL 0.5/50-28, ETHINYL ESTRADIOL

ORPHENADIN NE CI TRATE, ORPHENADIN NE CI TRATE

OXYCODONE AND ACETAMINOPHEN, ACETAMINOPHEN

PRAVASTATIN N SODIUM, PRAVASTATIN N SODIUM

PREDNISONE, PREDNISONE

PRI M DONE, PRI M DONE

PROMETHAZINE NE HYDROCHLORIDE DE, PROMETHAZINE NE HYDROCHLORIDE DE PROPRANOLOL HYDROCHLORIDE DE, PROPRANOLOL HYDROCHLORIDE DE QUASENSE, ETHINYL ESTRADIOL

QUI N DI NE SULFATE, QUI N DI NE SULFATE

RAM PRI L, RAM PRI L

RISTOGESTREL 0, 50-28, ETHINYL ESTRADIOL

SULFASALAZINE, SULFASALAZINE

SUMATRIPTAN SUCCINATE, SUMATRIPTAN SUCCINATE

TELMIAN, TELMIAN

TETRACYCLINE HYDROCHLORIDE DE, TETRACYCLINE HYDROCHLORIDE DE TOPI RAMATE, TOPI RAMATE

TRAMATORENE AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE

TRIHYPERSTEN DVL HYDROCHLORIDE DE, TRIHYPERSTEN DVL HYDROCHLORIDE DE

TRI MEFIBRIN M, TRI MEFIBRIN M

VANCOMYCIN N HYDROCHLORIDE DE, VANCOMYCIN N HYDROCHLORIDE DE

VERAPAMIL DVL HYDROCHLORIDE DE, VERAPAMIL DVL HYDROCHLORIDE DE ZOMIA 1/50E-28, ETHINYL ESTRADIOL

WATSON LABS INC

AMANTADI NE HYDROCHLORIDE DE, AMANTADI NE HYDROCHLORIDE DE AMLODIPI NE BESYLATE AND BENZAPRIN HYDROCHLORIDE DE, AMLODIPI NE BESYLATE

AMMONIUM LACTATE, AMMONIUM LACTATE

BUPROPION HYDROCHLORIDE DE, BUPROPION HYDROCHLORIDE DE

CELECOXIB, CELECOXIB

CI PROFLOXACIN N HYDROCHLORIDE DE, CI PROFLOXACIN N HYDROCHLORIDE DE

DI CLOFENAC SODIUM, DI CLOFENAC SODIUM

DROPIRENONE, ETHINYL ESTRADIOL AND LEVOMEFOLATE, ETHINYL ESTRADIOL AND LEVOMEFOLATE

EZETIMIDE, EZETIMIDE

EZETIMIDE M BE, EZETIMIDE M BE

METRONIDAZOLE, METRONIDAZOLE

MICANOXIL DI L (FOR MEN), MICANOXIL DI L (OTC)

MICANOXIL DI L (FOR WOMEN), MICANOXIL DI L (OTC)

MODAFVIN M, MODAFVIN M

MICANOXIL N HYDROCHLORIDE DE, MICANOXIL N HYDROCHLORIDE DE

MICANOXIL N HYDROCHLORIDE DE, MICANOXIL N HYDROCHLORIDE DE

MICANOXIL N HYDROCHLORIDE DE, MICANOXIL N HYDROCHLORIDE DE

MICANOXIL N HYDROCHLORIDE DE, MICANOXIL N HYDROCHLORIDE DE

MICANOXIL N HYDROCHLORIDE DE, MICANOXIL N HYDROCHLORIDE DE

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MICANOXIL N HYDROCHLORIDE DE, MICANOXIL N HYDROCHLORIDE DE

MICANOXIL N HYDROCHLORIDE DE, MICANOXIL N HYDROCHLORIDE DE

RASAGILINE MESYLATE, RASAGILINE MESYLATE

RASAGILINE MESYLATE, RASAGILINE MESYLATE

ROSUVASTATIN N CALCIUM, ROSUVASTATIN N CALCIUM

SILDENAFIL CITRATE, SILDENAFIL CITRATE

TICAGRELOR, TICAGRELOR

VALACYCLOVIR HYDROCHLORIDE DE, VALACYCLOVIR HYDROCHLORIDE DE
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<td>** W **</td>
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<tr>
<td>WATSON LABS TEVA</td>
<td>* WATSON LABORATORIES, INC. AN INDIAN-OWNED SUB OF TEVA PHARMACEUTICALS USA INC</td>
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* WEST-WARD PHARMACEUTICALS INTERNATIONAL LTD

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ETOMIDATE, ETOMIDATE
ETOPOSI DE, ETOPOSI DE
EVEROLI MUS, EVEROLI MUS
EXEMESTANE, EXEMESTANE
FAMOTI DI NE, FAMOTI DI NE
FAMOTI DI NE, FAMOTI DI NE
FENOLDOPAM MESYLATE, FENOLDOPAM MESYLATE
FENTANYL CI TRATE PRESERVATIVES FREE, FENTANYL CI TRATE
FLECAI NI DE ACETATE, FLECAI NI DE ACETATE
FLOXURI DI NE, FLOXURI DI NE
FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER, FLUCONAZOLE
FLUCONAZOLE IN SODIUM CHLORIDE 0.9%, FLUCONAZOLE
FLUCONAZOLE, FLUCONAZOLE
FLUCYTOSINE, FLUCYTOSINE
FLUMAZEN L, FLUMAZEN L
FLUPHENAZI NE DECANOATE, FLUPHENAZI NE DECANOATE
FLUTI CASONE PROPI ONATE, FLUTI CASONE PROPI ONATE
FLUTI CASONE PROPI ONATE, FLUTI CASONE PROPI ONATE (OTC)
FOSPHENYTOIN SODIUM IM, FOSPHENYTOIN SODIUM IM
FUROSEM DE, FUROSEM DE
GRANSETRON HYDROCHLORIDE, GRANSETRON HYDROCHLORIDE
HALOPERIDOL DECANOATE, HALOPERIDOL DECANOATE
HALOPERIDOL, HALOPERIDOL LACTATE
HEPARI N SODIUM, HEPARI N SODIUM
HEPATROMbine Hydrochloride DE, HYDRROMbine HYDROCHLORIDE DE
I DARUBI CI N HYDROCHLORIDE DE, I DARUBI CI N HYDROCHLORIDE DE
I FOSFAM DE, I FOSFAM DE
I MATI NI B MESYLATE, I MATI NI B MESYLATE
I PRAM NE PAMDATE, I PRAM NE PAMDATE
INDOMETHACIN SODIUM, INDOMETHACIN SODIUM
INFUMORPH, MORPHINE SULFATE
I PRATROP BROM DE, I PRATROP BROM DE
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LI NEZOLI D, LI NEZOLI D
LI THUUM CARBONATE, LI THUUM CARBONATE
LI THUUM CI TRATE, LI THUUM CI TRATE
LORAZEPAM I NTENSOL, LORAZEPAM
LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE AZI DE, HYDROCHLOROTHIAZIDE AZI DE
LOSARTAN POTASSIUM, LOSARTAN POTASSIUM
MEFLOQUINE HYDROCHLORIDE DE, MEFLOQUINE HYDROCHLORIDE DE
MEGESTROL ACETATE, MEGESTROL ACETATE
MEPHENALIN HYDROCHLORIDE DE, MEPHENALIN HYDROCHLORIDE DE
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METHOTREXATE SODIUM PRESERVATIVES FREE, METHOTREXATE SODIUM
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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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- **WOCHARDT USA LLC**
  - LANSOPRAZOLE, LANSOPRAZOLE

- **WRASER PHARMOLS, LLC**
  - CETRAXAL, CI PROFLIXACIN HYDROCHLORIDE DE

- **WRASER PHARMACEUTICALS LLC**
  - BUTALBITAL, ACETAMINOPHEN AND CAFFEINE, ACETAMINOPHEN
  - TREZI X, ACETAMINOPHEN

- **WASM CYCLOTRON**
  - VASHINGTION UNV SCH MEDI CI NE CYCLOTRON FACILTY FLUDEOXYGLUCOSE F18, FLUDEOXYGLUCOSE F-18

- **WYETH PHARMOLS**
  - DUAVEE, BAZEDOXI FENE ACETATE
  - EFFEXOR XR, VENLAFAXI NE HYDROCHLORIDE DE
  - PHOSPHOLIPID, ECHOTHIOPHATE I ODIE, ECHOTHIOPHATE I ODIE DE
  - PREMARI, N, ESTROGENS, CONJUGATED
  - PREMPHASE 14/14, ESTROGENS, CONJUGATED
  - PREMPRO, ESTROGENS, CONJUGATED
  - PROTONIX I V, PANTOPRAZOLE SODIUM UM
  - PROTONIX, PANTOPRAZOLE SODIUM UM
  - TRECATOR, ETHI ONAM DE
  - ZOSYN I N PLASTIC CONTAINER, PI PERACI LLI N SODIUM UM
  - ZOSYN, PI PERACI LLI N SODIUM UM

#### **X**

- **X GEN PHARMS**
  - ACETAZOLAM DE SODIUM, ACETAZOLAM DE SODIUM UM
  - AMPHOTERI CI N B, AMPHOTERI CI N B
  - BACI N M BACI TRACI N
  - COLI STI METHATE SODIUM, COLI STI METHATE SODIUM UM
  - LEVETI RACETAM, LEVETI RACETAM
  - LI OTHYRONI N SODIUM, LI OTHYRONI N SODIUM UM
  - NEOMYCIN AND POLYMIXI N B SULFATE, NEOMYCIN N SULFATE
  - NEOMYCIN N SULFATE, NEOMYCIN N SULFATE
  - NYSTATI N, NYSTATI N
  - POLYMIXI N B SULFATE, POLYMIXI N B SULFATE
  - STREPTOMYCIN SULFATE, STREPTOMYCIN SULFATE
  - TOBRAMYCIN SULFATE, TOBRAMYCIN SULFATE

- **X-GEN PHARMOLS**
  - PROMETHAZI NE HYDROCHLORIDE DE, PROMETHAZI NE HYDROCHLORIDE DE

- **X-GEN PHARMS INC**
  - ACETAZOLAM DE SODIUM, ACETAZOLAM DE SODIUM UM
  - AMPHOTERI CI N B, AMPHOTERI CI N B
  - BACI N M BACI TRACI N
  - COLI STI METHATE SODIUM, COLI STI METHATE SODIUM UM
  - LEVETI RACETAM, LEVETI RACETAM
  - LI OTHYRONI N SODIUM, LI OTHYRONI N SODIUM UM
  - NEOMYCIN AND POLYMIXI N B SULFATE, NEOMYCIN N SULFATE
  - NEOMYCIN N SULFATE, NEOMYCIN N SULFATE
  - NYSTATI N, NYSTATI N
  - POLYMIXI N B SULFATE, POLYMIXI N B SULFATE
  - STREPTOMYCIN SULFATE, STREPTOMYCIN SULFATE
  - TOBRAMYCIN SULFATE, TOBRAMYCIN SULFATE

- **XELLIA A PHARMS APS**
  - CASPOFUNGIN N ACETATE, CASPOFUNGIN N ACETATE
  - COLI STI METHATE SODIUM, COLI STI METHATE SODIUM UM
  - DAPTOMYCIN N, DAPTOMYCIN N
  - POLYMIXI N B SULFATE, POLYMIXI N B SULFATE
  - TOBRAMYCIN SULFATE, TOBRAMYCIN SULFATE
  - VANCOMYCIN N HYDROCHLORIDE DE, VANCOMYCIN N HYDROCHLORIDE DE
  - TRANEXAMIC C ACID, TRANEXAMIC C ACID

- **XI AMEN LP PHARM CO**
  - XI AMEN LP PHARMACEUTICALS LLC LTD
    - CLONIDI NE HYDROCHLORIDE DE, CLONIDI NE HYDROCHLORIDE DE
### APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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## APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

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**ZYDUS PHARMS USA INC**

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* ZYDUS PHARMACEUTICALS USA INC *
  - DILTIAZEM HYDROCHLORIDE
  - DIPYRIDAMOLE
  - DIVALPROEX SODIUM
  - DONEPEZIL HYDROCHLORIDE
  - DOXAZOSIN MESYLATE
  - DOXYCYCLINE HYCLATE
  - DOXYCYCLINE
  - DULOXETINE HYDROCHLORIDE
  - DUTASTERIDE AND TAMULOSIN HCL
  - ELETRIPTAN HYDROBROMIDE
  - ENTECAVIR
  - ESCITALOPRAM OXALATE
  - ETHACRYNATE SODIUM
  - ETODOLAC
  - ETOMIDATE
  - EXEMESTANE
  - EZETIMIBE
  - FELBAMATE
  - FESOTERODINE FUMARATE
  - FINASTERIDE
  - FLUCONAZOLE
  - FLUOCINONIDE
  - GABAPENTIN
  - GALANTAMINE HYDROBROMIDE
  - GEMFIBROZIL
  - GLIPIZIDE AND METFORMIN HCL
  - GLYBURIDE AND METFORMIN HCL
  - GLYBURIDE
  - HYDROXYCHLOROQUINE SULFATE
  - INDOMETHACIN
  - IRBESARTAN
  - ITRACONAZOLE
  - LABETALOL Hydrobromide
  - LABETALOL Hydrochloride
  - LAMOTRIGINE
  - LANSOPRAZOLE
  - LEVETIRACETAM
  - LEVOFLOXACIN
  - LINEZOLID
  - LOSARTAN POTASSIUM AND HYDROCHLORTIDE
  - LOSARTAN POTASSIUM
  - MEMANTINE HYDROCHLORIDE
  - MESALAMINE
  - METHYLPREDNISOLONE
  - METOPROLOL SODIUM
  - METRONIDAZOLE
  - MINOCYCLINE HYDROCHLORIDE
  - MIRTAZAPINE
  - MODAFINIL
  - MYCOPHENOLATE MOFETIL HYDROCHLORIDE
  - NADOLOL
  - NATEGLINIDE
  - NIFEDIPINE
  - NITROFURANTOIN
  - NYSTATIN AND TRIAMCINOLONE ACETONIDE
  - NYSTADINE
  - NITROGESTREL AND ETINYL ESTRADIOL
  - NITROGESTREL
  - OLANZAPINE
  - OLMESARTAN Medoxomil
  - OMEPRAZOLE AND SODIUM BICARBONATE
  - OMEPRAZOLE
  - OMEPRAZOLE (OTC)
  - OMEPRAZOLE
APPENDIX B - PRODUCT NAME SORTED BY APPLICANT

** Z **

* ZYDUS PHARMACEUTICALS USA INC
  OXYBUTYNIN N CHLORIDE, OXYBUTYNIN N CHLORIDE
  PHENTERMINE HYDROCHLORIDE, PHENTERMINE HYDROCHLORIDE
  PI NDOLOL, PI NDOLOL
  PI OGLI TAZONE HYDROCHLORIDE, PI OGLI TAZONE HYDROCHLORIDE
  PI ROKI CAM, PI ROKI CAM
  POTASSIUM CITRATE, POTASSIUM CITRATE
  PRAMIPEXOLE DI HYDROCHLORIDE, PRAMIPEXOLE DI HYDROCHLORIDE
  PROPRANOLOL HYDROCHLORIDE, PROPRANOLOL HYDROCHLORIDE
  PYRIDIUM BROMIDE, PYRIDIUM BROMIDE
  RANITIDINE HYDROCHLORIDE, RANITIDINE HYDROCHLORIDE
  RAPID-ONTOSE SODIUM, RAPID-ONTOSE SODIUM
  REXERINE SODIUM, REXERINE SODIUM
  RISPERIDONE, RISPERIDONE
  ROPINIROLE HYDROCHLORIDE, ROPINIROLE HYDROCHLORIDE
  SIROLIMUS, SIROLIMUS
  SPIRONOLACTONE, SPIRONOLACTONE
  TAMSULOSIN HYDROCHLORIDE, TAMSULOSIN HYDROCHLORIDE
  TELMISARTAN AND HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE
  TELMISARTAN, TELMISARTAN
  TEMOZOLOMIDE, TEMOZOLOMIDE
  TEZOLIZIDE, TEZOLIZIDE
  TOPIRAMATE, TOPIRAMATE
  TRANEXAMIC ACID, TRANEXAMIC ACID
  TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN, ACETAMINOPHEN
  TRAMADOL HYDROCHLORIDE, TRAMADOL HYDROCHLORIDE
  TRANEXAMIC ACID, TRANEXAMIC ACID
  TRAZODONE HYDROCHLORIDE, TRAZODONE HYDROCHLORIDE
  TRIMETHOPRIM AND SULFAMETOXAZOLE, SULFAMETOXAZOLE
  TRIMETHOPRIM, TRIMETHOPRIM
  VENLAFAXINE HYDROCHLORIDE, VENLAFAXINE HYDROCHLORIDE
  VORICONAZOLE, VORICONAZOLE
  ZA PRASIDONE HYDROCHLORIDE, ZA PRASIDONE HYDROCHLORIDE
  ZOLIM TRIPTAN, ZOLIM TRIPTAN
  ZYMIYRA, ZYMIYRA

* ZYDUS WORLDWIDE DMCC
  AZITHROMYCIN, AZITHROMYCIN
  BACLOFEN, BACLOFEN
  MINOCYCLINE HYDROCHLORIDE, MINOCYCLINE HYDROCHLORIDE
  URSODIOL, URSODIOL
APPENDIX C

UNIFORM TERMS

DOSAGE FORMS

AEROSOL, FOAM
AEROSOL, METERED
CAPSULE
CAPSULE, DELAYED REL PELLETS
CAPSULE, DELAYED RELEASE
CAPSULE, EXTENDED RELEASE
CAPSULE, PELLET
CLOTH
CONCENTRATE
CREAM
CREAM, AUGMENTED
ELIXIR
EMULSION
ENEMA
FILM
FILM, EXTENDED RELEASE
FOR SOLUTION
FOR SUSPENSION
FOR SUSPENSION, DELAYED RELEASE
FOR SUSPENSION, EXTENDED RELEASE
GAS
GEL
GEL, AUGMENTED
GEL, METERED
GRANULE
GRANULE, DELAYED RELEASE
GUM, CHEWING
IMPLANT
INHALANT
INJECTABLE
INJECTABLE, LIPID COMPLEX
INJECTABLE, LIPOSOMAL
INJECTION, EXTENDED RELEASE
INSERT
INSERT, EXTENDED RELEASE
INTRAUTERINE DEVICE
JELLY
LIQUID
LOTION
LOTION, AUGMENTED
LOTION/SHAMPOO
OIL
OIL/DROPS

OINTMENT
OINTMENT, AUGMENTED
PASTE
PATCH
PELLET
POWDER
POWDER, EXTENDED RELEASE
POWDER, METERED
RING
SHAMPOO
SOLUTION
SOLUTION FOR SLUSH
SOLUTION, EXTENDED RELEASE
SOLUTION, GEL FORMING/DROPS
SOLUTION, METERED
SOLUTION/DROPS
SPONGE
SPRAY
SPRAY, METERED
SUPPOSITORY
SUSPENSION
SUSPENSION, EXTENDED RELEASE
SUSPENSION, LIPOSOMAL
SUSPENSION/DROPS
SWAB
SYRUP
SYSTEM
SYSTEM, EXTENDED RELEASE
TABLET
TABLET, CHEWABLE
TABLET, DELAYED RELEASE
TABLET, EFFERVESCENT
TABLET, EXTENDED RELEASE
TABLET, EXTENDED RELEASE, CHEWABLE
TABLET, FOR SUSPENSION
TABLET, ORALLY DISINTEGRATING
TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE
TABLET, ORALLY DISINTEGRATING, EXTENDED RELEASE
TAPE
TROCHE/LOZENGE

Note: Terms comprise currently marketed products
### APPENDIX C

#### UNIFORM TERMS

**ROUTES OF ADMINISTRATION**

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*Note: Terms comprise currently marketed products*
## APPENDIX C

### UNIFORM TERMS

### ABBREVIATIONS

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This Addendum identifies drugs that qualify under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for periods of exclusivity and provides patent information that has been submitted to the Food and Drug Administration (FDA) concerning the listed drug products.

**Exclusivity**

During relevant exclusivity periods, certain abbreviated new drug applications (ANDAs) and applications described in Section 505(b)(2) of the FD&C Act (505(b)(2) applications) may not be submitted or approved as described below. This Addendum identifies drugs approved under section 505(c) of the FD&C Act that qualify under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) for five-year and three-year periods of exclusivity pursuant to Section 505(c)(3)(E) and Section 505(j)(5)(F) and certain generic drugs approved under section 505(j) of the FD&C Act that have qualified for 180-day exclusivity pursuant to Section 505(j)(5)(B)(iv). This Addendum also identifies those drugs that have qualified for Orphan Drug Exclusivity pursuant to Section 527 of the FD&C Act, those drugs that have qualified for Pediatric Exclusivity pursuant to Section 505A of the FD&C Act, those drugs that have qualified for Generating Antibiotics Incentives Now (GAIN) exclusivity pursuant to Section 505E of the FD&C Act, and those generic drugs that have qualified for Competitive Generic Therapy (CGT) exclusivity pursuant to Section 505(j)(5)(B)(v) of the FD&C Act. This section is arranged in alphabetical order by active ingredient name followed by the proprietary name. Active ingredient headings for multiple ingredient fixed-combination drug products are arranged alphabetically.

For an explanation of the codes used in the Addendum, see the Patent and Exclusivity Terms Section. The exclusivity codes are general shorthand descriptions and do not necessarily identify, with specificity, the actual scope of exclusivity. Please note that beginning with the publication of the 38th edition of the Orange Book, individual descriptions of the protected use have been added to each Orphan Drug Exclusivity entry listed in the Orange Book. In previous editions of the Orange Book, Orphan Drug Exclusivity was not described with any specificity.

Exclusivity does not prevent the submission or approval of an application submitted pursuant to Section 505(b)(1) of the FD&C Act that would otherwise be blocked if it had been submitted pursuant to Section 505(b)(2) or 505(j), except in the case of Orphan Drug Exclusivity. Drugs approved under section 505(c) of the FD&C Act that may qualify for periods of exclusivity include:

(1) A new chemical entity, submitted in a new drug application under Section 505(b) of the FD&C Act and approved after September 24, 1984. A new chemical entity is an active ingredient that contains “no active ingredient (including any ester or salt of the active ingredient)” that has been approved by FDA in any other application submitted under Section 505(b) of the FD&C Act. An active ingredient would be eligible for 5-year exclusivity for a new chemical entity, provided that it meets the definition of a new chemical entity, regardless of whether that active ingredient is approved in a single-ingredient drug product, in a fixed-combination with another active ingredient that contains no other previously approved active moiety, or in a fixed-combination with
another active ingredient that contains a previously approved active moiety. No subsequent ANDA or 505(b)(2) application for a drug that contains the same active moiety may be submitted for a period of five years from the date of approval of the original application, except that such an application may be submitted after four years if it contains a certification that a patent claiming the drug is invalid or will not be infringed by the product for which approval is sought. See Sections 505(j)(5)(F)(ii) and 505(c)(3)(E)(ii) of the FD&C Act.

(2) A new drug application approved after September 24, 1984, for a drug product containing “an active ingredient (including any ester or salt of the active ingredient)” that has been approved in an earlier new drug application and that includes reports of new clinical investigations (other than bioavailability studies). Such investigations must have been conducted or sponsored by the applicant and must have been essential to approval of the application. If these requirements are met, a subsequent ANDA or a 505(b)(2) application may not be approved for the exclusivity-protected “conditions of approval of such drug” before the expiration of three years from the date of approval of the original application. See Sections 505(j)(5)(F)(iii) and 505(c)(3)(E)(iii) of the FD&C Act. If an NDA has exclusivity only for a new indication or use, this exclusivity generally does not preclude the approval of an ANDA or 505(b)(2) application for indications and uses not covered by the exclusivity, assuming the proposed drug product will be safe and effective as labeled.

(3) A supplement to a new drug application for a drug containing a previously approved “active ingredient (including any ester or salt of the active ingredient)” approved after September 24, 1984, that contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the applicant. See Sections 505(j)(5)(F)(iv) and 505(c)(3)(E)(iv) of the FD&C Act. A subsequent ANDA or 505(b)(2) application may not be approved for an exclusivity-protected change approved in the supplement for three years from the date of approval of the supplement.

**Patent Information**

The FD&C Act requires that patent information be filed with all newly submitted Section 505(b) drug applications. No NDA may be approved after September 24, 1984, without the submission of patent information to the Agency. Effective August 18, 2003, this information must be filed using Form FDA 3542a “Patent Information Submitted with the Filing of an NDA, Amendment or Supplement”.

Effective August 18, 2003, upon approval of an application, patent information for purposes of listing in the Orange Book must be submitted to the Agency within 30 days of the date of approval on Form FDA 3542 “Patent

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1 For more information on exclusivity for fixed-dose combination drug products that include new chemical entities, see FDA’s guidance on New Chemical Entity Exclusivity Determinations for Certain Fixed-Dose Combination Drug Products at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm386685.pdf.
Information Submitted Upon and After Approval of an NDA or Supplement.”² In November 2017, the Agency began including in the Orange Book the patent submission date (i.e., the date on which the FDA receives patent information from the NDA holder) for each newly listed patent to facilitate assessments of whether patent information is untimely filed with respect to a pending 505(b)(2) application or ANDA.³ Patent information on unapproved applications or on patents beyond the scope of the FD&C Act (i.e., process or manufacturing patents) will not be published. Form FDA 3542 will be the only form used for purposes of this publication.

The patents that FDA regards as covered by the statutory provisions for submission of patent information are: patents that claim the active ingredient(s); drug product patents, which include formulation/composition patents; method-of-use patents that claim one or more approved methods of using the approved drug product; and certain other patents as detailed in the regulations and on Form FDA 3542.⁴ This information, as provided by the sponsor on Form FDA 3542, will be published as described above. As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that the patent claims either the drug substance or the drug product.

A requirement for submission of patent information to FDA for certain old antibiotics became effective October 7, 2008 under Section 4(b)(1) of the QI Program Supplemental Funding Act (Public Law 110-379) (QI Act).

Upon approval of an NDA or at such time as patent information is updated for the drug product, FDA adds to the Orange Book the patent number, expiration date, type of patent, and submission date... The Addendum lists patent and exclusivity information up to January of the Edition year. The monthly Cumulative Supplements to the annual edition list patent and exclusivity information changes since the Annual Edition Addendum. Since all parts of this publication are subject to changes, additions, or deletions, the Orange Book, updated daily, should be consulted for the most recent patent and exclusivity information.

² Please note that the date of approval for an NDA for a drug for which FDA intends to recommend controls under the Controlled Substances Act is the later of the date on the approval letter for the NDA or the date of issuance of the interim final rule controlling the drug (see Section 505(x)(1) and (2) of the FD&C Act).
³ See 21 CFR 314.50(i)(4) and 314.94(a)(12)(vi). The submission date for patent information is determined in accordance with 21 CFR 314.53(d)(5).
⁴ See 21 CFR 314.53(c)(2)(ii)(N), (N)(2) and (N)(3).
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### PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

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See report footnote for information regarding report content.

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# 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

## PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnote for information regarding report content

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### CARBIDOPA; LEVODOPA - DUOPA

- **N 203952 001**

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- 9522191 Jun 15, 2027 DP

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- **N 202714 001** 7232818 Apr 14, 2025 DS DP D-172 Sep 28, 2021
- 7417042 Jul 20, 2026 DS DP I-722 Jan 21, 2019
- 7491704 Apr 14, 2025 U-1260 I-723 Jan 21, 2019
- 7737112 Dec 07, 2027 DP ODE-27 Jul 20, 2019
- 8129346 Apr 14, 2025 U-1260
- 8207125 Apr 14, 2025 DS DP
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- 9511109 Oct 21, 2029 U-1924

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- 7943621 Dec 16, 2028 DS DP NCE Sep 17, 2020
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# 39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST

## PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnote for information regarding report content

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**Notes:**
- The table provides a list of approved drug products, their patent numbers, expiration dates, and exclusivity information.
- Each product has a corresponding patent and exclusivity code with an expiration date.
- The exclusivity code(s) are indicated along with the expiration date in the respective columns.
- The patent expiration dates are specified in the format DD MMM YYYY.
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**PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST**

See report footnote for information regarding report content

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### Prescripion and OTC Drug Product Patent and Exclusivity List

**See report footnote for information regarding report content.**

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See report footnote for information regarding report content

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See report footnote for information regarding report content

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# Prescription and OTC Drug Product Patent and Exclusivity List

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### Prescripion and OTC Drug Product Patent and Exclusivity List

**See report footnote for information regarding report content**

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**LOPERAMIDE HYDROCHLORIDE - IMODIUM A-D EZ CHEWS**

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**PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST**

See report footnote for information regarding report content

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| **LOPINAVIR; RITONAVIR - KALETRA**

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| **LOPINAVIR; RITONAVIR - KALETRA**

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See report footnote for information regarding report content

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### PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

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## Prescriptions and OTC Drug Product Patent and Exclusivity List

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## PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnote for information regarding report content

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## ZIPrasidone Hydrochloride - Geodon

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## ZIPrasidone Hydrochloride - Geodon

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**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
PATENT & EXCLUSIVITY ABBREVIATIONS

<table>
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<tr>
<th>Abbreviation</th>
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<tr>
<td>CGT</td>
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<td>D</td>
<td>NEW DOSING SCHEDULE (SEE INDIVIDUAL REFERENCES)</td>
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<td>EXCLUSIVITY ON THIS APPLICATION EXPIRING ON THIS DATE HAS BEEN WAIVED BY SPONSOR - SEE SECTION 1.8 OF ORANGE BOOK PREFACE WAIVED EXCLUSIVITY</td>
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EXCLUSIVITY DOSING SCHEDULE

| D-1            | ONCE A DAY APPLICATION |
| D-2            | ONCE DAILY DOSING |
| D-3            | SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE |
| D-4            | SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE |
| D-5            | TEN DAYS/ELEVEN DAYS DOSING SCHEDULE |
| D-6            | SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE |
| D-7            | BID DOSING |
| D-8            | INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING |
| D-9            | NARCOTIC OVERDOSE IN ADULTS |
| D-10           | NARCOTIC OVERDOSE IN CHILDREN |
| D-11           | POSTOPERATIVE NARCOTIC DEPRESSION IN CHILDREN |
| D-12           | BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE DUODENAL ULCER |
| D-13           | INCREASED MAXIMUM DAILY DOSAGE RECOMMENDATION |
| D-14           | BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE BENIGN GASTRIC ULCER |
| D-15           | SINGLE DAILY DOSE OF 25MG/37.5MG |
| D-16           | CONTINUOUS INTRAVENOUS INFUSION |
| D-17           | 400MG EVERY 12 HOURS FOR THREE DAYS FOR UNCOMPLICATED URINARY TRACT INFECTIONS |
| D-18           | LOWER RECOMMENDED STARTING DOSE GUIDELINES |
| D-19           | BOLUS DOSING GUIDELINES |
| D-20           | SINGLE 32MG DOSE |
| D-21           | ALTERNATIVE DOSAGE OF 300MG ONCE DAILY AFTER THE EVENING MEAL |
| D-22           | REDUCTION IN INFUSION TIME FROM 24 TO 4 HOURS FOR THE 60MG DOSE |
| D-23           | INCREASE MAXIMUM DOSE AND VARIATIONS IN THE DOSING REGIMEN |
| D-24           | FOR OVARIAN CANCER THE RECOMMENDED REGIMEN IS 135MG/M2 OR 175MG/M2 INTRAVENOUSLY OVER THREE HOURS EVERY THREE WEEKS |
| D-25           | ADDITIONAL DOSAGE REGIMEN EQUAL TO HALF THE ORIGINAL DOSING REGIMEN |
**39TH EDITION - 2019 - APPROVED DRUG PRODUCT LIST**

**PATENT AND EXCLUSIVITY TERMS**

**EXCLUSIVITY DOSING SCHEDULE**

**D-26**
ONCE WEEKLY APPLICATION

**D-27**
BID DOSING IN PATIENTS 12 YEARS OF AGE AND OLDER FOR PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH MODERATE EMETOGENIC CANCER CHEMOTHERAPY

**D-28**
USE OF ISOVUE-370 IN EXCRETORY UROGRAPHY AT EQUIVALENT GRAMS OF IODINE TO THE CURRENTLY APPROVED ISOVUE-250 AND ISOVUE-300

**D-29**
INCREASE OF CUMULATIVE DOSE TO 0.3MMOL/KG FOR MRI OF CNS IN ADULTS

**D-30**
5000 IU DOSE FOR PROPHYLAXIS AGAINST DEEP VEIN THROMBOSIS

**D-31**
CHANGE IN RECOMMENDED TOTAL DAILY DOSE TO 80MG (40MG BID)

**D-32**
REMOVAL OF THE RESTRICTIONS LIMITING TREATMENT TO TWO CONSECUTIVE WEEKS AND TO SMALL AREAS

**D-33**
ONCE DAILY DOSING FOR PLAQUE PSORIASIS

**D-34**
EVERY FOUR MONTHS DOSAGE REGIMEN

**D-35**
FOR A ONE WEEK DOSING OF INTERDIGITAL TINEA PEDIS

**D-36**
FOR A SINGLE 2MG DOSE AS AN ALTERNATIVE TO THE 1MG DOSE GIVEN TWICE DAILY

**D-37**
DOsing REGIMEN FOR ADMINISTRATION EITHER ONCE DAILY (QD) OR TWICE DAILY (BID)

**D-38**
CONTINUOUS INFUSION AS AN ALTERNATE METHOD OF ADMINISTRATION

**D-39**
CHANGE IN TIME TO TAKE THE DRUG PRIOR TO A MEAL TO PREVENT MEAL-INDUCED HEARTBURN SYMPTOMS FROM "..1/2 TO 1 HOUR BEFORE EATING" TO ".. RIGHT BEFORE EATING OR UP TO 60MIN BEFORE CONSUMING..."

**D-40**
ONCE-A-DAY DOSING REGIMEN

**D-41**
DRUG MAY BE DOSED RIGHT BEFORE A MEAL OR ANY TIME UP TO 30MIN BEFORE EATING OR DRINKING FOOD AND BEVERAGES THAT WOULD BE EXPECTED TO CAUSE SYMPTOMS

**D-42**
TEN DAY DOSING REGIMEN FOR TRIPLE THERAPY, PREVACID IN COMBINATION WITH CLARITHROMYCIN AND AMOXICILLIN, FOR THE ERADICATION OF H.PYLORI IN PATIENTS WITH DUODENAL ULCER DISEASE

**D-43**
INITIATION OF TREATMENT WITH 900MG/DAY BY DELETION OF THE REQUIREMENT TO TITRATE TO 900MG/DAY OVER A 3-DAY PERIOD

**D-44**
IN A CLINICAL TRIAL, FEWER DISCONTINUATIONS DUE TO ADVERSE EVENTS, ESPECIALLY DIZZINESS AND VERTIGO, WERE OBSERVED WHEN TITRATING THE DOSE IN INCREMENTS OF 5MG/DAY EVERY 3 DAYS UNTIL AN EFFECTIVE DOSE (NOT EXCEEDING 400MG/DAY) WAS REACHED

**D-45**
ONCE DAILY DOSING FOR MAINTENANCE ONLY

**D-46**
NEW DOSING REGIMEN OF 80MG DAILY

**D-47**
PREVENTION OF HEARTBURN SYMPTOMS WHEN ADMINISTERED FROM 15 MINUTES UP TO, BUT NOT INCLUDING, 1 HOUR PRIOR TO A PROVOCATIVE MEAL

**D-48**
ADMINISTRATION OF CISATRACURIUM A NEUROMUSCULAR BLOCKING AGENT AT DOSES OF 3 AND 4X THE ED95 OF CISATRACURIUM FOLLOWING INDUCTION WITH THIOPENTAL

**D-49**
PEDIATRIC DOSING GUIDELINES

**D-50**
INFORMATION FOR USE OF CORVERT IN POST-CARDIAC SURGERY PATIENTS

**D-51**
OPTIONAL STARTING DOSE OF 40MG/DAY

**D-52**
ALTERNATE DOSING REGIMEN OF 1250MG TWICE DAILY

**D-53**
USE IN PEDIATRIC PATIENTS FROM 1 MONTH TO 16 YEARS OF AGE

**D-54**
USE OF ZYBAN FOR MAINTENANCE THERAPY. TREATMENT UP TO 6 MONTHS WAS SHOWN EFFICACIOUS

**D-55**
ADDITION OF A HIGHER DOSE OF NUTROPIN FOR PUBERTAL PATIENTS (PUBERTAL DOSE LESS THAN OR EQUAL TO 0.7MG/KG/WEEK)

**D-56**
ADDITION OF POSTPRANDIAL DOSING

**D-57**
3-HOUR INFUSION OF TAXOL GIVEN EVERY THREE WEEKS AT A DOSE OF 175MG/M2 FOLLOWED BY CISPLATIN AT A DOSE OF 75MG/M2 FOR THE FIRST-LINE TREATMENT OF ADVANCED OVARIAN CANCER

**D-58**
CHANGE IN DOSING INTERVAL TO ONCE-DAILY ADMINISTRATION

**D-59**
REDUCTION OF ELEVATED LDL-C IN A NEW, HIGHER STRENGTH TABLET, 0.8MG, AND FOR EXTENSION OF THE DOSAGE RANGE TO 0.8MG DAILY
EXCLUSIVITY DOSING SCHEDULE

D-60 ADDITION OF A POST-OPERATIVE DOSING REGIMEN
D-61 ONCE WEEKLY DOSING FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
D-62 ONCE WEEKLY DOSING FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
D-63 TO ALLOW A TITRATION DOSING REGIMEN USING A 25MG DOSE
D-64 INCREASING DOSAGE FOR NERVE BLOCK ANESTHESIA USING NAROPIN 7.5MG/ML AND FOR EXTENDING THE DURATION OF TREATMENT FOR POSTOPERATIVE ANALGESIA USING NAROPIN 2MG/ML
D-65 CHANGE DOSING AND ADMINISTRATION TO INDICATE MAINTENANCE OF WEIGHT LOSS OVER AN 18 MONTH PERIOD Thus EXTENDING THE USE OF THIS DRUG FROM ONE TO TWO YEARS
D-66 DOSING RECOMMENDATIONS FOR PATIENTS UNDERGOING PCI
D-67 SHORTER TREATMENT COURSE OF THREE DAYS IN THE TREATMENT OF RECURRENT EPISODES OF GENITAL HERPES
D-68 CHANGE OF ADMIN RATE FOR INFUSION OF AREDIA FOR TREATMENT OF MODERATE AND SEVERE HYPERCALCEMIA OF MALIGNANCY FROM 24 HOURS TO 2 HOURS UP TO BUT NOT INCLUDING 24 HOURS
D-69 SHORTENED DOSING REGIMEN TO 5 DAYS FOR THE TREATMENT OF ACUTE EXACERBATION OF CHRONIC BRONCHITIS
D-70 80MG ONCE DAILY DOSING REGIMEN
D-71 EIGHT WEEK DOSING REGIMEN
D-72 INFORMATION REGARDING INCREASED RATE OF INFUSION FOR DEPACON
D-73 ONCE A WEEK DOSING FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
D-74 ONCE A WEEK DOSING FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
D-75 INTERMITTENT DOSING REGIMEN, STARTING DAILY DOSE 14 DAYS PRIOR TO THE ANTICIPATED ONSET OF MENSTRUATION THROUGH THE FIRST FULL DAY OF MENSES AND REPEATING WITH EACH NEW CYCLE
D-76 FOR USE ON AN "AS NEEDED" OR PRN BASIS FOR THE MANAGEMENT OF NASAL SYMPTOMS IN PATIENTS WHO THE DRUG IS INDICATED
D-77 ADDITION OF 20MG AND 40MG DAILY AS OPTIONAL STARTING DOSES WITH 40MG INTENDED FOR PATIENTS WHO REQUIRE A LARGE REDUCTION IN LDL-C (MORE THAN 45%)
D-78 USE OF FLEXERIL 5MG FOR THE RELIEF OF MUSCLE SPASM ASSOCIATED WITH ACUTE, PAINFUL, MUSCULOSKELETAL CONDITIONS
D-79 NEW LOWER STARTING DOSE FOR MODERATE TO SEVERE VASOMOTOR SYMPTOMS AND/OR MODERATE TO SEVERE SYMPTOMS OF VULVAR AND VAGINAL ATROPHY ASSOCIATED W/ THE MENOPAUSE
D-80 CHANGE OF DOSING SCHEDULE FOR LANTUS FROM ONCE DAILY AT BEDTIME TO FLEXIBLE DAILY DOSING
D-81 NEW LOWER STARTING DOSE FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
D-82 USE OF PREMARIN 0.3 MG AND 0.45 MG FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
D-83 750 MG, ONCE DAILY FOR 5 DAYS FOR COMMUNITY ACQUIRED PNEUMONIA (CAP)
D-84 ONCE-A-DAY DOSING OF FLOXACIN OTIC FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS (AGES 6 MO & OLDER) W/ OTITIS EXTERNA CAUSED BY SUSCEPTIBLE STRAINS OF E.COLI, P.AERUGINOSA AND S.AUREUS
D-85 LOWER RECOMMENDED STARTING DOSE GUIDELINES FOR TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH THE MENOPAUSE
D-86 FOR USE IN SELECT EXTERNAL INSULIN PUMPS
D-87 ADDITION OF ONCE-WEEKLY DOSING FOR THE TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS
D-88 NEW DOSING RANGE OF 200-400MG PER DAY IN TWO DIVIDED DOSES FOR ADULTS WITH PARTIAL SEIZURES
D-89 USE OF REYATAZ 300 MG/RITONAVIR 100 MG ONCE DAILY FOR TREATMENT IN HIV-INFECTED ANTIRETROVIRAL-EXPERIENCED PATIENTS
D-90 ADDITION OF DAYTIME ADMINISTRATION TO TREAT VULVOVAGINAL CANDIDIASIS
D-91 ALTERNATE INTERMITTENT DOSING REGIMEN
EXCLUSIVITY DOSING SCHEDULE

D-92 ALTERNATIVE DOSAGE OF 1000MG ONCE DAILY AT BEDTIME
D-93 ALTERNATE TWO OR THREE TIMES DAILY DOSING REGIMENS
D-94 NEW MAXIMUM DOSAGE OF 72 MG/DAY IN ADOLESCENTS 13-17 YEARS OF AGE WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)
D-95 BROADENED INITIAL STARTING DOSE FOR HYPERTENSION FROM 50 MG TO 100 MG TO 25 MG TO 100 MG DOSE RANGE
D-96 ONCE-MONTHLY TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS WITH BONIVA (IBANDRONATE SODIUM) 150 MG TABLETS
D-97 PED CANCER PT POPULATION EXPANDED TO INCLUDE PTS 6 MOS UP TO BUT NOT INCLUDING 4 YRS AND DOSING INSTRUCTIONS TO ADMIN 30 MIN BEFORE CHEMO WITH SECOND AND THIRD DOSES 4 & 8 HOURS AFTER FIRST DOSE
D-98 DOSING FOR PED SURGICAL PTS EXPANDED TO INCLUDE PTS 1 MONTH UP TO BUT NOT INCLUDING 2 YEARS OF AGE
D-99 ONCE DAILY ADMINISTRATION FOR THE TREATMENT OF HIV INFECTION IN THERAPY NAIVE ADULT PATIENTS
D-100 750 MG ONCE DAILY FOR FIVE DAYS FOR THE TREATMENT OF ACUTE BACTERIAL SINUSITIS
D-101 ONCE DAILY IN CHRONIC IDIOPATHIC URTICARIA FOR ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER
D-102 NEW DOSING REGIMEN OF ONE SPRAY TWICE DAILY FOR SEASONAL ALLERGIC RHINITIS IN PATIENTS 12 YRS OF AGE AND OLDER
D-103 NEW DOSING RECOMMENDATION FOR THE TREATMENT OF RECURRENT GENITAL HERPES IN IMMUNOCOMPETENT PATIENTS, SPECIFICALLY A REDUCTION IN COURSE OF THERAPY FROM FAMCICLOVIR 125 MG TWICE-A-DAY FOR 5 DAYS TO 1000 MG TWICE-A-DAY FOR 1 DAY.
D-104 0.5MG/0.1MG FOR THE TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE IN WOMEN WHO HAVE A UTERUS
D-105 USE OF ACTONEL 75MG TWO CONSECUTIVE DAYS PER MONTH FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
D-106 FIVE DAY TREATMENT OF SELECTED SUSCEPTIBLE STRAINS OF STREPTOCOCCUS PNEUMONIAE, HAEMOPHILUS INFLUENZA, MYCOPLASMA PNEUMONIAE, AND CHLAMYDIA PNEUMONIAE FOR COMMUNITY-ACQUIRED PNEUMONIA
D-107 PROVIDES FOR THE COMBINATION TABLET OF 70MG ALENDRONATE AND 5600 IU OF VITAMIN D3 FOR THE TREATMENT OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN AND TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS
D-108 TREATMENT OF COMPLICATED URINARY TRACT INFECTION AND ACUTE PYELONEPHRITIS WITH LEVAQUIN 750MG ONCE DAILY FOR FIVE DAYS
D-109 PROVIDE FOR THE USE OF A LOWER DOSE FOR THE TREATMENT OF ADULTS WITH CHRONIC PHASE CHRONIC MYELOID LEUKEMIA (CML) WITH RESISTANCE OR INTOLERANCE TO PRIOR THERAPY INCLUDING IMATINIB MESYLATE
D-110 TREATMENT OF SCHIZOPHRENIA IN ADOLESCENTS AGED 13-17
D-111 PROVIDES FOR ONCE DAILY USE OF CIALIS, 2.5 MG AND 5 MG, FOR THE TREATMENT OF ERECTILE DYSFUNCTION
D-112 PROVIDES FOR PEDIATRIC PUMP USE
D-113 ONCE DAILY DOSING REGIMEN FOR PATIENTS WHO BECOME CONSTIPATED ON TWICE DAILY REGIMEN
D-114 NEW DOSING RECOMMENDATIONS FOR USE OF SIROLIMUS IN COMBINATION WITH CYCLOSPORINE FOR THE PROPHYLAXIS OF REJECTION IN HIGH-RISK RENAL TRANSPLANT RECIPIENTS
D-115 STARTING DOSE OF 15MG/DAY FOR MONOTHERAPY IN ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED
D-116 ALTERNATIVE DOSING REGIMEN ATAZANAVIR SULFATE CO-ADMINISTERED WITH RITONAVIR FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT NAIVE PATIENTS
D-117 50 MG TABLET FOR INITIATION OF DOSE TITRATION FOR BIPOLAR DISORDER
D-118 TWO 400MG TABLETS ONCE DAILY, CO-ADMINISTERED WITH 100MG RITONAVIR
D-119 DOSING RECOMMENDATIONS FOR HIV INFECTED PEDIATRIC PATIENTS 6 TO LESS THAN 18 YEARS OF AGE
D-120 DOSING REGIMEN ADJUSTMENTS
D-121 CHANGE TO REMOVE 20 MG MAXIMUM DOSAGE RESTRICTION
**EXCLUSIVITY DOSING SCHEDULE**

D-122 USE OF VAGIFEM 10 MCG FOR THE TREATMENT OF ATROPHIC VAGINITIS DUE TO MENOPAUSE

D-123 ALTERNATIVE DOSING REGIMEN DOSE OF 20 MG/METER SQUARE BY CONTINUOUS INTRAVENOUS INFUSION OVER 1 HOUR REPEATED DAILY FOR 5 DAYS

D-124 ONCE DAILY DOSING REGIMEN IN ADULT PATIENTS WITH LESS THAN THREE LOPINAVIR RESISTANCE-ASSOCIATED SUBSTITUTIONS

D-125 EXTEND CURRENT DOSING REGIMEN TO 900MG (2-450MG TABLETS) ONCE A DAY WITHIN 10 DAYS OF TRANSPLANTATION UNTIL 200 DAYS POST-TRANSPLANTATION FOR THE PREVENTION OF CYTOMEGALOVIRUS (CMV) DISEASE IN ADULT KIDNEY TRANSPLANT PATIENTS AT HIGH RISK.

D-126 CHANGE DOSAGE REGIMEN FROM 250MG TO 500MG

D-127 DOSING REGIMEN FOR ADULT PATIENTS WITH CHRONIC HEPATITIS B (CHB) AND DECOMPENSATED LIVER DISEASE

D-128 SINGLE IV DOSE OF FOSAPREPITANT 150MG, DOSED CONCOMITANTLY WITH 5HT3 RECEPTOR ANTAGONIST & CORTICOSTEROID, FOR PREVENTION OF ACUTE & DELAYED NAUSEA & VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF HIGHLY EMETOGENIC CANCER CHEMO

D-129 800/100 MG DARUNAVIR/RITONAVIR, ONCE DAILY, IN TREATMENT-EXPERIENCED HIV-1 INFECTED PATIENTS WITH NO DARUNAVIR RESISTANCE ASSOCIATED SUBSTITUTIONS

D-130 DOSING RECOMMENDATIONS FOR TREATMENT OF HIV-1 INFECTION DURING PREGNANCY BASED ON DATA FROM STUDY A1424-182, A STUDY OF ATAZANAVIR/RITONAVIR IN COMBINATION WITH ZIDOVUDINE/LAMIVUDINE IN HIV INFECTED PREGNANT WOMEN

D-131 EVERY 6 TO 8 WEEKS FOR THE 120MG STRENGTH FOR PATIENTS WHO ARE CONTROLLED ON SOMATULINE DEPOT 60MG OR 90MG

D-132 45MG FOR 6 MONTH ADMINISTRATION

D-133 NEW EFFICACY DATA AND DOSING REGIMEN FOR PREGNANCY IN NORMAL OVULATORY WOMEN UNDERGOING CONTROLLED OVARIAN STIMULATION AS PART OF AN IVF OR INTRACYTOPLASMIC SPERM INJECTION (ICSI) CYCLE

D-134 INCREASING MAXIMUM DOSING OF PATIENTS WITH SCHIZOPHRENIA TO 160 MG/DAY

D-135 UPDATE LABELING WITH ONCE DAILY DOSING IN HIV-1 INFECTED, TREATMENT-NAIVE PEDIATRIC PATIENTS 12 TO LESS THAN 18 YEARS OF AGE

D-136 ALTERNATE DOSING REGIMEN FOR UNCOMPPLICATED URETHRAL OR ENDOCERVICAL INFECTION CAUSED BY CHLAMYDIA TRACHOMATIS, ADMINISTER 200 MG BY MOUTH ONCE-A-DAY FOR 7 DAYS

D-137 NEW LOWER DOSING REGIMEN FOR REVATIO IN THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (WHO GROUP 1) IN ADULTS

D-138 80 MG DOSING REGIMEN FOR THE RISK REDUCTION OF REBLEEDING OF GASTRIC AND DUODENAL ULCERS IN THE FIRST 72 HOURS FOLLOWING THERAPEUTIC ENDOSCOPY IN ADULTS

D-139 ADDITIONAL INFORMATION ADDED TO THE DOSING AND ADMINISTRATION SECTION OF THE LABELING REGARDING THE ADMINISTRATION OF BRAVELLE AND MENOPUR IN THE SAME SYRINGE TO OVULATORY WOMEN AS PART OF AN ART CYCLE

D-140 REVISED DOSING SCHEDULE TO ADMINISTER AVANAFIL 15 MINUTES PRIOR TO SEXUAL ACTIVITY

D-141 DOSING INFORMATION IN PREVIOUSLY UNTREATED MANTLE CELL LYMPHOMA

D-142 DOSE MODIFICATION GUIDELINES FOR BORTEZOMIB WHEN GIVEN IN COMBINATION WITH RITUXIMAB, CYCLOPHOSPHAMIDE, DOXORUBICIN, AND PREDNISONE

D-143 INITIATION OF VIMPAT THERAPY WITH A LOADING DOSE OF 200MG

D-144 LOWER LIMIT OF 15 MINUTES FOR THE INFUSION DURATION

D-145 UPDATES TO THE DOSAGE AND ADMINISTRATION SECTION OF THE LABELING TO REFLECT THE RESULTS OF TWO SHORT TERM STUDIES EVALUATING THE SAFETY AND EFFICACY OF INTUNIV IN CHILDREN AND ADOLESCENTS AGES 6 TO 17 WITH ADHD.

D-146 CHANGE IN TARGET DOSING TO 20MG TO 40MG ORALLY ONCE DAILY

D-147 ONCE DAILY DOSING IN PEDIATRIC PATIENTS 3 MONTHS OF AGE AND OLDER IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION

D-148 EXTENDED THE DURATION OF THE DOSING REGIMEN FROM 100 DAYS TO 200 DAYS POST-TRANSPLANTATION FOR THE PREVENTION OF CMV DISEASE IN PEDIATRIC KIDNEY TRANSPLANT

D-149 DOSING INFORMATION ADDED TO THE LABELING REGARDING PEDIATRIC PATIENTS 6 YEARS AND OLDER WITH ITP
EXCLUSIVITY DOSING SCHEDULE

D-150  1600MG DAILY FOR PATIENTS ON ADJUNCTIVE THERAPY WHO DID NOT ACHIEVE A SATISFACTORY RESPONSE ON 1200MG DAILY DOSE

D-151  DOSING RECOMMENDATIONS FOR THE TREATMENT OF CHRONIC HEPATITIS C IN PATIENTS CO-INFECTED WITH HIV-1

D-152  DOSING RECOMMENDATIONS AS NECESSARY FOR FEVER AND PAIN FOR AGES 6MO TO LESS THAN 12 YEARS AND 12 TO 17 YEARS.

D-153  IN COMBINATION WITH RIBAVIRIN FOR 12 WEEKS, FOR THE TREATMENT OF GENOTYPE 1, CHRONIC HEPATITIS C TREATMENT EXPERIENCED PATIENTS WITH COMPENSATED CIRRHOSIS BASED UPON THE RESULTS OF THE SIRIUS STUDY

D-154  ADDITION OF A 1500MG-SINGLE-DOSE REGIMEN FOR THE TREATMENT OF ADULT PATIENTS WITH ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSI)

D-155  SINGLE IV DOSE OF FOSAPREPITANT 150MG DOSED CONCOMITANTLY WITH 5HT3 RECEPTOR ANTAGONIST & CORTICOSTEROID FOR PREVENTION OF DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF MODERATELY EMETOGENIC CANCER CHEMOTHERAPY

D-156  DOSING INFORMATION ADDED TO THE LABELING PROVIDING INFORMATION ON TRANSITIONING FROM SUBCUTANEOUS OR INTRAVENOUS ROUTES OF ADMINISTRATION OF TREPROMERIN

D-157  UPDATED INFORMATION ADDED TO THE DOSAGE AND ADMINISTRATION SECTION OF THE LABELING PROVIDING DOSAGE RECOMMENDATIONS FOR INTERRUPTIONS AND DISCONTINUATION OF THERAPY

D-158  REVISED DOSING TO EXPAND PATIENT POPULATION TO INCLUDE LIVER TRANSPLANT RECIPIENTS WITH GENOTYPE 1 HCV INFECTION

D-159  REVISED DOSING TO EXPAND PATIENT POPULATION TO INCLUDE LIVER TRANSPLANT RECIPIENTS WITH GENOTYPE 4 HCV INFECTION

D-160  REVISED DOSING TO EXPAND PATIENT POPULATION TO INCLUDE PATIENTS WITH DECOMPENSATED CIRRHOSIS WITH GENOTYPE 1 HCV INFECTION

D-161  DOSAGE RECOMMENDATIONS ADDED TO INCLUDE TREATMENT OF HCV GENOTYPE 3 SUBJECTS CO-INFECTED WITH HIV-1

D-162  DOSING TO INCLUDE PATIENTS WITH CHRONIC HCV GENOTYPE 1 INFECTION WITH COMPENSATED (CHILD-PUGH A) OR DECOMPENSATED (CHILD-PUGH B OR C) CIRRHOSIS AND TREATMENT OF CHRONIC HCV GENOTYPE 3 INFECTION IN SUBJECTS WITH DECOMPENSATED (CHILD-PUGH B OR C) CIRRHOSIS

D-163  DOSING TO INCLUDE PATIENTS WITH CHRONIC HCV GENOTYPE 1A INFECTION WITH COMPENSATED (CHILD-PUGH A) CIRRHOSIS AND GENOTYPE 1B WITH OR WITHOUT COMPENSATED (CHILD-PUGH A) CIRRHOSIS

D-164  UPDATES TO THE DOSAGE AND ADMINISTRATION, DOSE MODIFICATIONS SECTION OF THE LABELING

D-165  DOSING RECOMMENDATION ADDED TO THE LABELING FOR IMBRUVICA USE IN COMBINATION WITH BENDAMUSTINE AND RITUXIMAB FOR THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)/SMALL LYMPHOCYTIC LEUKEMIA (SLL)

D-166  BROADEN INITIAL STARTING DOSE FOR BIPOLAR I DISORDER TO 5-10MG TWICE DAILY

D-167  ADDITION OF 1200 MG ONCE DAILY DOSING FOR TREATMENT-NAIVE PATIENTS OR PATIENTS WHO ARE ViroLOGICALLY SUPPRESSED ON AN INITIAL REGIMEN OF RALTEGRAVIR FILM-COATED TABLETS 400 MG TWICE DAILY

D-168  NEW DOSING REGIMEN OF 10 MG ONCE DAILY FOR THE REDUCTION IN THE RISK OF RECURRENCE OF DEEP VEIN THROMBOSIS (DVT) AND/OR PULMONARY EMBOLISM (PE) IN PATIENTS AT CONTINUED RISK FOR DVT AND/OR PE AFTER COMPLETION OF INITIAL TREATMENT LASTING AT LEAST 6 MONTHS

D-169  ONCE-DAILY DOSING FOR PATIENTS 5 YEARS OF AGE AND OLDER WHO HAVE UNDETECTABLE SERUM AND URINE SUCCINYLACETONE CONCENTRATIONS AFTER A MINIMUM OF 4 WEEKS ON A STABLE DOSAGE OF NITISINONE

D-170  TO ALLOW WITHDRAWAL THERAPY OF PATIENTS WITH PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA IN CHRONIC PHASE WHO HAVE ACHIEVED A SUSTAINED MOLECULAR RESPONSE ON NILOTINIB THERAPY FOR A MINIMUM OF ONE YEAR PRIOR TO DISCONTINUATION

D-171  REvised DOSING TO INCLUDE UP-TITRATION AS A STRATEGY TO IMPROVE TolerABILITY AND THEREBY REDUCE TREATMENT DISCONTINUATION FOR ROFLUMILAST MAINTENANCE DOSAGE OF 500 MCG DAILY

D-172  ADDITION OF A ONCE WEEKLY DOSING REGIMEN FOR CARFILZOMIB IN COMBINATION WITH Dexamethasone FOR PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE
EXCLUSIVITY DOSING SCHEDULE

D-173
Dosing Recommendation for the use of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Fixed Dose Combination in HIV-1 Infected Adult Patients with End-Stage-Renal Disease Who Are Receiving Chronic Hemodialysis

EXCLUSIVITY INDICATION

I-1  Dysmenorrhea
I-2  Cholangiopancreatography
I-3  Intravenous Digital Subtraction Angiography
I-4  Peripheral Venography (Phlebography)
I-5  Hysterosalpingography
I-6  Treatment of Juvenile Arthritis
I-7  Biopsy Proven Minimal Change Nephrotic Syndrome in Children
I-8  Adult Intravenous Contrast-Enhanced Computed Tomography of the Head and Body
I-9  Prevention of Postoperative NAusea and vomiting
I-10  Prevention of Postoperative Deep Venous Thrombosis and Pulmonary Embolism in Total Hip Replacement Surgery
I-11  Relief of Mild to Moderate Pain
I-12  Treatment of Cutaneous Candidiasis
I-13  Urinary Tract Infection (UTI) Prevention for Periods Up to Five Months in Women with a History of Recurrent UTI
I-14  Seborrheic Dermatitis
I-15  Photopheresis in the Palliative Treatment of Skin Manifestations of Cutaneous T-Cell Lymphoma in Persons Not Responsive to Other Treatment
I-16  Stimulate the Development of Multiple Follicles/Oocytes in Ovulatory Patients Participating in an In Vitro Fertilization Program
I-17  Management of Congestive Heart Failure
I-18  Endoscopic Retrograde Pancreatography
I-19  Herniography
I-20  Knee Arthrography
I-21  High Dose Methotrexate with Leucovorin Rescue in Combination with Other Chemotherapeutic Agents to Delay Recurrence in Patients with Nonmetastatic Osteosarcoma Who Have Undergone Surgical Resection or Amputation for the Primary Tumor
I-22  Rescue After High-Dose Methotrexate Therapy in Osteosarcoma
I-23  Short-Term Treatment of Active Benign Gastric Ulcer
I-24  Treatment of Rheumatoid Arthritis
I-25  Adult Intra-Arterial Digital Subtraction Angiography of the Head, Neck, Abdominal, Renal and Peripheral Vessels
I-26  Treatment of Liver Flukes
I-27  Adjunctive Therapy to Diet to Reduce the Risk of Coronary Artery Disease
I-28  Selective Adult Visceral Arteriography
I-29  Metastatic Breast Cancer in Premenopausal Women as an Alternative to Oophorectomy or Ovarian Irradiation
I-30  Treatment of Tinea Pedis
I-31  Contrast Enhancement Agent to Facilitate Visualization of Lesions in the Spine and Associated Tissues
I-32  Pediatric Myelography
I-33  Oral Use of Diluted Omnipaque Injection in Adults for Contrast Enhanced Computed Tomography of the Abdomen
EXCLUSIVITY INDICATION

I-34 ORAL USE IN ADULTS FOR PASS-THROUGH EXAMINATION OF THE GASTROINTESTINAL TRACT
I-35 PEDIATRIC CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC HEAD IMAGING
I-36 ARTHROGRAPHY OF THE SHOULDER JOINTS IN ADULTS
I-37 RADIOGRAPHY OF THE TEMPOROMANDIBULAR JOINT IN ADULTS
I-38 CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS OF THE CENTRAL NERVOUS SYSTEM IN CHILDREN (2 YEARS OF AGE AND OLDER)
I-39 TREATMENT OF ACUTE MYOCARDIAL INFARCTION
I-40 PRIMARY NOCTURNAL ENURESIS
I-41 MIGRAINE HEADACHE PROPHYLAXIS
I-42 HERPES ZOSTER
I-43 HERPES SIMPLEX ENCEPHALITIS
I-44 MAINTENANCE THERAPY IN HEALED DUODENAL ULCER PATIENTS AT DOSE OF 1 GRAM TWICE DAILY
I-45 ACUTE TREATMENT OF VARICELLA ZOSTER VIRUS
I-46 USE IN PEDIATRIC COMPUTED TOMOGRAPHIC HEAD AND BODY IMAGING
I-47 TREATMENT OF PEDIATRIC PATIENTS WITH SYMPTOMATIC HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
I-48 PEDIATRIC ANGIOCARDIOGRAPHY
I-49 TREATMENT OF TRAVELERS' DIARRHEA DUE TO SUSCEPTIBLE STRAINS OF ENTEROTOXIGENIC ESCHERICHIA COLI
I-50 FOR USE IN WOMEN WITH AXILLARY NODE-NEGATIVE BREAST CANCER
I-51 TREATMENT OF PRIMARY DYSMENORRHEA AND FOR THE TREATMENT OF IDIOPATHIC HEAVY MENSTRUAL BLOOD LOSS
I-52 PEDIATRIC EXCRETORY UROGRAPHY
I-53 TREATMENT OF PANIC DISORDER, WITH OR WITHOUT AGORAPHOBIA
I-54 RENAL CONCENTRATION CAPACITY TEST
I-55 HYPERTENSION
I-56 EROSIve GASTroEsophageAL reflux DISEASE
I-57 SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER
I-58 INITIAL TREATMENT OF ADVANCED OVARIAN CARCINOMA IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC AGENTS
I-59 ENDOSCOPICALLY DIAGNOSED ESOPHAGITIS, INCLUDING EROSIve AND ULcerATIVE ESOPHAGITIS, AND ASSOCIATED HEARTBURN DUE TO GAStroEsophageAL reflux DISEASE
I-60 SINGLE APPLICATION TREATMENT OF HEAD LICE IN CHILDREN TWO MONTHS TO TWO YEARS IN AGE
I-61 FEMALE ANDROGENETIC ALOPECIA
I-62 PREVENTION AND TREATMENT OF POSTMENOPAUSAL OSTEOPOpOSIS
I-63 ONCE DAILY TREATMENT AS INITIAL THERAPY IN THE TREATMENT OF HYPERTENSION
I-64 PREVENTION OF SUPRAVENTRICULAR TACHYCARDIAS
I-65 PREVENTION OF UPPER GASTROINTESTINAL BLEEDING IN CRITICALLY ILL PATIENTS
I-66 UNCOMPPLICATED GONORRHEA
I-67 TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER
I-68 CENTRAL PRECOCIOUS PUBERTY
I-69 SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTroEsophageAL reflux DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY
I-70 USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER
I-71 VARICELLA INFECTIONS (CHICKENPOX)
I-72 PREVENTION OF CMV DISEASE IN TRANSPLANT PATIENTS AT RISK FOR CMV DISEASE
I-73 INITIATE AND MAINTAIN MONITORED ANESTHESIA CARE (MAC) SEDATION DURING DIAGNOSTIC PROCEDURES
I-74 INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY
I-75 TREATMENT OF ENDOSCOPICALLY DIAGNOSEDEROSE EROSOE ESOPHAGITIS
I-76 PREVENTION OF OSTEOPOROSIS
I-77 DERMAL INFECTIONS-TINEA PEDIS, TINEA CORPORIS, TINEA CRURIS DUE TO EPIDERMOPHYTON FLOCCOSUM
I-78 CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY AND INTRAVENOUS EXCRETORY UROGRAPHY
I-79 MANAGEMENT OF CHRONIC STABLE ANGINA AND ANGINA DUE TO CORONARY ARTERY SPASM
I-80 DIAGNOSIS AND LOCALIZATION OF ISCHEMIA AND CORONARY HEART DISEASE
I-81 PROPHYLAXIS IN DESIGNATED IMMUNOCOMPROMISED CONDITIONS TO REDUCE THE INCIDENCE OF OROPHARYNGEAL CANDIDIASIS
I-82 TREATMENT OF TRAVELERS' DIARRHEA
I-83 ANGIOCARDIOGRAPHY, CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY IN CHILDREN
I-84 INTRAOPERATIVE AND POSTOPERATIVE TACHYCARDIA AND/OR HYPERTENSION
I-85 TREATMENT OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS
I-86 TREATMENT OF SECONDARY CARNITINE DEFICIENCY
I-87 RENAL IMAGING AGENT FOR USE IN CHILDREN
I-88 MANAGEMENT OF ENDOMETRIOSIS
I-89 EPIDURAL USE IN LABOR AND DELIVERY AS AN ALGESIC ADJUNCT TO BUPIVACAINE
I-90 INTENSIVE CARE UNIT SEDATION
I-91 ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE
I-92 PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS
I-93 USE WITH MRI IN ADULTS TO PROVIDE CONTRAST ENHANCEMENT AND FACILITATE VISUALIZATION OF LESIONS IN THE BODY [EXCLUDING THE HEART]
I-94 TREATMENT OF LEFT VENTRICULAR DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION
I-95 TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA
I-96 ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINATION OF THE GASTROINTESTINAL TRACT
I-97 TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE ASSOCIATED WITH CHRONIC RENAL INSUFFICIENCY
I-98 PEDIATRIC ANESTHESIA IN CHILDREN 3 YEARS AND OLDER
I-99 TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY
I-100 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN-DEPENDENT DIABETES MELLITUS AND RETINOPATHY
I-101 TREATMENT OF OBESIVE-COMPULSIVE DISORDER
I-102 PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOCOMPROMISED AND CONSIDERED TO BE AT RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA
I-103 TREATMENT OF PULMONARY AND EXTRAPULMONARY ASPERGILLOSIS IN PATIENTS WHO ARE INTOLERANT OF OR WHO ARE REFRAC TORY TO AMPHOTERICIN B THERAPY
I-104 TREATMENT OF METASTATIC CARCINOMA OF THE BREAST AFTER FAILURE OF FIRST-LINE OR SUBSEQUENT CHEMOTHERAPY
I-105 TREATMENT OF ACROMEGALY
I-106 VAGINAL CANDIDIASIS
I-107 EXPANDED USE-OF ICU PATIENTS UNDERGOING LONG-TERM INFUSION DURING MECHANICAL VENTILATION
I-108 TYPHOID FEVER
EXCLUSIVITY INDICATION

I-110 Prevention of nausea and vomiting associated with radiotherapy
I-111 Treatment of Paget's disease of bone
I-112 Management of moderate to severe pain
I-113 Treatment of prostatitis
I-114 Use in children to visualize lesions with abnormal vascularity in the brain (intracranial lesions), spine, and associated tissue
I-115 Use in MRI in adults to visualize lesions in the head and neck
I-116 Maintenance of healing of erosive esophagitis
I-117 To slow the progression of coronary atherosclerosis in patients with coronary heart disease
I-118 Prevention of deep vein thrombosis, which may lead to pulmonary embolism following knee replacement surgery
I-119 Treatment of anemia caused by uterine leiomyomata in women who fail iron therapy
I-120 Maintenance therapy for gastric ulcer patients at reduced dosage after healing acute ulcers
I-121 Expanded patient population -- use in ICU patients
I-122 Psoriasis of the scalp
I-123 Relief of mild to moderate pain in patients aged 6 months and older
I-124 Leukocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease
I-125 Expansion of conscious sedation indication to include short therapeutic procedures
I-126 Adjunct to thallium-201 myocardial perfusion in patients unable to exercise adequately
I-127 Treatment of acyclovir-resistant herpes in immunocompromised patients
I-128 In pt w/ CH disease and hypercholesterolemia: reduce risk total mortality by reducing coronary death; reduce risk non-fatal MI; reduce risk undergoing myocardial revascularization procedures; reduction elevated total and LDL CHOL levels...
I-129 Treatment of alcohol dependence
I-130 Maintenance of healing of erosive esophagitis
I-131 Peripheral arteriography
I-132 Treatment of manic phase of bipolar disorder
I-133 Management of chronic stable angina
I-134 Heart failure post myocardial infarction
I-135 Bone metastases associated with multiple myeloma
I-136 Idiopathic chronic urticaria
I-137 Prevention of metal-induced heart burn, acid indigestion, and sour stomach when taken 30 minutes prior to consuming food or beverages
I-138 Treatment of acute recurrent genital herpes
I-139 Palliative treatment of advanced breast cancer in pre- and perimenopausal women
I-140 Prevention of cytomegalovirus (CMV) disease in individuals with HIV infection at risk for developing CMV disease
I-141 Treatment of hemodynamically stable patients within 24 hours of acute myocardial infarction to improve survival
I-142 Localize myocardial ischemia (reversible defect) and infarction (non-reversible defects) in evaluating myocardial function
I-143 Episodic treatment of recurrent genital herpes in immunocompetent adults
I-144 Enhancement of MRI of the adult body internal organs
I-145 0.1mmol/kg as a single intravenous bolus for MRI of the CNS in children
I-146 Contrast enhancement and facilitation of visualization of extracranial head and neck lesions
I-147 PREVENTION OF GALLSTONE FORMATION IN OBESE PATIENTS EXPERIENCING RAPID WEIGHT LOSS

I-148 TREATMENT OF ACUTE PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN HIV-INFECTED PATIENTS WHOSE ALVEOLAR-ARTERIAL OXYGEN DIFFERENCE (AaDO2) IS LESS THAN OR EQUAL TO 55 TORR

I-149 TREATMENT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER

I-150 TREATMENT OF OBSESSIVE COMPELLING DISORDER AND PANIC DISORDER

I-151 PREVENTION OF AND PREVENTION OF FURTHER POSTOPERATIVE NAUSEA AND VOMITING IN PEDIATRIC PATIENTS RECEIVING GENERAL ANESTHESIA

I-152 SLOWING THE PROGRESSION OF CORONARY ATHEROSCLEROSIS AND REDUCING THE RISK OF ACUTE CORONARY EVENTS

I-153 MANAGEMENT OF SEVERE SPASTICITY (ENCOMPASSES SPINAL AND CEREBRAL ORIGIN)

I-154 PATIENT POPULATION ALTERED TO INCLUDE PEDIATRIC USE

I-155 TREATMENT OF ONYCHOMYCOSIS DUE TO DERMATOPHYTES (TINEA UNguium) OF THE TOENAIL WITH OR WITHOUT FINGERNAIL INVOLVEMENT

I-156 ADDITIONAL DATA REGARDING THE SAFE USE OF NORVASC IN PATIENTS WITH HEART FAILURE

I-157 TREATMENT OF ACUTE UNCOMPLICATED CYSTITIS IN FEMALES

I-158 TREATMENT OF OSTEOLYTIC BONE METASTASES OF BREAST CANCER

I-159 FOR HYPERCHOLESTEROLEMIC PATIENTS WITHOUT CLINICALLY EVIDENT HEART DISEASE REDUCE THE RISK OF MYOCARDIAL INFARCTION, REVASCULARIZATION, AND DEATH DUE TO CARDIOVASCULAR CAUSES WITH NO INCREASE IN DEATH FROM NON-CARDIOVASCULAR CAUSES

I-160 TREATMENT OF BACTERIAL CORNEAL ULCERS

I-161 TREATMENT OF ADULT-ONSET OR CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENCY

I-162 FOR USE IN PATIENTS 6-11 YEARS OF AGE

I-163 TREATMENT OF PHOTOPHOBIA

I-164 CHRONIC BACTERIAL PROSTATITIS

I-165 MANAGEMENT OF ADULTS WITH ACTIVE, CLASSIC AND DEFINITIVE RHEUMATOID ARTHRITIS WHO HAVE HAD INSUFFICIENT THERAPEUTIC RESPONSE TO OR ARE INTOLERANT OF AN ADEQUATE TRIAL OF FULL DOSES OF ONE OR MORE NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

I-166 TREATMENT OF BULIMIA

I-167 COMPLICATED INTRA-ABDOMINAL INFECTIONS (USED IN COMBINATION WITH METRONIDAZOLE) CAUSED BY MIXED AEROBIC/ANAEROBIC PATHOGENS

I-168 MANAGEMENT OF LOCALLY CONFINED STAGE B2-C METASTATIC CARCINOMA OF THE PROSTATE (IN COMBINATION WITH LH-RH AGONISTS)

I-169 USE IN COMBINATION WITH CORTICOSTEROIDS AS INITIAL CHEMOTHERAPY FOR THE TREATMENT OF PATIENTS WITH PAIN RELATED TO ADVANCED HORMONE-REFRACTORY PROSTATE CANCER

I-170 PROPHYLACTIC USE DURING HEAD LICE EPIDEMICS

I-171 RELIEF OF SYMPTOMS OF THE COMMON COLD

I-172 TREATMENT OF INITIAL EPISODE OF GENITAL HERPES

I-173 PREOPERATIVELY FOR THE PREVENTION OF INFECTION IN TRANSRECTAL PROSTATE BIOPSY

I-174 PELVIC INFLAMMATORY DISEASE

I-175 TREATMENT OF TINEA CORPORIS AND TINEA CRURIS

I-176 TREATMENT OF POSTOPERATIVE INFLAMMATION IN PATIENTS WHO HAVE UNDERGONE CATARACT EXTRATION

I-177 TX OF MODERATE ACNE VULGARIS IN FEMALES, GREATER OR EQUAL TO 15YRS OF AGE, WHO HAVE NO KNOWN CONTRAINDICATIONS TO ORAL CONTRACEPTIVE THERAPY, DESIRE CONTRACEPTION, HAVE ACHIEVED MENARCHE AND ARE UNRESPONSIVE TO TOPICAL ANTI-ACNE MEDICATIONS

I-178 TREATMENT OF ONYCHOMYCOSIS OF THE FINGERNAIL WITHOUT CONCOMITANT ONYCHOMYCOSIS OF THE TOENAIL WITH A PULSE DOSING REGIMEN

I-179 NOSOCOMIAL PNEUMONIA-MILD TO MODERATE AND SEVERE CAUSED BY HAEMOPHILUS INFLUENZAE OR KLEBSIELLA PNEUMONIAE
PATENT AND EXCLUSIVITY TERMS

EXCLUSIVITY INDICATION

I-180 - TREATMENT OF PLANTAR TINEA PEDIS (MOCCASIN TYPE)
I-181 - TREATMENT OF PATIENTS WITH COMPLEX PARTIAL SEIZURES WITH AND WITHOUT SECONDARY GENERALIZATION
I-182 - TREATMENT OF GROWTH FAILURE ASSOCIATED WITH TURNER SYNDROME
I-183 - MAINTENANCE THERAPY IN THE MANAGEMENT OF MILD TO MODERATE ASTHMA IN PEDIATRIC PATIENTS AGES 6-11
I-184 - TREATMENT OF PANIC DISORDER AT A RECOMMENDED DOSE RANGE OF 1 TO 2MG/DAY (MAXIMUM OF 4MG)
I-185 - PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
I-186 - TREATMENT OF TINEA (PITYRIASIS) VERSICOLOR CAUSED BY OR PRESUMED TO BE CAUSED BY PITYROSPORUM ORBICULARE (ALSO KNOWN AS MALASSEZIA FURFUR OR M. ORBICULARE)
I-187 - PREVENTION OF FRACTURES IN THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
I-188 - TREATMENT OF ACUTE SINUSITIS AND ACUTE EXACERBATION OF CHRONIC SINUSITIS
I-189 - TREATMENT OF ACUTE OTITIS MEDIA IN PEDIATRIC PATIENTS
I-190 - PLANAR IMAGING AS A SECOND LINE DIAGNOSTIC DRUG AFTER MAMMOGRAPHY TO ASSIST IN THE EVALUATION OF BREAST LESIONS IN PATIENTS WITH AN ABNORMAL MAMMOGRAM OR A PALPABLE BREAST MASS
I-191 - ENDOMETRIAL THINNING AGENT PRIOR TO ENDOMETRIAL ABLATION FOR DYSFUNCTIONAL UTERINE BLEEDING
I-192 - THE PREVENTION OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING ABDOMINAL SURGERY WHO ARE AT RISK FOR THROMBOEMBOLIC COMPLICATIONS AND A NEW DOSAGE REGIMEN, 40MG ONCE DAILY, FOR THIS INDICATION
I-193 - TREATMENT OF PANIC DISORDER IN A RECOMMENDED DOSE RANGE OF 50 TO 200MG/DAY
I-194 - CONGESTIVE HEART FAILURE
I-195 - FOR USE OF LANSOPRAZOLE IN COMBINATION WITH CLARITHROMYCIN AND AMOXICILLIN FOR THE ERADICATION OF HELICOBACTER PYLORI IN PATIENTS WITH ACTIVE DUODENAL ULCER DISEASE OR A ONE-YEAR HISTORY OF DUODENAL ULCER
I-196 - ACUTE TREATMENT OF ACTIVE BENIGN GASTRIC ULCER
I-197 - MAINTENANCE OF HEALING OF DUODENAL ULCER
I-198 - FOR THE USE OF LANSOPRAZOLE IN COMBINATION WITH AMOXICILLIN FOR THE ERADICATION OF HELICOBACTER PYLORI IN PATIENTS WITH ACTIVE DUODENAL ULCER DISEASE OR A ONE-YEAR HISTORY OF A DUODENAL ULCER
I-199 - MONOTHERAPY AND COMBINATION THERAPY WITH SULFONYLUREA IN THE TREATMENT OF TYPE II DIABETES
I-200 - TREATMENT OF TINEA (PITYRIASIS) VERSICOLOR
I-201 - EMPIRICAL THERAPY FOR FEBRILE NEUTROPENIC PATIENTS
I-202 - SECOND-LINE TREATMENT OF AIDS-RELATED KAPOSI’S SARCOMA
I-203 - MAINTENANCE OF REMISSION OF ULCERATIVE COLITIS
I-204 - USE IN PEDIATRIC PATIENTS BETWEEN THE AGES OF 6 AND 11 FOR THE TREATMENT OF THE NASAL SYMPTOMS OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS
I-205 - INITIAL ANTICONVULSANT TREATMENT OF STATUS EPILEPTICUS
I-206 - TREATMENT OF EDEMA ASSOCIATED WITH CHRONIC RENAL FAILURE
I-207 - FOR THE SUPPRESSION OF RECURRENT EPISODES OF GENITAL HERPES IN IMMUNOCOMPETENT ADULTS
I-208 - TREATMENT OF OBSESSIVE COMPULSIVE DISORDER IN THE PEDIATRIC POPULATION
I-209 - PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA (PSVT)
I-210 - TO SLOW THE PROGRESSION OF CORONARY ATHEROSCLEROSIS IN PATIENTS WITH CORONARY HEART DISEASE AS PART OF A TREATMENT STRATEGY TO LOWER TOTAL AND LDL CHOLESTEROL TO TARGET LEVELS
I-211 - FOR USE IN PEDIATRIC POPULATION
I-212 - TREATMENT OF SYMPTOMS OF DRY MOUTH IN PATIENTS WITH SJOGREN’S SYNDROME
I-213 - TEMPORARY RELIEF OF PAIN AND PHOTOPHOBIA IN PATIENTS UNDERGOING CORNEAL REFRACTIVE SURGERY
EXCLUSIVITY INDICATION

I-214 TREATMENT OF OSTEOPOROSIS

I-215 PRE-PROCEDURAL APPLICATION TO ADULT MALE GENITAL SKIN PRIOR TO SITE-SPECIFIC SUBCUTANEOUS INFILTRATION WITH LIDOCAINE FOR THE REMOVAL OF GENITAL WARTS

I-216 FOR THE LONG-TERM TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD, INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA

I-217 PREVENTION (DURING AND FOLLOWING HOSPITALIZATION) OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY

I-218 USE OF LIPITOR AS AN ADJUNCTIVE THERAPY TO DIET FOR THE TREATMENT OF PATIENTS WITH ELEVATED SERUM TRIGLYCERIDE LEVELS (FREDERICKSON TYPE IV)

I-219 USE OF LIPITOR BY PATIENTS WITH PRIMARY DYSBETALIPOPROTEINEMIA (FREDERICKSON TYPE III) WHO DO NOT RESPOND ADEQUATELY TO DIET

I-220 TREATMENT OF EPISODIC-HEARTBURN, ACID INDIGESTION AND SOUR STOMACH

I-221 TREATMENT OF BENIGN PROSTATIC HYPERPLASIA (BPH) IN MEN WITH AN ENLARGED PROSTATE TO IMPROVE SYMPTOMS, REDUCE THE RISK OF ACUTE URINARY RETENTION AND REDUCE THE RISK OF THE NEED OF SURGERY

I-222 PREVENTION OF ISCHEMIC COMPLICATIONS OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION, WHEN CONCURRENTLY ADMINISTERED WITH ASPIRIN

I-223 USE IN THE SYMPTOMATIC RELIEF OF RHINORRHEA ASSOCIATED WITH ALLERGIC AND NONALLERGIC-PERENNIAL RHINITIS IN CHILDREN AGE 6-11 YEARS

I-224 FOR THE USE IN PEDIATRIC PATIENTS 4 TO 11 YEARS OF AGE FOR THE MANAGEMENT OF THE NASAL SYMPTOMS OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS

I-225 USE IN PATIENTS WITH PREVIOUS MI AND NORMAL CHOLESTEROL LEVELS, TO REDUCE RISK OF RECURRENT MI, MYOCARDIAL REVASCULARIZATION, AND CEREBROVASCULAR DISEASE EVENTS

I-226 FIRST-LINE THERAPY FOR THE TREATMENT OF ADVANCED CARCINOMA OF THE OVARY IN COMBINATION WITH CISPLATIN

I-227 SHORT-TERM TREATMENT OF SYMPTOMATIC GASTROESOPHAGEAL REFLUX DISEASE (GERD)

I-228 PREVENTION OF MEAL INDUCED HEARTBURN AT A DOSE OF 75MG TAKEN 30-60MIN PRIOR TO A MEAL

I-229 PRILOSEC (OMEPRAZOLE), AMOXICILLIN, AND CLARITHROMYCIN FOR THE ERADICATION OF H. PYLORI IN PATIENTS WITH DUODENAL ULCER DISEASE

I-230 IN COMBINATION WITH CIS-PLATIN, FOR THE FIRST LINE TREATMENT OF NON-SMALL CELL LUNG CANCER IN PATIENTS WHO ARE NOT CANDIDATES FOR POTENTIALLY CURATIVE SURGERY AND/OR RADIATION

I-231 TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CANCER AFTER FAILURE OF PRIOR CHEMOTHERAPY

I-232 TREATMENT OF RECURRENT MUCOCUTANEOUS HERPES SIMPLEX INFECTIONS IN HIV-AFFECTED PATIENTS AT A DOSE OF 500MG TWICE DAILY

I-233 PROPHYLACTIC USE TO REDUCE PERIODIC BLOOD LOSS AND THE NEED FOR BLOOD TRANSFUSION IN PATIENTS UNDERGOING CARDIOPULMONARY BYPASS IN THE COURSE OF CORONARY ARTERY BYPASS GRAFT SURGERY

I-234 FOR USE IN COMBINATION WITH CISPLATIN FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH INOPERABLE LOCALLY ADVANCED (STAGE IIIA OR IIIB) OR METASTATIC (STAGE IV) NON-SMALL CELL LUNG CANCER

I-235 PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN PATIENTS 12 YEARS OF AGE AND OLDER

I-236 PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN PATIENTS 4 YEARS OF AGE AND OLDER

I-237 MAINTENANCE TREATMENT OF ASTHMA AND PREVENTION OF BRONCHOSPASM IN PATIENTS 4 YEARS OF AGE AND OLDER

I-238 ADJUNCTIVE TREATMENT OF LENNOX-GASTAUT SYNDROME IN PEDIATRIC AND ADULT PATIENTS

I-239 TREATMENT OF PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA

I-240 MANAGEMENT OF SECONDARY HYPERPARATHYROIDISM AND RESULTANT METABOLIC BONE DISEASE IN PATIENTS WITH MODERATE TO SEVERE CHRONIC RENAL FAILURE (CCR 15 TO 55ML/MIN) NOT YET ON DIALYSIS

I-241 USE IN PHOTODYNAMIC THERAPY (PDT) FOR REDUCTION OF OBSTRUCTION AND PALLIATION OF SYMPTOMS IN PATIENTS WITH COMPLETELY OR PARTIALLY OBSTRUCTING ENDOBRONCHIAL
PATENT AND EXCLUSIVITY TERMS

EXCLUSIVITY INDICATION

I-242 TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH THE MENOPAUSE AND IN THE TREATMENT OF VULVAR AND VAGINAL ATROPHY IN WOMEN WITH AN INTACT UTERUS

I-243 USE IN THE SYMPTOMATIC RELIEF OF RHINORRHEA ASSOCIATED WITH THE COMMON COLD IN CHILDREN AGE 5 TO 11 YEARS

I-244 REDUCE THE INCIDENCE OF BREAST CANCER IN WOMEN AT HIGH RISK FOR BREAST CANCER

I-245 TREATMENT OF ACUTE SINUSITIS

I-246 TREATMENT OF UNCOMPPLICATED URINARY TRACT INFECTIONS

I-247 USE IN CONVERSION TO MONOTHERAPY IN ADULTS WITH PARTIAL SEIZURES WHO ARE RECEIVING TREATMENT WITH A SINGLE ENZYME-INDUCING ANTIEPILEPTIC DRUG

I-248 INPATIENT TREATMENT OF ACUTE DEEP VEIN THROMBOSIS WITH/WITHOUT PULMONARY EMBOLISM WHEN ADMIN WITH WARFARIN SODIUM AND OUTPATIENT TREATMENT OF ACUTE DEEP VEIN THROMBOSIS WITHOUT PULMONARY EMBOLISM WHEN ADMIN WITH WARFARIN SODIUM

I-249 TREATMENT OF CHRONIC HEPATITIS C IN PATIENTS WITH COMPENSATED LIVER DISEASE PREVIOUSLYUNTREATED WITH ALPHA INTERFERON THERAPY

I-250 PRIMARY PREVENTION OF CORONARY HEART DISEASE IN PATIENTS WITHOUT SYMPTOMATIC CARDIOVASCULAR DISEASE WHO HAVE AVERAGE TO MODERATELY ELEVATED TOTAL-C AND LDL-C AND BELOW AVERAGE HDL-C

I-251 TREATMENT OF GENERALIZED ANXIETY DISORDER

I-252 NEW COMBINATION USE OF PRECOSEx FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS METFORMIN

I-253 COMBINATION USE OF PRECOSEx FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS INSULIN

I-254 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS (LOSS OF BONE MASS)

I-255 PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP)

I-256 USE IN TREATMENT OF SMALL CELL LUNG CANCER SENSITIVE DISEASE AFTER FAILURE OF FIRST-LINE CHEMOTHERAPY

I-257 TREATMENT OF CHRONIC HEPATITIS B ASSOCIATED WITH EVIDENCE OF HEPATITIS B VIRAL REPLICATION AND ACTIVE LIVER INFLAMMATION

I-258 FOR PERENNIAL NONALLERGIC RHINITIS FOR AGES 4 AND ABOVE

I-259 PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT), WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY

I-260 EXPANDED PEDIATRIC USE IN CHILDREN YOUNGER THAN ONE MONTH OF AGE TO BIRTH (WITH A GESTATIONAL AGE OF 37 WEEKS OR GREATER)

I-261 TREATMENT OF SOCIAL ANXIETY DISORDER

I-262 TREATMENT OR PREVENTION OF BRONCHOSPASM WITH REVERSIBLE OBSTUCTIVE AIRWAY DISEASE AND FOR THE PREVENTION OF EXERCISE INDUCED BRONCHOSPASM IN CHILDREN AGES 4-12

I-263 TREATMENT OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION FOR THE PREVENTION OF ISCHEMIC COMPLICATIONS IN PATIENTS ON CONCURRENT ASPIRIN THERAPY

I-264 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH RADIATION, INCLUDING TOTAL BODY IRRADIATION (TBI) AND FRACTIONATED ABDOMINAL RADIATION

I-265 TREATMENT OF ATOPIC DERMATITIS IN PEDIATRIC PATIENTS 6 YEARS AND OLDER

I-266 USE OF TOPAMAX AS ADJUNCTIVE THERAPY IN PEDIATRIC PATIENTS AGES 2-16 YEARS WITH PARTIAL ONSET SEIZURES

I-267 USE IN PEDIATRIC PATIENTS 3 MONTHS OLD AND OLDER - FOR CORTICOSTEROID-RESPONSIVE DERMATOSSES

I-268 PROPHYLAXIS AND CHRONIC TREATMENT OF ASTHMA IN PATIENTS 7-11 YEARS OF AGE

I-269 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH HIGHLY EMETOGENIC CANCER CHEMOTHERAPY, INCLUDING CISPLATIN

I-270 ADJUVANT TREATMENT OF NODE-POSITIVE BREAST CANCER ADMINISTERED SEQUENTIALLY TO STANDARD DOXORUBICIN-CONTAINING COMBINATION CHEMOTHERAPY

I-271 TREATMENT OF OSTEOPOOROSIS IN POSTMENOPAUSAL WOMEN

I-272 TREATMENT OF GLUCOCORTICOID-INDUCED OSTEOPOOROSIS IN MEN AND WOMEN RECEIVING
EXCLUSIVITY INDICATION

GLUCOCORTICOIDS IN A DAILY DOSE EQUIVALENT TO 7.5MG OR GREATER OF PREDNISONE AND WHO HAVE LOW BONE MINERAL DENSITY

I-273 ADJUNCT TO DIET TO INCREASE HDL-C IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA (HETEROZYGOUS FAMILIAL AND NON FAMILIAL) AND MIXED DYSLIPIDEMIA (FREDERICKSON TYPES IIA AND IIB)

I-274 USE OF TOPAMAX AS ADJUNCTIVE THERAPY IN THE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

I-275 USE IN COMBINATION WITH METFORMIN AND SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES

I-276 USE OF REZULIN IN COMBINATION WITH METFORMIN AND SULFONYLUREAS IN PATIENTS WITH TYPE 2 DIABETES

I-277 TREATMENT OF TYPE III HYPERLIPOPROTEINEMIA

I-278 TREATMENT OF PATIENTS WITH ISOLATED HYPERTRIGLYCERIDEMIA (FREDERICKSON TYPE IV)

I-279 TREATMENT OF POST-TRAUMATIC STRESS DISORDER

I-280 USE OF CARNITOR INJECTION FOR THE PREVENTION AND TREATMENT OF CARNITINE DEFICIENCY IN PATIENTS WITH END STAGE RENAL DISEASE WHO ARE UNDERGOING DIALYSIS

I-281 INCREASING HDL-C IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA (HETEROZYGOUS FAMILIAL AND NONFAMILIAL) AND MIXED DYSLIPIDEMIA (FREDERICKSON TYPES IIA AND IIB)

I-282 TREATMENT OF PATIENTS WITH LOCALIZED ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER AFTER FAILURE OF PRIOR PLATINUM-BASED CHEMOTHERAPY

I-283 TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS

I-284 TO REDUCE THE NUMBER OF ADENOMATOUS COLORECTAL POLYPS IN FAMILIAL ADENOMATOUS POLYPOSIS PATIENTS AS AN ADJUNCT TO USUAL CARE

I-285 TREATMENT OF NASAL SYMPTOMS OF SEASONAL AND PERENNIAL RHINITIS IN ADULTS AND CHILDREN 3 YEARS OF AGE AND OLDER

I-286 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III

I-287 USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH

I-288 CHANGES IN SEVERAL SECTIONS OF THE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINOPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE

I-289 USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL

I-290 PREVENTION OF CORTICOSTEROID-INDUCED OSTEOPOROSIS

I-291 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

I-292 TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS

I-293 TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS

I-294 TREATMENT OF UNCOMPROMICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS

I-295 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS

I-296 LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY

I-297 SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER

I-298 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA

I-299 USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FUOROURACIL AND LEUCOVORIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM

I-300 PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE

I-301 TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS

I-302 TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME
PATENT AND EXCLUSIVITY TERMS

EXCLUSIVITY INDICATION

I-303 INCREASING HDL-CHOLESTEROL IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIAS

I-304 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IV

I-305 TREATMENT OF LEVOFLOXACIN SUSCEPTIBLE STRAINS OF PENICILLIN-RESISTANT STREPTOCoccus PNEUMONIAE IN PATIENTS WITH COMMUNITY ACQUIRED PNEUMONIA

I-306 INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE

I-307 NEW COMBINATION USE OF METFORMIN AND INSULIN IN TYPE 2 DIABETES

I-308 TREATMENT OF PEDIATRIC PATIENTS WITH POLYARTICULAR COURSE JUVENILE RHEUMATOID ARTHRITIS WHO RESPONDED INADEQUATELY TO SALICYLATES OR OTHER NSAIDS

I-309 USE OF ACTONEL 35MG ONCE A WEEK TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS

I-310 REDUCTION IN RISK OF MYOCARDIAL INFARCTION, STROKE, AND DEATH FROM CARDIOVASCULAR CAUSES

I-311 ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL SEIZURES IN PEDIATRIC PATIENTS AGE 3 TO 12 YEARS

I-312 FIRST LINE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE OR HORMONE RECEPTOR UNKNOWN LOCALLY ADVANCED OR METASTATIC BREAST CANCER

I-313 EXTENSION OF INDICATION TO PROVIDE FOR MAINTENANCE OF RESPONSE

I-314 TOPICAL ANESTHETIC FOR SUPERFICIAL MINOR SURGERY OF GENITAL MUCOUS MEMBRANES AND AS AN ADJUNCT FOR LOCAL INFILTRATION ANESTHESIA IN GENITAL MUCOUS MEMBRANES

I-315 THROMBOPROPHYLAXIS OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN MEDICAL PATIENTS WHO ARE AT RISK FOR THROMBOEMBOLIC COMPLICATIONS DUE TO SEVERELY RESTRICTED MOBILITY DURING ACUTE ILLNESS

I-316 TREATMENT OF NSAID-ASSOCIATED GASTRIC ULCER PATIENTS WHO CONTINUE NSAID USE AND REDUCING RISK OF NSAID-ASSOCIATED GASTRIC ULCERS IN PATIENTS WITH HISTORY OF DOCUMENTED GASTRIC ULCER WHO REQUIRE USE OF AN NSAID

I-317 PROPHYLAXIS OF INFLUENZA IN ADULTS AND ADOLESCENTS 13 YEARS AND OLDER

I-318 FIRSTLINE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE OR HORMONE RECEPTOR UNKNOWN LOCALLY ADVANCED OR METASTATIC BREAST CANCER

I-319 USE FOR SUSPECTED OR CONFIRMED METHANOL POISONING, EITHER ALONE OR IN COMBINATION WITH HEMODIALYSIS

I-320 TREATMENT OF TYPE 2 DIABETES IN PEDIATRIC PATIENTS (AGES 10-16 YEARS)

I-321 JUVENILE RHEUMATOID ARTHRITIS

I-322 USE OF DIPRIVAN IN PATIENTS 3 MONTHS TO 16 YEARS

I-323 COLORECTAL CANCER

I-324 REDUCING NEUROLOGIC DISABILITY AND/OR FREQUENCY OF CLINICAL RELAPSES IN PATIENTS WITH SECONDARY (CHRONIC) PROGRESSIVE, PROGRESSIVE RELAPSING, OR WORSENING RELAPSING-REMitting MULTIPLE SCLEROSIS

I-325 PREVENTION OF RELAPSE AND RECURRENCE OF DEPRESSION

I-326 GENERALIZED ANXIETY DISORDER

I-327 SYMPTOMATIC RELIEF OF RHINORRHEA ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS IN PATIENTS 5 YEARS AND OLDER

I-328 PROPHYLAXIS AND CHRONIC TREATMENT OF ASThma IN PATIENTS 5-6 YEARS OF AGE

I-329 UNCOMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS

I-330 MAINTENANCE OF HEALING OF EROsIVE ESOPHAGITIS AND CONTROL OF DAYTIME AND NIGHTTIME HEARTBURN SYMPTOMS IN PATIENTS WITH GERD

I-331 TREATMENT OF MODERATE ACNE VULGARIS

I-332 EMPIRIC THERAPY IN FEBRILE NEUTROPenic PATIENTS WITH SUSPECTED FUNGAL INFECTIONS (EFTN)

I-333 TOPICAL TREATMENT OF TINEA (PItyRIASIS) VERSICOLOR DUE TO MALASSEZIA FURFUR (FORMERLY PITYROSporUM ORBITCALARE)

I-334 LONG-TERM TREATMENT OF GROWTH FAILURE IN CHILDREN BORN SMALL FOR GESTATIONAL AGE WHO FAIL TO MANIFEST CATCH-UP GROWTH BY TWO YEARS OF AGE
EXCLUDIBLE INDICATION

I-335  ADJUNCTIVE THERAPY IN PATIENTS TWO YEARS AND OLDER WITH SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME

I-336  EXPANSION OF INDICATION TO INCLUDE THE TREATMENT OF PATIENTS WITH PREDOMINATELY CLASSIC SUBFOveal CHOROIDAL NEOVASCULARIZATION DUE TO PATHOLOGIC MYOPIA OR PRESUMED OCULAR HISTOPLASMOsis

I-337  PATHOLOGICAL HYPERSECRETION ASSOCIATED WITH ZOLLINGER-ELLISON SYNDROME

I-338  MANAGEMENT OF ACUTE PAIN IN ADULTS AND TREATMENT OF PRIMARY DYSEMENORRHEA

I-339  TREATMENT OF HEPATITIS B IN PEDIATRIC PATIENTS AGES 2-17 YEARS

I-340  ATOPIC DERMATITIS IN PEDIATRIC PATIENTS AGES 2-5

I-341  BREAST CANCER COMBINATION THERAPY

I-342  USE OF FORADIL FOR LONG-TERM, TWICE DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHO-CONSTRICTION IN PATIENTS WITH COPD INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA

I-343  USE OF COREG FOR SEVERE HEART FAILURE

I-344  ACNE VULGARIS

I-345  TREATMENT OF POSTTRAUMATIC STRESS DISORDER

I-346  TREATMENT OF SYMPTOMATIC GASTRO ESOPHAEGAL REFLUX DISEASE (GERD)

I-347  TREATMENT OR PREVENTION OF BRONCHOSPASM IN CHILDREN 6 YEARS OF AGE AND OLDER WITH OBSTRUCTIVE AIRWAY DISEASE

I-348  LONG-TERM, TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD (INCLUDING EMPHYSEMA AND CHRONIC BRONCHITIS)

I-349  ACUTE CORONARY SYNDROME

I-350  TREATMENT OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA IN ADOLESCENT BOYS AND GIRLS AT LEAST ONE YEAR POSTMENARCHAL, AGES 10 TO 17 YEARS, WITH A RECOMMENDED DOSING RANGE OF 10 TO 40MG ONCE DAILY

I-351  PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR ALL STRENGTHS

I-352  ANTICOAGULANT IN PATIENTS WITH OR AT RISK FOR HEPARIN-INDUCED THROMBOCYTOPENIA UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS (PCI)

I-353  TREATMENT OF SIGNS AND SYMPTOMS OF RHEUMATOID ARTHRITIS

I-354  MANAGEMENT OF POST HERPETIC NEURALGIA

I-355  PREMENSTRUAL DYSPHORIC DISORDER

I-356  TREATMENT OF PATHOLOGICAL HYPERSECRETORY CONDITIONS, INCLUDING ZOLLINGER-ELLISON SYNDROME

I-357  TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS

I-358  TREATMENT OF PANIC DISORDER

I-359  TREATMENT OF VULVAR AND VAGINAL ATROPHY ASSOCIATED WITH MENOPAUSE

I-360  TREATMENT OF NASAL SYMPTOMS OF SEASONAL AND PERENNIAL RHINITIS IN CHILDREN AGES TWO UP TO AGE THREE

I-361  TREATMENT OF MULTIPLE MYELOMA AND DOCUMENTED BONE METASTASES FROM SOLID TUMORS, IN CONJUNCTION WITH STANDARD ANTI NEOPLASTIC THERAPY. PROSTATE CANCER SHOULD HAVE PROGRESSED AFTER TREATMENT WITH AT LEAST ONE HORMONAL THERAPY

I-362  TREATMENT OF PANIC DISORDER, WITH OR WITHOUT AGORAPHOBIA

I-363  ADJUVANT TREATMENT OF POST MENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE EARLY BREAST CANCER

I-364  TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA IN ADULTS

I-365  TREATMENT OF HEART FAILURE (NYHA CLASS II-IV) IN PATIENTS WHO ARE INTOLERANT TO AN ACE INHIBITOR

I-366  PREVENTION OF RELAPSE FOLLOWING LONG-TERM TREATMENT OF MAJOR DEPRESSIVE DISORDER

I-367  COMBINATION THERAPY WITH THIAZOLIDINEDIONE TO LOWER BLOOD GLUCOSE IN PTS WHOSE HYPERGLYCEMIA CANNOT BE CONTROLLED BY DIET/EXERCISE PLUS MONOTHERAPY WITH ANY OF THE FOLLOWING AGENTS: METFORMIN, SULFONYLUREAS, REPAGLINIDE, OR THIAZOLIDINEDIONES
EXCLUSIVITY INDICATION

I-368 USE OF GLUCOVANCE WITH A THIAZOLIDINEDIONE WHEN GLYCEMIC CONTROL IS NOT OBTAINED WITH GLUCOVANCE ALONE

I-369 PREVENTION AND TREATMENT OF POSTOPERATIVE NAUSEA AND VOMITING

I-370 TREATMENT OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA IN CHILDREN, AGES 8-13 YEARS, WITH RECOMMENDED DOSE OF 20MG ONCE DAILY AND IN ADOLESCENTS, AGES 14-18 WITH A RECOMMENDED DOSE OF 40MG ONCE DAILY

I-371 HELICOBACTER PYLORI ERADICATION TO REDUCE THE RISK OF DUODENAL ULCER RECURRENT

I-372 NOSOCOMIAL PNEUMONIA

I-373 TREATMENT OF TYPE 2 DIABETIC NEPHROPATHY

I-374 SHORT TERM TOPICAL TREATMENT OF MILD TO MODERATE PLAQUE-TYPE PSORIASIS OF NON SCALP REGIONS

I-375 FIRST LINE THERAPY FOR THE REDUCTION OF INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION

I-376 TREATMENT OF NEWLY DIAGNOSED ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (CML)

I-377 USE OF BRAVELLE FOR MULTIPLE FOLLICULAR DEVELOPMENT (CONTROLLED OVARIAN STIMULATION) DURING ASSISTED REPRODUCTIVE TECHNOLOGY CYCLES IN PATIENTS WHO HAVE PREVIOUSLY RECEIVED PITUITARY SUPPRESSION

I-378 RELIEF OF SYMPTOMS OF SEASONAL ALLERGIC RHINITIS IN ADULTS AND PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER

I-379 USE TAXOTERE IN COMBINATION WITH CISPLATIN FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER WHO HAVE NOT PREVIOUSLY RECEIVED CHEMOTHERAPY FOR THIS CONDITION

I-380 TO TREAT PATIENTS WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER AT RISK FOR EMERGENT SUICIDAL BEHAVIOR

I-381 TREATMENT OF COLD SORES (HERPES LABIALIS) IN ADULT AND ADOLESCENT PATIENTS 12 YEARS OF AGE AND OLDER

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I-502  FOR PTS WITH ST-SEGMENT ELEVATION ACUTE MYOCARDIAL INFARCTION, PLAVIX TO REDUCE RATE OF DEATH FROM ANY CAUSE AND THE RATE OF A COMBINED ENDPOINT OF DEATH, REINFARCTION OR STROKE. NOT KNOWN TO PERTAIN TO PTS WHO RECEIVE PRIMARY ANGIOPLASTY

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EXCLUSIVITY INDICATION

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I-520  USE OF EXENATIDE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WHO ARE USING A THIAZOLIDINEDIONE ALONE OR IN COMBINATION WITH METFORMIN BUT HAVE NOT ACHIEVED ADEQUATE GLYCEMIC CONTROL

I-521  TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA WHO HAVE RECEIVED AT LEAST 1 YEAR PRIOR THERAPY

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I-523  USE IN ADULT PATIENTS WITH CLINICALLY EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF NONFATAL MYOCARDIAL INFARCTION, FATAL AND NONFATAL STROKE, ANGINA, REVASCULARIZATION PROCEDURES AND HOSPITALIZATION FOR CONGESTIVE HEART FAILURE

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I-525  USE OF 0.5MG/0.1MG FOR PREVENTION OF POST-MENOPAUSAL OSTEOPOROSIS

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I-527  ADJUNCTIVE THERAPY IN THE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER WITH IDIOPATHIC GENERALIZED EPILEPSY

I-528  TREATMENT OF MODERATE TO SEVERE VAGINAL DRYNESS AND PAIN WITH INTERCOURSE, SYMPTOMS OF VULVAR AND VAGINAL ATROPHY ASSOCIATED WITH MENopause

I-529  TREATMENT OF DEMENTIA OF THE ALZHEIMER'S TYPE IN PATIENTS WITH SEVERE ALZHEIMER'S DISEASE

I-530  PREVENTION OF EXERCISE-INDUCED BRONCHOCONSTRICTION IN PATIENTS 15 YEARS OF AGE AND OLDER

I-531  MAINTENANCE TREATMENT OF SCHIZOPHRENIA

I-532  TREATMENT OF BACTERIAL VAGINOSIS IN NON-PREGNANT FEMALES

I-533  ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI)

I-534  EXTENDED TREATMENT OF SYMPTOMATIC VENOUS THROMBOEMBOLISM (VTE) AND/OR PULMONARY EMBOLISM TO REDUCE THE RECURRENCE OF VTE IN PATIENTS WITH CANCER

I-535  MANAGEMENT OF FIBROMYALGIA

I-536  FOR THE TREATMENT OF SHORT STATURE IN CHILDREN WITH NOONAN SYNDROME

I-537  LONG TERM TREATMENT OF PANIC DISORDER

I-538  SHORT TERM TREATMENT OF PANIC DISORDER
EXCLUSIVITY INDICATION

I-539 REDUCTION IN RISK OF INVASIVE BREAST CANCER IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS OR AT HIGH RISK FOR INVASIVE BREAST CANCER

I-540 TREATMENT OF SCHIZOPHRENIA IN ADOLESCENTS AGES 13-17

I-541 TREATMENT OF BIPOLAR I DISORDER IN CHILDREN AGES 10-12 AND ADOLESCENTS AGES 13-17

I-542 EXPANSION OF PATIENT POPULATION FOR HEAD AND NECK CANCER FROM "INOPERABLE" PATIENTS TO ALL PATIENTS

I-543 USE IN COMBINATION WITH CISPLATIN AND FLUOROURACIL FOR THE INDUCTION TREATMENT OF PATIENTS WITH LOCALLY ADVANCED SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN)

I-544 ADJUNCTIVE THERAPY OF MYOCLONIC SEIZURES IN ADULTS AND ADOLESCENTS AGE 16 AND OVER WITH JUVENILE MYOCLONIC EPILEPSY

I-545 ADJUNCTIVE TREATMENT TO TREAT PATIENTS WITH MAJOR DEPRESSIVE DISORDER

I-546 TREATMENT OF UNRESECTABLE HEPATOCELLULAR CARCINOMA

I-547 ADJUNCTIVE THERAPY TO DIET TO SLOW THE PROGRESSION OF ARTERIOSCLEROSIS IN ADULT PATIENTS AS PART OF A TREATMENT STRATEGY TO LOWER TOTAL-C AND LDL-C TO TARGET LEVELS

I-548 SEASONAL ALLERGIC RHINITIS IN PATIENTS 6 THROUGH LESS THAN 12 YEARS OF AGE

I-549 USE OF AVALIDE TABLETS AS INITIAL THERAPY IN PATIENTS WHO ARE LIKELY TO NEED MULTIPLE DRUGS TO ACHIEVE THEIR BLOOD PRESSURE GOALS

I-550 TREATMENT OF HYPERTENSION IN PEDIATRIC PATIENTS 6-16 YEARS OF AGE

I-551 TREATMENT OF SHORT STATURE IN CHILDREN WITH TURNER'S SYNDROME

I-552 ADJUNCTIVE THERAPY FOR RADIOIODINE ABLATION OF THYROID TISSUE REMNANTS IN PATIENTS WHO HAVE UNDERGONE THYROIDECTOMY FOR WELL-DIFFERENTIATED THYROID CANCER AND WHO DO NOT HAVE EVIDENCE OF METASTATIC THYROID CANCER

I-553 FOR USE AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

I-554 TREATMENT OF PATIENTS WITH CANDIDEMIA, ACUTE DISSEMINATED CANDIDIASIS, CANDIDA PERITONITIS AND ABSCESS

I-555 TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10-17 YEARS

I-556 PREVENTION OF POST OPERATIVE Nausea AND VOMITING FOR UP TO 24 HOURS FOLLOWING SURGERY

I-557 USE OF AMITIZA (LUBIPROSTONE) 8 MCG TWICE DAILY FOR TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN WOMEN GREATER THAN OR EQUAL TO 18 YEARS OLD

I-558 MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION AND REDUCING EXACERBATIONS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA

I-559 ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN SHORT TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED

I-560 MAINTENANCE TREATMENT FOR BIPOLAR I DISORDER, AS ADJUNCTIVE THERAPY TO LITHIUM OR DIVALPROEX

I-561 LONG-TERM TREATMENT OF SOCIAL ANXIETY DISORDER

I-562 MAINTENANCE TREATMENT OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER (ADHD) IN CHILDREN AND ADOLESCENTS

I-563 ADJUNCTIVE THERAPY IN THE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SIEZURES IN ADULTS AND CHILDREN 16 YEARS OF AGE AND OLDER WITH IDIOPATHIC GENERALIZED EPILEPSY

I-564 TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA

I-565 USE OF DUTASTERIDE IN COMBINATION WITH TAMUSULOSIN FOR THE TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA (BPH)

I-566 MANAGEMENT OF FIBROMYALGIA

I-567 INITIAL THERAPY IN PATIENTS LIKELY TO NEED MULTIPLE DRUGS TO ACHIEVE THEIR BLOOD PRESSURE GOALS

I-568 USE OF APTIVUS, CO-ADMINISTERED W/ RITONAVIR, FOR COMBINATION ANTIRETROVIRAL TREATMENT OF HIV-1 INFECTED PED (AGE 2-18 YRS) PATIENTS WHO ARE TREATMENT-
EXCLUSIVITY INDICATION

I-569  TREATMENT OF CHRONIC HEPATITIS B
I-570  TREATMENT OF CHICKEN POX IN IMMUNOCOMPETENT PEDIATRIC PATIENTS 2 TO <18 YEARS OF AGE
I-571  NON-SMALL CELL LUNG CANCER IN COMBINATION WITH CISPLATIN AND AS SINGLE AGENT FOR NONSQAUMOUS NON-SMALL CELL LUNG CANCER
I-572  TREATMENT OF GROWTH FAILURE IN CHILDREN BORN SMALL FOR GESTATIONAL AGE (SGA) WITH NO CATCH-UP BY AGE 2-4 YRS.
I-573  TO TREAT PATIENTS WITH PRIMARY DysbetaLIPOPROTEINEMIA (FREDRICKSON TYPE III HYPERLIPOPROTEINEMIA) AS AN ADJUNCT TO DIET
I-574  MONOTHERAPY IN THE TREATMENT OF BIPOLAR DEPRESSION
I-575  MONOTHERAPY IN THE TREATMENT OF BIPOLAR MANIA
I-576  ADJUNCTIVE THERAPY IN THE TREATMENT OF BIPOLAR MANIA
I-577  SEDATION OF NON-INTUBATED PATIENTS PRIOR TO AND/OR DURING SURGICAL AND OTHER PROCEDURES
I-578  EXPANSION OF INDICATION TO INCLUDE TREATMENT OF HIV IN TREATMENT NAIVE ADULTS
I-579  TREATMENT OF MODERATE TO SEVERE DYSpareunIA, A SYMPTOM OF VULVAR AND VAGINAL ATROPHY, DUE TO MENopause AND NEW TWICE WEEKLY DOSING REGIMEN FOR THIS INDICATION
I-580  INDOLENT B-CELL NON-HODGKINS LYMPHOMA (NHL) THAT HAS PROGRESSED DURING OR WITHIN SIX MONTHS OF TREATMENT WITH RITUXIMAB OR A RITUXIMAB CONTAINING REGIMEN
I-581  TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS
I-582  TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE
I-583  ADJUVANT TREATMENT OF ADULT PATIENTS FOLLOWING COMPLETE GROSS RESECTION OF KIT (CD117) POSITIVE GASTROINTESTINAL StromAL TUMORS (GIST)
I-584  TREATMENT AND PREVENTION OF GluCOcORTICOID-INDUCED OSTEOPOROSIS IN PATIENTS EXPECTED TO BE ON GLuCOcORTICOIDs FOR AT LEAST 12 MONTHS
I-585  TREATMENT OF SHORT STATURE IN PEDIATRIC PATIENTS SMALL FOR GESTATIONAL AGE WHO DO NOT MANIFEST CATCH UP GROWTH BY AGE 2 TO 4 YEARS
I-586  COMMUNITY ACQUIRED BACTERIAL PNEUMONIA
I-587  ADDITIONAL PATHOGENS TO COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS INDICATION
I-588  ADDITIONAL PATHOGENS TO COMPLICATED INTRA-ABDOMINAL INFECTIONS INDICATION
I-589  TREATMENT OF TREATMENT RESISTANT DEPRESSION (TRD) IN COMBINATION WITH OLANZAPINE
I-590  ACUTE TREATMENT OF DEPRESSIVE EPISODES ASSOCIATED WITH BIPOLAR DISORDER (IN COMBINATION WITH OLANZAPINE)
I-591  TREATMENT OF TREATMENT RESISTANT DEPRESSION (TRD) IN COMBINATION WITH FLUOXETINE
I-592  ACUTE TREATMENT OF DEPRESSIVE EPISODES ASSOCIATED WITH BIPOLAR DISORDER (IN COMBINATION WITH FLUOXETINE)
I-593  TREATMENT OF TREATMENT RESISTANT DEPRESSION (TRD)
I-594  INDICATION EXPANDED TO INCLUDE PATIENTS WHO HAVE EXPERIENCED A FIRST CLINICAL EPISODE AND HAVE MRI FEATURES CONSISTENT WITH MULTIPLE SCLEROSIS
I-595  PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
I-596  USE AS ADJUNCTIVE THERAPY WITH LITHIUM OR VALPROATE FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER
I-597  MONOTHERAPY FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER
I-598  TREATMENT OF PULMONARY ARTERIAL HYPERTENSION INDICATION EXPANDED TO INCLUDE DELAY IN CLINICAL WORSENING
I-599  PREVENTION AND TREATMENT OF SECONDARY HYPERPARATHYROIDISM ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD) STAGE 5 IN PATIENTS ON HEMODIALYSIS OR PERITONEAL DIALYSIS
I-600  FOR USE AS INITIAL THERAPY IN PATIENTS WHO ARE LIKELY TO NEED MULTIPLE DRUGS TO ACHIEVE THEIR BLOOD PRESSURE GOALS
EXCLUSIVITY INDICATION

I-601 MAINTENANCE TREATMENT IN PATIENTS WITH ADVANCED OR METASTATIC NON-SQUAMOUS NON-SMALL CELL LUNG CANCER WHOSE DISEASE HAS NOT PROGRESSED AFTER FOUR CYCLES OF PLATINUM-BASED FIRST LINE CHEMOTHERAPY

I-602 TREATMENT OF MEN AND WOMEN WITH OSTEOPOROSIS ASSOCIATED WITH SUSTAINED SYSTEMIC GLUCOCORTICOID THERAPY AT HIGH RISK FOR FRACTURE

I-603 GOUT FLARES

I-604 PREVENTION OF CMV DISEASE IN KIDNEY AND HEART TRANSPLANT PATIENTS 4 MONTHS TO 16 YEARS AT HIGH RISK

I-605 ADJUNCT TO MOOD STABILIZERS AND/OR ANTIDEPRESSANTS FOR SCHIZOAFFECTIVE DISORDER

I-606 TREATMENT OF SCHIZOAFFECTIVE DISORDER AS MONOTHERAPY

I-607 INDICATION EXPANDED TO INCLUDE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (WHO GROUP I) IN PATIENTS WITH CLASS II SYMPTOMS

I-608 REDUCE LDL-C LEVELS IN BOYS AND POSTMENARCHAL GIRLS, 10 TO 17 YEARS OF AGE, WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AS MONOTHERAPY OR IN COMBINATION WITH A STATIN AFTER Failing AN ADEQUATE TRIAL OF DIET THERAPY

I-609 TREATMENT OF HEAVY MENSTRUAL BLEEDING FOR WOMEN WHO CHOOSE TO USE INTRAUTERINE CONTRACEPTION AS THEIR METHOD OF CONTRACEPTION

I-610 TREATMENT OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA IN ADOLESCENT BOYS AND POSTMENARCHAL GIRLS, AGES 10 TO 17 YEARS, WITH A RECOMMENDATION DOSING RANGE OF 5 TO 20 MG ONCE DAILY

I-611 REDUCE LDL-C LEVELS IN PATIENTS WITH ADVANCED OR METASTATIC BREAST CANCER WHOSE DISEASE HAS NOT PROGRESSED AFTER FOUR CYCLES OF PLATINUM-BASED FIRST LINE CHEMOTHERAPY

I-612 TREATMENT OF OSTEOPOROSIS ASSOCIATED WITH SUSTAINED SYSTEMIC GLUCOCORTICOID THERAPY AT HIGH RISK FOR FRACTURE

I-613 ADJUNCTIVE THERAPY WITH EITHER LITHIUM OR VALPROATE FOR THE ACUTE TREATMENT OF MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER

I-614 TREATMENT OF PATIENTS WITH SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) ASSOCIATED WITH TUBEROUS SCLEROSIS (TS) WHO REQUIRE THERAPEUTIC INTERVENTION BUT
EXCLUSIVITY INDICATION

I-631 PREVENTION OF RELAPSE TO OPIOID DEPENDENCE FOLLOWING OPIOID DETOXIFICATION
I-632 MANAGEMENT OF CHRONIC MUSCULOSKELETAL PAIN
I-633 MAINTENANCE TREATMENT OF BIPOLAR I DISORDER AS AN ADJUNCT TO LITHIUM OR VALPROATE
I-634 TREATMENT OF SEVERE HYPERCALCEMIA IN PATIENTS WITH PRIMARY HYPERPARATHYROIDISM WHO ARE UNABLE TO UNDERGO PARATHYROIDECTOMY
I-635 ADJUNCTIVE TREATMENT WITH LONG-ACTING ORAL PSYCHOSTIMULANTS FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)
I-636 TREATMENT OF EXTERNAL GENITAL AND PERIANAL WARTS/CONDYLOMA ACUMINATA IN PATIENTS 12 YEARS OR OLDER
I-637 USE IN COMBINATION CHEMOTHERAPY WITH 5-FLUOROURACIL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED METASTATIC COLORECTAL CANCER
I-638 FOR PATIENTS WITH PROGRESSIVE NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (PNET) THAT ARE UNRESECTABLE, LOCALLY ADVANCED, OR METASTATIC.
I-639 TREATMENT OF PROGRESSIVE, WELL-DIFFERENTIATED PANCREATIC NEUROENDOCRINE TUMORS IN PATIENTS WITH UNRESECTABLE, LOCALLY ADVANCED, OR METASTATIC DISEASE
I-640 MAINTENANCE OF REMISSION OF ULCERATIVE COLITIS
I-641 TREATMENT OF THE SIGNS AND SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA (BPH)
I-642 TREATMENT OF ERECTILE DYSFUNCTION (ED) AND THE SIGNS AND SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA (BPH)
I-643 REDUCE THE RISK OF STROKE AND SYSTEMIC EMBOLISM IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION.
I-644 MONOTHERAPY IN PATIENTS 13 YEARS OF AGE AND OLDER WITH PARTIAL SEIZURES WHO ARE RECEIVING THERAPY WITH A SINGLE ANTIEPILEPTIC DRUG (AED)
I-645 MAINTENANCE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN ADULTS
I-646 SIGNS AND SYMPTOMS OF ADVANCED PARKINSON'S DISEASE (APD)
I-647 SIGNS AND SYMPTOMS OF MODERATE TO SEVERE PRIMARY RESTLESS LEGS SYNDROME (RLS)
I-648 TREATMENT OF HEAVY MENSTRUAL BLEEDING IN WOMEN WITHOUT ORGANIC PATHOLOGY WHO CHOOSE TO USE AN ORAL CONTRACEPTIVE AS THEIR METHOD OF CONTRACEPTION
I-649 TREATMENT OF PATIENTS WITH ADVANCED SOFT TISSUE SARCOMA (STS) WHO HAVE RECEIVED PRIOR CHEMOTHERAPY
I-650 TREATMENT OF ADULTS WITH RENAL ANGIOMYOLIPOMA AND TUBEROUS SCLEROSIS COMPLEX (TSC), NOT REQUIRING IMMEDIATE SURGERY
I-651 MANAGEMENT OF NEUROPATHIC PAIN ASSOCIATED WITH SPINAL CORD INJURY
I-652 MANAGEMENT OF POSTHERPETIC NEURALGIA
I-653 TREATMENT OF ENDODENOUS ANTERIOR UVEITIS
I-654 MAGNETIC RESONANCE ANGIOGRAPHY (MRA) TO EVALUATE ADULTS WITH KNOWN OR SUSPECTED RENAL OR AORTO-ILI-O-FEMORAL OCCLUSIVE VASCULAR DISEASE
I-655 TREATMENT OF POSTMENOPAUSAL WOMEN WITH ADVANCED HORMONE RECEPTOR-POSITIVE,HER2-NEGATIVE BREAST CANCER (ADVANCED HR+BC) IN COMBINATION WITH EXEMESTANE, AFTER FAILURE OF TREATMENT WITH LETROZOLE OR ANASTROZOLE
I-656 MANAGEMENT OF NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY (DPN) IN ADULTS WHEN A CONTINUOUS, AROUND-THE-CLOCK OPIOID ANALGESIC IS NEEDED FOR AN EXTENDED PERIOD OF TIME
I-657 PLAQUE PSORIASIS OF THE SCALP
I-658 FIRST-LINE TREATMENT OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER, IN COMBINATION WITH CARBOPLATIN, IN PATIENTS WHO ARE NOT CANDIDATES FOR CURATIVE SURGERY OR RADIATION THERAPY
I-659 PLAQUE PSORIASIS OF THE BODY
I-660 TREATMENT OF DEEP VEIN THROMBOSIS
I-661 TREATMENT OF PULMONARY EMBOLISM
I-662 REDUCTION IN RISK FOR DEEP VEIN THROMBOSIS AND THE REDUCTION IN RISK FOR
EXCLUSIVITY INDICATION

I-663  IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

I-664  TREATMENT OF THROMBOCYTOPENIA IN PATIENTS WITH CHRONIC HEPATITIS C TO ALLOW THE INITIATION AND MAINTENANCE OF INTERFERON-BASED THERAPY

I-665  TREATMENT OF CHRONIC IRON OVERLOAD IN PATIENTS 10 YRS OF AGE AND OLDER WITH (NTDT) SYNDROMES AND WITH A (LIC) OF AT LEAST 5 MG OF IRON PER GRAM OF LIVER DRY WEIGHT (MG FE/G DW) AND SERUM FERRITIN GREATER THAN 300MCG/L

I-666  TREATMENT OF PATIENTS WITH NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME-POSITIVE ACUTE LYMPHOBlastic LEUKEMIA (PH+ALL) IN COMBINATION WITH CHEMOTHERAPY

I-667  TREATMENT OF PATIENTS WITH LOCALLY ADVANCED, UNRESECTABLE OR METASTATIC GASTROINTESTINAL STROMAL TUMOR (GIST) WHO HAVE BEEN PREVIOUSLY TREATED WITH IMATINIB MESYLATE AND SUNITINIB MALATE

I-668  PROPHYLAXIS OF ALLOGRAFT REJECTION IN ADULT PATIENTS RECEIVING A LIVER TRANSPLANT

I-669  SCINTIGRAPHIC ASSESSMENT OF SYMPATHETIC INNERVATION OF THE MYOCARDIUM BY MEASUREMENT OF THE HEART TO MEDIASTINUM (H/M) RATIO OF RADIOACTIVITY UPTAKE IN PATIENTS WITH NYHA CLASS II OR CLASS III HEART FAILURE AND LVEF LESS THAN 35%

I-670  TREATMENT OF OPIOID-INDUCED CONSTIPATION (OIC) IN ADULTS WITH CHRONIC, NON-CANCER PAIN

I-671  FIRSTLINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21(L858R) SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST

I-672  USE IN PATIENTS WITH MANTLE CELL LYMPHOMA WHOSE DISEASE HAS RELapsed OR PROGRESSED AFTER TWO PRIOR THERAPIES, ONE OF WHICH INCLUDED BORTEZOMIB

I-673  TREATMENT OF HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA/VENTILATOR-ASSOCIATED BACTERIAL PNEUMONIA (HABP/VABP) CAUSED BY SUSCEPTIBLE ISOLATES OF S. AUREUS (INCLUDING M ETHICILLIN-SUSCEPTIBLE AND RESISTANT ISOLATES) WHEN ALTERNATIVE TREATMENTS ARE NOT SUITABLE

I-674  TREATMENT OF PATIENTS WITH DEPRESSIVE EPISODES ASSOCIATED WITH BIPOLAR I DISORDER (BIPOLAR DEPRESSION) AS MONOTHERAPY AND AS ADJUNCTIVE THERAPY WITH LITHIUM OR VALPROATE

I-675  MAINTENANCE TREATMENT OF MAJOR DEPRESSIVE DISORDER

I-676  FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC ADENOCARCINOMA OF THE PANCREAS, IN COMBINATION WITH GEMCITABINE

I-677  TREATMENT OF PATIENTS WITH LOCALLY RECURRENT OR METASTATIC, PROGRESSIVE, DIFFERENTIATED THYROID CARCINOMA (DTC) THAT IS REFRACTORY TO RADIOACTIVE IODINE TREATMENT

I-678  TRAMETINIB, IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST

I-679  RISK REDUCTION OF REBLEEDING OF GASTRIC OR DUODENAL ULCERS FOLLOWING THERAPEUTIC ENDOSCOPY IN ADULTS

I-680  TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

I-681  PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT) WHICH MAY LEAD TO PULMONARY EMBOLISM (PE), IN ADULT PATIENTS WHO HAVE UNDERGONE HIP OR KNEE REPLACEMENT

I-682  TREATMENT OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WHO HAVE BEEN TREATED WITH A PARENTERAL ANTICOAGULANT FOR 5-10 DAYS

I-683  TO REDUCE THE RISK OF RECURRENCE OF DVT AND PE IN PATIENTS WHO HAVE BEEN PREVIOUSLY TREATED

I-684  PREVENTION OF ACUTE NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF EMETOGENIC CANCER CHEMOTHERAPY, INCLUDING HIGHLY EMETOGENIC CANCER CHEMOTHERAPY IN PEDIATRIC PATIENTS AGED 1 MONTH TO LESS THAN 17 YEARS

I-685  EXPANDED INDICATION OF RASAGILINE AS AN ADD-ON THERAPY TO STABLE DOSES OF DOPAMINE AGONISTS IN THE TREATMENT OF EARLY PARKINSON’S DISEASE

I-686  INDICATED FOR THE TREATMENT OF DIABETIC MACULAR EDEMA IN PATIENTS WHO ARE PSEUDOPHAKIC OR ARE PHAKIC AND SCHEDULED FOR CATARACT SURGERY
I-687 GUIDING SENTINEL LYMPH NODE BIOPSY, USING A HAND-HELD GAMMA COUNTER IN PATIENTS WITH CLINICALLY NODE NEGATIVE SQUAMOUS CELL CARCINOMA OF THE ORAL CAVITY

I-688 GADAVIST IS INDICATED WITH MRI TO DETECT THE PRESENCE AND EXTENT OF MALIGNANT BREAST DISEASE

I-689 TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WITH 17P DELETION

I-690 INDICATED FOR THE TREATMENT OF DEEP VEIN THROMBOSIS (DVT)

I-691 INDICATED TO REDUCE THE RISK OF RECURRENT DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) FOLLOWING INITIAL THERAPY

I-692 INDICATED FOR MANAGEMENT OF OSTEOARTHRITIS PAIN.

I-693 TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (CRPC)

I-694 TREATMENT OF PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS WHO ARE CANDIDATES FOR PHOTOTHERAPY OR SYSTEMIC THERAPY

I-695 REVISED INDICATION FOR BORTEZOMIB IN THE TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA

I-696 USE AS MONOTHERAPY IN THE TREATMENT OF PARTIAL-ONSET SEIZURES IN PATIENTS WITH EPILEPSY AGE 17 YEARS AND OLDER

I-697 FOR USE IN COMBINATION WITH SOFOSBUVIR FOR THE TREATMENT OF PATIENTS WITH CHRONIC HEPATITIS C VIRUS GENOTYPE 1 INFECTION

I-698 SCHIZOAFFECTIVE DISORDER AS MONOTHERAPY AND AS AN ADJUNCT TO MOOD STABILIZERS OR ANTIDEPRESSANTS

I-699 FOR TREATMENT OF PATIENTS WITH POLYCYTHEMIA VERA WHO HAVE HAD AN INADEQUATE RESPONSE TO OR ARE INTOLERANT OF HYDROXYUREA

I-700 TREATMENT OF PEDIATRIC PATIENTS WITH TOURETTE’S DISORDER (6–18 YEARS)

I-701 FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE, WELL-OR MODERATELY-DIFFERENTIATED, LOCALLY ADVANCED OR METASTATIC GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS (GEP-NETS) TO IMPROVE PROGRESSION FREE SURVIVAL

I-702 FOR THE TREATMENT OF PATIENTS WITH WALDENSTROM MACROGLOBULINEMIA

I-703 MODERATE TO SEVERE BINGE EATING DISORDER (BED)

I-704 EXPANDED INDICATION TO INCLUDE PATIENTS WHO ARE VIROLOGICALLY-SUPPRESSED (HIV-1 RNA <50 COPIES/ML) ON A STABLE ANTIRETROVIRAL REGIMEN FOR AT LEAST 6 MONTHS WITH NO HISTORY OF TREATMENT FAILURE IN ORDER TO REPLACE THEIR CURRENT REGIMEN

I-705 TREATMENT OF CYSTIC FIBROSIS IN PATIENTS 6 YEARS AND OLDER WHO HAVE AN R117H MUTATION IN THE CFTR GENE

I-706 EXPANDED INDICATION FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA

I-707 POMALYST, IN COMBINATION WITH DEXAMETHASONE, IS INDICATED FOR PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST 2 PRIOR THERAPIES AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY

I-708 DAILY TREATMENT OF ASTHMA IN PATIENTS AGED 18 YEARS AND OLDER

I-709 TREATMENT OF IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) IN ADULTS

I-710 ADJUNCTIVE THERAPY FOR THE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC (PG TC) SEIZURES IN PATIENTS WITH EPILEPSY 12 YEARS OF AGE OR OLDER.

I-711 INCLUSION OF PEDIATRIC PATIENTS AGES 6 YRS AND OLDER FOR THE TREATMENT OF THROMBOCYTOPENIA IN PATIENTS WITH CHRONIC ITP WHO HAVE HAD AN INSUFFICIENT RESPONSE TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR SPLENECTOMY.

I-712 EXPANDED INDICATION FOR USE IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH RELAPSED MULTIPLE MYELOMA WHO HAVE RECEIVED ONE TO THREE PRIOR LINES OF THERAPY

I-713 REVISIONS TO THE LABELING TO PERMIT THE USE OF ZUBSOLV AS INITIAL (“INDUCTION”) TREATMENT OF OPIOID DEPENDENCE

I-714 EXTENDS THE 2011 APPROVAL OF BRILINTA FOR USE BEGINNING WITH ACS TO USE BEGINNING MORE REMOTE FROM MYOCARDIAL INFARCTION

I-715 FOR THE ADDITION OF THE INDICATION FOR MONOTHERAPY TREATMENT IN PARTIAL-ONSET SEIZURES IN ADULTS.

I-716 REVISED INDICATION TO INCLUDE LANGUAGE ABOUT THE BENEFITS OF USING LETAIRIS IN
EXPANSION OF THE INDICATION TO INCLUDE THE TREATMENT OF CHRONIC HEPATITIS C GENOTYPE 4

I-717

EXPANDED INDICATION TO INCLUDE THE TREATMENT OF CHRONIC HEPATITIS C GENOTYPE 6 VIRUS INFECTION BASED UPON THE RESULTS OF THE ELECTRON-2 STUDY

I-718

EXPANDED INDICATION TO INCLUDE THE TREATMENT OF SUBJECTS WITH CHRONIC HEPATITIS C VIRUS INFECTION BASED UPON THE RESULTS FROM STUDY GS-US-337-119.

I-719


I-720

TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC LIPOSARCOMA WHO HAVE RECEIVED A PRIOR ANTHRACYCLINE-CONTAINING REGIMEN.

I-721

REVISED INDICATION FOR USE IN COMBINATION WITH DEXAMETHASONE OR WITH LENALIDOMIDE PLUS DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED ONE TO THREE LINES OF THERAPY.

I-722

AS A SINGLE AGENT FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED ONE OR MORE LINES OF THERAPY.

I-723

TREATMENT OF ADULT PATIENTS WITH PROGRESSIVE, WELL DIFFERENTIATED, NONFUNCTIONAL NEUROENDOCRINE TUMORS (NET) OF GI OR LUNG ORIGIN WITH UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC DISEASE.

I-724

TREATMENT OF HORMONE RECEPTOR (HR)-POSITIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER IN COMBINATION THERAPY WITH PALBOCICLIB AND FULVESTRANT IN WOMEN WITH DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY.

I-725

EXPANSION OF THE PATIENT POPULATION TO INCLUDE PATIENTS WITH RECURRENCE OF HEPATITIS C VIRUS (HCV) GENOTYPE 1 OR 3 AFTER LIVER TRANSPLANTATION.

I-726

EXPANSION OF THE INDICATION TO INCLUDE TREATMENT OF SUBJECTS WITH GENOTYPE-1 CHRONIC HEPATITIS C VIRUS INFECTION, INCLUDING SUBJECTS WHO ARE CO-INFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS (HIV-1) BASED ON THE RESULTS FROM THE ALLY-2 CLINICAL TRIAL.

I-727

EXPANDED INDICATION FOR USE IN ULTRASONOGRAPHY OF THE LIVER FOR CHARACTERIZATION OF FOCAL LIVER LESIONS IN ADULT AND PEDIATRIC PATIENTS.

I-728

PROVIDES FOR THE FRONTLINE INDICATION FOR THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA.

I-729

NEW INDICATION FOR THE TREATMENT OF PATIENTS WITH METASTATIC, SQUAMOUS, NON-SMALL CELL LUNG CANCER PROGRESSING AFTER PLATINUM-BASED CHEMOTHERAPY.

I-730

FOR USE IN MAGNETIC RESONANCE ANGIOGRAPHY IN ADULT AND PEDIATRIC PATIENTS (INCLUDING TERM NEONATES) TO EVALUATE KNOWN OR SUSPECTED SUPRA-AORTIC OR RENAL ARTERY DISEASE.

I-731

TREATMENT OF PEDIATRIC PATIENTS 7 TO 17 YEARS OF AGE WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA TO REDUCE LDL-C, TOTAL C, NONHDL-C AND APOB AS AN ADJUNCT TO DIET, EITHER ALONE OR WITH OTHER LIPID-LOWERING TREATMENTS.

I-732

USE OF CANAGLIFLOZIN FOR INITIAL THERAPY IN COMBINATION WITH METFORMIN.

I-733

EXPANDED INDICATION FOR THE USE OF LENVIMA IN COMBINATION WITH EVEROLIMUS FOR THE TREATMENT OF PATIENTS WITH ADVANCED RCC FOLLOWING ONE PRIOR ANTI-ANGIOGENIC THERAPY.

I-734

AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHEN TREATMENT WITH BOTH CANAGLIFLOZIN AND METFORMIN IS APPROPRIATE.

I-735

REVISED INDICATION TO INCLUDE THE TREATMENT OF PATIENTS WITH SMALL LYMPHOCYTIC LEUKEMIA (SIL).

I-736

REVISED INDICATION TO INCLUDE THE TREATMENT OF PATIENTS WITH SMALL LYMPHOCYTIC LEUKEMIA (SIL) WITH 17P DELETION.

I-737

REVISED INDICATION TO INCLUDE THE TREATMENT OF PATIENTS WITH SMALL LYMPHOCYTIC LEUKEMIA (SIL) WITH 17P DELETION.

I-738

REVISED TO THE INDICATIONS AND USAGE SECTION WITH RESPECT TO COMPLICATED INTRA-ABDOMINAL INFECTIONS.

I-739


I-740
EXCLUSIVITY INDICATION

I-741 TREATMENT OF PATIENTS WITH MARGINAL ZONE LYMPHOMA (MZL) WHO REQUIRE SYSTEMIC THERAPY AND HAVE RECEIVED AT LEAST ONE PRIOR ANTI-CD20-BASED THERAPY

I-742 TREATMENT OF NODAL MARGINAL ZONE LYMPHOMA

I-743 INFORMATION ADDED TO THE LABELING FOR THE ADDITION OF THE TREATMENT OF CHRONIC HEPATITIS C VIRUS (HCV) GENOTYPE 4 (GT4) INFECTED PATIENTS WITH COMPENSATED CIRRHOSIS BASED ON RESULTS FROM STUDY M11-665

I-744 TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC) WHO HAVE BEEN PREVIOUSLY TREATED WITH SORAFENIB

I-745 MEKINIST, IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST.

I-746 NEW INDICATION OF MAINTENANCE MONOTHERAPY TREATMENT OF BIPOLAR I DISORDER IN ADULTS

I-747 FOR REDUCING THE RISK OF GRAFT REJECTION WHEN USED WITH HIGH-DOSE BUSULFAN AND CYCLOPHOSPHAMIDE AS A PREPARATIVE REGIMEN FOR ALLOGENEIC HEMATOPOIETIC PROGENITOR (STEM) CELL TRANSPLANTATION FOR PEDIATRIC PATIENTS WITH CLASS 3 BETA-THALASSEMSIA

I-748 TO REDUCE THE ACUTE COMPlications OF SICKLE CELL DISEASE IN ADULT AND PEDIATRIC PATIENTS FIVE YEARS OF AGE AND OLDER

I-749 MONOTHERAPY FOR THE TREATMENT OF HORMONE RECEPTOR (HR) POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE, ADVANCED BREAST CANCER IN POSTMENOPAUSAL WOMEN NOT PREVIOUSLY TREATED WITH ENDOCRINE THERAPY

I-750 REDUCE THE RISK OF MAJOR ADVERSE CARDIOVASCULAR EVENTS IN ADULTS WITH TYPE 2 DIABETES MELLITUS AND ESTABLISHED CARDIOVASCULAR DISEASE

I-751 TREATMENT OF TARDIVE DYSKINESIA

I-752 CORONARY COMPUTED TOMOGRAPHY ANGIOGRAPHY (CCTA) TO ASSIST DIAGNOSTIC EVALUATION OF PATIENTS WITH SUSPECTED CORONARY ARTERY DISEASE

I-753 TREATMENT OF ADULT PATIENTS WITH CHRONIC GRAFT VERSUS HOST DISEASE (CGVHD) AFTER FAILURE OF ONE OR MORE LINES OF SYSTEMIC THERAPY

I-754 TO REDUCE THE FREQUENCY OF SHORT-ACTING SOMATOSTATIN ANALOG RESCUE THERAPY WHEN USED FOR THE TREATMENT OF ADULTS WITH CARCINOID SYNDROME

I-755 ADJUVANT TREATMENT OF ADULT PATIENTS AT HIGH RISK OF RECURRENT RENAL CELL CARCINOMA (RCC) FOLLOWING NEPHRECTOMY

I-756 EXPANDED THE APPROVED INDICATION BY REMOVING THE RESTRICTION FOR USE ONLY IN PATIENTS WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB

I-757 TREATMENT OF PATIENTS WITH ERDHEIM-CHESTER DISEASE WITH BRAF V600 MUTATION

I-758 FOR USE WITH RILPIVIRINE AS A COMPLETE REGIMEN TO REPLACE THE CURRENT ARV REGIMEN IN ViroLOGICALLY SUPPRESSED PATIENTS ON A STABLE ARV REGIMEN FOR AT LEAST 6 MONTHS WITH NO HISTORY OF TX FAILURE OR KNOWN SUBSTITUTIONS ASSOC. WITH RESISTANCE TO EITHER ARV

I-759 TREATMENT OF ADULT PATIENTS WITH NEWLY-DIAGNOSED CHRONIC PHASE (CP) PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOGENOUS LEUKEMIA (PH+CML)

I-760 FOR THE TREATMENT OF PATIENTS WITH ADVANCED RENAL CELL CARCINOMA

I-761 TREATMENT OF ADULT PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE OR INTOLERANCE TO METHOTREXATE OR OTHER NON-BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS

I-762 TREATMENT OF DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE BRCA-MUTATED, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-NEGATIVE METASTATIC BREAST CANCER WHO HAVE BEEN TREATED WITH CHEMOTHERAPY IN THE NEOADJUVANT, ADJUVANT OR METASTATIC SETTING

I-763 TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER WHOSE TUMORS HAVE NON-RESISTANT EPIDERMAL GROWTH FACTOR RECEPTOR MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST

I-764 TREATMENT IN ADULT PATIENTS FOR IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C)

I-765 ABIRATERONE ACETATE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC HIGH-RISK CASTRATION-SENSITIVE PROSTATE CANCER

I-766 TREATMENT OF MINIMALLY TO MODERATELY THICK ACTINIC KERATOSIS OF THE UPPER...
EXCLUSIVITY INDICATION

I-767  TREATMENT OF IRON DEFICIENCY ANEMIA IN ADULT PATIENTS WHO HAVE INTOLERANCE TO ORAL IRON OR HAVE HAD UNSATISFACTORY RESPONSE TO ORAL IRON

I-768  IN COMBINATION WITH AN AROMATASE INHIBITOR AS INITIAL ENDOCRINE-BASED THERAPY FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER

I-769  TREATMENT OF DYSKINESIA IN PATIENTS WITH PARKINSON'S DISEASE RECEIVING LEVODOPA-BASED THERAPY, WITH OR WITHOUT CONCOMITANT DOPAMINERGIC MEDICATIONS

I-770  TREATMENT OF ACUTE OTITIS EXTERNA IN PATIENTS 6 MONTHS OF AGE AND OLDER DUE TO PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS

I-771  REVISION OF THE INDICATION SECTION OF THE PACKAGE INSERT REGARDING AN INTERSCALENE BRACHIAL PLEXUS NERVE BLOCK TO PRODUCE POSTSURGICAL REGIONAL ANALGESIA

I-772  FOR THE MAINTENANCE TREATMENT OF ADULT PATIENTS WITH RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER WHO ARE IN A COMPLETE OR PARTIAL RESPONSE TO PLATINUM-BASED CHEMOTHERAPY

I-773  FOR THE ADJUNCTIVE TREATMENT OF ADULT AND PEDIATRIC PATIENTS AGE 2 YEARS AND OLDER WITH TUBERCULOUS SCLEROSIS COMPLEX (TSC)-ASSOCIATED PARTIAL-ONSET SEIZURES

I-774  TO ALLOW FOR FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 (L858R) SUBSTITUTION MUTATIONS, AS DETECTED BY AN FDA APPROVED TEST

I-775  REVISED INDICATION FOR FIXED-DOSE COMBINATION OF FLUTICASONE FUROATE, UMECLIDINIUM, AND VILANTEROL TO TREAT AIRFLOW OBSTRUCTION IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AND TO REDUCE COPD EXACERBATIONS IN PTS WITH HISTORY OF EXACERBATIONS

I-776  FIRSTLINE MAINTENANCE TX IN PTS W/ DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE, SOMATIC BRCA-MUTATED ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CA WHO ARE IN COMPLETE OR PARTIAL RESPONSE TO FIRSTLINE PLATINUM-BASED CHEMOTHERAPY

I-777  CO-ADMINISTRATION THERAPY OF MIRABEGRON WITH SOLIFENACIN SUCINICATE FOR TREATMENT OF OVERACTIVE BLADDER WITH SYMPTOMS OF URGE URINARY INCONTINENCE, URGENCY, AND URINARY FREQUENCY

I-778  DABRAFENIB IN COMBINATION WITH TRAMETINIB FOR THE ADJUVANT TREATMENT OF PATIENTS WITH MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST, AND INVOLVEMENT OF LYMPH NODE(S), FOLLOWING COMPLETE RESECTION

I-779  USE OF TOLVAPTAN TO SLOW KIDNEY FUNCTION DECLINE IN ADULTS AT RISK OF RAPIDLY PROGRESSING AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)

I-780  TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC)

I-781  DABRAFENIB IN COMBINATION WITH TRAMETINIB FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC ANAPLASTIC THYROID CANCER (ATC) WITH BRAF V600E MUTATION AND WITH NO SATISFACTORY LOCOREGIONAL TREATMENT OPTIONS

I-782  REVISIONS TO INDICATION FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL), WITH OR WITHOUT 17P DELETION, WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

I-783  EXPANDED INDICATION TO INCLUDE RIBOCICLIB WITH AN AROMATASE INHIBITOR IN PRE/PERIMENOPAUSAL WOMEN WITH HORMONE RECEPTOR-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER, AS INITIAL ENDOCRINE-BASED THERAPY

I-784  RIBOCICLIB WITH FULVESTRANT FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HR-POSITIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER, AS INITIAL ENDOCRINE BASED THERAPY OR FOLLOWING DISEASE PROGRESSION ON ENDOCRINE THERAPY

I-785  TREATMENT OF PATIENTS WITH CUSHING'S DISEASE FOR WHOM PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE

I-786  TREATMENT OF PATIENTS WITH NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

I-787  FIRST-LINE TREATMENT OF PATIENTS WITH UNRESECTABLE HEPATOCellular CARCINOMA (HCC)

I-788  NEW INDICATION FOR CANAGLIFLOZIN TO REDUCE THE RISK OF MAJOR ADVERSE CARDIOVASCULAR EVENTS (CARDIOVASCULAR DEATH, NONFATAL MYOCARDIAL INFARCTION AND
EXCLUSIVITY INDICATION

I-789 VENETOCLAX IN COMBO WITH AZACITIDINE OR DECITABINE OR LOW-DOSE CYTARABINE FOR THE TX OF NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA IN ADULTS WHO ARE AGE 75 YEARS OR OLDER, OR WHO HAVE COMORBIDITIES THAT PRECLUDE USE OF INTENSIVE INDUCTION CHEMOTHERAPY

I-791 TREATMENT OF PEDIATRIC PATIENTS ONE YEAR OF AGE AND OLDER WITH NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME-POSITIVE (PH+) ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN COMBINATION WITH CHEMOTHERAPY

EXCLUSIVITY MISCELLANEOUS

M-1 INFORMATION REGARDING SUPERIORITY CLAIM OVER RANITIDINE FOR DAY AND NIGHT HEARTBURN ADDED TO CLINICAL STUDIES SECTION

M-2 APPROVAL FOR ADDITION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE

M-3 ADDITION OF EFFICACY AND SAFETY INFORMATION IN WHICH FOSAMAX WAS USED CONCOMITANTLY WITH ESTROGEN ALONE OR WITH ESTROGEN PLUS PROGESTIN

M-4 CHANGES TO PEDIATRIC USE SECTION TO PROVIDE INFORMATION REGARDING SAFETY AND EFFICACY IN PEDIATRIC PATIENTS AS YOUNG AS 2 YEARS OLD

M-5 INFORMATION REGARDING EFFECTS IN PATIENTS WITH ASTHMA ON CONCOMITANT INHALED CORTICOSTEROIDS IN CLINICAL PHARMACOLOGY SECTION

M-6 ADDITIONAL INFORMATION REGARDING CLINICAL STUDIES DONE WITH GLUCOPHAGE/GLYBURIDE COMBINATION ADDED TO CLINICAL PHARMACOLOGY AND DOSING AND ADMINISTRATION

M-7 CLINICAL PHARMACOLOGY IN PEDIATRIC PATIENTS; DOSAGE AND ADMINISTRATION INFORMATION

M-8 ADDITIONAL INFORMATION FOR THE USE OF SONATA CAPSULES FOR UP TO 5 WEEKS (35 NIGHTS) OF TREATMENT IN A CONTROLLED TRIAL SETTING

M-9 ADDITION TO THE CLINICAL STUDIES SECTION OF THE LABELING OF TEXT AND TWO TABLES CONTAINING INFORMATION FOR THE PRESCRIBING PHYSICIAN ON BLOOD PRESSURE, HEART RATE, AND HEART RATE VARIABILITY

M-10 INFORMATION REGARDING MAINTENANCE OF AN ANTIDEPRESSANT EFFECT UP TO 1 YEAR OF DOSING

M-11 USE FOR LONG-TERM TREATMENT OF POSTTRAUMATIC STRESS DISORDER

M-12 NEW LANGUAGE FOR PEDIATRIC USE

M-13 INFORMATION FROM PEDIATRIC STUDIES ADDED TO CLINICAL PHARMACOLOGY, PRECAUTIONS, AND DOSAGE AND ADMINISTRATION

M-14 ADDITIONAL CLINICAL TRIAL INFORMATION ADDED TO PEDIATRIC USE SUBSECTION

M-15 LONGER TERM EFFICACY INFORMATION FOR RISPERIDONE IN THE TREATMENT OF SCHIZOPHRENIA

M-16 CHANGE IN WORDING OF THE PEDIATRIC SECTION OF THE PACKAGE INSERT

M-17 INFORMATION REGARDING USE OF ULTANE IN PEDIATRIC PATIENTS WITH CONGENITAL HEART DISEASE

M-18 INFORMATION DENOTING THE EFFICACY OF REMERON IN MAINTAINING A RESPONSE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD)

M-19 INFORMATION REGARDING USE IN PEDIATRIC PATIENTS TWO YEARS OF AGE AND OLDER

M-20 LABELING REVISIONS RELATED TO MCCUNE ALBRIGHT SYNDROME

M-21 COMPARISON DATA ON THE ANTIHYPERTENSIVE EFFECTS OF ATACAND AND COZAAR

M-22 CHANGE IN TIME TO ONSET OF ACTION

M-23 INFORMATION REGARDING ELIMINATION ADDED TO CLINICAL PHARMACOLOGY, STUDY RESULTS IN PATIENTS WITH HEPATIC AND RENAL IMPAIRMENT

M-24 INFORMATION ON RESULTS OF A LONG TERM LONGITUDINAL GROWTH STUDY AND PEDIATRIC SAFETY INFORMATION

M-25 ADDITIONAL SAFETY AND PHARMACOKINETICS INFORMATION IN CHILDREN 6 MONTHS TO LESS THAN 6 YEARS OF AGE ADDED TO PACKAGE INSERT
EXCLUSIVITY MISCELLANEOUS

M-26 INTEGRATION OF INFORMATION CONTAINED IN THE PEG-INTRON PACKAGE INSERT INTO THE REBETOL PACKAGE INSERT AND MEDGUIDE-PEG-INTRON WAS APPROVED FOR USE IN COMBINATION WITH REBETOL FOR TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION ON 8/7/01

M-27 INFORMATION DESCRIBING ASPIRIN ENDOSCOPY STUDY AND THE MAXIMUM RECOMMENDED DOSE FOR PATIENTS WITH MODERATE HEPATIC INSUFFICIENCY

M-28 INFORMATION FROM A STUDY IN PEDIATRIC PATIENTS IN ASSOCIATION WITH A NEUROLOGICAL CONDITION

M-29 LABELING CHANGES TO PROVIDE INFORMATION IN THE MANAGEMENT OF OBESITY IN ADOLESCENTS AGED 12 TO 16 YEARS

M-30 CHANGES TO CLINICAL PHARMACOLOGY, PRECAUTIONS, AND DOSAGE AND ADMINISTRATION SECTIONS OF LABELING CONCERNING USE OF LOTENSIN IN PEDIATRIC PATIENTS WITH HYPERTENSION

M-31 INFORMATION FOR USE IN PEDIATRIC PATIENTS WITH CHRONIC KIDNEY DISEASE STAGE 5 (END-STAGE RENAL DISEASE)

M-32 ADDITIONAL LANGUAGE TO CLINICAL PHARMACOLOGY AND CLINICAL STUDIES

M-33 INFORMATION FOR USE OF ADVAIR DISKUS 100/50 IN CHILDREN 4 TO 11 YEARS OF AGE WITH ASTHMA

M-34 EXPANDED INFORMATION TO PEDIATRIC USE SUBSECTION OF LABELING IN RESPONSE TO PEDIATRIC WRITTEN REQUEST

M-35 ADDITIONAL INFORMATION REGARDING CLINICAL STUDIES DONE WITH ACTOS IN COMBINATION WITH METFORMIN, A SULFONYLUREA, OR INSULIN ADDED TO CLINICAL PHARMACOLOGY

M-36 ADDITION OF INFORMATION TO CLINICAL STUDIES REGARDING PREVENTION OF CARDIOVASCULAR DISEASE

M-37 INFORMATION ADDED TO THE LABELING THAT DETAILS INFORMATION RELATIVE TO STUDIES DONE IN PEDIATRIC POPULATIONS IN THE CLINICAL PHARMACOLOGY AND PEDIATRIC USE SUBSECTIONS

M-38 SAFETY AND IOP-LOWERING EFFECTS OF TRUSOPT HAVE BEEN DEMONSTRATED IN PEDIATRIC PATIENTS IN A 3 MONTH, MULTI-CENTER DOUBLE MASKED ACTIVE-TREATMENT-CONTROLLED TRIAL

M-39 FOR LABELING CHANGES BASED ON RESULTS OF THE SPD422-202 CLINICAL STUDY REPORT (CSR) SUBMITTED IN RESPONSE TO THE WRITTEN REQUEST

M-40 ADDITIONAL INFORMATION REGARDING CLINICAL STUDIES PERFORMED IN PEDIATRIC PATIENTS WITH LEUKEMIA ADDED TO PRECAUTIONS

M-41 REVISION TO THE PEDIATRIC USE PRECAUTIONS OF THE PRESCRIBING INFORMATION TO INCORPORATE THE RESULTS FROM THE CAPPS-169 STUDY ENTITLED "THE EFFECT OF ORTHO TRICYCLEN ON BONE MINERAL DENSITY IN PEDIATRIC SUBJECTS WITH ANOREXIA NERVOSA"

M-42 ADDITION OF A GERIATRIC USE SUBSECTION TO THE PRECAUTIONS SECTION OF THE PACKAGE INSERT AND GERIATRIC DOSING INFORMATION

M-43 INCLUSION OF RESULTS OF STUDY "PLACEBO-CONTROLLED STUDY TO EVALUATE SAFETY AND PILOT EFFICACY OF ILOPROST AS ADD ON THERAPY WITH BOSEN TAN IN SUBJECTS WITH PULMONARY ARTERIAL HYPERTENSION"

M-44 CLINICAL INFORMATION ADDED TO THE PEDIATRIC USE SUBSECTION OF PRECAUTIONS REGARDING THE USE OF NOVOLOG IN ADOLESCENTS WITH TYPE 1 DIABETES AGE 6 TO 18

M-45 INFORMATION ADDED TO CLINICAL TRIALS SECTION OF LABELING, "EFFECTS OF HUMATROPE TREATMENT IN ADULTS WITH GROWTH HORMONE DEFICIENCY"

M-46 PROVISION OF RESULTS OF STUDY AND PROPOSED REVISIONS TO PACKAGE INSERT SEE SECTION ON CARDIAC ELECTROPHYSIOLOGY

M-47 PROVIDES FOR USE OF ANTARA WITHOUT REGARD TO MEALS

M-48 CHANGES TO THE LABELING DESCRIBING THE RESULTS OF A STUDY OF THE USE OF NOVOLOG MIX 70/30 WITH ORAL ANTIDIABETIC AGENTS IN PATIENTS WITH TYPE 2 DIABETES

M-49 CLINICAL DATA ADDED TO THE CLINICAL PHARMACOLOGY SECTION REGARDING EFFECT OF SINGULAIR ON GROWTH RATES IN PREPUBERTAL CHILDREN

M-50 NEW INFO TO THE CLINICAL STUDIES, ADULT GROWTH HORMONE DEFICIENCY (GHD) SUBSECTION OF THE NUTROPIN AQ PACKAGE INSERT DESCRIBING THE EFFECTS OF SOMATROPIN ON VISUAL ADIPOSE TISSUE IN THE ADULT GROWTH HORMONE DEFICIENT PATIENT POPULATION

M-51 INFORMATION ADDED TO LABELING REGARDING OSTEOGENESIS IMPERFECTA STUDY
M-52 INFORMATION ADDED TO THE CLINICAL PHARMACOLOGY/CLINICAL STUDIES SECTION REGARDING THE USE OF RISEDRONATE ADMINISTERED ONCE A WEEK IN THE PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN

M-53 FOR LABELING CHANGES TO THE QUALITY OF LIFE (QOL) STATEMENT IN THE APPROVED PACKAGE INSERT

M-54 INFORMATION FROM PEDIATRIC STUDIES ADDED TO LABEL

M-55 INFORMATION ON RESULTS OF A STUDY OF THE USE OF SANDOSTATIN LAR DEPOT IN PEDIATRIC PATIENTS WITH HYPOTHALAMIC OBESITY.

M-56 INFORMATION ADDED TO CLINICAL TRIAL SECTION WITH INFORMATION ON "GEMINI" TRIAL

M-57 CLINICAL DATA ADDED TO THE CLINICAL PHARMACOLOGY SECTION REGARDING THE PHARMACOKINETICS OF EZETIMIBE IN ASIAN SUBJECTS

M-58 CHANGES TO THE CLINICAL STUDIES, PRIMARY HYPERCHOLESTEROLEMIA, VYTORIN SUBSECTION OF THE PACKAGE INSERT TO ADD EFFICACY DATA FOR THE EZETIMIBE/SIMVASTATIN COMBINATION PRODUCT AND FOR AN ATORVASTATIN PRODUCT ON LDL-C AND OTHER LIPID PRMTRS

M-59 RESULTS OF THE T20-310 STUDY WHICH EVALUATED THE PHARMACOKINETICS, SAFETY, AND ANTIVIRAL ACTIVITY OF FUZEON IN TREATMENT EXPERIENCED PATIENTS AND ADOLESCENTS WAS ADDED TO THE PEDIATRIC SUBSECTION OF PRECAUTIONS

M-60 CHANGES TO CLINICAL STUDIES, PRIMARY HYPERCHOLESTEROLEMIA, TO ADD EFFICACY DATA FOR THE EZETIMIBE/SIMVASTATIN COMBINATION PRODUCT AND FOR A ROSUVASTATIN PRODUCT ON LDL-C AND OTHER LIPID PARAMETERS IN PATIENTS WITH HYPERCHOLESTEROLEMA

M-61 REVISIONS TO LABELING BASED ON DATA SUBMITTED IN RESPONSE TO PEDIATRIC WRITTEN REQUEST

M-62 CLINICAL INFORMATION FROM ONE CLINICAL STUDY INVESTIGATING THE USE OF AVANDAMET PLUS INSULIN IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WHO HAVE NOT ACHIEVED ADEQUATE GLYCEMIC CONTROL WITH PREVIOUS ANTI-DIABETIC THERAPIES

M-63 DETAILED INFORMATION ON AN INCONCLUSIVE PEDIATRIC STUDY

M-64 CHANGES TO CLINICAL PHARMACOLOGY DETAILING STUDY RESULTS

M-65 ADDITION OF INFORMATION TO LABEL TO INCLUDE INFORMATION REGARDING USE IN PATIENTS WITH HIV-ASSOCIATED ADIPOSE REDISTRIBUTION SYNDROME (HARS)

M-66 USE IN SPECIFIC POPULATIONS - PATIENTS WITH CONCOMITANT ILLNESS SUBSECTION OF THE LABELING REGARDING USE OF STRATTERA IN PATIENTS WITH ADHD WHO HAVE COMORBID DISORDER

M-67 INDICATION EXPANDED TO INCLUDE PATIENTS ON PERITONEAL DIALYSIS

M-68 DESCRIPTION OF RESULTS OF STUDY OF INITIAL THERAPY IN COMBINATION WITH METFORMIN WHEN DIET AND EXERCISE DO NOT PROVIDE GLYCEMIC CONTROL

M-69 RESULTS OF STUDY OF COMBINATION THERAPY AND NON-INFERIORITY STUDY

M-70 PROVISION OF INFORMATION OF THE RESULTS OF A PHASE 2 RANDOMIZED TRIAL OF SPRYCEL 70MG TWICE DAILY OR IMATINIB 800MG DAILY

M-71 REVISIONS TO PROVIDE FOR RESULTS OF MAINTENANCE DATA IN ADULT PATIENTS WITH MAJOR DEPRESSIVE DISORDER

M-72 INFORMATION ABOUT USE OF INSPIRA (EPLERENONE) FOR HYPERTENSION IN PEDIATRIC PATIENTS

M-73 NEW INFORMATION ADDED REGARDING THE TUMOR SHRINKING POTENTIAL OF SANDOSTATIN LAR DEPOT INJECTION ON GH - SECRETING PITUITARY ADENOMAS

M-74 REVISIONS TO CLINICAL STUDIES - CHILDREN AND ADOLESCENTS BASED ON CLINICAL TRIAL DATA TO SUPPORT A DURATION OF ACTION CLAIM UP TO 12 HOURS

M-75 PROVISION FOR USE OF ARGATROBAN IN CERTAIN PEDIATRIC PATIENTS WITH HEPARIN-INDUCED THROMBOCYTOPENIA (HIT) OR HEPARIN-INDUCED THROMBOCYTOPENIA WITH THROMBOSIS (HITTS)

M-76 REMOVAL OF SCREEN REQUIREMENT IN PTS WITH G6PD DEFICIENCY PRIOR TO INITIATING ACZONE TREATMENT; REMOVAL OF BLOOD COUNT & RETICULOCYTE MONITORING DURING TREATMENT IN G6PD DEFICIENT PTS AND IN PATIENTS WITH HISTORY OF ANEMIA

M-77 USE IN COMBINATION WITH THE NEW AKTILITE CLI128 LAMP FOR THE TREATMENT OF THIN AND MODERATELY THICK, NON-HYPERKERATOTIC, NON-PIGMENTED ACTINIC KERATOSES OF THE FACE AND SCALP IN IMMUNOCOMPETENT PATIENTS

M-78 CLINICAL TRIAL INFO ON USE OF STRATTERA IN PATIENTS WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) AND COMORBID ANXIETY DISORDER WITHOUT CAUSING
WORSERING OF ANXIETY

M-79 LABELING REVISIONS RELATED TO SMOKING AND ERLOTINIB EXPOSURE

M-80 ADDITIONAL TIME POINT OF 30 MINUTES (0.5 HOUR) IN CHILDREN AGED 6-12 YEARS WITH A DIAGNOSIS OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER (ADHD)

M-81 ADDITIONAL INFO FOR PEDIATRIC USE FOR CASODEX (STUDIED IN COMBINATION WITH ARIMIDEX) IN THE PEDIATRIC POPULATION, SPECIFICALLY BOYS WITH FAMILIAL MALE-LIMITED PRECOCIOUS PUBERTY (TESTOTOXICOSIS)

M-82 LABELING REVISIONS RELATED TO CLINICAL STUDIES

M-83 ADDITIONAL INFORMATION ADDED TO LABELING REGARDING ESTABLISHMENT OF EFFICACY IN ADDITIONAL CLINICAL TRIALS AND ONE MAINTENANCE TRIAL

M-84 STUDY INFORMATION ADDED TO LABEL REGARDING USE OF PREVACID IN PATIENTS LESS THAN 1 YEAR WITH SYMPTOMATIC GERD

M-85 LABELING CHANGES SUBMITTED IN RESPONSE TO PEDIATRIC WRITTEN REQUEST FOR INFANTS AGES BIRTH TO 11 MONTH INCLUSIVE REFLECTING LACK OF EFFICACY FOR GERD INDICATION FOR THIS PATIENT POPULATION

M-86 INCLUSION OF RESULTS FROM TWO DRUG INTERACTION STUDIES WITH LIPITOR AND CRESTOR IN CLINICAL PHARMACOLOGY SECTION

M-87 ADDITION OF INFORMATION REGARDING ABUSE POTENTIAL OF CONCERTA VERSUS IMMEDIATE-RELEASE METHYLPHENIDATE

M-88 PROVIDES FOR REVISIONS TO MULTIPLE SECTIONS OF THE PACKAGE INSERT TO REFLECT RESULTS OF CLINICAL TRIALS 205.235 (UPLIFT) AND 205.266 (VA STUDY) IN SUPPORT OF EXACERBATION CLAIM

M-89 STUDY INFORMATION ADDED TO LABEL REGARDING USE OF PREVACID IN PATIENTS LESS THAN 1 YEAR WITH SYMPTOMATIC GERD

M-90 LABELING CHANGES BASED ON DATA FROM CLINICAL STUDIES NV20235 AND NV20236 STUDIES OF SEASONAL PROPHYLAXIS OF INFLUENZA IN IMMUNOCOMPROMISED PATIENTS AND CHILDREN AGES 1-12

M-91 UPDATED LABELING BASED UPON STUDY: A SINGLE-DOSE, SINGLE-BLIND, PLACEBO-AND MOXIFLOXACIN-CONTROLLED 2-PERIOD, RANDOMIZED, CROSSOVER, 3RD PERIOD SEQUENTIAL STUDY OF SIDE EFFECTS OF TEMSIROLIMUS ON CARDIAC REPOLARIZATION IN HEALTHY SUBJECTS

M-92 UPDATES TO THE PACKAGE INSERT BASED UPON THE TRIAL ENTITLED "A PHASE I PHARMACOKINETIC AND PHARMACODYNAMIC STUDY OF TEMSIROLIMUS IN PATIENTS WITH ADVANCED MALIGNANCIES AND NORMAL AND IMPAIRED LIVER FUNCTION"

M-93 EXPANSION OF LABELING TO INCLUDE INFORMATION ON SAFETY AND EFFICACY OF CREON IN PATIENTS AGES 7 YEARS THROUGH 11 YEARS WITH PANCREATIC EXOCRINE INSUFFICIENCY DUE TO CYSTIC FIBROSIS

M-94 INFO ADDED TO LABEL RELATED TO NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME POSITIVE (PH+) CHRONIC MYELOID LEUKEMIA IC CHRONIC PHASE

M-95 INFORMATION FOR TREATMENT OF CHRONIC HEPATITIS B (CHB) IN ADULT PATIENTS WITH DECOMPENSATED LIVER DISEASE BASED ON DATA FROM CLINICAL TRIAL GS-US-174-0108

M-96 UPDATED INFORMATION IN THE CLINICAL STUDIES SECTION RELATED TO THE LOSS AND RECOVERY OF BONE MINERAL DENSITY IN ADOLESCENT GIRLS DURING AND FOLLOWING THE USE OF DEPO-PROVERA CONTRACEPTIVE INJECTION

M-97 LABELING CHANGES IN RESPONSE TO PEDIATRIC STUDIES - NOT INDICATED FOR USE IN PEDIATRIC POPULATION

M-98 NEW INFORMATION FROM A STUDY WHICH EVALUATED THE SAFETY AND EFFICACY OF FAMVIR IN TREATING RECURRENT GENITAL HERPES IN IMMUNOCOMPETENT BLACK/AFRICAN AMERICAN SUBJECTS.

M-99 ADDITION OF FINDINGS FROM A SINGLE PEDIATRIC CLINICAL TRIAL (P04292) OF NASONEX NASAL SPRAY IN THE TREATMENT OF NASAL POLYPS IN PATIENTS 6 TO <18 YEARS OF AGE TO THE PACKAGE INSERT.

M-100 INFORMATION ADDED TO LABEL BASED UPON COMPLETED CLINICAL TRIAL REPORTS

M-101 INCLUSION OF DATA FROM AN ADDITIONAL 19 SUBJECTS WITH HYPERCALCEMIA FROM PARATHYROID CARCINOMA TO THE INFORMATION CURRENTLY PRESENTED IN THE LABEL

M-102 INFORMATION FROM PEDIATRIC STUDY REPORT ML16633, "INTRAVENOUS GRANISTRON (KYTRIL) IN THE PREVENTION OF POST-OPERATIVE NAUSEA AND VOMITING (PONV) IN PEDIATRIC SUBJECTS UNDERGOING TONSILLECTOMY OR ADENOTONSILLECTOMY."

M-103 SAFETY, EFFICACY AND PHARMACOKINETIC INFO FOR FASLODEX IN THE PEDIATRIC
EXCLUSIVITY MISCALLORED

POPULATION, SPECIFICALLY FOR GIRLS WITH PROGRESSIVE PRECOCIOUS PUBERTY ASSOCIATED WITH MCCUNE-ALBRIGHT SYNDROME ADDED TO THE PEDIATRIC USE SECTION OF THE LABELING

M-104 INFORMATION ADDED TO DOSING AND ADMINISTRATION REGARDING A 26 WEEK STUDY

M-105 NEW LANGUAGE ADDED TO CLINICAL STUDIES REGARDING USE IN SMOKERS WITH CARDIOVASCULAR DISEASE, CHRONIC OBSTRUCTIVE PULMONARY DISEASE, AND USE ACCORDING TO AN ALTERNATIVE SET OF DIRECTIONS FOR SETTING A QUIT DATE

M-106 ADDITION OF THE T1-WEIGHTED GD-ENHANCED LESION EFFICACY VARIABLE IN THE CLINICAL STUDIES SECTION 14 OF THE PACKAGE INSERT

M-107 INFORMATION TO THE CLINICAL STUDIES SECTION OF THE LUPRON DEPOT-PED 1-MONTH BASED UPON THE PHASE 3/4 COMPLETED CLINICAL STUDY REPORT FOR STUDY M90-516 ENTITLED "STUDY OF LUPRON DEPOT IN THE TREATMENT OF CENTRAL PRECOCIOUS PUBERTY".

M-108 CHANGES ARE BASED ON RESULTS FROM STUDY CV181057

M-109 CHANGES TO THE PACKAGE INSERT TO REFLECT THE RESULTS OF THE STUDY OF HEART AND RENAL PROTECTION (SHARP) TRIAL

M-110 CHANGES TO THE PACKAGE INSERT TO REFLECT THE RESULTS OF THE STUDY OF HEART AND RENAL PROTECTION (SHARP) TRIAL

M-111 LABELING CHANGES BASED ON STUDY H80-EM-GWCI ENTITLED A PLACEBO AND POSITIVE CONTROLLED STUDY OF THE ELECTROPHYSIOLOGICAL EFFECTS OF A SINGLE 10 MCG DOSE OF EXENATIDE ON THE 12 LEAD ELECTROCARDIOGRAM QT INTERVAL IN HEALTHY SUBJECTS

M-112 REVISIONS TO THE PEDIATRIC USE SECTION OF THE PACKAGE INSERT TO ADD INFORMATION FROM A PEDIATRIC STUDY IN PATIENTS AGED 12 YEARS TO LESS THAN 18 YEARS OF AGE WITH RECURRENT HERPES LABIALIS

M-113 LABELING CHANGES BASED ON STUDY H80-US-GWCO ENTITLED A RANDOMIZED TRIAL COMPARING EXENATIDE WITH PLACEBO IN SUBJECTS WITH TYPE 2 DIABETES ON INSULIN GLARGINE WITH OR WITHOUT ORAL ANTIDIABETIC MEDICATIONS

M-114 CHANGES IN SECTION 14 OF THE PACKAGE INSERT TO INCLUDE DATA FROM THE SWITCHMRK STUDIES (SWITCH OF SUPPRESSED SUBJECTS FROM LOPINAVIR/RTV TO RALTEGRAVIR)

M-115 REVISIONS TO THE PI BASED ON RESULTS FROM STUDY NN2211-1842, ENTITLED THE EFFECT OF INSULIN DETEMIR IN COMBINATION WITH LIRAGLUTIDE AND METFORMIN COMPARED TO LIRAGLUTIDE AND METFORMIN IN SUBJECTS WITH TYPE 2 DIABETES

M-116 LABELING CHANGES BASED ON RESULTS FROM CLINICAL STUDY 01-06-TL-OPIMET-008

M-117 ADDITION OF RESULTS OF PEDIATRIC TRIAL TO LABEL

M-118 LABELING CHANGES BASED UPON SAFETY AND EFFICACY RESULTS FROM TRIAL 1218.36

M-119 LABELING CHANGES REGARDING MISSED DOSES

M-120 CHANGES TO CLINICAL TRIALS DETAILING STUDY RESULTS

M-121 LABELING CHANGES BASED UPON SAFETY AND EFFICACY RESULTS FROM TRIAL 1218.43

M-122 LABELING CHANGES TO INCLUDE THE RESULTS OF THE PARAMOUNT TRIAL

M-123 UPDATED RESULTS OF CLINICAL TRIALS DETAILING STUDY RESULTS

M-124 NEW LANGUAGE ADDED TO CLINICAL STUDIES REGARDING USE IN SMOKERS WITH CARDIOVASCULAR DISEASE, CHRONIC OBSTRUCTIVE PULMONARY DISEASE, AND USE ACCORDING TO AN ALTERNATIVE SET OF DIRECTIONS FOR SETTING A QUIT DATE

M-125 LABELING CHANGES TO INCLUDE LACK OF EFFICACY IN CHILDREN 6 MONTHS TO 4 YEARS OF AGE

M-126 ADDITION OF INFORMATION ON LONG-TERM TREATMENT WITH VPRIV IN THE CLINICAL TRIALS SECTION OF THE PACKAGE INSERT

M-127 INFORMATION FROM STUDIES CONDUCTED IN PEDIATRIC PATIENTS WITH NEWLY DIAGNOSED NON-DISSEMINATED DIFFUSED INTRINSIC BRAINSTEM GLIOMAS

M-128 REVISIONS TO THE CLINICAL TRIALS SECTION IN THE INOMAX LABEL TO REFLECT RESULTS
EXCLUSIVITY MISCELLANEOUS

M-133 INFORMATION ADDED TO THE LABELING REGARDING THE ADDITION OF SILDENAFIL TO BOSENTAN THERAPY

M-134 ADDITIONAL INFORMATION REGARDING CLINICAL STUDIES PERFORMED WITH SAXAGLIPTIN IN COMBINATION WITH METFORMIN AND A SULFONYLUREA ADDED TO THE LABELING

M-135 ADDITION OF INFORMATION TO THE CLINICAL STUDIES - RADIOGRAPHIC RESPONSE SECTION OF THE PACKAGE INSERT

M-136 ADDITIONAL INFORMATION ADDED TO THE USE IN SPECIFIC POPULATIONS SECTION OF THE LABELING REGARDING POST-OPERATIVE NAUSEA AND VOMITING STUDIES IN PEDIATRIC PATIENTS

M-137 LABELING REVISIONS RESULTING FROM A MAINTENANCE TRIAL IN PEDIATRIC PATIENTS WITH IRRITABILITY ASSOCIATED WITH AUTISTIC DISORDER

M-138 INFORMATION ADDED TO THE 8.4 PEDIATRIC USE SECTION ON THE USE OF MEMANTINE IN CHILDREN AGES 6-12 YEARS WITH AUTISM SPECTRUM DISORDER

M-139 INFORMATION ADDED TO THE DOSING AND ADMINISTRATION SECTION OF THE PACKAGE INSERT REGARDING RETREATMENT WITH VELCADE FOR PATIENTS WITH MULTIPLE MYELOMA

M-140 INFORMATION ADDED TO THE PEDIATRIC USE SECTION OF THE LABELING REGARDING USE OF LATISSE IN PATIENTS WHO WERE POST-CHEMOTHERAPY OR HAD ALOPECIA AREATA, AND ADOLESCENTS WHO HAD HYPERTRICHOSIS WITH NO ASSOCIATED MEDICAL CONDITION

M-141 REVISIONS TO THE PEDIATRIC USE SECTION OF THE LABELING TO INCORPORATE STUDY RESULTS FOR TREATMENT OF MAJOR DEPRESSIVE DISORDER IN ADOLESCENTS (AGES 12-17)

M-142 ADDITIONS TO THE LABELING DESCRIBING RESULTS FROM STUDY H6P-MC-HDAY

M-143 INFORMATION ADDED TO THE LABELING REGARDING THE SAFETY AND EFFICACY OF VARENICLINE FOR SMOKING CESSATION IN PATIENTS WITH CURRENT OR PAST HISTORY OF MAJOR DEPRESSIVE DISORDER

M-144 INFORMATION ADDED TO THE LABELING REGARDING THE SAFETY AND EFFICACY OF VARENICLINE FOR SMOKING CESSATION IN PATIENTS WHO HAD BEEN PREVIOUSLY TREATED WITH VARENICLINE

M-145 ADDITION OF INFORMATION ABOUT LONG-TERM TREATMENT OF PULMONARY ARTERIAL HYPERTENSION TO THE CLINICAL STUDIES SECTION OF THE LABELING

M-146 INFORMATION ADDED TO THE CLINICAL STUDIES SECTION ON INITIAL COMBINATION THERAPY WITH LINAGLIPTIN AND METFORMIN VS. LINAGLIPTIN MONOTHERAPY IN TREATMENT NAIVE PATIENTS

M-147 OTC USE FOR TEMPORARY RELIEF OF OCULAR SYMPTOMS DUE TO HAY FEVER OR OTHER UPPER RESPIRATORY ALLERGIES

M-148 LABELING CHANGES BASED ON STUDY H80-EW-GWDM

M-149 INFORMATION ADDED TO THE LABELING REGARDING MAINTENANCE MONOTHERAPY FOR ADHD

M-150 ADDITION OF THE RESULTS OF A CONTROLLED CLINICAL STUDY TREATING ADULT PATIENTS WITH SCHIZOPHRENIA EXPERIENCING AN ACUTE RELAPSE

M-151 REVISIONS TO THE LABELING BASED ON THE OUTCOMES OF PEDIATRIC STUDIES CONDUCTED TO ASSESS THE SAFETY AND EFFICACY OF XOPENEX IN SUBJECTS LESS THAN 6 YEARS OF AGE

M-152 INFORMATION ADDED TO THE CLINICAL PHARMACOLOGY SECTION OF THE LABELING REGARDING A SAFETY STUDY IN PEDIATRIC SUBJECTS AGES 6 MONTHS TO 4 YEARS OF AGE WITH AN ACTIVE HEAD LICE INFESTATION

M-153 ADDITION OF INFORMATION REGARDING THE INTRANASAL ABUSE POTENTIAL OF OXYCONTIN

M-154 UPDATE TO THE LABELING TO REFLECT THE RESULTS OF A LONG-TERM MAINTENANCE TREATMENT STUDY OF ADHD IN CHILDREN AND ADOLESCENTS AGES 6-17.

M-155 ADDITION OF CLINICAL FINDINGS FROM AN OBSERVATIONAL STUDY IN A PEDIATRIC AGE GROUP GREATER THAN 2 MONTHS TO 18 YEARS IN SECTION 8.4 PEDIATRIC USE OF THE PACKAGE INSERT

M-156 UPDATE TO THE LABELING WITH INFORMATION REGARDING A CLINICAL TRIAL IN CHILDREN LESS THAN 4 YEARS OF AGE.

M-157 INFORMATION ADDED TO THE LABELING REGARDING THE SAFETY AND EFFICACY OF DAPAGLIFLOZIN 10MG ONCE DAILY IN PATIENTS WITH TYPE 2 DIABETES WHO HAVE INADEQUATE GLYCEMIC CONTROL ON A BACKGROUND COMBINATION OF METFORMIN AND SULFONYLUREA
M-158 UPDATES TO THE LABELING TO REFLECT SAFETY RESULTS FROM CLINICAL TRIALS IN SCHIZOPHRENIA ADOLESCENT PATIENTS AGED 12 TO 17 YEARS

M-159 ADDITION OF PED SAFETY INFORMATION DERIVED FROM A MAINTENANCE TREATMENT STUDY OF BIPOLAR 1 DISORDER TO DELAY THE TIME TO OCCURRENCE OF MOOD EPISODES IN PATIENTS (> THAN OR = TO 13 YRS OF AGE) TREATED FOR ACUTE MOOD EPISODES WITH STANDARD THERAPY

M-160 UPDATED LABELING WITH DATA FROM A RANDOMIZED, DOUBLE-BLIND ACTIVE-CONTROLLED STUDY COMPARING EMPAGLIFLOZIN TO GLIMEPIRIDE IN PATIENTS WITH TYPE 2 DIABETES AND INSUFFICIENT GLYCEMIC CONTROL DESPITE METFORMIN TREATMENT

M-161 UPDATED LABELING WITH DATA FROM A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF EMPAGLIFLOZIN IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND INSUFFICIENT GLYCEMIC CONTROL ON A MULTIPLE DAILY INJECTION INSULIN REGIMEN ALONE OR WITH METFORMIN

M-162 INCLUSION OF EFFICACY AND SAFETY DATA TO THE PRESCRIBING INFORMATION OF BYDUREON BASED ON STUDY GDWE

M-163 INFORMATION ADDED TO THE LABELING REGARDING PREVIOUSLY UNTREATED ALK-POSITIVE METASTATIC NON SMALL CELL LUNG CANCER (NSCLC)

M-164 REVISES THE CLINICAL TRIALS SECTION OF THE PRESCRIBING INFORMATION TO INCORPORATE THE RESULTS FROM STUDY E7273-G000-601 ENTITLED "PHASE IV RANDOMIZED STUDY OF TWO DOSE LEVELS OF TARGRETIN CAPSULES IN SUBJECTS WITH REFRACTORY CUTANEOUS T-CELL LYMPHOMA"

M-165 PROVIDES FOR UPDATES TO THE PEDIATRIC USE SECTION BASED ON THE PEDIATRIC STUDY REPORT ENTITLED, "A PHASE II PILOT TRIAL OF BORTEZOMIB IN COMBINATION WITH INTENSIVE RE-INDUCTION THERAPY IN CHILDREN WITH RELAPSED ACUTE LYMPHOBLASTIC LYMPHOMA (LL)"

M-166 UPDATE TO LABELING WITH WEEK 48 RESULTS FROM VIKING-4 IN ANTIRETROVIRAL THERAPY (ART) - EXPERIENCED INTEGRASE STRAND TRANSFER INHIBITOR (INSTI) - RESISTANT SUBJECTS

M-167 APPROVED FOR REVISIONS TO THE LABELING BASED ON THE CLINICAL STUDY ENTITLED "BRONCHOPULMONARY DYSPLASIA (BPD) IN PRETERM INFANTS REQUIRING MECHANICAL VENTILATION OR POSITIVE PRESSURE SUPPORT ON DAYS 5 TO 14 AFTER BIRTH".

M-168 INFORMATION ADDED TO THE CLINICAL STUDIES SECTION OF THE LABELING REGARDING THE RE-NOVATE AND RE-NOVATE LL STUDIES (PROPHYLAXIS OF DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM FOLLOWING HIP REPLACEMENT SURGERY)

M-169 UPDATES TO LABELING DESCRIBING RESPONSE TO A REPEAT COURSE OF PICATO GEL 0.015% ON THE FACE OR SCALP IF AN INCOMPLETE RESPONSE IS OBSERVED AT A FOLLOW-UP EXAMINATION.

M-170 INFORMATION ADDED TO THE CLINICAL STUDIES SECTION REGARDING USE FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST

M-171 UPDATES TO LABELING WITH RESULTS TO THE TIGER CLINICAL TRIAL

M-172 UPDATES TO THE CLINICAL TRIALS SECTION OF THE LABELING TO INCLUDE RESULTS OF STUDIES PERFORMED TO EVALUATE THE BENEFIT OF ADDING INCruise ELLIPTA TO PATIENTS WHO ARE ON BACKGROUND THERAPY WITH BREO ELLIPTA AND ADVAIR DISKUS

M-173 INFORMATION ADDED TO THE CLINICAL STUDIES SECTION OF THE LABELING DESCRIBING THE EFFECTS OF STIOLTO RESPIMAT ON COPD PATIENTS

M-174 INFORMATION ADDED TO CLINICAL STUDIES SECTION OF THE LABELING REGARDING INITIAL COMBINATION THERAPY OF EMPAGLIFLOZIN WITH METFORMIN

M-175 INFORMATION ADDED TO THE LABELING DESCRIBING SAVOR, A PHASE IV TRIAL EVALUATING THE EFFECT OF SAXAGLIPTIN ON THE INCIDENCE OF CARDIOVASCULAR DEATH, MYOCARDIAL INFARCTION OR ISCHAEMIC STROKE IN PATIENTS WITH TYPE 2 DIABETES

M-176 INFORMATION ADDED TO THE LABELING DESCRIBING TRIAL NN2211-3916, A TRIAL EVALUATING THE SAFETY AND EFFICACY OF LIRAGLUTIDE IN SUBJECTS WITH TYPE 2 DIABETES AND MODERATE RENAL IMPAIRMENT

M-177 INFORMATION ADDED TO THE LABELING DESCRIBING EXAMINE, A TRIAL EVALUATING CARDIOVASCULAR ISCHEMIC RISKS ASSOCIATED WITH ALOGLIPTIN USE IN PATIENTS WITH TYPE 2 DIABETES AT HIGH RISK OF ISCHEMIC CARDIOVASCULAR DISEASE

M-178 INFORMATION ADDED TO THE LABELING REGARDING MAINTENANCE OF REMISSION IN CROHN’S DISEASE IN PEDIATRIC PATIENTS

M-179 UPDATES TO THE PRODUCT LABELING WITH STUDY REPORTS FROM THE OPTIMIST-1 AND
EXCLUSIVITY MISCELLANEOUS

OPTIMIST-2 CLINICAL TRIALS

M-180 INFORMATION ADDED TO THE LABELING REGARDING THE ADDITION OF MAINTENANCE TREATMENT IN PATIENTS WITH SCHIZOPHRENIA

M-181 UPDATE TO THE DOSAGE AND ADMINISTRATION, PATIENT SELECTION (2.1), SECTION OF THE PACKAGE INSERT TO INCLUDE THE USE OF AN FDA-APPROVED PLASMA TEST FOR THE IDENTIFICATION OF EGFR EXON 19 DELETION OR EXON 21 (L858R) SUBSTITUTION MUTATIONS

M-182 UPDATES TO THE PRODUCT LABELING BASED ON THE RESULTS OF STUDY H7T-MC-TADO TITLED, "A PHASE 3 DOUBLE-BLIND, RANDOMIZED, MULTICENTER, EFFICACY AND SAFETY STUDY OF FRASUGREL COMPARED TO PLACEBO IN PEDIATRIC PATIENTS WITH SICKLE CELL DISEASE"

M-183 CHANGES TO THE DOSAGE AND ADMINISTRATION AND CLINICAL STUDIES SECTIONS OF THE LABELING TO SUPPORT THE REDUCE-TO-QUIT PARADIGM

M-184 UPDATES MADE TO THE LABELING TO INCLUDE INFORMATION FROM STUDY MO25743 ON THE ANTI-TUMOR ACTIVITY OF VEMURAFENIB IN THE TREATMENT OF PATIENTS WITH BRAF V600E MUTATION-POSITIVE MELANOMA WITH BRAIN METASTASES

M-185 UPDATES TO THE LABELING TO INCLUDE RESULTS OF A TRIAL TO EVALUATE THE SAFETY OF MOXIFLOXACIN IN PEDIATRIC PATIENTS WITH COMPLICATED INTRA-ABDOMINAL INFECTIONS

M-186 UPDATES TO THE PRODUCT INFORMATION REGARDING MAINTENANCE TREATMENT OF SCHIZOPHRENIA IN ADULTS BASED UPON THE RESULTS FROM STUDY 331-10-232

M-187 ADDITION OF CLINICAL INFORMATION OBTAINED FROM A PEDIATRIC TRIAL TO SECTION 8.4 OF THE LABELING

M-188 PROVIDES FOR DATA SUPPORTING THE SAFETY AND EFFECTIVENESS FOR THE MAINTENANCE TREATMENT OF MODERATE TO SEVERE BINGE EATING DISORDER (BED)

M-189 LABELING DESCRIBING THE EXPECTED REDUCTION OF ABUSE OF SINGLE-ENTITY MORPHINE BY THE INTRANASAL ROUTE OF ADMINISTRATION DUE TO PHYSICOCHEMICAL PROPERTIES

M-190 INFORMATION ADDED TO THE CLINICAL STUDIES SECTION OF THE LABELING REGARDING THE LACK OF EFFICACY OF TARCEVA IN MAINTENANCE TREATMENT OF PATIENTS WITHOUT EGFR MUTATIONS

M-191 ADDITION OF DATA BASED ON PEDIATRIC STUDIES TO FULFILL THE POSTMARKETING REQUIREMENT 1857-2

M-192 PROVIDES FOR DATA EVALUATING THE NEUROPSYCHIATRIC SAFETY AND EFICACY OF VARENICLINE FOR SMOKING CESSATION IN SUBJECTS WITH AND WITHOUT A HISTORY OF PSYCHIATRIC DISORDERS

M-193 INFORMATION ADDED TO THE LABELING REGARDING A 15-WEEK, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO-CONTROLLED FLEXIBLE-DOSE SAFETY AND EFICACY STUDY OF PREGABALIN IN ADOLESCENTS (12 THROUGH 17 YEARS OLD) WITH FIBROMYALGIA

M-194 INFORMATION ADDED TO THE LABELING REGARDING USE OF REGADENOSON ADMINISTRATION FOLLOWING AN INADEQUATE EXERCISE STRESS TEST AS COMPARED TO REGADENOSON ALONE

M-195 REVISIONS TO THE PEDIATRIC USE SECTION OF THE LABELING REFLECTING LACK OF EFFICACY FOR IRRITABILITY ASSOCIATED WITH AUTISTIC DISORDER IN PEDIATRIC PATIENTS AGES 6-17

M-196 REVISIONS TO THE PACKAGE INSERT BASED ON DATA FROM A RANDOMIZED, PLACEBO CONTROLLED, MULTICENTER STUDY OF INTRAVENOUS ACETAMINOPHEN FOR THE TREATMENT OF ACUTE PAIN IN PEDIATRIC PATIENTS TO FULFILL THE POST-MARKETING REQUIREMENT 1704-1

M-197 NEW CLINICAL DATA ADDED TO THE PRESCRIBING INFORMATION REGARDING CANAGLIFLOZIN ADD-ON COMBINATION THERAPY WITH METFORMIN AND A DIPEPTIDYL-PEPTIDASE-4 INHIBITOR

M-198 PACKAGE INSERT UPDATED WITH RESULTS FROM STUDY CV181166, A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, PHASE 3 TRIAL TO EVALUATE THE SAFETY AND EFICACY OF SAXAGLIPTIN ADDED TO DAPAGLIFLOZIN AND METFORMIN

M-199 INFORMATION ADDED TO LABELING REGARDING THE TREATMENT OF PATIENTS WITH ALK-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAD NOT RECEIVED PRIOR SYSTEMIC THERAPY FOR METASTATIC DISEASE.

M-200 CLINICAL INFORMATION ADDED TO THE USE IN SPECIFIC POPULATIONS SECTION OF THE LABELING.

M-201 REVISIONS TO THE PACKAGE INSERT BASED ON DATA FROM AN OPEN LABEL, MULTI-CENTER STUDY OF CABASITAXEL IN PEDIATRIC PATIENTS WITH REFRACTORY SOLID TUMORS INCLUDING TUMORS OF THE CENTRAL NERVOUS SYSTEM.
INCLUSION OF DATA FROM THE SUMMIT STUDY FOR BREO ELLIPTA (FLUTICASONE FUROATE/VILANTEROL TRIFENATATE) INHALATION POWDER IN THE PACKAGE INSERT.

PROVIDES FOR REVISIONS TO THE PACKAGE INSERT TO REFLECT RESULTS OF TWO POSTMARKETING REQUIREMENT STUDIES ROP111662 AND ROP111569.

CLINICAL INFORMATION ADDED TO THE PACKAGE INSERT REGARDING USE OF ATORVASTATIN IN CHILDREN AND ADOLESCENTS AGES 10-17 WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH).

INFORMATION ADDED TO THE LABELING REGARDING RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDIES ON PATIENTS WITH SEVERE RENAL IMPAIRMENT.

INFORMATION ADDED TO LABELING REGARDING 48 WEEK EFFICACY, RESISTANCE AND SAFETY DATA ON VIROLOGICALLY SUPPRESSED HIV-1 INFECTED ADULTS SWITCHING FROM COMPLERA TO ODEFSEY.

INFORMATION ADDED TO LABELING REGARDING 48 WEEK EFFICACY, RESISTANCE AND SAFETY DATA ON VIROLOGICALLY SUPPRESSED HIV-1 INFECTED ADULTS SWITCHING FROM ATRIPLA TO ODEFSEY.

INFORMATION ADDED TO THE LABELING TO INCLUDE RESULTS OF A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY IN PATIENTS WITH SEVERE COPD ASSOCIATED WITH CHRONIC BRONCHITIS AND A HISTORY OF EXACERBATIONS.

INFORMATION ADDED TO THE LABELING TO SUPPORT THE USE OF SYMBICORT TO REDUCE EXACERBATIONS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD).

PROVIDES FOR LABELING CHANGES REGARDING THE USE OF DAPTOMYCIN IN THE PEDIATRIC POPULATION FOR STAPHYLOCOCCUS AUREUS BACTEREMIA (SAB) BASED ON RESULTS OF A TRIAL IN PEDIATRIC PATIENTS 1 TO 17 YEARS OF AGE.

INFORMATION ADDED TO THE LABELING REGARDING THE SAFETY AND EFFICACY OF DAPAGLIFLOZIN IN PATIENTS WITH TYPE 2 DIABETES WHO HAVE INADEQUATE GLYCEMIC CONTROL ON A BACKGROUND COMBINATION OF METFORMIN AND EXENATIDE EXTENDED RELEASE.

INFORMATION ADDED TO THE LABELING REGARDING THE SAFETY AND EFFICACY OF CARIPRAZINE RELATIVE TO PLACEBO IN THE PREVENTION OF RELAPSE OF SYMPTOMS IN PATIENTS WITH SCHIZOPHRENIA.

INFORMATION ADDED TO THE CLINICAL TRIALS SECTION OF THE LABELING REGARDING A POSTMARKETING SAFETY AND EFFICACY STUDY EVALUATING THE RISK OF SERIOUS ASTHMA-RELATED EVENTS.

INFORMATION ADDED TO THE LABELING REGARDING THE COMPARISON OF PALIPERIDONE PALMITATE COMPARED WITH ORAL ANTIPSYCHOTIC TREATMENT IN DELAYING TIME TO TREATMENT FAILURE IN ADULTS WITH SCHIZOPHRENIA WHO HAVE BEEN INCARCERATED.

UPDATE THE PRESCRIBING INFORMATION AND PATIENT LABELING WITH FINDINGS FROM STUDY RP103-08 CONDUCTED IN TREATMENT-NAIVE NEPHROPATHIC CYSTINOSIS PATIENTS TO EXPAND THE INDICATED POPULATION TO PATIENTS 1 YEAR AND OLDER.

INFORMATION ADDED TO SECTION 8.1 OF THE LABELING REGARDING PREGNANT PATIENTS WHO ARE ALREADY ON A STABLE RILPIVIRINE REGIMEN PRIOR TO PREGNANCY AND WHO ARE VIROLOGICALLY SUPPRESSED (HIV-1 RNA LESS THAN 50 COPIES/ML).

INFORMATION ADDED TO SECTION 8.1 OF THE LABELING REGARDING PREGNANT PATIENTS WHO ARE ALREADY ON A STABLE RILPIVIRINE REGIMEN PRIOR TO PREGNANCY AND WHO ARE VIROLOGICALLY SUPPRESSED (HIV-1 RNA LESS THAN 50 COPIES/ML).

INFORMATION ADDED TO THE LABELING REGARDING THE SAFETY AND EFFICACY OF EXENATIDE EXTENDED RELEASE AS ADD-ON IN PATIENTS WITH TYPE 2 DIABETES WHO HAVE INADEQUATE...
EXCLUSIVITY MISCELLANEOUS

M-225 REVISIONS TO SECTION 8.4 OF THE PRESCRIBING INFORMATION TO INCLUDE A SAFETY AND EFFICACY STUDY IN PEDIATRIC PATIENTS AGES >=6 YEARS TO <18 YEARS WITH CHRONIC IDIOPATHIC CONSTIPATION

M-226 CHANGES TO THE LABELING BASED ON RESULTS FROM A CONTROLLED CLINICAL TRIAL IN PATIENTS WITH LATER-ONSET SPINAL MUSCULAR ATROPHY

M-227 ADDITION TO THE CLINICAL STUDIES SECTION OF THE LABELING WITH THE SUBSECTION ENTITLED DIGIT SYMBOL SUBSTITUTION TEST IN MAJOR DEPRESSIVE DISORDER

M-228 INFORMATION ADDED TO THE PACKAGE INSERT REGARDING THE REVISION OF THE MONOTHERAPY INDICATION OF VENETOCLAX

M-229 REVISED LABELING TO INCORPORATE THE PEDIATRIC USE OF LOPREDNOL ETABONATE GEL IN PATIENTS FOR THE TREATMENT OF POSTOPERATIVE INFLAMMATION FOLLOWING OCULAR SURGERY

M-230 REVISIONS TO THE GLECAPREVIR/PIBRENTASVIR COMBINATION PRODUCT PRESCRIBING INFORMATION TO INCLUDE SAFETY AND EFFICACY DATA FROM THE HCV/HIV-1 COINFECTION STUDY M14-730 AND FROM THE LIVER AND RENAL TRANSPLANT STUDY M13-596

M-231 REVISIONS TO THE USE IN SPECIFIC POPULATIONS SECTION (SECTION 8.3) OF THE PACKAGE INSERT WITH THE RESULTS OF CLINICAL TRIAL WV25651, CONDUCTED TO EVALUATE THE EFFECT OF VALGANCYCLOVIR ON SPERMATOGENESIS AND TO FULFILL PMR 1670-3

M-232 INFORMATION ADDED TO SECTION 8.4 OF THE LABELING TO DESCRIBE THE RESULTS FROM PEDIATRIC STUDIES

M-233 INFORMATION ADDED TO THE LABELING TO DESCRIBE FIXED-DOSE COMBINATION OF TIOTROPIUM BROMIDE AND OLODATEROL TO INCLUDE REDUCTION OF COPD EXACERBATIONS

M-234 UPDATE TO THE PRESCRIBING INFORMATION FOR VORTIOXETINE ON TREATMENT-EMERGENT SEXUAL DYSFUNCTION COMPARING VORTIOXETINE AND SSRIS

M-235 INFORMATION ADDED TO SECTION 14 OF THE LABELING TO DESCRIBE STUDY LAP016A2307 TO FULFILL POSTMARKETING STUDY REQUIREMENT 1586-1

ORPHAN DRUG EXCLUSIVITY

ODE-1 TO REDUCE CHRONIC DROOLING IN PATIENTS AGED 3 - 16 WITH NEUROLOGIC CONDITIONS ASSOCIATED WITH PROBLEM DROOLING (E.G. CEREBRAL PALSY)

ODE-2 FOR TREATMENT OF NON-INFECTIOUS UVEITIS AFFECTING THE POSTERIOR SEGMENT OF THE EYE

ODE-3 TO TREAT INFANTILE SPASMS

ODE-4 TREATMENT OF PATIENTS WITH SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) ASSOCIATED WITH TUBEROUS SCLEROSIS WHO REQUIRE THERAPEUTIC INTERVENTION BUT ARE NOT CANDIDATES FOR CURATIVE SURGICAL RESECTION

ODE-5 FOR SEQUENTIAL USE FOR THE TREATMENT OF CYANIDE POISONING THAT IS JUDGED TO BE LIFE-THREATENING

ODE-6 FOR THE MANAGEMENT OF POSTHERPETIC NEURALGIA

ODE-7 TO REDUCE THE RISK OF PRETERM BIRTH IN WOMEN WITH SINGLETON PREGNANCY WHO HAVE A HISTORY OF SINGLETON SPONTANEOUS PRETERM BIRTH

ODE-8 TREATMENT OF SEVERE HYPERCALCEMIA IN PATIENTS WITH PRIMARY HYPERPARATHYROIDISM WHO ARE UNABLE TO UNDERGO PARATHYROIDECTOMY

ODE-9 TREATMENT OF ASYMPTOMATIC OR PROGRESSIVE MEDULLARY THYROID CANCER IN PATIENTS WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC DISEASE

ODE-10 FOR USE IN COMBINATION CHEMOTHERAPY WITH 5-FLUOROURACIL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED METASTATIC COLORECTAL CANCER

ODE-11 TREATMENT OF PROGRESSIVE NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (PNET) IN PATIENTS WITH UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC DISEASE

ODE-12 TREATMENT OF PERIPHERAL T-CELL LYMPHOMA (PTCL) IN PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

ODE-13 TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA WITH THE BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST

ODE-14 TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIODEMA IN ADULTS 18 YEARS OF AGE AND OLDER
ODE-15  TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE AS DETECTED BY AN FDA APPROVED TEST.

ODE-16  TREATMENT OF PATIENTS WITH TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMA SYNDROMES WHEN CURRENT CHELATION THERAPY IS INADEQUATE.

ODE-17  ADJUNCTIVE TREATMENT OF SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME IN PATIENTS 2 YEARS OF AGE OR OLDER.

ODE-18  ADJUNCTIVE TREATMENT OF SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME IN PATIENTS 2 YEARS OF AGE OR OLDER.

ODE-19  TREATMENT OF PATIENTS WITH INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS, INCLUDING PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS AND POST-ESSENTIAL THROMBOCYTHEMIA MYELOFIBROSIS.

ODE-20  TREATMENT OF CYSTIC FIBROSIS (CF) IN PATIENTS AGE 6 YEARS AND OLDER WHO HAVE A G551D MUTATION IN THE CFTR GENE.

ODE-21  AN ADJUNCT TO AB EXTERNO GLAUCOMA SURGERY.

ODE-22  FOR THE CONTROL OF HYPERGLYCEMIA SECONDARY TO HYPERCORTISOLISM IN ADULT PATIENTS WITH ENDGENOUS CUSHING'S SYNDROME WHO HAVE TYPE 2 DIABETES MELLITUS OR GLUCOSE INTOLERANCE AND HAVE FAILED SURGERY OR ARE NOT CANDIDATES FOR SURGERY.

ODE-23  ADVANCED SOFT TISSUE SARCOMA (STS) WHO HAVE RECEIVED PRIOR CHEMOTHERAPY.

ODE-24  TREATMENT OF ADULTS WITH RENAL ANGIOMYOLIPOMA AND TUBEROUS SCLEROSIS COMPLEX (TSC) NOT REQUIRING IMMEDIATE SURGERY.

ODE-25  MANAGEMENT OF POSTHERPETIC NEURALGIA IN ADULTS.

ODE-26  TREATMENT OF ENDENOGNEUS ANTERIOR UVEITIS.

ODE-27  TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY.

ODE-28  TREATMENT OF ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME-NEGATIVE (PH-) ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN SECOND OR GREATER RELAPSE OR WHOSE DISEASE HAS PROGRESSED FOLLOWING TWO OR MORE ANTI-LEUKEMIA THERAPIES.

ODE-29  LOCALIZATION OF LYMPH NODES DRAINING A PRIMARY TUMOR IN PATIENTS WITH MELANOMA WHEN USED WITH A HAND-HELD GAMMA COUNTER.

ODE-30  TREATMENT OF ADULT PATIENTS WITH CHRONIC ANGIOFIBROBLASTIC TUMOR (CABT) TREATMENT OF PHILADELPHIA CHROMOSOME-POSITIVE (PH+) CHRONIC MYELOGENOUS LEUKEMIA (CML) WITH RESISTANCE, OR INTOLERANCE TO PRIOR THERAPY.

ODE-31  TREATMENT OF CORNEAL CYSTINE CRYSTAL ACCUMULATION IN PATIENTS WITH CYSTINOSIS.

ODE-32  TREATMENT OF ADULT PATIENTS WITH CHRONIC OR ACCELERATED PHASE CHRONIC MYELOID LEUKEMIA (CML) WITH RESISTANCE AND/OR INTOLERANCE TO TWO OR MORE TYROSINE KINASE INHIBITORS (TKI).

ODE-33  TREATMENT OF PROGRESSIVE, METASTATIC MEDULLARY THYROID CANCER (MTC).

ODE-34  TREATMENT OF ADULT PATIENTS WITH CUSHING'S DISEASE FOR WHOM PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE.

ODE-35  TREATMENT OF ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ALL) THAT IS RESISTANT OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY.

ODE-36  ADJUNCT TO A LOW-FAT DIET AND OTHER LIPID-LOWERING TREATMENTS, INCLUDING LDL Apheresis WHERE AVAILABLE, TO REDUCE LDL-C, TC, APOLIPOPROTEIN B, & NON-HDL-C IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.

ODE-37  TREATMENT OF ADULT PATIENTS WITH SHORT BOWEL SYNDROME (SBS) WHO ARE DEPENDENT ON PARENTERAL SUPPORT.

ODE-38  PART OF COMBINATION THERAPY IN ADULTS (GREATER THAN OR EQUAL TO 18 YEARS) WITH PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)

ODE-39  TREATMENT OF CHRONIC IRON OVERLOAD IN PATIENTS 10 YRS. & OLDER WITH NON-TRANSFUSION DEPENDENT THALASSEMA (NTDT) SYNDROMES AND WITH A LIVER IRON CONCENTRATION OF AT LEAST 5 MG OF IRON PER GRAM OF LIVER DRY WEIGHT & SERUM FERRITIN GREATER THAN 300 MCG/L.

ODE-40  TREATMENT OF PEDIATRIC PATIENTS WITH NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME-POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ ALL) IN COMBINATION WITH
ORPHAN DRUG EXCLUSIVITY

CHEMOTHERAPY, APPROVED UNDER NDA #21588/S-037

ODE-41
ADJUNCT TO LIPID-LOWERING MEDICATIONS AND DIET TO REDUCE LDL-C, APOB, TOTAL CHOLESTEROL (TC), AND NON-HIGH DENSITY LIPOPROTEIN-CHOLESTEROL (NON-HDL-C) IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH).

ODE-42
USE AS A NITROGEN-BINDING ADJUNCTIVE THERAPY FOR CHRONIC MGMT OF ADULT AND PEDIATRIC PATIENTS AT LEAST 2 YRS WITH UREA CYCLE DISORDERS THAT CANNOT BE MANAGED BY DIETARY PROTEIN RESTRICTION AND/OR AMINO ACID SUPPLEMENTATION ALONE.

ODE-43
TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING LENALIDOMIDE AND BORTEZOMIB AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY.

ODE-44
TREATMENT OF PATIENTS WITH LOCALLY ADVANCED, UNRESECTABLE OR METASTATIC GASTROINTESTINAL STROMAL TUMOR (GIST) WHO HAVE BEEN PREVIOUSLY TREATED WITH IMATINIB MESYLATE AND SUNITINIB MALATE.

ODE-45
MANAGEMENT OF NEPHROPATHIC CYSTINOSIS IN ADULTS AND CHILDREN AGES 6 YEARS AND OLDER.

ODE-46
IMPROVEMENT OF NEUROLOGICAL OUTCOME BY REDUCING THE INCIDENCE AND SEVERITY OF ISCHEMIC DEFICITS IN ADULT PATIENTS WITH SUBARACHNOID HEMORRHAGE FROM Ruptured INTRACRANIAL BERRY ANEURYSMS REGARDLESS OF THEIR POST-ICTUS NEUROLOGICAL CONDITION.

ODE-47
TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E MUTATION AS DETECTED BY AN FDA APPROVED TEST.

ODE-48
TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS AS DETECTED BY AN FDA APPROVED TEST.

ODE-49
TREATMENT OF MANTLE CELL LYMPHOMA WHOSE DISEASE HAS RELAPSED OR PROGRESSED AFTER TWO PRIOR THERAPIES, ONE OF WHICH INCLUDED BORTEZOMIB.

ODE-50
FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 (L858R) SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST.

ODE-51
TOPICAL TREATMENT OF STAGE 1A AND 1B MYCOSIS FUNGOIDES-TYPE CUTANEOUS T-CELL LYMPHOMA IN PATIENTS WHO HAVE RECEIVED PRIOR SKIN-DIRECTED THERAPY.

ODE-52
TREATMENT OF METASTATIC ADENOCARCINOMA OF THE PANCREAS AS FIRST-LINE TREATMENT, IN COMBINATION WITH GEMCITABINE.

ODE-53
TREATMENT OF ADULTS WITH PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP 1, TO IMPROVE EXERCISE CAPACITY, WHO FUNCTIONAL CLASS AND TO DELAY CLINICAL WORSENING.

ODE-54
TX OF PAH TO DELAY DISEASE PROGRESSION. DISEASE PROGRESSION INCLUDED: DEATH, INITIATION OF IV OR SC PROSTANOIDS, OR CLINICAL WORSENING OF PAH (DECREASED 6-MINUTE WALK DISTANCE, WORSENED PAH SYMPTOMS AND NEED FOR ADDITIONAL PAH TREATMENT).

ODE-55
TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY.

ODE-56
TREATMENT OF PATIENTS WITH LOCALLY RECURRENT OR METASTATIC, PROGRESSIVE, DIFFERENTIATED THYROID CARCINOMA (DCT) THAT IS REFRACTORY TO RADIOACTIVE IODINE TREATMENT.

ODE-57
TRAMETINIB IN COMBO WITH DABRAFENIB FOR TX. OF PTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST. THIS INDICATION IS BASED ON THE DEMONSTRATION OF DURABLE RESPONSE RATE.

ODE-58
DABRAFENIB IN COMBO WITH TRAMETINIB FOR TX. OF PTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST. THIS INDICATION IS BASED ON THE DEMONSTRATION OF DURABLE RESPONSE RATE.

ODE-59
TREATMENT OF NON-24-HOUR SLEEP-WAKE DISORDER.

ODE-60
TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY.

ODE-61
TREATMENT OF NEUROGENIC SYMPTOMATIC ORTHOSTATIC HYPOTENSION IN PATIENTS WITH PRIMARY AUTONOMIC FAILURE, Dopamine-Beta-Hydroxylase Deficiency, and Nondiabetic Autonomic Neuropathy.

ODE-62
TREATMENT OF PROLIFERATING INFANTILE HEMANGIOMA REQUIRING SYSTEMIC THERAPY.
ORPHAN DRUG EXCLUSIVITY

ODE-63  TREATMENT OF VISCERAL LEISHMANIASIS DUE TO LEISHMANIA DONOVANI; CUTANEOUS LEISHMANIASIS DUE TO LEISHMANIA BRAZILIENSIS, LEISHMANIA GUYANENSIS, AND LEISHMANIA PANAMENSIS; AND MUCOSAL LEISHMANIASIS DUE TO LEISHMANIA BRAZILIENSIS.

ODE-64  SELECTIVE HEPATIC INTRA-ARTERIAL USE FOR IMAGING TUMORS IN ADULTS WITH KNOWN HEPATOCARCINOMA (HCC).

ODE-65  TREATMENT OF PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA AS PART OF A COMBINATION REGIMEN.

ODE-66  TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB.

ODE-67  GUIDING SENTINEL LYMPH NODE BIOPSY, USING A HAND-HELD GAMMA COUNTER IN PATIENTS WITH CLINICALLY NODE NEGATIVE SQUAMOUS CELL CARCINOMA OF THE ORAL CAVITY.

ODE-68  TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA.

ODE-69  TREATMENT OF MALIGNANT HYPERERMIA IN CONJUNCTION WITH APPROPRIATE SUPPORTIVE MEASURES AND FOR THE PREVENTION OF MALIGNANT HYPERERMIA IN PATIENTS AT HIGH RISK.

ODE-70  RELAPSED CLL, IN COMBO. WITH RITUXIMAB, IN PATIENTS FOR WHOM RITUXIMAB ALONE WOULD BE CONSIDERED APPROPRIATE THERAPY DUE TO OTHER CO-MORBIDITIES; AND RELAPSED SLL IN PATIENTS WHO HAVE RECEIVED AT LEAST 2 PRIOR SYSTEMIC THERAPIES.

ODE-71  RELAPSED PELLICULAR B-CELL NON-HODGKIN LYMPHOMA (FL) IN PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES.

ODE-72  TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA WITH 17P DELETION WHO HAVE NOT RECEIVED AT LEAST ONE PRIOR THERAPY.

ODE-73  LONG-TERM TREATMENT OF ADULT PATIENTS WITH GAUCHER DISEASE TYPE 1 WHO ARE CYP2D6 EXTENSIVE METABOLIZERS (EMS), INTERMEDIATE METABOLIZERS (IMS), OR POOR METABOLIZERS (PMS) AS DETECTED BY AN FDA-CLEARED TEST.

ODE-74  FOR USE IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE NOT RECEIVED AT LEAST ONE PRIOR THERAPY (FIRST LINE TREATMENT).

ODE-75  TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST 2 PRIOR REGIMENS, INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT.
ORPHAN DRUG EXCLUSIVITY

ODE-90  TREATMENT OF INVASIVE MUCORMYCOSIS IN PATIENTS 18 YEARS OF AGE AND OLDER
ODE-91  TREATMENT OF BILE ACID SYNTHESIS DISORDERS DUE TO SINGLE ENZYME DEFECTS
ODE-92  TREATMENT OF LYMPHANGIOLEIOMYOMATOSIS (LAM)
ODE-93  TREATMENT OF CYSTIC FIBROSIS IN PATIENTS AGE 12 YEARS AND OLDER WHO ARE HOMOZYGOS FOR F508DEL MUTATION IN THE CFTR GENE
ODE-94  PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY TRANSPLANT PATIENTS CONVERTED FROM TACROLIMUS IMMEDIATE-RELEASE FORMULATIONS IN COMBINATION WITH OTHER IMMUNOSUPPRESSANTS
ODE-95  FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 (L858R) SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST
ODE-96  TREATMENT OF PRIMARY HYPERKALEMIC PERIODIC PARALYSIS, PRIMARY HYPOKALEMIC PERIOD PARALYSIS, AND RELATED VARIANTS
ODE-97  TO EXPAND THE INDICATION TO PEDIATRIC PATIENTS 2–6 YEARS OF AGE WITH NEPHROPATHIC CYSTINOSIS
ODE-98  TREATMENT OF HEREDITARY OROTIC ACIDURIA
ODE-99  FOR USE IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN, FOR THE TREATMENT OF PATIENTS WITH METASTATIC ADENOCARCINOMA OF THE PANCREAS THAT HAS PROGRESSED FOLLOWING GEMCITABINE-BASED THERAPY
ODE-100 FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC LIPOSARCOMA OR LEIOMYOSARCOMA WHO RECEIVED A PRIOR ANTHRACYCLINE-CONTAINING REGIMEN
ODE-101 FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATION, IN COMBINATION WITH VEMURAFENIB. COTELIC IS NOT INDICATED FOR TREATMENT OF PATIENTS WITH WILD-TYPE BRAF MELANOMA
ODE-102 FOR TREATMENT OF PATIENTS WITH METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) T790M MUTATION-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC), AS DETECTED BY AN FDA-APPROVED TEST, WHO HAVE PROGRESSED ON OR AFTER EGFR TKI THERAPY
ODE-103 USE IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WHO RECEIVED A PRIOR ANTHRACYCLINE-CONTAINING REGIMEN
ODE-104 EMERGENCY TX OF PTS FOLLOWING A FU OR CAPECITABINE OD, OR WHO EXHIBIT EARLY-ONSET, SEVERE OR LIFE-THREATENING TOXICITY AFFECTING THE CARDIAC SYSTEM OR CNS, AND/OR EARLY-ONSET, UNUSUALLY SEVERE AR W/IN 96 HRS FOLLOWING THE END OF FU OR CAPECITABINE ADMIN.
ODE-105 TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC), WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB
ODE-106 FOR USE OF UPTRAVI (SELEXIPAG) TABLETS, 200, 400, 600, 800, 1000, 1200, 1400, AND 1600 MCG FOR TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH, WHO GROUP I) TO REDUCE THE RISKS OF DISEASE PROGRESSION AND HOSPITALIZATION FOR PAH
ODE-107 TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC LIPOSARCOMA WHO HAVE RECEIVED A PRIOR ANTHRACYCLINE-CONTAINING REGIMEN
ODE-108 TREATMENT OF ADULT PATIENTS WITH PROGRESSIVE, WELL-DIFFERENTIATED, NON-FUNCTIONAL, NEUROENDOCRINE TUMORS (NET) OF GASTROINTESTINAL (GI) OR LUNG ORIGIN, (EXCLUDING PANCREATIC) WITH UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC DISEASE
ODE-109 INDICATED FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA WITHOUT 17P DELETION WHO HAVE NOT RECEIVED AT LEAST ONE PRIOR THERAPY (FIRST LINE THERAPY)
ODE-110 FOR HIGH-DOSE CONDITIONING TREATMENT PRIOR TO HEMATOPOIETIC PROGENITOR (STEM) CELL TRANSPLANTATION IN PATIENTS WITH MULTIPLE MYELOMA
ODE-111 TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER WHOSE TUMORS ARE ROS-1 POSITIVE.
ODE-112 FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH HEPATIC VENO-OCLUSION DISEASE (VOD), ALSO KNOWN AS SINUSOIDAL OBSTRUCTION SYNDROME (SOS), WITH RENAL OR PULMONARY DYSFUNCTION FOLLOWING HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT).
ODE-113 FOR TREATMENT OF PEDIATRIC AND ADULT PATIENTS WITH ACQUIRED METHEMOGLOBINEMIA.
ODE-114 TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WITH 17P DELETION, AS DETECTED BY AN FDA APPROVED TEST, WHO HAVE RECEIVED AT LEAST ONE PRIOR
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ODO-115 TREATMENT OF PATIENTS WITH METASTATIC, SQUAMOUS, NON-SMALL CELL LUNG CANCER PROGRESSING AFTER PLATINUM-BASED CHEMOTHERAPY

ODO-116 TREATMENT OF PROGRESSIVE KERATOCONUS

ODO-117 FOR TREATMENT OF PATIENTS WITH SMALL LYMPHOCYTIC LYMPHOMA (SLL)

ODO-118 AN ADJUNCT TO DIET TO REDUCE LDL-C, TOTAL-C, NONHDL-C AND APOB IN CHILDREN AND ADOLESCENTS 7 TO 17 YEARS OF AGE WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA, EITHER ALONE OR WITH OTHER LIPID-LOWERING TREATMENTS (E.G., LDL APHERESIS)

ODO-119 TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC) IN COMBINATION WITH URSODEOXYCHOLIC ACID (UDCA) IN ADULTS WITH AN INADEQUATE RESPONSE TO UDCA, OR AS MONOTHERAPY IN ADULTS UNABLE TO TOLERATE UDCA

ODO-120 FOR USE AFTER RADIOLABELING WITH GA 68, WITH POSITRON EMISSION TOMOGRAPHY (PET) FOR LOCALIZATION OF SOMATOSTATIN RECEPTOR POSITIVE NEUROENDOCRINE TUMORS (NETS) IN ADULT AND PEDIATRIC PATIENTS.

ODO-121 TREATMENT OF CORNEAL ECTASIA FOLLOWING REFRACTIVE SURGERY

ODO-122 TREATMENT OF DUCHENNNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS WHO HAVE A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING

ODO-123 TREATMENT OF CYSTIC FIBROSIS (CF) IN PATIENTS AGE 6-11 YEAR OLD WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE

ODO-124 REPLACEMENT THERAPY FOR ORAL CARBAMAZEPINE FORMULATIONS, WHEN ORAL ADMINISTRATION IS TEMPORARILY NOT FEASIBLE, IN ADULTS WITH THE FOLLOWING SEIZURE TYPES: PARTIAL WITH COMPLEX SYMPTOMATOLOGY, GENERALIZED CLONIC-TONIC, AND MIXED

ODO-125 INDICATED IN PEDIATRIC PATIENTS 10 YEARS AND OLDER FOR THE PREVENTION AND TREATMENT OF SECONDARY HYPERPARATHYROIDISM ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD) STAGES 3 AND 4 AND CKD STAGE 5 IN PATIENTS ON HEMODIALYSIS OR PERITONEAL DIALYSIS

ODO-126 AS MONOTHERAPY FOR THE TREATMENT OF PATIENTS WITH DELETERIOUS BRCA MUTATION (GERMLINE AND/OR SOMATIC) ASSOCIATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH TWO OR MORE CHEMOTHERAPIES

ODO-127 TREATMENT OF SPINAL MUSCULAR ATROPHY IN PEDIATRIC AND ADULT PATIENTS

ODO-128 TREATMENT OF PATIENTS WITH MARGINAL ZONE LYMPHOMA (MZL) WHO REQUIRE SYSTEMIC THERAPY AND HAVE RECEIVED AT LEAST ONE PRIOR ANTI-CD20-BASED THERAPY

ODO-129 INDICATED FOR REDUCING THE RISK OF GRAFT REJECTION WHEN USED IN CONJUNCTION WITH HIGH-DOSE BUSULFAN & CYCLOPHOSPHAMIDE AS A PREPARATIVE REGIMEN FOR ALLOGENIC HEMATOPOIETIC PROGENITOR CELL TRANSPLANTATION FOR PEDS. PATIENTS WITH CLASS 3 BETA-THALASSEMIA

ODO-130 TREATMENT OF DUCHENNNE MUSCULAR DYSTROPHY IN PATIENTS 5 YEARS OF AGE AND OLDER

ODO-131 TREATMENT OF MULTIPLE MYELOMA (MM), AS MAINTENANCE FOLLOWING AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION (AUTO-HSCT)

ODO-132 TREATMENT OF CARCINOID SYNDROME DIARRHEA IN COMBINATION WITH SOMATOSTATIN ANALOG (SSA) THERAPY IN ADULTS INADEQUATELY CONTROLED BY SSA THERAPY

ODO-133 INDICATED FOR MAINTENANCE TREATMENT OF ADULT PATIENTS WITH RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER WHO ARE IN A COMPLETE OR PARTIAL RESPONSE TO PLATINUM-BASED CHEMOTHERAPY

ODO-134 TREATMENT OF CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE

ODO-135 TREATMENT OF CHRONIC HCV GENOTYPE 2 OR 3 INFECTION IN PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER OR WEIGHTING AT LEAST 35 KG WITHOUT CIRRHOSIS OR WITH COMPENSATED CIRRHOSIS FOR USE IN COMBINATION WITH RIBAVIRIN

ODO-136 TREATMENT OF PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER OR WEIGHTING AT LEAST 35 KG WITH CHRONIC HEPATITIS C VIRUS GENOTYPE 1, 4, 5, OR 6 INFECTION WITHOUT CIRRHOSIS OR WITH COMPENSATED CIRRHOSIS

ODO-137 TREATMENT OF OLIGOARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PERSISTENT OLI GOARTHRITIS, PSORIATIC JUVENILE IDIOPATHIC ARTHRITIS, ENTHESIS-RELATED ARTHRITIS, OR UNDIFFERENTIATED ARTHRITIS) & POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS IN CHILDREN 0-16 YRS

ODO-138 TREATMENT OF PEDIATRIC PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA AS A COMPONENT OF A COMBINATION CHEMOTHERAPY MAINTENANCE REGIMEN

ODO-139 TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC OR LIVER CANCER) WHO
ORPHAN DRUG EXCLUSIVITY

ODE-140  TREATMENT OF ADULT PATIENTS WITH AGGRESSIVE SYSTEMIC MASTOCYTOSIS (ASM), SYSTEMIC MASTOCYTOSIS WITH ASSOCIATED HEMATOLOGICAL NEOPLASM (SM-AHN), OR MAST CELL LEUKEMIA (NCL)

ODE-141  TREATMENT OF ADULT PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) THAT IS FLT3 MUTATION-POSITIVE AS DETECTED BY AN FDA APPROVED TEST, IN COMBINATION WITH STANDARD CYTARABINE AND DAUNORUBICIN INDUCTION AND CYTARABINE CONSOLIDATION

ODE-142  TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB

ODE-143  TO DECREASE THE RECURRENCE OF PNEUMOTHORAX IN ADULTS

ODE-144  TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)

ODE-145  TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS ARE ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE AS DETECTED BY AN FDA-APPROVED TEST

ODE-146  OPTICAL IMAGING AGENT INDICATED IN PATIENTS WITH GLIOMA (SUSPECTED WORLD HEALTH ORGANIZATION GRADES III OR IV ON PREOPERATIVE IMAGING) AS AN ADJUNCT FOR THE VISUALIZATION OF MALIGNANT TISSUE DURING SURGERY

ODE-147  DABRAFENIB IN COMBINATION WITH TRAMETINIB, FOR THE TX. OF PTS WITH METASTATIC NON-SMALL CELL LUNG CANCER WITH BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST

ODE-148  TRAMETINIB IN COMBINATION WITH DABRAFENIB, FOR THE TX. OF PTS WITH METASTATIC NON-SMALL CELL LUNG CANCER WITH BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST

ODE-149  TREATMENT OF PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER WITH CENTRAL PREOCIOUS PUBERTY

ODE-150  TO REDUCE THE ACUTE COMPLICATIONS OF SICKLE CELL DISEASE IN ADULT AND PEDIATRIC PATIENTS 5 YEARS OF AGE AND OLDER.

ODE-151  TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA WITH AN ISOCITRATE DEHYDROGENASE-2 (IDH2) MUTATION AS DETECTED BY AN FDA-APPROVED TEST

ODE-152  TREATMENT OF ADULT PATIENTS WITH CHRONIC GRAFT VERSUS HOST DISEASE (CGVHD)

ODE-153  TREATMENT OF DYSKINESIA IN PATIENTS WITH PARKINSON'S DISEASE RECEIVING LEVODOPA-BASED THERAPY WITH OR WITHOUT CONCOMITANT DOPAMINERGIC MEDICATIONS

ODE-154  FOR USE IN CHILDREN AGES 2 TO 12 YEARS OLD WITH CHAGAS DISEASE

ODE-155  TREATMENT OF ADULT PATIENTS WITH RELAPSED FOLLCULAR LYMPHOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES

ODE-156  TREATMENT OF ADULTS WITH CARCINOID SYNDROME; WHEN USED, IT REDUCES THE FREQUENCY OF SHORT-ACTING SOMATOSTATIN ANALOG RESCUE THERAPY

ODE-157  FOR USE AS A NITROGEN-BINDING AGENT FOR CHRONIC MANAGEMENT OF PEDIATRIC PATIENTS >=2 MONTHS AND < 2 YEARS OF AGE WITH UREASE CYCLE DISORDERS (UCDS) WHO CANNOT BE MANAGED BY DIETARY PROTEIN RESTRICTION AND/OR AMINO ACID SUPPLEMENTATION ALONE

ODE-158  TREATMENT OF PATIENTS WITH ERDHEIM-CHESTER DISEASE WITH BRAF V600 MUTATION

ODE-159  FOR TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK) POSITIVE, METASTATIC NON-SMALL-CELL LUNG CANCER (NSCLC) AS DETECTED BY AN FDA APPROVED TEST, EXCLUDING PATIENTS WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB

ODE-160  FOR TREATMENT OF SCURVY IN ADULT AND PEDIATRIC PATIENTS AGE 5 MONTHS AND OLDER FOR WHOM ORAL ADMINISTRATION IS NOT POSSIBLE, INSUFFICIENT OR CONTRAINDICATED

ODE-161  TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH) (WHO GROUP 1) IN PEDIATRIC PATIENTS AGED 3 YRS AND OLDER WITH IDIOPATHIC OR CONGENITAL PAH TO IMPROVE PULMONARY VASCULAR RESISTANCE (PVR), WHICH IS EXPECTED TO RESULT IN AN IMPROVEMENT IN EXERCISE ABILITY

ODE-162  TREATMENT OF NEPHROPATHIC CYSTINOSIS IN PEDIATRIC PATIENTS 1 YEAR OF AGE TO LESS THAN 2 YEARS OF AGE

ODE-163  TREATMENT OF ADULT PATIENTS WITH NEWLY-DIAGNOSED CHRONIC PHASE (CP) PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOGENOUS LEUKEMIA (PH+ CML)

ODE-164  TREATMENT OF PEDIATRIC PATIENTS WITH PHILADELPHIA CHROMOSOME-POSITIVE (PH+)
PATENT AND EXCLUSIVITY TERMS

ORPHAN DRUG EXCLUSIVITY

CHRONIC MYELOID LEUKEMIA (CML) IN CHRONIC PHASE

ODE-165  PROPHYLAXIS OF CYTOMEGALOVIRUS (CMV) INFECTION AND DISEASE IN ADULT CMV- SEROPOSITIVE RECIPIENTS [R+] OF AN ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT)

ODE-166  TREATMENT OF SOMATOSTATIN RECEPTOR-POSITIVE GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS (GEP-NETS) INCLUDING FOREGUT, MIDGUT, AND HINDGUT NEUROENDOCRINE TUMORS IN ADULTS

ODE-167  ARSENIC TRIoxide FOR USE IN COMBINATION WITH TRETINOIN FOR TREATMENT OF ADULTS WITH NEWLY-DIAGNOSED LOW-RISK ACUTE PROMYELOCYTIC LEUKEMIA (APL) WHOSE APL IS CHARACTERIZED BY THE PRESENCE OF THE T(15;17) TRANSLOCATION OR PML/RAR-ALPHA GENE EXPRESSION

ODE-168  FOR THE MAINTENANCE TREATMENT OF ADULT PATIENTS WITH RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER WHO ARE IN A COMPLETE OR PARTIAL RESPONSE TO PLATINUM-BASED CHEMOTHERAPY

ODE-169  FOR THE ADJUNCTIVE TREATMENT OF ADULT AND PEDIATRIC PATIENTS AGED 2 YEARS AND OLDER WITH TUBEROUS SCLEROSIS COMPLEX (TSC)-ASSOCIATED PARTIAL-ONSET SEIZURES

ODE-170  FOR THE DIAGNOSIS OF ADULT GROWTH HORMONE DEFICIENCY (AGHD)

ODE-171  TREATMENT OF PEDIATRIC PATIENTS GREATER THAN OR EQUAL TO 1 YEAR OF AGE WITH NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (PH+CML) IN CHRONIC PHASE

ODE-172  TREATMENT OF PEDIATRIC PATIENTS GREATER THAN OR EQUAL TO 1 YEAR OF AGE WITH CHRONIC PHASE PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA WITH RESISTANCE OR INTOLERANCE TO PRIOR TYROSINE-KINASE INHIBITOR THERAPY

ODE-173  TREATMENT OF PATIENTS WITH CYSTIC FIBROSIS AGED 12 YEARS AND OLDER WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION OR WHO HAVE AT LEAST ONE MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR GENE RESPONSIVE TO TEZACAFTOR/IVACAFTOR

ODE-174  FOR THE TREATMENT OF THROMBOCYTOPENIA IN ADULT PATIENTS WITH CHRONIC IMMUNE THROMBOCYTOPENIA (ITP) WHO HAVE HAD AN INSUFFICIENT RESPONSE TO A PREVIOUS TREATMENT

ODE-175  TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

ODE-176  INDICATED FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 L858R MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST

ODE-177  TO REDUCE THE FREQUENCY OF PAINFUL CRISSES AND TO REDUCE THE NEED FOR BLOOD TRANSFUSIONS IN PEDIATRIC PATIENTS, 2 YEARS OF AGE AND OLDER, WITH SICKLE CELL ANEMIA WITH RECURRENT MODERATE TO SEVERE PAINFUL CRISIS

ODE-178  INDICATED TO SLOW KIDNEY FUNCTION DECLINE IN ADULTS AT RISK OF RAPIDLY PROGRESSING AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)

ODE-179  TREATMENT OF PATIENTS WITH CLL AND TREATMENT OF PATIENTS WITH INDOLENT B-CELL NHL THAT HAS PROGRESSED DURING OR WITHIN SIX MONTHS OF TREATMENT WITH RITUXIMAB OR A RITUXIMAB CONTAINING REGIMEN

ODE-180  MAINTENANCE TREATMENT OF ADULT PATIENTS WITH RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER, WHO ARE IN A COMPLETE OR PARTIAL RESPONSE TO PLATINUM-BASED CHEMOTHERAPY

ODE-181  TREATMENT OF ADULT PATIENTS WITH DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE BRCA-MUTATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH THREE OR MORE PRIOR LINES OF CHEMOTHERAPY

ODE-182  TRAMETINIB IS INDICATED, IN COMBINATION WITH DABRAFENIB, FOR THE ADJUVANT TREATMENT OF PATIENTS WITH MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST, AND INVOLVEMENT OF LYMPH NODE(S), FOLLOWING COMPLETE RESECTION

ODE-183  TRAMETINIB AND DABRAFENIB IN COMBINATION, FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC ANAPLASTIC THYROID CANCER (ATC) WITH BRAF V600E MUTATION AND WITH NO SATISFACTORY LOCOREGIONAL TREATMENT OPTIONS

ODE-184  INDICATED IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF PEDIATRIC PATIENTS WITH HIV-1 INFECTION

ODE-185  INDICATED FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)
ORphan Drug Exclusivity


ODE-187 TREATMENT OF CYSTIC FIBROSIS (CF) IN PATIENTS AGE 6 YEARS AND OLDER WHO HAVE AN R117H MUTATION IN THE CFTR GENE


ODE-191 TO DECREASE THE RECURRENCE OF MALIGNANT PLEURAL EFFUSIONS IN SYMPTOMATIC PATIENTS FOLLOWING MAXIMAL DRAINAGE OF THE PLEURAL EFFUSION

ODE-192 INDICATED TO INDUCE CONTROLLED CARDIAC SEPTAL INFRACTION TO IMPROVE EXERCISE CAPACITY IN ADULTS WITH SYMPTOMATIC HYPERTROPHIC OBSTRUCTIVE CARDIOMYOPATHY WHO ARE NOT CANDIDATES FOR SURGICAL MYECTOMY

ODE-193 INDICATED FOR THE TREATMENT OF ONCHOCERCIASIS DUE TO ONCHOCERCA VOLVULUS IN PATIENTS AGED 12 YEARS AND OLDER

ODE-194 ENCORAFENIB IS INDICATED IN COMBINATION WITH BINIMETINIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH A BRAF V600E OR V600K MUTATION, AS DETECTED BY AN FDA-APPROVED TEST

ODE-195 FOR THE TREATMENT OF CYSTIC FIBROSIS (CF) IN PATIENTS AGE 2 THROUGH 5 YEARS OLD WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE

ODE-196 INDICATED FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH UNRESECTABLE HEPATOCELLULAR CARCINOMA (HCC)

ODE-197 INDICATED FOR THE TREATMENT OF THE POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS IN ADULTS

ODE-198 INDICATED FOR THE TREATMENT OF SEIZURES ASSOCIATED WITH DRAVET SYNDROME (DS) IN PATIENTS 2 YEARS OF AGE AND OLDER TAKING CLOBAZAM

ODE-199 THE TREATMENT OF CYSTIC FIBROSIS (CF) IN PATIENTS AGE 12 MONTHS AND OLDER WHO HAVE ONE MUTATION IN THE CFTR GENE THAT IS RESPONSIVE TO IVACAFTOR POTENTIATION BASED ON CLINICAL AND/OR IN VITRO ASSAY DATA

ODE-200 INDICATED FOR THE TREATMENT OF HUMAN SMALLPOX DISEASE CAUSED BY VARIOLA VIRUS IN ADULTS AND PEDIATRIC PATIENTS WEIGHING AT LEAST 13 KG

ODE-201 INDICATED FOR THE RADICAL CURE (PREVENTION OF RELAPSE) OF PLASMODIUM VIVAX MALARIA IN PATIENTS AGED 16 YEARS AND OLDER WHO ARE RECEIVING APPROPRIATE ANTIMALARIAL THERAPY FOR ACUTE P. VIVAX INFECTION

ODE-202 INDICATED AS A SOURCE OF CALORIES AND FATTY ACIDS IN PEDIATRIC PATIENTS WITH PARENTERAL NUTRITION-ASSOCIATED CHOLESTASIS (PNAC)

ODE-203 INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA (AML) WITH A SUSCEPTIBLE ISOCITRATE DEHYDROGENASE-1 (IDH1) MUTATION AS DETECTED BY AN FDA-APPROVED TEST

ODE-204 TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH IOBENGUANE SCAN POSITIVE, UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC PHEOCHROMOCYTOMA OR PARAGANGLIOMA WHO REQUIRE SYSTEMIC ANTICANCER THERAPY

ODE-205 INDICATED FOR THE TREATMENT OF ADULTS WITH A CONFIRMED DIAGNOSIS OF FABRY DISEASE AND AN AMENABLE GALACTOSIDASE ALPHA GENE (GLA) VARIANT BASED ON IN VITRO ASSAY DATA

ODE-206 FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETION OR EXON 21 L858R SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST

ODE-207 TREATMENT OF STATUS EPILEPTICUS IN ADULTS

ODE-208 TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC
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PATENT AND EXCLUSIVITY TERMS

ORPHAN DRUG EXCLUSIVITY

LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL) AFTER AT LEAST TWO PRIOR THERAPIES

ODE-209 TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL) AFTER AT LEAST TWO PRIOR SYSTEMIC THERAPIES

ODE-210 INDICATED IN COMBINATION WITH STANDARD IMMUNOSUPPRESSIVE THERAPY FOR THE FIRST-LINE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 2 YEARS AND OLDER WITH SEVERE APLASTIC ANEMIA

ODE-211 INDICATED IN COMBO WITH AZACITIDINE, OR DECITABINE, OR LOW-DOSE CYTARABINE FOR THE TX OF NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA IN ADULTS WHO ARE AGE 75 YEARS OR OLDER, OR WHO HAVE COMORBIDITIES THAT PRECLUDE USE OF INTENSIVE INDUCTION CHEMOTHERAPY

ODE-212 INDICATED FOR THE TREATMENT OF THE POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS IN ADULTS

ODE-213 INDICATED FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EPIDERMAL GROWTH FACTOR (EGFR) EXON 19 DELETION OR EXON 21 L858R SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST

ODE-214 TX OF MAC LUNG DISEASE IN ADULTS WITH LIMITED OR NO ALTERNATIVE TX OPTIONS AS PART OF A COMBO ANTIBACTERIAL DRUG REGIMEN WHO DO NOT ACHIEVE NEGATIVE SPUTUM CULTURES AFTER A MINIMUM OF 6 CONSECUTIVE MONTHS OF A MULTIDRUG BACKGROUND REGIMEN THERAPY

ODE-215 INDICATED FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH SOLID TUMORS THAT HAVE A NEUROTROPHIC RECEPTOR TYROSINE KINASE (NTRK) GENE FUSION WITHOUT A KNOWN ACQUIRED RESISTANCE MUTATION

ODE-216 INDICATED FOR THE TREATMENT OF SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME (LGS) OR DRAVET SYNDROME (DS) IN PATIENTS 2 YEARS OF AGE AND OLDER

ODE-217 INDICATED FOR THE TREATMENT OF PATIENTS WITH ANAPLASTIC LYMHPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE DISEASE HAS PROGRESSED ON CRIZOTINIB AND AT LEAST ONE OTHER ALK INHIBITOR FOR METASTATIC DISEASE

ODE-218 INDICATED FOR THE TREATMENT OF PATIENTS WITH ANAPLASTIC LYMHPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE DISEASE HAS PROGRESSED ON ALECTINIB AS THE FIRST ALK INHIBITOR THERAPY FOR METASTATIC DISEASE

ODE-219 INDICATED FOR THE TREATMENT OF PATIENTS WITH ANAPLASTIC LYMHPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE DISEASE HAS PROGRESSED ON CERITINIB AS THE FIRST ALK INHIBITOR THERAPY FOR METASTATIC DISEASE

ODE-220 INDICATED FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH SOLID TUMORS THAT ARE METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY

ODE-221 INDICATED FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH SOLID TUMORS THAT HAVE NO SATISFACTORY ALTERNATIVE TREATMENTS OR THAT HAVE PROGRESSED FOLLOWING TREATMENT

ODE-222 INDICATED FOR THE TREATMENT OF ADULT PATIENTS WHO HAVE RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA (AML) WITH A FMS-LIKE TYROSINE KINASE 3 (FLT3) MUTATION AS DETECTED BY AN FDA-APPROVED TEST

ODE-223 INDICATED FOR THE TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME (LEMS) IN ADULTS

ODE-224 INDICATED, IN COMBINATION WITH LOW-DOSE CYTARABINE, FOR THE TREATMENT OF NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) IN ADULT PATIENTS WHO ARE >=75 YEARS OLD OR WHO HAVE COMORBIDITIES THAT PRECLUDE USE OF INTENSIVE INDUCTION CHEMOTHERAPY

PATENT USE

U-1 PREVENTION OF PREGNANCY

U-2 TREATMENT OR PROPHYLAXIS OF ANGINA PECTORIS AND ARRHYTHMIA

U-3 TREATMENT OF HYPERTENSION

U-4 PROVIDING PREVENTION AND TREATMENT OF EMESIS AND NAUSEA IN MAMMALS

U-5 METHOD OF PRODUCING BRONCHODILATION
PATENT USE

U-6  METHOD OF PRODUCING SYMPATHOMIMETIC EFFECTS
U-7  INCREASING CARDIAC CONTRACTILITY
U-8  ACUTE MYOCARDIAL INFARCTION
U-9  CONTROL OF EMESIS ASSOCIATED WITH ANY CANCER CHEMOTHERAPY AGENT
U-10 DIAGNOSTIC METHOD FOR DISTINGUISHING BETWEEN HYPOTHALAMIC MALFUNCTIONS OR LESIONS IN HUMANS
U-11 TREATMENT OR PROPHYLAXIS OF CARDIAC DISORDERS
U-12 METHOD OF TREATING A HUMAN SUFFERING FROM DEPRESSION
U-13 A METHOD FOR TREATING ANXIETY IN A HUMAN SUBJECT IN NEED OF SUCH TREATMENT
U-14 ADJUNCTIVE THERAPY FOR THE PREVENTION AND TREATMENT OF HYPERAMMONEMIA IN THE CHRONIC MANAGEMENT OF PATIENTS WITH UREA CYCLE ENZYMOPATHIES
U-15 METHOD OF LOWERING INTRAOCULAR PRESSURE
U-16 USE IN LUNG SCANNING PROCEDURES
U-17 TREATMENT OF VENTRICULAR AND SUPRAVENTRICULAR ARRHYTHMIAS
U-18 METHOD FOR INHIBITING GASTRIC SECRETION IN MAMMALS
U-19 TREATMENT OF INFLAMMATION
U-20 A PROCESS FOR TREATING A PATIENT SUFFERING FROM PARKINSON'S SYNDROME AND IN NEED OF TREATMENT
U-21 TREATMENT OF HUMANS SUFFERING UNDESIRABLE UROTOXIC SIDE EFFECTS CAUSED BY CYTOSTATICALLY ACTIVE ALKYLATING AGENTS
U-22 METHOD OF COMBATTING PATHOLOGICALLY REDUCED CEREBRAL FUNCTIONS AND PERFORMANCE WEAKNESSES, CEREBRAL INSUFFICIENCY AND DISORDERS IN CEREBRAL CIRCULATION AND METABOLISM IN WARM-BLOODED ANIMALS
U-23 METHOD FOR TREATING PROSTATIC CARCINOMA COMPRISING ADMINISTERING FLUTAMIDE
U-24 METHOD FOR TREATING PROSTATE ADENOCARCINOMA COMPRISING ADMINISTERING AN ANTIANDROGEN INCLUDING FLUTAMIDE AND AN LHRH AGONIST
U-25 REDUCING CHOLESTEROL IN CHOLELITHIASIS PATIENTS
U-26 REDUCING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-27 DISSOLVING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-28 CEREBRAL, CORONARY, PERIPHERAL, VISCERAL AND RENAL ARTERIOGRAPHY, AORTOGRAPHY AND LEFT VENTRICULOGRAPHY
U-29 CT IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY
U-30 CEREBRAL ANGIOGRAPHY, AND VENOGRAPHY
U-31 INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
U-32 PALLIATIVE TREATMENT OF PATIENTS WITH OVARIAN CARCINOMA RECURRENT AFTER PRIOR CHEMOTHERAPY, INCLUDING PATIENTS WHO HAVE BEEN PREVIOUSLY TREATED WITH CISPLATIN
U-33 TREATING VIRAL INFECTIONS IN A MAMMAL
U-34 TREATING VIRAL INFECTIONS IN A WARM-BLOODED ANIMAL
U-35 TREATING CYTOMEGALOVIRUS IN A HUMAN WITH AN INJECTABLE COMPOSITION
U-36 METHODS OF TREATING BACTERIAL ILLNESSES
U-37 METHOD OF TREATING GASTROINTESTINAL DISEASE
U-38 TREATMENT OF PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA
U-39 ANGINA PECTORIS
U-40 METHOD OF TREATMENT OF BURNS
U-41 METHOD OF TREATING CARDIAC ARRHYTHMIAS
U-42 ADJUVANT TREATMENT IN COMBINATION WITH FLUOROURACIL AFTER SURGICAL RESECTION IN PATIENTS WITH DUKES' STAGE C COLON CANCER
U-43 MANAGEMENT OF CHRONIC PAIN IN PATIENTS REQUIRING OPIOID ANALGESIA
U-44 RELIEF OF NAUSEA AND VOMITING
U-45 TREATMENT OF INFLAMMATION AND ANALGESIA
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-46 TREATMENT OF PANIC DISORDER
U-47 STIMULATION OF THE RELEASE OF GROWTH HORMONE
U-48 ANALGESIA
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U-50 USE IN TREATING INFLAMMATORY DERMATOSES
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U-355 METHOD OF ASSISTING PERSON TO QUIT SMOKING...TRANSDERMALLY ADMIN NICOTINE VIA..PATCH ADHERED TO SKIN AT DOING RATE APPROX SAME AS ABSORBED FROM SMOKING
U-356 DELIVERING A MEDICINAL AEROSOL FORMULATION USING CFC-FREE PROPELLANT 134A.
U-357 USE OF THE DRUG PRODUCT IN PHOTODYNAMIC THERAPEUTIC PROTOCOLS FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION AND RELATED CONDITIONS INVOLVING UNWANTED NEOVASCULARITY IN THE EYE
U-358 DEPRESSION, OBSESSIVE COMPULSIVE DISORDER, PANIC DISORDER AND SOCIAL ANXIETY DISORDER
U-359 METHOD OF USE OF VISICOL
U-360 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF PATHOLOGICAL PSYCHOLOGICAL CONDITIONS INCLUDING MENTAL DISORDERS EMPLOYING OLanzAPINE AS PER THE INDICATION WHICH IS THE SUBJECT MATTER OF THIS SNDA-011
U-361 MANAGEMENT OF ANXIETY DISORDERS AND THE SHORT-TERM RELIEF OF THE SYMPTOMS OF ANXIETY
U-362 USE OF APPROVED FORMULATIONS TO TREAT ALL APPROVED DISEASE INDICATIONS
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U-364 TREATING A PATIENT SUFFERING FROM OR SUSCEPTIBLE TO ANY NUMBER OF LISTED CONDITIONS INCLUDING PSYCHOSIS, EMPLOYING OLanzAPINE AS PER THE INDICATION WHICH IS THE SUBJECT Matter OF THIS SNDA-011
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U-367 TREATMENT OF CARDIOVASCULAR DISORDERS
U-368 HEARTBURN
U-369 METHOD OF CONTROLLING AND LOWERING INTRAOCULAR PRESSURE
U-370 INTRAVAGINAL TREATMENT OF VAGINAL INFECTIONS WITH BUFFERED METRONIDAZOLE COMPOSITIONS
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-371 APPROVAL FOR MARKETING ONLY UNDER A SPECIAL RESTRICTION PROGRAM APPROVED BY FDA CALLED "SYSTEM FOR THALIDOMIDE EDUCATION AND PRESCRIBING SAFETY" (S.T.E.P.S.)

U-372 METHOD FOR ADMINISTERING A BENEFICIAL DRUG TO THE GI TRACT OF AN ANIMAL, WHICH METHOD COMPRISSES ADMITTING AN OSMOTIC DEVICE ORALLY INTO THE ANIMAL...

U-373 GENERAL USE CLAIM SUBMITTED FOR 12 NEXIUM PATIENTS STATING "PERTINENT TO THE CAPSULE FORMULATION FOR NEXIUM AND ITS INDICATIONS FOR THE TREATMENT OF GERD AND ERADICATION OF H.PYLORI TO REDUCE THE RISK OF DUODENAL ULCER RECURRENT...

U-374 KIT ADAPTED AND DESIGNED TO PROVIDE BOTH DATA ON THE CURRENT REPRODUCTIVE STATUS OF A PATIENT AND CONTRACEPTION FOR THOSE WHO ARE NOT PREGNANT, BUT RECENTLY ENGAGED IN UNPROTECTED SEX

U-375 METHOD OF USING RIBAVIRIN FOR TREATING A DISEASE RESPONSIVE TO RIBAVIRIN, E.G. HEPATITIS C

U-376 TREATMENT OF INFLUENZA

U-377 METHOD OF TREATING PT WITH CHRONIC HEPATITIS C HAVING HCV GENOTYPE 1 AND VIRAL LOAD GREATER THAN 2 MILLION COPIES/ML TO ERADICATE DETECTABLE HCV-RNA BY ADMIN COMBINATION OF RIBAVIRIN AND INTERFERON ALFA-2B FOR A LEAST 24 WEEKS

U-378 METHOD FOR TREATING INCONTINENCE

U-379 METHOD OF TREATING ONYCHOMYCOSIS

U-380 COMBINATIONS OF TAXOL (PACLITAXEL) AND CISPLATIN WHICH ARE SUITABLE FOR THE TREATMENT OF OVARIAN AND NON-SMALL CELL LUNG CARCINOMAS

U-381 TREATMENT OF HYPERPHOSPHATEMIA

U-382 METHOD OF STABILIZING PROSTAGLANDIN

U-383 METHOD FOR TREATING GLAUCOMA AND OCULAR HYPERTENSION

U-384 TREATMENT OF CMV RETINITIS

U-385 TREATMENT OF PEPTIC ULCERS

U-386 TREATMENT OF PATIENTS SUFFERING FROM A LATE ASTHMATIC REACTION OR LATE PHASE ASTHMA

U-387 TREATMENT OF PATIENTS WITH RESPIRATORY DISORDERS

U-388 SMOKING CESSATION AID APPLIED TO THE SKIN

U-389 SMOKING CESSATION AID APPLIED TO THE SKIN ON WAKING AND REMOVED PRIOR TO SLEEP AFTER ABOUT 16 HOURS

U-390 METHOD OF USING THE DRUG TO TREAT NEUROIMMUNOLOGIC DISEASES (INCLUDING MULTIPLE SCLEROSIS)

U-391 USE OF CASODEX IN COMBINATION WITH LHRH AGONISTS FOR THE TREATMENT OF PROSTATE CANCER

U-392 TREATMENT OF PATIENTS FOR INFLAMMATION

U-393 MANAGEMENT OF INCONTINENCE, MGT OF HORMONE REPLACEMENT THERAPY, TREATMENT OF INVOLUNTARY INCONTINENCE, MGT OVERACTIVE BLADDER AND INCREASING COMPLIANCE IN SUCH PT

U-394 METHOD OF USE OF ALPHAGAN

U-395 METHOD OF USE OF ALPHAGAN P

U-396 METHOD OF TREATING PEOPLE SUFFERING FROM DEPRESSION

U-397 METHOD OF TREATING PEOPLE SUFFERING FROM DEPRESSION WITHOUT AN INCREASE IN NAUSEA

U-398 TREATMENT OF GENERALIZED ANXIETY DISORDER

U-399 IN-THE-EYE USE OF CHLORINE DIOXIDE CONTAINING COMPOSITIONS

U-400 USE OF RIBAVIRIN TO INCREASE TYPE 1 CYTOKINE RESPONSE AND SUPPRESS TYPE 2 CYTOKINE RESPONSE TO LYMPHOCYTES, INCLUDING METHODS THAT TAKE ADVANTAGE OF SUCH MODULATION TO TREAT INFECTIONS AND INFESTATIONS

U-401 USE OF LOPINAVIR IN COMBINATION WITH REVERSE TRANSCRIPTASE INHIBITORS FOR TREATING HIV INFECTION AND IN COMBO WITH OTHER HIV PROTEASE INHIBITORS

U-402 TREATMENT OF ACTINIC KERATOSES

U-403 ANTI-ALLERGIC FOR VARIOUS ALLERGIC DISEASES
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-404 TREATMENT OF ALLERGIC CONJUNCTIVITIS
U-405 FOR WOMEN WITH SEVERE DIARRHEA-PREDOMINANT IRRITABLE BOWEL SYNDROME (IBS)
U-406 METHOD OF USE OF ATOVACOQUE AND PROGUANIL
U-407 METHOD OF TREATING OTOPATHY
U-408 FOR INDUCING OVULATION IN CONJUNCTION WITH A GONADOTROPIN RELEASING FACTOR ANTAGONIST AND RECRUITING OOCYTES FOR IN-VITRO FERTILIZATION
U-409 METHOD OF TREATING INFLAMMATION USING DRUG SUBSTANCE
U-410 METHOD OF REDUCING AMOUNT OF RESPECTIVE ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT BY ADMINISTERING A CHEMICAL COMPOUND HAVING A PARTICULAR FORMULA (INCLUDING PIOGLITAZONE) IN COMBINATION WITH AN INSULIN SECRETION ENHANCER
U-411 METHOD OF REDUCING THE SIDE EFFECTS OF ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT BY ADMINISTERING A CHEMICAL COMPOUND HAVING A PARTICULAR FORMULA (WHICH INCLUDES PIOGLITAZONE) IN COMBINATION WITH AN INSULIN PREPARATION
U-412 TREATMENT OF TYPE 2 DIABETES
U-413 USE OF THE ACTIVE INGREDIENT FOR INHIBITING THE BIOSYNTHESIS OF CHOLESTEROL AND TREATMENT OF ATHEROSCLEROSIS
U-414 A METHOD OF TREATING GLYCOMETABOLISM DISORDERS BY ADMINISTERING AN INSULIN SENSITIVITY ENHANCER (INCLUDING PIOGLITAZONE) IN COMBINATION WITH A BIGUANIDE
U-415 A METHOD FOR REDUCING THE AMOUNT OF ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT BY ADMINISTERING AN INSULIN SENSITIVITY ENHANCER (INCLUDING PIOGLITAZONE) IN COMBINATION WITH A BIGUANIDE AS SAID ACTIVE COMPONENTS
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U-417 COMBINATION USE OF AD-4833 WITH A BIGUANIDE
U-418 A METHOD OF TREATING LIPID METABOLISM DISORDERS BY ADMINISTERING A CHEMICAL COMPOUND HAVING A PARTICULAR FORMULA (WHICH INCLUDES PIOGLITAZONE) IN COMBINATION WITH AN INSULIN SENSITIVITY ENHANCER
U-419 A METHOD OF TREATING LIPID METABOLISM DISORDERS BY ADMINISTERING AN INSULIN SENSITIVITY ENHANCER (INCLUDING PIOGLITAZONE) IN COMBINATION WITH A BIGUANIDE
U-420 METHOD OF TREATMENT OF TYPE II DIABETES
U-421 USE FOR SEDATION
U-422 METHOD OF TREATING AT LEAST ONE OF ATTENTION DEFICIT DISORDER AND ATTENTION DEFICIT HYPERACTIVITY DISORDER
U-423 METHOD OF TREATING AT LEAST ONE OF ATTENTION DEFICIT DISORDER, ATTENTION DEFICIT HYPERACTIVITY DISORDER, OR AIDS RELATED DEMENTIA
U-424 FOR ONCE DAILY, BOLUS ADMINISTRATION TO A PATIENT IN ORDER TO ENGENDER TREATMENT FOR A NERVOUS DISORDER FOR SUBSTANTIALLY AN ENTIRE DAY ON A CHRONIC BASIS
U-425 METHOD OF REDUCING SIDE EFFECTS OF ACTIVE COMPONENTS ADMIN TO A DIABETIC BY ADMIN A CHEMICAL COMPOUND HAVING FORMULA (INCL PIOGLITAZONE) IN COMBINATION WITH AN INSULIN SECRETION ENHANCER
U-426 PREVENTION OF PREMATURE LH SURGES IN WOMEN UNDERGOING CONTROLLED OVARIAN STIMULATION
U-427 METHOD OF TREATING ALLERGIC REACTIONS IN MAMMALS
U-428 METHOD OF TREATING ALLERGY IN A MAMMAL USING THIS ACTIVE METABOLITE
U-429 METHOD OF USING DESLORATADINE TO TREAT ALLERGIC RHINITIS
U-430 METHOD OF TREATING A DIABETIC BY ADMINISTERING AN INSULIN SENSITIZER IN COMBINATION WITH AN INSULIN SECRETION ENHANCER, AND A DRUG PRODUCT COMPRISING AN INSULIN SENSITIZER AND AN INSULIN SECRETION ENHANCER
U-431 POSTTRAUMATIC STRESS DISORDER
U-432 REDUCTION OF ATHEROSCLEROTIC EVENTS (MYOCARDIAL INFARCTION, STROKE, AND VASCULAR DEATH) IN PATIENTS WITH ATHEROSCLEROSIS DOCUMENTED BY RECENT STROKE, RECENT MYOCARDIAL INFARCTION OR ESTABLISHED PERIPHERAL ARTERIAL DISEASE
U-433 USE OF LEVOCARNITINE IN PREVENTION AND TREATMENT OF CARNITINE DEFICIENCY IN PATIENTS WITH END STAGE RENAL DISEASE WHO ARE UNDERGOING DIALYSIS
PATENT AND EXCLUSIVITY TERMS

U-434  CONTROLLED SYMPTOMS OF DIARRHEA, BLOATING PRESSURE AND CRAMPS, COMMONLY REFERRED TO AS GAS
U-435  A TITRATION DOSING REGIMEN FOR THE TREATMENT OF PAIN USING AN INITIAL DOSE OF ABOUT 25MG
U-436  ACUTE TREATMENT OF MIGRAINE ATTACKS WITH OR WITHOUT AURA IN ADULTS
U-437  METHOD OF USE EQUAL TO PROCESS OF PREPARATION
U-438  TREATMENT/PREVENTION OF NEURODEGENERATIVE DISEASE
U-439  TREATMENT OF OBESITY
U-440  METHOD FOR TRANSDERMAL ADMINISTRATION OF A DRUG THROUGH NON-SCROTAL SKIN USING A TRANSDERMAL DRUG DELIVERY DEVICE CONTAINING THE DRUG AND HAVING AN ADHESIVE SURFACE
U-441  METHOD OF TREATING MS BY ADMINISTERING COPAXONE
U-442  METHOD FOR DELIVERING A DRUG TO A PATIENT IN NEED OF THE DRUG, WHILE AVOIDING THE OCCURRENCE OF AN ADVERSE SIDE EFFECT KNOWN OR SUSPECTED OF BEING CAUSED BY SAID DRUG
U-443  MANAGEMENT OF MODERATE TO SEVERE PAIN WHEN A CONTINUOUS, AROUND-THE-CLOCK ANALGESIC IS NEEDED FOR AN EXTENDED PERIOD OF TIME
U-444  TREATMENT OF MIGRAINE
U-445  USE AS AN ANTIMYCOTIC AGENT
U-446  TOPICAL TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA
U-447  METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-448  METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID WITHOUT CAUSING TREATMENT-LIMITING ELEVATIONS IN URIC ACID OR GLUCOSE LEVELS OR CAUSING LIVER DAMAGE, BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-449  USE IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN FOR THE TREATMENT OF METASTATIC COLORECTAL CANCER WHERE THE DOSE OF LEUCOVORIN IS AT LEAST 200MG PER SQUARE METER
U-450  INTERMEDIATE REL NICOTINIC ACID FORMULATIONS HAVING UNIQUE URINARY METAB PROFILES RESULTING FROM ABSORPTION PROFILES OF NICOTINIC ACID FROM THE INTERMEDIATE NICOTINIC ACID FORMULATIONS, SUITABLE FOR TX HYPERLIPIDEMIA FOLLOWING QD DOSING
U-451  TREATMENT OF DEPRESSION AND GENERALIZED ANXIETY DISORDER
U-452  USE OF LANSOPRAZOLE FOR COMBATTING DISEASES CAUSED BY THE GENUS CAMPYLOBACTER (C.PYLORI=H.PYLORI)
U-453  TREATMENT OF PLATELET ASSOCIATED ISCHEMIC DISORDERS
U-454  METHOD OF TX A PT SUSPECTED OF HAVING HEPATITIS C BY ADMIN, IN COMBINATION, A CONJUGATE COMPRISING PEG 12000 & INTERFERON ALFA-2B IN AN AMT OF FROM 0.5MCG/KG TO 2MCG/KG, ONCE WEEKLY, AND RIBAVIRIN
U-455  TREATMENT OF PULMONARY HYPERTENSION WITH UT-15
U-456  METHOD OF DECREASING THE PRODUCTION OF A-BETA USING A COMPOSITION WHICH DECREASES BLOOD CHOLESTEROL IN PATIENTS AT RISK OF OR EXHIBITING SYMPTOMS OF ALZHEIMER’S DISEASE
U-457  METHOD OF TREATING A VAGINAL FUNGAL INFECTION IN A FEMALE HUMAN
U-458  METHOD OF USE OF IMAGENT
U-459  TREATMENT OF DEPRESSION AND GENERALIZED ANXIETY DISORDER
U-460  METHOD OF TREATING PSYCHIATRIC SYMPTOMS ASSOCIATED WITH PREMENSTRUAL DISORDERS USING SERTRALINE
U-461  METHOD OF TREATMENT OF LATE LUTEAL PHASE DYSPHORIC DISORDER (PMDD) USING SERTRALINE
U-462  SIGNS AND SYMPTOMS OF OSTEOARTHRITIS AND ADULT RHEUMATOID ARTHRITIS AND TREATMENT OF PRIMARY DYSMENORRHEA
U-463  VENOGRAPHY
U-464  PERIPHERAL ARTERIOGRAPHY
PATENT AND EXCLUSIVITY TERMS

U-465 CT IMAGING OF THE HEAD
U-466 TREATMENT OF IRRITABLE BOWEL SYNDROME
U-467 USE OF EPLERENONE IN COMBINATION WITH AN ANGIOTENSIN CONVERTING ENZYME (ACE) INHIBITOR FOR TREATING HYPERTENSION
U-468 METHOD OF USING FEXOFENADINE HCL IN TREATING ALLERGIC RHINITIS
U-469 TREATMENT OF GASTROESOPHAGEAL REFLEX DISEASE (GERD) AND ERADICATION OF H. PYLORI TO REDUCE RISK OF DUODENAL ULCER RECURRENT
U-470 THERAPY IN CHRONIC HEPATITIS B VIRUS INFECTION
U-471 METHOD OF TREATING A PATIENT SUFFERING FROM DIABETES MELLITUS
U-472 TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER USING METHYLPHENIDATE BI-MODAL RELEASE PROFILE EXTENDED-RELEASE CAPSULES
U-473 TO REDUCE PLASMA CHOLESTEROL LEVELS IN A MAMMAL
U-474 TO REDUCE PLASMA CHOLESTEROL LEVELS BY ADMIN EZETIMIBE IN COMBO WITH CHOLESTEROL BIOSYNTHESIS INHIB SELECTED FROM GROUP CONSISTING OF HMG COA REDUCTASE INHIBITORS INCL SIMVASTATIN
U-475 TREATMENT OF CUTANEOUS MANIFESTATIONS OF CUTANEOUS T-CELL LYMPHOMA IN PATIENTS WHO ARE REFRACORY TO AT LEAST ONE PRIOR SYSTEMIC THERAPY
U-476 METHOD OF TREATING ANDROGEN RESPONSIVE/MEDIATED CONDITION IN MAMMAL BY ADMIN A SAFE, EFFECTIVE AMOUNT OF DU TASTERIDE OR PHARMACEUTICALLY ACCEPTABLE DERIVATIVE THEREOF..CONDITIONS INCLUDE BENIGN PROSTATIC HYPERPLASIA
U-477 METHOD OF INHIBITING 5 ALPHA TESTOSTERONE REDUCTASE ENZYME WITH DU TASTERIDE OR ITS DERIVATIVE AND TREATING ANDROGEN RESPONSIVE/MEDIATED DISEASE INCLUDING BENIGN PROSTATIC HYPERPLASIA
U-478 METHOD OF TREATING HEPATITIS C VIRAL INFECTION BY CONTINUOUS PARENTERAL ADMIN INTERFERON ALPHA 2-10 MILLION IU WEEKLY, SUBCUTANEOUSLY, INJECTION OF POLYMER-INTERFERON ALPHA CONJUGATE-POLYMER IS PEG-INTERFERON IS ALPHA 2B
U-479 METHOD OF USING PEG-INTRON/REBETOL COMBINATION THERAPY AND INTRON/REBETOL COMBINATION THERAPY
U-480 CONTRAST AGENT FOR MRI
U-481 DISUBSTITUTED ACETYLENES BEARING HETEROAROMATIC AND HETEROBICYCLIC GROUPS HAVING RETINOID-LIKE ACTIVITY
U-482 METHOD OF IN VITRO FERTILIZATION THERAPY INCLUDING MEANS FOR INDUCING OVULATION....
U-483 METHOD FOR THE ADMINISTRATION OF DRUGS USING THAT COMPOUND
U-484 METHOD OF TREATING A SKIN DISEASE WITH A CORTICOSTEROID-CONTAINING PHARMACEUTICAL COMPOSITION
U-485 METHOD AND COMPOSITION FOR REDUCING NERVE INJURY PAIN ASSOCIATED WITH SHINGLES (HERPES ZOSTER AND POST-HERPETIC NEURALGIA)
U-486 EXTERNAL PREPARATION FOR APPLICATION TO THE SKIN CONTAINING LIDOCAINE-DRUG RETAINING LAYER PLACED ON SUPPORT AND COMPRIS DES ADHESIVE GEL BASE 1-10% BY WEIGHT OF LIDOCAINE
U-487 METHOD AND COMPOSITION FOR REDUCING NERVE INJURY PAIN ASSOCIATED WITH SHINGLES (HERPES ZOSTER AND POST-HERPETIC NEURALGIA)
U-488 METHOD FOR REDUCING THE PAIN ASSOCIATED WITH HERPES-ZOSTER AND POST-HERPETIC NEURALGIA
U-489 EXPECTORANT
U-490 TESTOSTERONE REPLACEMENT THERAPY IN MALES FOR CONDITIONS ASSOCIATED WITH A DEFICIENCY OR ABSENCE OF ENDOGENOUS TESTOSTERONE
U-491 METHOD OF DELIVERING A DRUG TO THE LUNG
U-492 METHOD FOR THE TREATMENT OF SKIN, SUFFERING FROM A CONDITION SELECTED FROM A GROUP CONSISTING OF NONACNE INFLAMMATORY DERMATOSES... COMPRISING APPLYING TO AFFECTED AREA. A THERAPEUTICALLY EFFECTIVE AMT AZELAIC ACID
U-493 TREATMENT OF TYPE 2 DIABETES MELLITUS
U-494 TREATMENT OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER
U-495 PERITONEAL DIALYSIS SOLUTION
PATENT AND EXCLUSIVITY TERMS

U-496 METHOD FOR TREATING CHRONIC RENAL FAILURE
U-497 RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS
U-498 INTRA-ARTERIAL AND INTRAVENOUS USES OF ULTRAVIST
U-499 METHOD OF USING REBETOL CAPSULES IN COMBINATION WITH A CONJUGATE COMPRISING POLYETHYLENE GLYCOL(PEG) AND AN ALPHA INTERFERON, INCLUDING, FOR EXAMPLE, PEG-INTRON POWDER FOR INJECTION
U-500 USE AS AN ANTIHYPERTENSIVE AGENT
U-501 TREATMENT OF RECURRENT HERPES LABIALIS (COLD SORES) IN ADULTS
U-502 PITYRIASIS VERSICOLOR
U-503 GENERATOR MUST BE USED WITH INFUSION SYSTEM SPECIFICALLY LABELED FOR USE WITH GENERATOR
U-504 TINEA PEDIS, TINEA CRURIS, TINEA CORPORIS
U-505 ULTRASOUND CONTRAST AGENT
U-506 PHARM PRODUCT CONTAINER 1ST CHAMBER IS DISPOSED AQUEOUS DILUENT SOL 2ND CHAMER PHARM ACTIVE AGENT COMPRISING ACETYLCHOLINE,BUFFER IN 1ST CHAM IS SUFFICIENT TO BUFFER PH OF MIXED SOL RESULTING MIXTURE OF AQUEOUS DILUENT SOL & PHARM ACTIVE..
U-507 ACROMEGALY IN PATIENTS W/INADEQUATE RESPONSE TO SURGERY AND/OR RADIATION THERAPY AND/OR MEDICAL THERAPIES, OR FOR WHOM THESE THERAPIES ARE NOT APPROPRIATE
U-508 METHOD OF RELEASING 17-BETA OESTRADIOL PRECURSOR IN A SUBSTANTIALLY ZERO ORDER PATTERN FOR AT LEAST THREE WEEKS
U-509 TREATMENT OF CUTANEOUS MANIFESTATIONS OF CUTANEOUS T-CELL LYMPHOMA IN PATIENTS WHO ARE REFRACTORY TO AT LEAST ONE PRIOR SYSTEMIC THERAPY
U-510 TOPICAL TREATMENT OF CUTANEOUS LESIONS IN PATIENTS WITH CUTANEOUS T-CELL LYMPHOMA (STAGE IA AND IB) WHO HAVE REFRACTORY OR PERSISTENT DISEASE AFTER OTHER THERAPIES OR WHO HAVE NOT TOLERATED OTHER THERAPIES
U-511 USE OF QUINOLONE COMPOUNDS AGAINST ANAEROBIC PATHOGENIC BACTERIA
U-512 USE OF QUINOLONE COMPOUNDS AGAINST ATYPICAL UPPER RESPIRATORY PATHOGENIC BACTERIA
U-513 METHODS OF USE OF ANTIMICROBIAL COMPOUNDS AGAINST PATHOGENIC AMYCOPLASMA BACTERIA
U-514 PREVENTION OF OVULATION IN A WOMAN
U-515 TREATMENT OF MULTIPLE MYELOMA PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES AND HAVE DEMONSTRATED DISEASE PROGRESSION ON THE LAST THERAPY
U-516 METHOD OF TREATING A PSYCHOTIC DISEASE
U-517 STABLE GEL FORMULATION FOR TOPICAL TREATMENT OF SKIN CONDITIONS
U-518 OBSESSIVE COMPULSIVE DISORDER
U-519 POST OPERATIVE NAUSEA AND VOMITING
U-520 PREMENOPAUSAL OSTEOPOROSIS
U-521 METHOD OF USING RIBAVIRIN IN COMBINATION WITH INTRON A (INTERFERON ALPHA-2 B RECOMBINANT) INJECTION TO TREAT PATIENTS WITH CHRONIC HEPATITIS C
U-522 TREATMENT OF CMV RETINITIS BY INTRAVITREAL ADMIN OF A PHOSPHOROTHIOATE Oligonucleotide CAPABLE OF HYBRIDIZING WITH CMV MRNA
U-523 METHOD OF TREATING INFECTION BY CRYPTOSPORIDIUM PARVUM IN AN IMMUNOCOMPROMISED MAMMAL
U-524 METHOD OF TREATING DIARRHEA
U-525 METHOD OF TREATING PARASITIC INFECTIONS
U-526 METHOD OF PROVIDING CONTROLLED RELEASE OF A TREATING AGENT USING A CONTROLLED RELEASE COMPOSITION
U-527 METHOD OF DELIVERING AN ACTIVE INGREDIENT USING A PROGRESSIVE HYDRATION BIOADHESIVE
U-528 PREVENTION OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING
U-529 ONCE DAILY TREATMENT OF ASTHMA WITH NEBULIZED BUDESONIDE
U-530 TREATMENT OF HERPES ZOSTER, TREATMENT OF GENITAL HERPES, TREATMENT OF COLD
PATENT USE

SORES, SUPPRESSION OF GENITAL HERPES IN IMMUNOCOMPETENT AND HIV-INFECTED INDIVIDUALS; REDUCTION OF RISK OF HETEROSEXUAL TRANSMISSION OF GENITAL HERPES

U-531 TREATMENT OF PATIENTS WITH ESSENTIAL HYPERTENSION. MAY BE USED ALONE OR GIVEN WITH OTHER CLASSES OF ANTIHYPERTENSIVES, ESPECIALLY THIAZIDE DERIVATIVES

U-532 TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD IN PATIENTS REQUIRING MORE THAN ONE BRONCHO DILATOR

U-533 ERECTILE DYSFUNCTION

U-534 HUMALOG IS AN INSULIN ANALOG THAT IS INDICATED IN THE TREATMENT OF PATIENTS WITH DIABETES MELLITUS FOR THE CONTROL OF HYPERGLYCEMIA

U-535 TREATMENT OF SOCIAL ANXIETY DISORDER

U-536 CONTRAST AGENT FOR MAGNETIC RESONANCE IMAGING

U-537 TREATMENT OF CONDITIONS RELATED TO HYPERALDOSTERONISM SUCH AS HYPERTENSION AND CARDIAC INSUFFICIENCY, WITH EPLERENONE

U-538 FIRST LINE TREATMENT OF SEVERE HYPERTENSION, IN PATIENTS WITH HYPERTENSION SEVERE ENOUGH THAT THE VALUE OF ACHIEVING PROMPT BLOOD PRESSURE CONTROL EXCEEDS THE RISK OF INITIATING COMBINATION THERAPY IN THESE PATIENTS

U-539 TREATMENT OF MODERATE TO SEVERE DEMENTIA OF THE ALZHEIMER'S TYPE

U-540 TREATMENT OF FUNGAL INFECTIONS

U-541 METHOD OF TREATMENT OF ADULTS INFECTED WITH HIV-1

U-542 METHOD OF TREATING PATIENT WITH TYPE 2 DIABETES BY ONCE DAILY ADMINISTRATION

U-543 TREATMENT OF SCHIZOPHRENIA

U-544 TREATMENT OF OVERACTIVE BLADDER. TREATMENT OF URINARY INCONTINENCE.

U-545 METHOD FOR THE PREVENTION AND/OR TREATMENT OF THROMBOTIC EPISODES, SUCH AS MYOCARDIAL INFARCTION, IN A HUMAN PATIENT AND METHOD FOR THE PREVENTION OF VENOUS THROMBOSIS IN A POSTOPERATIVE HUMAN PATIENT

U-546 USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE

U-547 MAINTENANCE MONOTHERAPY FOR BIPOLAR DISORDER

U-548 A METHOD OF REDUCING FLUSH IN AN INDIVIDUAL BEING TREATED FOR A LIPIDEMIC DISORDER AND EFFECTIVELY TREATING THE LIPIDEMIC DISORDER

U-549 USE IN THE TREATMENT OF MEN WITH ADVANCED SYMPTOMATIC PROSTATE CANCER

U-550 TREATMENT OF BIPOLAR DISORDER AND SCHIZOPHRENIA

U-551 METHOD FOR REDUCING TOXICITY OF ALIMTA TREATED PATIENTS BY ADMINISTERING FOLIC ACID

U-552 TREATMENT OF HYPERTENSION AND HYPERLIPIDEMIA WITH A SINGLE COMPOSITION

U-553 MANAGEMENT OF PAIN AND DISCOMFORT ASSOCIATED WITH PERIDONTAL SCALING AND ROOT PLANNING PROCEDURES BY APPLICATION OF AN EUTECTIC MIXTURE OF LOCAL ANESTHETICS TO PERIDONTAL POCKETS

U-554 TREATING HIV INFECTION WITH INDINAVIR SULFATE IN COMBINATION WITH ANTIRETROVIRAL AGENTS

U-555 TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS AND ACUTE UNCOMPlicated PYELONEPHRITIS

U-556 USE AS ADJUNCT DIAGNOSTIC FOR SERUM THYROGLOBULIN (TG) TESTING

U-557 NASAL TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS

U-558 INDICATED FOR THE RELIEF OF BRONCHOSPASM IN PATIENTS 2-12 YEARS OF AGE WITH ASTHMA (REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE)

U-559 METHOD OF DECREASING OR REDUCING PARATHYROID HORMONE LEVEL; METHOD OF MODULATING PARATHYROID HORMONE SECRETION; METHOD OF TREATING HYPERPARATHYROIDISM; METHOD OF REDUCING SERUM IONIZED CALCIUM LEVEL

U-560 METHOD OF DECREASING PARATHYROID HORMONE LEVEL; METHOD OF TREATING HYPERPARATHYROIDISM

U-561 COSOPT IS INDICATED FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION WHO ARE INSUFFICIENTLY RESPONSIVE TO BETA BLOCKERS

U-562 TOPICAL TREATMENT OF CUTANEOUS LESIONS IN PATIENTS WITH AIDS-RELATED KAPOSI'S
PATENT USE

SARCOMA

U-563  MARINOL IS INDICATED FOR, INTER ALIA, ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS

U-564  TREATMENT OF HIV IN CONCOMITANT THERAPY

U-565  TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS, AND CHRONIC URTICARIA

U-566  FOR THE LONG-TERM, ONCE-DAILY, MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA

U-567  METHOD OF TREATING INFERTILITY

U-568  METHOD OF USING FSH ALONE (WITHOUT EXOGENOUS LH) IN IN VITRO FERTILIZATION

U-569  METHOD OF USING FSH ALONE (WITHOUT EXOGENOUS LH) IN IN VITRO FERTILIZATION AND WHEREIN THEREAFTER AN OVULATORY INDUCING AMOUNT OF HCG IS ADMINISTERED

U-570  METHOD OF USING FSH ALONE (WITHOUT EXOGENOUS LH) IN IN VITRO FERTILIZATION AND WHEREIN THE DAILY AMOUNT OF FSH IS ABOUT 5-10 IU/KG

U-571  TREATMENT OF AGITATION ASSOCIATED WITH SCHIZOPHRENIA AND BIPOLAR I MANIA

U-572  INTENSIVE CARE UNIT SEDATION

U-573  TREATMENT OF ACUTE PROMYELOGENOUS LEUKEMIA (APL)

U-574  PROPHYLAXIS AND TREATMENT OF THE NASAL SYMPTOMS OF SEASONAL ALLERGIC RHINITIS AND TREATMENT OF THE NASAL SYMPTOMS OF PERENNIAL ALLERGIC RHINITIS IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER

U-575  LOTEMAX OPHTHALMIC SUSPENSION IS INDICATED FOR THE TREATMENT OF STEROID RESPONSIVE CONDITIONS OF THE PALPEBRAL BULBAR CONJUNCTIVA, CORNEA AND ANTERIOR SEGMENT OF THE GLOBE.

U-576  ALREX OPHTHALMIC SUSPENSION IS INDICATED FOR THE TEMPORARY RELIEF OF THE SIGNS AND SYMPTOMS OF SEASONAL ALLERGIC CONJUNCTIVITIS.

U-577  TREATMENT OF BENIGN PROSTATIC HYPERPLASIA WITH FINASTERIDE IN COMBINATION WITH DOXAZOSIN

U-578  TREATMENT OF COMMUNITY ACQUIRED PNEUMONIA, ACUTE EXACERBATION OF CHRONIC BRONCHITIS, AND ACUTE BACTERIAL SINUSITIS CAUSED BY SUSCEPTIBLE STRAINS OF DESIGNATED MICROORGANISMS IN PATIENTS 18 YEARS AND OLDER.

U-579  TREATMENT OF EPILEPSY AND/OR MIGRAINE.

U-580  TREATMENT OF DISORDERS OF THE SEROTONERGIC SYSTEM SUCH AS DEPRESSION AND ANXIETY-RELATED DISORDERS

U-581  METHOD OF TREATING A CONDITION CAPABLE OF TREATMENT BY INHALATION, E.G. ASTHMA, COMPRISING ADMINISTRATION OF A FORMULATION CLAIMED IN US PATENT NO. 6743413

U-582  METHOD FOR THE TREATMENT OF A RESPIRATORY DISORDER, E.G. ASTHMA, COMPRISING ADMINISTERING AN EFFECTIVE AMOUNT OF AN AEROSOL COMPOSITION TO A PATIENT FROM A METERED DOSE INHALER SYSTEM AS CLAIMED IN US PATENT NO. 6253762

U-583  METHOD FOR THE TREATMENT OF A RESPIRATORY DISORDER, E.G. ASTHMA, COMPRISING ADMINISTERING TO A PATIENT BY INHALATION, A METERED AEROSOL DOSE OF A DRUG FORMULATION FROM THE METERED DOSE INHALER SYSTEM CLAIMED IN US 6546928

U-584  SINGLE-DOSE ADMINISTRATION BY THE EPIDURAL ROUTE, AT THE LUMBAR LEVEL, FOR THE TREATMENT OF PAIN FOLLOWING MAJOR SURGERY

U-585  TO PROMOTE WEIGHT GAIN AFTER WEIGHT LOSS IN CERTAIN TYPES OF PATIENTS

U-586  AN INTERMEDIATE RELEASE NICOTINIC ACID FORMULATION SUITABLE FOR ORAL ADMINISTRATION ONCE-A-DAY AS A SINGLE DOSE FOR TREATING HYPERLIPIDEMIA WITHOUT CAUSING DRUG-INDUCED HEPATOTOXICITY OR ELEVATIONS IN URIC ACID OR GLUCOSE OR BOTH

U-587  USE OF EPLERENONE IN COMBINATION WITH AN ANGIOTENSIN CONVERTING ENZYME (ACE) INHIBITOR (AND OPTIONALLY A DIURETIC) FOR TREATING CONGESTIVE HEART FAILURE AND HYPERTENSION

U-588  SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER; TREATMENT OF HEARTBURN AND OTHER SYMPTOMS ASSOCIATED WITH GERD; SHORT-TERM TREATMENT OF EROSIVE ESOPHAGITIS; MAINTENANCE OF HEALING OF EROSIVE ESOPHAGITIS

U-589  METHOD FOR TREATMENT OF A RESPIRATORY DISORDER, E.G., BRONCHOSPASM, COMPRISING ADMINISTERING AN EFFECTIVE AMOUNT OF AN AEROSOL COMPOSITION TO A PATIENT FROM A
PATENT AND EXCLUSIVITY TERMS

U-590 METERED DOSE INHALER SYSTEM AS CLAIMED IN U.S. PATENT NO. 6131966

U-591 METHOD FOR TREATMENT OF A RESPIRATORY DISORDER, E.G., BRONCHOSPASM, COMPRISING ADMINISTERING TO A PATIENT BY ORAL OR NASAL INHALATION A DRUG FORMULATION BY USING THE METERED DOSE INHALER SYSTEM AS CLAIMED IN US PATENT NO. 6532955

U-592 TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER USING A DOSAGE FORM WHICH PROVIDES ONCE-DAILY ORAL ADMINISTRATION OF A PHENIDATE DRUG

U-593 TREATMENT OF PRIMARY HYPERCHOLESTEROLEMIA, MIXED HYPERLIPIDEMIA AND/OR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH)

U-594 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

U-595 35 MG ORALLY ONCE A WEEK FOR PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN; 35 MG ORALLY ONCE A WEEK FOR TREATMENT OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN

U-596 TREATMENT OF HORMONE RECEPTOR POSITIVE METASTATIC BREAST CANCER IN POSTMENOPAUSAL WOMEN WITH DISEASE PROGRESSION FOLLOWING ANTIESTROGEN THERAPY

U-597 FORTEO IS INDICATED FOR THE TREATMENT OF POST MENOPAUSAL WOMEN WITH OSTEOPOROSIS WHO ARE AT HIGH RISK FOR FRACTURE

U-598 PROPHYLACTIC TREATMENT OF MIGRAINE

U-599 METHOD FOR TREATING ALLERGIC CONJUNCTIVITIS

U-600 A METHOD OF TREATING A PATIENT IN NEED OF OPHTHALMIC ANTIMICROBIAL THERAPY WITH LEVOFLAXACIN

U-601 TREATMENT OF BIPOLAR DISORDER

U-602 SIGNS AND SYMPTOMS OF OSTEOARTHRITIS, RHEUMATOID ARTHRITIS IN ADULTS, AND/OR PAuciARTICULAR OR PAUCIARTICULAR COURSE JUVENILE RHEUMATOID ARTHRITIS, ACUTE PAIN IN ADULTS; PRIMARY DYSMENORRHEA; AND/OR ACUTE MIGRAINE ATTACKS IN ADULTS

U-603 METHOD OF TREATING INFECTIONS COMPRISING ORALLY ADMINISTERING AN EFFECTIVE AMOUNT OF THE FDA APPROVED ORAL SUSPENSION

U-604 METHOD OF LOWERING BLOOD GLUCOSE BY ONCE DAILY ADMINISTRATION

U-605 TREATMENT OF MAJOR DEPRESSIVE DISORDER (MDD); ALTHOUGH THE MECHANISM OF THE ANTIDEPRESSANT ACTION OF DULOXETINE IN HUMANS IS UNKNOWN, IT IS BELIEVED TO BE RELATED TO ITS POTENTIATION OF SERATONERGIC AND NORADRENERGIC ACTIVITY IN THE CNS

U-606 USE OF IRINOTECAN IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN FOR THE TREATMENT OF METASTATIC COLORECTAL CANCER

U-607 CANCIDAS IS INDICATED FOR EMPIRICAL THERAPY FOR PRESUMED FUNGAL INFECTIONS IN FEBRILE, NEUTROPENIC PATIENTS.

U-608 USE OF QUINOLONE COMPOUNDS AGAINST PNEUMOCOCCAL PATHOGENIC BACTERIA

U-609 USE OF QUINOLONE COMPOUNDS AGAINST QUINOLONE-RESISTANT PNEUMOCOCCAL PATHOGENIC BACTERIA

U-610 ATROVENT HFA (IPRATROPIUM BROMIDE HFA) INHALATION AEROSOL IS INDICATED AS A BRONCHODILATOR FOR MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE, INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA.

U-611 METHOD OF USING DESLORATADINE TO TREAT SEASONAL AND PERENNIAL ALLERGIC RHINITIS, PRURITIS, AND CHRONIC IDIOPATHIC URTICARIA IN PATIENTS 2 YEARS OF AGE AND OLDER

U-612 TREATMENT OF SEASONAL ALLERGY SYMPTOMS WITH NASAL CONGESTION IN ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

U-613 REDUCTION OF SERUM PHOSPHATE

U-614 TREATMENT OF SEXUAL DYSFUNCTION

U-615 ADJUNCTIVE THERAPY TO DIET IN ADULTS TO REDUCE LDL-C, TOTAL-C, TRIGLYCERIDES AND APO B, AND INCREASE HDL-C IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA OR MIXED DYSLIPIDEMIA (TYPES IIA, IIB) AND TO TREAT HYPERTRIGLYCERIDEMIA (TYPES IV, V)

U-616 MANAGEMENT OF PERSISTENT, MODERATE TO SEVERE PAIN IN PATIENTS REQUIRING CONTINUOUS, AROUND-THE-CLOCK ANALGESIA WITH A HIGH POTENCY OPIOID FOR AN EXTENDED PERIOD OF TIME GENERALLY WEEKS TO MONTHS OR LONGER

U-617 TREATMENT OF ACUTE PROMYELOGENOUS LEUKEMIA (APL)

U-618 USE OF ROSUVASTATIN CALCIUM TO REDUCE ELEVATED TOTAL-C, LDL-C, APOB, NONHDL-C OR
PATENT USE

TG LEVELS; TO INCREASE HDL-C IN ADULT PATIENTS WITH PRIMARY HYPERLIPIDEMIA OR MIXED DYSLIPIDEMIA; AND TO SLOW THE PROGRESSION OF ATHEROSCLEROSIS.

U-619 TREATMENT OF MALIGNANT NEOPLASM
U-620 TREATMENT OF INSOMNIA
U-621 METHOD OF TREATING CANCER
U-622 TREATMENT OF VEGF MEDIATED OCULAR DISEASE.
U-623 SHORT TERM TREATMENT OF ACTIVE BENIGN GASTRIC ULCER
U-624 REDUCTION OF RISK OF UPPER GASTROINTESTINAL BLEEDING IN CRITICALLY ILL PATIENTS
U-625 ALLERGIC RHINITIS OR NASAL POLYPS
U-626 CLOLAR IS INDICATED FOR THE TREATMENT OF PEDIATRIC PATIENTS 1 TO 21 YEARS OLD WITH RELAPSED OR REFRACTORY ACUTE LYMPHOBLASTIC LEUKEMIA AFTER AT LEAST TWO PRIOR REGIMENS
U-627 TREATMENT OF PATIENTS USING EXTENDED-RELEASE CARBAMAZEPINE
U-628 USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA, AND IN COMBINATION WITH METFORMIN AND A SULFONYLUREA TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
U-629 METHOD OF INDUCING A HYPNOTIC OR SEDATIVE EFFECT IN A HUMAN BY ADMINISTERING ESZOPICLONE
U-630 TREATING URINARY INCONTINENCE BY ADMINISTERING AN EXTENDED-RELEASE FORM OF DARIFENACIN
U-631 TREATING A DISEASE OF ALTERED MOTILITY OR TONE OF SMOOTH MUSCLE BY ADMINISTERING A MUSCARINIC RECEPTOR ANTAGONIZING AMOUNT OF DARIFENACIN
U-632 METHOD OF TREATMENT OF CANCER BY ADMINISTERING PARTICLES OF PACLITAXEL THAT HAVE A PROTEIN COATING
U-633 METHOD FOR TREATMENT OF TUMORS BY ADMINISTERING PACLITAXEL AT A DOSE IN THE RANGE OF ABOUT 30MG/METER SQUARE TO ABOUT 100MG/METER SQUARE IN A PHARMACEUTICALLY ACCEPTABLE FORMULATION THAT DOES NOT CONTAIN CREMOPHOR
U-634 METHOD FOR DELIVERY OF A BIOLOGIC (INCLUDING ANTI-NEOPLASTIC AGENTS) BY ADMINISTERING TO A PATIENT AN EFFECTIVE AMOUNT OF A BIOLOGIC AS A SOLID OR LIQUID WITH A POLYMERIC BIOMATERIAL
U-635 TREATMENT OF GERD, MAINTENANCE OF HEALING OF EROSIIVE ESOPHAGITIS AND RISK REDUCTION OF NSAID ASSOCIATED GASTRIC ULCERS
U-636 TREATMENT OR PREVENTION OF BRONCHOSPASM OR ASTHMATIC SYMPTOMS
U-637 TREATMENT OF DIABETES WITH AN AMYLIN AGONIST
U-638 TREATMENT OF DIABETES WITH AN AMYLIN AGONIST, INCLUDING WITH INSULIN
U-639 TREATMENT OF A MAMMAL HAVING A NEED OF OR REDUCED ABILITY TO PRODUCE INSULIN WITH AN INSULIN AND AN AMYLIN SUCH AS PRAMLINTIDE
U-640 USE OF AN AMYLIN AGONIST TO REDUCE GASTRIC MOTILITY AND TREAT POST PRANDIAL HYPERGLYMCEMIA
U-641 USE OF AN AMYLIN AGONIST HAVING SPECIFIED BINDING ACTIVITY TO REDUCE GASTRIC MOTILITY, INCLUDING USE THROUGH PARENTERAL ADMINISTRATION
U-642 TREATMENT AND PREVENTION OF OSTEOPOROSIS
U-643 THE SHORT TERM TREATMENT (UP TO 10 DAYS) IN PTS HAVING GASTROESOPHAGEAL REFLUX DISEASE (GERD) AS AN ALTERNATIVE TO ORAL THERAPY IN PTS WHEN THERAPY WITH NEXIUM CAPSULES IS NOT POSSIBLE OR APPROPRIATE
U-644 TREATMENT OF SEASONAL ALLERGIC RHINITIS
U-645 TREATMENT OF ASTHMA
U-646 METHOD OF TREATING OITIS
U-647 TREATMENT OF OSTEOPOROSIS IN POST MENOPAUSAL WOMEN AND/OR THE TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS
U-648 THE TREATMENT OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN AND/OR THE TREATMENT TO INCREASE BONE MASS IN MEN
U-649 A METHOD FOR TREATING A TUMOR DISEASE
U-650 TREATMENT OF ESOPHAGEAL CANDIDIASIS AND PROPHYLAXIS OF CANDIDA INFECTIONS IN
PATENT USE

HSCT PATIENTS
U-651 TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA (APL)
U-652 TREATMENT OF CARDIAC ARRHYTHMIA
U-653 STIMULATING INSULIN RELEASE BY ADMINISTERING EXENATIDE
U-654 LOWERING PLASMA GLUCAGON IN A SUBJECT IN NEED THEREOF, INCLUDING ONE WITH TYPE 2 DIABETES, BY ADMINISTERING AN EXENDIN OR ANALOG, SUCH AS EXENDIN-4
U-655 TREATMENT OF MILD TO MODERATE ACTIVE CHRONH'S DISEASE INVOLVING THE ILEUM AND/OR THE ASCENDING COLON AND THE MAINTENANCE OF CLINICAL REMISSION OF MILD TO MODERATE CROHN'S DISEASE INVOLVING THE ILEUM AND/OR ASCENDING COLON FOR UP TO 3 MONTHS
U-656 REDUCING GASTRIC MOTILITY OR DELAYING GASTRIC EMPTYING BY ADMINISTERING AN EXENDIN, SUCH AS EXENDIN-4
U-657 PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
U-658 TREATMENT OF ADVANCED HORMONE-DEPENDENT BREAST CANCER
U-659 TREATMENT OF LOCALLY ADVANCED OR METASTATIC NON SMALL-CELL LUNG CANCER (NSCLC) AFTER FAILURE OF AT LEAST ONE PRIOR CHEMOTHERAPY REGIMEN
U-660 TREATMENT OF HYPERTENSION AND TREATMENT OF HEART FAILURE
U-661 TREATMENT OF SEIZURE DISORDER
U-662 TREATMENT OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
U-663 THE TREATMENT OF UNCOMPLICATED URINARY TRACT INFECTIONS
U-664 TREATMENT OF CONDITIONS FOR WHICH AN ALDOSTERONE RECEPTOR BLOCKER IS INDICATED, SUCH AS HYPERTENSION, HEART FAILURE, AND POST-MYOCARDIAL INFARCTION
U-665 METHOD OF USING THE DRUG SUBSTANCE/DRUG PRODUCT FOR ULTRASOUND IMAGING
U-666 METHOD OF TREATING ADHD
U-667 MANAGEMENT OF INCONTINENCE; METHOD FOR TREATING INCONTINENCE
U-668 LEVEMIR IS A LONG-ACTING BASAL INSULIN ANALOG THAT IS INDICATED IN THE TREATMENT OF PATIENTS WITH DIABETES MELLITUS
U-669 INDICATION OF TYPE II DIABETES
U-670 TREATMENT OF HIV-1 INFECTION BY THE CO-ADMINISTRATION OF TIPRANAVIR AND RITONAVIR.
U-671 PREVENTION AND TREATMENT OF SECONDARY HYPERPARATHYROIDISM ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD) STAGE 3 AND 4
U-672 TREATMENT OF INFLAMMATION OR AN INFLAMMATION-ASSOCIATED DISORDER
U-673 METHOD OF TREATMENT WITH ONCE-DAILY DOSES OF 625MG/5ML
U-674 METHOD OF TREATING INSOMNIA CHARACTERIZED BY DIFFICULTY WITH SLEEP ONSET
U-675 PROPHYLAXIS AND CHRONIC TREATMENT OF ASTHMA; RELIEF OF SYMPTOMS OF ALLERGIC RHINITIS
U-676 METHOD OF TREATING ATTENTION DEFICIT DISORDER USING ORAL ADMINISTRATION OF A BI-MODAL OR PULSATILE RELEASE COMPOSITION
U-677 A METHOD OF TREATING DISEASE AMENABLE TO TREATMENT WITH A PHENIDATE DRUG BY ONCE DAILY ORAL ADMINISTRATION OF AN EXTENDED RELEASE DOSAGE FORM
U-678 METHOD OF TREATING ATTENTION DEFICIT DISORDER AND/OR ATTENTION DEFICIT HYPERACTIVITY DISORDER
U-679 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES WHO ARE ALREADY TREATED WITH A PIOLITAZONE AND METFORMIN
U-680 A METHOD OF TREATING DYSLIPIDEMIA AND DYSLIPOPROTEINEMIA USING A DOSAGE FORM THAT CAN PROVIDE AN EFFECTIVE AMOUNT OF FENOFIBRATE TO A PATIENT IN A FASTED STATE WHICH IS AT LEAST 90% OF THE AUC AMOUNT PROVIDED BY THE DOSAGE FORM
U-681 TREATMENT OF PRIMARY IGF-1 DEFICIENCY
U-682 NON-BENZODIAZEPINE HYPNOTIC AGENT INDICATED FOR TREATMENT OF INSOMNIA, CHARACTERIZED BY DIFFICULTIES WITH SLEEP ONSET AND/OR SLEEP MAINTENANCE
U-683 PREVENTION OR TREATMENT OF ISCHEMIC HEART DISEASE
U-684 TREATMENT OF UNCOMPLICATED SKIN MANIFESTATIONS OF CHRONIC IDIOPATHIC URTICARIA
PATENT USE

IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER

U-685 EXPECTORANT AND COUGH SUPPRESSANT
U-686 EXPECTORANT AND NASAL DECONGESTANT
U-687 REDUCING FOOD INTAKE IN A SUBJECT WITH TYPE 2 DIABETES BY ADMINISTERING AN EXENDIN, SUCH AS EXENDIN-4
U-688 TREATMENT OF HIV-INFECTION IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS
U-689 TREATMENT OF PATIENTS WITH T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA WHOSE DISEASE HAS NOT RESPONDED TO OR HAS RELAPSED FOLLOWING TREATMENT WITH AT LEAST TWO CHEMOTHERAPY REGIMENS
U-690 TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
U-691 USE AS A MONOTHERAPY, IN COMBINATION WITH A SULFONYLUREA, METFORMIN OR INSULIN OR IN COMBINATION WITH A SULFONYLUREA PLUS METFORMIN TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
U-692 USE OF VALSARTAN TO REDUCE CARDIOVASCULAR MORTALITY IN CLINICALLY STABLE PATIENTS WITH LEFT VENTRICULAR FAILURE OR LEFT VENTRICULAR DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION
U-693 THE RECOMMENDED INITIAL DOSE OF EQUETRO IS 400MG/DAY GIVEN IN DIVIDED DOSES, TWICE DAILY. THE DOSE SHOULD BE ADJUSTED IN 200MG DAILY INCREMENTS TO ACHIEVE OPTIMAL CLINICAL RESPONSE.
U-694 LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY.
U-695 TREATMENT OF PATIENTS WITH T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA AND T-CELL LYMPHOBLASTIC LYMPHOMA WHOSE DISEASE HAS NOT RESPONDED TO OR HAS RELAPSED FOLLOWING TREATMENT WITH AT LEAST TWO CHEMOTHERAPY REGIMENS
U-696 TREATMENT OF PATIENTS WITH T-CELL LYMPHOBLASTIC LYMPHOMA WHOSE DISEASE HAS NOT RESPONDED TO OR HAS RELAPSED FOLLOWING TREATMENT WITH AT LEAST TWO CHEMOTHERAPY REGIMENS
U-697 A METHOD OF USING RINFABATE RECOMBINANT (RHIGFBP-3) WITH MECASERMIN RECOMBINANT (RHIGF-1) TO PROMOTE LINEAR GROWTH IN THE TREATMENT OF PRIMARY IGF-1 DEFICIENCY
U-698 METHOD OF USING ANTAGONIST OF ARGinine VASOPRESSin (AVA) VIA AND V2 RECEPTORS FOR INTRAVENOUS TREATMENT OF PATIENTS WITH EUVOLEMIC HYPONATREMIA
U-699 NASAL TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS
U-700 TREATMENT AND PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
U-701 TREATMENT OF HYPERCHOLESTEROLEMIA AND/OR HYPERTRIGLYCERIDEMIA
U-702 TOPICAL AEROSOL HAIR REGROWTH TREATMENT
U-703 TREATMENT OF PROTEIN KINASE RELATED DISORDERS, SUCH AS GASTROINTESTINAL STROMAL TUMOR AND RENAL CELL CARCINOMA WITH SUNITINIB
U-704 METHOD OF ADMINISTERING INSULIN VIA INHALATION
U-705 TREATING CHRONIC ANGINA BY ADMINISTERING AN EXTENDED RELEASE FORM OF RANOLAZINE
U-706 TREATMENT OF BENIGN PROSTATIC HYPERPLASIA
U-707 ALLERGIC RHINITIS
U-708 TREATMENT OF CHRONIC NON-INFECTIONOUS UVEITIS AFFECTING THE POSTERIOR SEGMENT OF THE EYE
U-709 METHOD OF COMBATING BACTERIA IN A PATIENT
U-710 A METHOD OF TREATING RESPIRATORY DISORDERS, E.G., ASTHMA, WHICH COMPRISES ADMINISTRATION BY INHALATION OF AN EFFECTIVE AMOUNT OF A PHARMACEUTICAL FORMULATION AS CLAIMED IN US PATENT NO. 5658549
U-711 ACUTE AND LONGER-TERM TREATMENT OF MAJOR DEPRESSIVE DISORDER
U-712 A METHOD OF USING A NICOTINIC ACID FORMULATION TO REDUCE ELEVATED TC, LDL-C AND TG LEVELS, AND RAISE HDL-C LEVELS IN PATIENTS WITH HYPERLIPIDEMIA
U-713 TREATMENT OF MILD TO MODERATE DEMENTIA OF THE ALZHEIMER'S TYPE
U-714 TOPICAL TREATMENT OF INTERDIGITAL TINEA PEDIS AND TINEA CORPORIS DUE TO TRICHOPHYTON RUBRUM, TRICHOPHYTON MENTAGROPHYTES OR EPIDERMOPHYTON FLOCCOSUM
PATENT USE

U-715 FOR CLEANSING THE BOWEL IN PREPARATION FOR COLONOSCOPY, IN ADULTS 18 YEARS OF AGE OR OLDER

U-716 THE TREATMENT OR PREVENTION OF BRONCHOSPASM IN ADULTS AND CHILDREN 4 YEARS OF AGE AND OLDER WITH REVERSIBLE OBSTRUCTIVE AIRWAYS DISEASE AND THE PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN PATIENTS 4 YEARS OF AGE AND OLDER

U-717 METHOD OF RELIEVING OR PREVENTING CONSTIPATION IN A HUMAN CONSTIPATED PATIENT

U-718 TREATMENT OF FUNGAL INFECTIONS

U-719 TREATMENT OF PSYCHOSIS

U-720 TREATMENT OF NEUROLEPTIC DISEASES

U-721 TREATMENT OF INFLUENZA

U-722 PROPHYLAXIS OF INFLUENZA

U-723 PROPHYLACTIC TREATMENT OF MIGRAINE

U-724 METHOD OF TREATING SEIZURES

U-725 ALLERGIC RHINITIS AND URTICARIA

U-726 ALLERGIC RHINITIS

U-727 FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

U-728 METHOD FOR TREATING BACTERIAL INFECTION

U-729 TREATMENT OF GASTROESOPHAGEAL REFUX DISEASE (GERD), RISK-REDUCTION OF NSAID-ASSOCIATED GASTRIC ULCER, H. PYLORI ERADICATION TO REDUCE THE RISK OF DUODENAL ULCER RECURRENCE

U-730 USE AS A NASAL SPRAY FOR TREATMENT OF THE SYMPTOMS OF SEASONAL ALLERGIC RHINITIS AND NASOMOTOR RHINITIS

U-731 USE IN COMBINATION WITH DEXAMETHASONE IS INDICATED FOR THE TREATMENT OF PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA

U-732 ACUTE TREATMENT OF THE CUTANEOUS MANIFESTATIONS OF MODERATE TO SEVERE ERYTHEMA NODOSUM LEPROSUM (ENL)

U-733 MAINTENANCE THERAPY FOR PREVENTION AND SUPPRESSION OF THE CUTANEOUS MANIFESTATIONS OF ENL RECURRENCE

U-734 FIRST LINE THERAPY FOR TYPE 2 DIABETES MELLITUS

U-735 METHOD OF TREATING CHRONIC IRON OVERLOAD

U-736 METHOD FOR IONTOPHORETIC TRANSDERMAL DELIVERY OF FENTANYL HYDROCHLORIDE

U-737 DISINFECTION OF PATIENT SKIN PRIOR TO AN INVASIVE PROCEDURE

U-738 INDICATED FOR THE LONG-TERM, TWICE-DAILY MAINTENANCE TREATMENT OF ASTHMA IN PATIENTS 12 YEARS OF AGE OR OLDER

U-739 METHOD FOR TREATING CONSTIPATION BY OPENING CIC CHANNELS IN A MAMMALIAN SUBJECT

U-740 FOR THE TREATMENT OF PATIENTS WITH PRIMARY BILIARY CIRRHOSIS

U-741 COMBINATION THERAPY WITH CISPLATIN FOR THE TREATMENT OF LATE STAGE CERVICAL CANCER

U-742 TWICE DAILY TOPICAL TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS.

U-743 ONCE A DAY TOPICAL TREATMENT OF THE INFLAMMATORY LESIONS OF ROSACEA

U-744 TREATMENT OF HIV INFECTION IN ANTIRETROVIRAL TREATMENT-EXPERIENCED ADULT PATIENTS

U-745 TREATMENT OR PREVENTION OF EMESIS

U-746 PREVENTION OR TREATMENT OF NAUSEA OR EMESIS INDUCED BY A CANCER CHEMOTHERAPEUTIC AGENT

U-747 PREVENTION OR TREATMENT OF POST-OPERATIVE NAUSEA AND VOMITING

U-748 A METHOD FOR THE TREATMENT OF A PROTEIN TYROSINE KINASE-ASSOCIATED DISORDER

U-749 METHOD OF CONTRACEPTION

U-750 TREATMENT OF HIV-1 INFECTION IN ADULTS

U-751 ONCE DAILY DOSING OF BUDESONIDE VIA NEBULIZER FOR THE TREATMENT OF ASTHMA

U-752 SUNSCREEN
U-753  AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES

U-754  USE FOR THE LONG-TERM MAINTENANCE TREATMENT OF ASTHMA

U-755  TREATMENT OF ANOREXIA, CACHEXIA, OR AN UNEXPLAINED, SIGNIFICANT WEIGHT LOSS IN PATIENTS WITH A DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

U-756  ADDITION OF ONCE-WEEKLY DOSING FOR THE TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS

U-757  USE AS A BILE ACID SEQUESTRANT FOR LOWERING CHOLESTEROL

U-758  TREATMENT OF SYMPTOMS OF PREMENSTRUAL DYSPHORIC DISORDER

U-759  METHOD OF USE OF ADMINISTERING LEVOTHYROXINE

U-760  PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS AND TREATMENT OF OROPHARYNGEAL CANDIDIASIS

U-761  TREATMENT OF SCHIZOPHRENIA INCLUDING MAINTAINING STABILITY IN PATIENTS WITH SCHIZOPHRENIA

U-762  TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

U-763  ADMINISTRATION OF ARIPIPRAZOLE BY INJECTION

U-764  TREATMENT OF SCHIZOPHRENIA

U-765  METHOD OF TREATING ALLERGIC CONJUNCTIVITIS

U-766  TREATMENT OF SEIZURES

U-767  MANAGEMENT OF BREAKTHROUGH PAIN IN PATIENTS WITH CANCER

U-768  A METHOD OF REDUCING THE CAPACITY OF EXTENDED RELEASE NICOTINIC ACID TO PROVOKE A FLUSHING REACTION BY PRETREATING AN INDIVIDUAL WITH A FLUSH INHIBITING AGENT PRIOR TO THE ADMINISTRATION OF THE EXTENDED RELEASE NICOTINIC ACID

U-769  REV'LIMID (LENALIDOMIDE) IN COMBINATION WITH DEXAMETHASONE IS INDICATED FOR THE TREATMENT OF MULTIPLE MYELOMA PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

U-770  LONG-TERM TREATMENT OF PATHOLOGICAL HYPERSECRETORY CONDITIONS

U-771  METHOD FOR THE TREATMENT OF DIABETES MELLITUS, SUCH AS TYPE 1 DIABETES MELLITUS OR TYPE 2 DIABETES MELLITUS, IN A HUMAN PATIENT

U-772  RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS IN CHILDREN 2 TO 11 YEARS AND FOR THE RELIEF OF SYMPTOMS ASSOCIATED WITH UNCOMPLICATED SKIN MANIFESTATIONS OF CHRONIC IDIOPATHIC URTICARIA IN CHILDREN 6 MONTHS TO 11 YEARS

U-773  PATHOLOGICAL HYPERSECRETORY CONDITIONS

U-774  METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-IV INHIBITOR

U-775  METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-IV INHIBITOR IN COMBINATION WITH METFORMIN AND/OR A SULFONYLUREA

U-776  TREATMENT OF CUTANEOUS MANIFESTATION IN PATIENTS WITH CUTANEOUS T-CELL LYMPHOMA (CTCL) WHO HAVE PROGRESSIVE, PERSISTENT OR RECURRENT DISEASE ON OR FOLLOWING TWO SYSTEMIC THERAPIES.

U-777  DECREASING MORTALITY CAUSED BY CONGESTIVE HEART FAILURE

U-778  REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA OR OCULAR HYPERTENSION

U-779  A METHOD FOR TREATMENT OF A CANCER, WHEREIN THE CANCER IS CHRONIC MYELOGENOUS LEUKEMIA

U-780  A METHOD FOR THE TREATMENT OF CANCER

U-781  FOR TREATMENT OF ADULT PATIENTS WITH TYPE 2 DIABETES MELLITUS WHO ARE NAIVE TO PHARMACOLOGIC THERAPY

U-782  TREATMENT OF CHRONIC HEPATITIS B IN ADULT PATIENTS WITH EVIDENCE OF VIRAL REPLICATION AND EITHER EVIDENCE OF PERSISTANT ELEVATIONS IN SERUM AMINOTRANSFERASES (ALT OR AST) OR HISTOLOGICALLY ACTIVE DISEASE

U-783  DESONATE GEL IS INDICATED FOR THE TREATMENT OF MILD TO MODERATE ATOPIC DERMATITIS IN PATIENTS 3 MONTHS OF AGE AND OLDER

U-784  TREATMENT OF MODERATE TO SEVERE PRIMARY RESTLESS LEGS SYNDROME (RLS)
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-785 USE AS REPLACEMENT SOLUTION, HEMOFILTRATION SOLUTION OR HEMODIAFILTRATION SOLUTION IN CONTINUOUS RENAL REPLACEMENT THERAPY

U-786 PRODUCT IS APPROVED FOR THE TOPICAL TREATMENT OF TINEA PEDIS

U-787 MAINTENANCE TREATMENT OF ASThma AS PROPHYLACTIC THERAPY IN ADULT AND PEDIATRIC PATIENTS SIX YEARS OF AGE OR OLDER, INCLUDING PATIENTS REQUIRING ORAL CORTICOSTEROID THERAPY FOR ASTHMA

U-788 METHOD OF TREATING PSYCHIATRIC SYMPTOMS ASSOCIATED WITH PREMENSTRUAL DISORDERS USING PAROXETINE

U-789 TREATMENT OF KNOWN OR SUSPECTED CYANIDE POISONING

U-790 FORTEO IS INDICATED FOR THE TREATMENT OF POST MENOPAUSAL WOMEN WITH OSTEOPOROSIS WHO ARE AT RISK FOR FRACTURE. FORTEO CAN BE USED BY PEOPLE WHO HAVE HAD A FRACTURE RELATED TO OSTEOPOROSIS

U-791 GLEEVEC IS ALSO INDICATED FOR THE TREATMENT OF PATIENTS WITH KIT (CD117) POSITIVE UNRESECTABLE AND/OR METASTATIC MALIGNANT GASTROINTESTINAL STROMAL TUMORS (GIST)

U-792 TREATMENT OF SEBORRHEA DERMATITIS IN HUMANS

U-793 FOR THE LONG TERM TREATMENT, TWICE DAILY (MORNING AND EVENING) MAINTENANCE TREATMENT OF BRONCHOCONSTRICTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA

U-794 CLOSURE OF A CLINICALLY SIGNIFICANT PATENT DUCTUS ARTERIOSUS IN PREMATURE INFANTS WEIGHING BETWEEN 500 AND 1500G, WHO ARE NO MORE THAN 32 WEEKS GESTATIONAL AGE WHEN USUAL MEDICAL MANAGEMENT ISINEFFECTIVE

U-795 METHOD FOR INHIBITING NOREPINEPHRINE UPTAKE

U-796 METHOD OF TREATING DEPRESSION

U-797 METHOD OF TREATING ANXIETY

U-798 TREATMENT AND PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN BY ONCE-MONTHLY ORAL ADMINISTRATION OF IBANDRONATE SODIUM MONOHYDRATE EQUIVALENT TO 150MG OF IBANDRONIC ACID

U-799 METHOD FOR INHIBITING SEROTONIN UPTAKE

U-800 TREATMENT OF PATIENTS WITH ADVANCED OR METASTATIC BREAST CANCER WHOSE TUMORS OVEREXPRESS HER2 AND WHO HAVE RECEIVED PRIOR THERAPY INCLUDING ANTHRACYCLINE, A TAXANE AND TRASTUZUMAB

U-801 METHOD OF TREATING CANCER

U-802 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-IV INHIBITOR

U-803 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-IV INHIBITOR IN COMBINATION WITH METFORMIN

U-804 TREATMENT OF ACTINIC KERATOSES BY PHOTODYNAMIC THERAPY

U-805 TREATMENT OF IMPETIGO DUE TO STAPHYLOCOCCUS AUREUS OR STREPTOCOCCUS PYOGENES

U-806 INTRATHECAL TREATMENT OF LYMPHOMATOUS MENINGITIS

U-807 PREVENTION OF EXERCISE-INDUCED BRONCHOCONSTRICTION

U-808 THE TREATMENT OF THE SYMPTOMS OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS IN PATIENTS 2 YEARS OF AGE AND OLDER

U-809 TREATMENT OF CHRONIC IDIOPATHIC URTICARIA

U-810 METHOD OF TREATMENT TO ALLEVIATE INFLAMMATION OF THE EYE

U-811 RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL AND PERENNIAL ALLERGIC RHINITIS AND TREATMENT OF THE UNCOMPLICATED SKIN MANIFESTATIONS OF CHRONIC IDIOPATHIC URTICARIA

U-812 RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL AND PERENNIAL ALLERGIC RHINITIS

U-813 MAINTENANCE TREATMENT OF BRONCHOCONSTRICITION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

U-814 TREATMENT OF SCHIZOPHRENIA

U-815 TREATS COLD SORES/FEVER BLISTERS ON THE FACE OR LIPS. SHORTENS HEALING TIME AND DURATION OF SYMPTOMS: TINGLING, PAIN, BURNING AND/OR ITCHING
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-816 DEPRESSION, PANIC DISORDER, PREMENSTRUAL DISORDERS AND SOCIAL ANXIETY DISORDER
U-817 NASAL ADMINISTRATION OF CYANOCOBALAMIN
U-818 TOPICAL TREATMENT OF ACNE VULGARIS
U-819 MANAGEMENT OF FIBROMYALGIA
U-820 IMPROVED WAKEFULNESS IN PATIENTS WITH EXCESSIVE SLEEPINESS ASSOCIATED WITH NARCOLEPSY, OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, AND SHIFT WORK SLEEP DISORDER
U-821 METHOD OF INHIBITING ENTHOTHELIN RECEPTORS BY ADMINISTERING AMBRISENTAN TO A PATIENT TO TREAT PULMONARY ARTERIAL HYPERTENSION.
U-822 USE IN LIPID MANAGEMENT
U-823 RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS AND FOR THE TREATMENT OF UNCOMPLICATED SKIN MANIFESTATIONS OF CHRONIC IDIOPATHIC URTICARIA IN CHILDREN 6 TO 11 YEARS OF AGE
U-824 METHOD OF TREATING PATIENTS INFECTED WITH CCR5-TROPIC HIV-1
U-825 USE FOR PREVENTION OF BREAST CANCER
U-826 RELIEF OF MODERATE TO SEVERE PAIN
U-827 USE FOR TREATMENT OF DIABETES, PARTICULARLY TYPE 2 DIABETES
U-828 PREVENTION OF PREGNANCY IN WOMEN WHO ELECT TO USE ORAL CONTRACEPTIVES AS A METHOD OF CONTRACEPTION
U-829 TREATMENT OF EXTRAVASATION RESULTING FROM IV ANTHRACYCLINE CHEMOTHERAPY
U-830 TREATMENT OF RELAPSED SMALL CELL LUNG CANCER
U-831 METHOD OF ADMINISTERING LANREOTIDE ACETATE
U-832 ZINGO IS INDICATED FOR THE USE ON INTACT SKIN TO PROVIDE LOCAL ANALGESIA PRIOR TO VENIPUNCTURE OR INTRAVENOUS CANNULATION.
U-833 METHOD OF TREATING PAIN USING A PHARMACEUTICALLY ACCEPTABLE SALT OF ROPIVACAINE AND ADMINISTERING A COMPOSITION CONTAINING LESS THAN 0.25% BY WEIGHT OF ROPIVACAINE
U-834 INVIRASE IN COMBINATION WITH RITONAVIR AND OTHER ANTIRETROVIRAL AGENTS IS INDICATED FOR THE TREATMENT OF HIV INFECTION
U-835 RELIEF OF THE INFLAMMATORY AND PRURITIC MANIFESTATIONS OF ATOPIC DERMATITIS IN PATIENTS ONE YEAR OF AGE OR OLDER
U-836 A METHOD FOR THE TREATMENT OF LEUKEMIAS
U-837 GASTROINTESTINAL LAVAGE INDICATED FOR CLEANSING OF THE COLON AS A PREPARATION FOR COLONOSCOPY IN ADULTS
U-838 METHOD OF TREATING PAIN USING A PHARMACEUTICALLY ACCEPTABLE SALT OF ROPIVACAINE AND ADMINISTERING A COMPOSITION CONTAINING LESS THAN 0.5% BY WEIGHT OF ROPIVACAINE
U-839 TREATMENT OF MAJOR DEPRESSIVE DISORDER (MDD)
U-840 TREATMENT FOR TYPE 2 DIABETES MELLITUS
U-841 INDICATED FOR THE LONG-TERM, MAINTENANCE TREATMENT OF ASTHMA IN PATIENTS 12 YEARS OF AGE AND OLDER
U-842 INDICATED FOR THE TREATMENT OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD)
U-843 METHOD FOR ADMINISTRATION OF TESTOSTERONE
U-844 PREFEST IS INDICATED IN WOMEN WHO HAVE A UTERUS FOR THE TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE; TREATMENT OF VULVAR AND VAGINAL ATROPHY; PREVENTION OF OSTEOPOROSIS
U-845 TREATMENT OF PATIENTS WITH CANDIDEMIA, ACUTE DISSEMINATED CANDIDIASIS, CANDIDA PERITONITIS AND ABSCESSES
U-846 USE FOR DELINEATION (VISUALIZATION) DURING A VITRECTOMY SURGICAL PROCEDURE
U-847 ADJUNCTIVE THERAPY TO DIET IN ADULTS TO REDUCE LDL-C, TRIGLYCERIDES AND APO B, AND INCREASE HDL-C IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA OR MIXED DYSLIPIDEMIA (TYPES IIA, IIB) AND TO TREAT HYPERTRIGLYCERIDEMIA (TYPES IV, V)
U-848 ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA
PATENT USE

U-849 REDUCTION OF ELEVATED INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH GLAUCOMA OR OCULAR HYPERTENSION WHO REQUIRE ADJUNCTIVE OR REPLACEMENT THERAPY DUE TO INADEQUATELY CONTROLLED IOP. DOSE IS ONE DROP OF COMBIGAN IN THE AFFECTED EYE TWICE DAILY

U-850 PREVENTION OR TREATMENT OF NAUSEA OR EMESIS INDUCED BY A CANCER CHEMOTHERAPEUTIC AGENT

U-851 TREATMENT OF TYPE 2 DIABETES MELLITUS

U-852 RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL AND PERENNIAL ALLERGIC RHINITIS

U-853 TREATMENT OR PREVENTION OF EMESIS

U-854 PREVENTION OF CMV DISEASE IN KIDNEY, HEART, AND KIDNEY-PANCREAS TRANSPLANT PATIENTS AT HIGH RISK (DONOR CMV SEROPOSITIVE/RECIPIENT CMV SERONEGATIVE)

U-855 METHOD TO INDUCE NATRIURESIS, DIURESIS AND/OR VASODILATION

U-856 SUPPORT EMBRYO IMPLANTATION AND EARLY PREGNANCY BY SUPPLEMENTATION OF CORPUS LUTEAL FUNCTION AS PART OF AN ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT PROGRAM FOR INFERTILE WOMEN

U-857 INHIBITION OF TRANSPLANT REJECTION

U-858 PEDIATRIC USE AGED 1-11 YEARS, GERD AND EROSIIVE ESOPHAGITIS

U-859 EROSIIVE ESOPHAGITIS, HYPERSECRETORY CONDITIONS INCLUDING ZOLLINGER-ELLISON SYNDROME, MAINTENANCE OF HEALING OF EROSIIVE ESOPHAGITIS AND REDUCTION OF SYMPTOMS IN PATIENTS WITH GERD

U-860 FOR THE APPROVED USES AND CONDITIONS OF USE, INCLUDING DEPRESSION

U-861 RELIEF OF THE INFLAMMATORY AND PRURITIC MANIFESTATIONS OF CORTICOSTEROID RESPONSIVE DERMATOSES IN PATIENTS 12 YEARS OF AGE OR OLDER

U-862 ADJUNCT TO DIET TO REDUCE ELEVATED TOTAL-C, LDL-C, NON-HDL-C, APO B, TG, AND LP(A) LEVELS AND TO INCREASE HDL-C IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA, MIXED DYSLIPIDEMIA, AND HYPERTRIGLYCERIDEMIA

U-863 TAKING ASPIRIN OR NON-STEROIDAL ANTI-INFLAMMATORY MEDICATIONS APPROXIMATELY 30 MINUTES BEFORE DOSING CAN MINIMIZE FLUSHING, A COMMON SIDE EFFECT OF NIACIN THERAPY

U-864 PEDIATRIC USE AGES 1-2 YEARS, GERD AND EROSIIVE ESOPHAGITIS

U-865 TREATMENT OF A WOMAN WITH OSTEOPOROSIS AND A HIGH RISK FOR BONE FRACTURE BY REDUCING THE RISK OF VERTEBRAL AND NONVERTEBRAL BONE FRACTURE

U-866 THE LABEL REFERENCES THE EFFECTS OF THE ACTIVE INGREDIENT OF REVLMID UPON CYTOKINES

U-867 TREATMENT OF MIGRAINE

U-868 METHOD OF USING ANTAGONIST OF ARGinine VASOPRESSIN (AVA) V1A AND V2 RECEPTORS FOR INTRAVENOUS TREATMENT OF PATIENTS WITH HYPERVoleMIC HYponATREMIa

U-869 METHOD FOR STIMULATING CORONARY VASODILATION FOR PURPOSES OF IMAGING THE HEART

U-870 METHOD OF PRODUCING CORONARY VASODILATION WITHOUT PERIPHERAL VASODILATION

U-871 METHOD OF REDUCING RISK OF MYOCARDIAL INFARCTION, STROKE AND DEATH

U-872 TWICE DAILY MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA. TO REDUCE EXACERBATIONS OF COPD IN PATIENTS WITH A HISTORY OF EXACERBATIONS

U-873 METHOD OF TREATING CONSTIPATION IN A PATIENT WITH IRRITABLE BOWEL SYNDROME BY OPENING CHLORIDE CHANNELS (CIC)

U-874 METHOD OF TREATING CONSTIPATION IN A PATIENT WITH IRRITABLE BOWEL SYNDROME

U-875 FIRST-LINE TREATMENT OF LOCALLY ADVANCED UNRESECTABLE OR METASTATIC PANCREATIC CANCER, IN COMBINATION WITH GEMCITABINE

U-876 TREATMENT OF MIGRAINE WITH OR WITHOUT AURA

U-877 FOR USE AS ADJUNCTIVE THERAPY IN THE TREATMENT OF PEPTIC ULCER

U-878 A METHOD FOR BINDING A PERIPHERAL OPIOID RECEPTOR

U-879 A METHOD OF TREATING OR PREVENTING ILEUS

U-880 ENDOMETRIN IS A PROGESTERONE INDICATED TO SUPPORT EMBRYO IMPLANTATION AND EARLY PREGNANCY BY SUPPLEMENTATION OF CORPUS LUTEAL FUNCTION AS PART OF AN ASSISTED
PATENT AND EXCLUSIVITY TERMS

PATENT USE

REPRODUCTIVE TECHNOLOGY (ART) TREATMENT PROGRAM FOR INFERTILE WOMEN

U-881 TREATMENT OF NON-SMALL CELL LUNG CANCER

U-882 MANAGEMENT OF FIBROMYALGIA (FM)

U-883 TREATMENT OF GASTROINTESTINAL STROMAL TUMOR WITH SUNITINIB

U-884 TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA

U-885 TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA WHO HAVE RECEIVED AT LEAST 1 PRIOR THERAPY

U-886 ADMINISTERING DESLORATADINE TO TREAT THE SYMPTOMS OF PERENNIAL ALLERGIC RHINITIS, SEASONAL ALLERGIC RHINITIS, OR CHRONIC IDIOPATHIC URTICARIA

U-887 TREATMENT AND PREVENTION OF OSTEOPOROSIS

U-888 FEMALE HORMONE REPLACEMENT THERAPY FOR POSTMENOPAUSAL WOMEN

U-889 MENOPAUSAL AND POSTMENOPAUSAL DISORDERS (INCLUDING VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE)

U-890 REDUCTION OF SERUM PHOSPHATE IN PATIENTS WITH END STAGE RENAL DISEASE

U-891 USE AS AN INTRACULAR IRRIGATING SOLUTION DURING SURGICAL PROCEDURES INVOLVING PERFUSION OF THE EYE

U-892 TREATMENT OF CUTANEOUS MANIFESTATIONS IN PATIENTS WITH CUTANEOUS T-CELL LYMPHOMA (CTCL)

U-893 CLEVIPREX IS A DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER INDICATED FOR THE REDUCTION OF BLOOD PRESSURE WHEN ORAL THERAPY IS NOT FEASIBLE OR NOT DESIRABLE

U-894 TREATMENT OF COLD SORES IN PEDIATRIC PATIENTS TWELVE YEARS OF AGE AND OLDER

U-895 TREATMENT OF HIV INFECTION IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS

U-896 TREATMENT OF NASAL SYMPTOMS OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS IN ADULTS AND CHILDREN TWO YEARS OF AGE AND OLDER

U-897 METHOD OF TREATING TONSILLITIS AND/OR PHARYNGITIS SECONDARY TO STREPTOCOCCUS PYOGENES IN A ONCE-A-DAY AMOXICILLIN PRODUCT

U-898 USE OF GLUTAMINE TOGETHER WITH GROWTH HORMONE FOR THE TREATMENT OF PATIENTS WITH SHORT BOWEL SYNDROME

U-899 USE OF THALIDOMIDE IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA

U-900 INTEGRASE INHIBITION FOR THE TREATMENT OF HIV INFECTION

U-901 PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING

U-902 USE IN THE TREATMENT OF THE SIGNS AND SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA (BPH)

U-903 TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN ADULT PATIENTS

U-904 TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE

U-905 TREATMENT OF MODERATE TO SEVERE VAGINAL DRYNESS AND PAIN WITH INTERCOURSE, SYMPTOMS OF VULVAR AND VAGINAL ATROPHY, ASSOCIATED WITH MENOPAUSE

U-906 PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS FOR THE MAINTENANCE OF REMISSION OF ULCERATIVE COLITIS IN SUBJECTS 18 YEARS OF AGE AND OLDER

U-907 PROPHYLAXIS OF ORGAN REJECTION IN PATIENTS RECEIVING ALLOGENEIC RENAL TRANSPLANTS

U-908 PROPHYLAXIS OF ORGAN REJECTION IN PATIENTS RECEIVING ALLOGENEIC RENAL TRANSPLANTS

U-909 TREATMENT OF CYSTIC FIBROSIS PATIENTS WITH PSEUDOMONAS AERUGINOSA

U-910 TREATMENT OF METASTATIC CARCINOMA OF THE OVARY AFTER FAILURE OF INITIAL OR SUBSEQUENT CHEMOTHERAPY

U-911 METHOD OF TREATING, AS ADJUNCTIVE THERAPY, PARTIAL-ONSET SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS AND OLDER WHEN ORAL TREATMENT IS TEMPORARILY NOT FEASIBLE

U-912 SEDATION OF NON-INUTUBATED PATIENTS PRIOR TO AND/OR DURING SURGICAL AND OTHER PROCEDURES

U-913 TREATMENT OF OVERACTIVE BLADDER WITH SYMPTOMS OF URGAL URINARY INCONTINENCE,
URGENCY, AND FREQUENCY

U-914  METHOD OF TREATING, AS ADJUNCTIVE THERAPY, PARTIAL-ONSET SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS AND OLDER

U-915  TREATMENT OF MUSCULOSKELETAL CONDITIONS

U-916  TOPICAL TREATMENT OF ACNE VULGARIS IN PATIENTS 12 YEARS OR OLDER

U-917  TREATMENT OF INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS

U-918  TO TREAT OR PREVENT INFECTIONS CAUSED BY SUSCEPTIBLE BACTERIA USING DELAYED-RELEASE TABLETS CONSISTING OF DOXYCYCLINE HYCLATE COATED PELLETS IN A TABLET

U-919  FOR THE TREATMENT OF DERMATITIS

U-920  STERIOD-RESPONSIVE INFLAMMATORY OCULAR CONDITIONS FOR WHICH A CORTICOSTEROID IS INDICATED AND WHERE SUPERFICIAL BACTERIAL OCULAR INFECTION OR A RISK OF BACTERIAL OCULAR INFECTION EXISTS

U-921  TREATMENT OF ACNE VULGARIS

U-922  FOR THE TREATMENT OF FUNGAL INFECTIONS

U-923  METHOD OF TREATING OPHTHALMIC INFLAMMATION AND INFECTION

U-924  TREATMENT OF MILD TO MODERATE INFECTION CAUSED BY SUSCEPTIBLE STRAINS

U-925  TREATMENT OF ONLY INFLAMMATORY LESIONS (PAPULES AND PUSTULES) OF ROSACEA

U-926  FOR THE TREATMENT OF PATIENTS WITH HELICOBACTER PYLORI INFECTION AND DUODENAL ULCER DISEASE TO ERADICATE H. PYLORI

U-930  TREATMENT OF IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP)

U-931  RELIEF OF MODERATE TO SEVERE ACUTE PAIN

U-932  PYLERA CAPSULES, IN COMBINATION WITH OMEPRAZOLE ARE INDICATED FOR THE TREATMENT OF PATIENTS WITH HELICOBACTER PYLORI INFECTION AND DUODENAL ULCER DISEASE TO ERADICATE H. PYLORI

U-933  FOR THE TREATMENT OF PATIENTS WITH HELICOBACTER PYLORI INFECTION AND DUODENAL ULCER DISEASE TO ERADICATE H. PYLORI. THE ERADICATION OF HELICOBACTER PYLORI HAS BEEN SHOWN TO REDUCE THE RISK OF DUODENAL ULCER RECURRENT

U-934  IN COMBINATION WITH GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF) TO MOBILIZE HEMATOPOIETIC STEM CELL TO THE PERIPHERAL BLOOD FOR COLLECTION AND SUBSEQUENT AUTOLOGOUS TRANSPLANTATION WITH NON-HODGKIN'S LYMPHOMA AND MULTIPLE MYELOMA

U-935  TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION IN ADULT PATIENTS, AND TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PEDIATRIC PATIENTS 6 YEARS OF AGE AND OLDER

U-936  USE IN COMBINATION WITH GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF) TO MOBILIZE HEMATOPOIETIC STEM CELLS TO PERIPHERAL BLOOD FOR COLLECTION & SUBSEQUENT AUTOLOGOUS TRANSPLANTATION IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA & MULTIPLE MYELOMA

U-937  TREATMENT OF PROSTATE CANCER

U-938  TREATMENT OF HAIR LOSS AND HYPOTRICHOSIS OF THE EYELASHES BY INCREASING THEIR GROWTH INCLUDING LENGTH, THICKNESS AND DARKNESS

U-939  TREATMENT OF HYPOTRICHOSIS OF THE EYELASHES BY INCREASING AND STIMULATING THEIR GROWTH INCLUDING LENGTH, THICKNESS AND DARKNESS

U-940  METHOD TO TREAT AIDS-RELATED KAPOSI’S SARCOMA

U-941  METHOD TO TREAT OVARIAN CANCER

U-942  METHOD TO TREAT MULTIPLE MYELOMA

U-943  GNRH ANTAGONIST INDICATED FOR TREATMENT OF PATIENTS WITH ADVANCED PROSTATE CANCER

U-944  TREATMENT OF PATIENTS WITH B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

U-945  SEDATIVE-HYPNOTIC AGENT INDICATED FOR MONITORED ANESTHESIA CARE (MAC) SEDATION
PATENT USE

U-946 TREATMENT OF BREAST CANCER

U-947 WHEN PATIENTS ARE UNABLE TO TAKE THE ORAL FORMULATIONS, PREVACID IV, FOR INJECTION IS INDICATED AS AN ALTERNATIVE FOR THE SHORT-TERM TREATMENT (UP TO 7 DAYS) OF ALL GRADES OF EROSIVE ESOPHAGITIS

U-948 TREATMENT OF DIABETES MELLITUS

U-949 HEALING OF ALL GRADES OF EROSIVE ESOPHAGITIS (EE) FOR UP TO 8 WEEKS

U-950 MAINTAIN HEALING OF EROSIVE ESOPHAGITIS (EE) FOR UP TO 6 MONTHS

U-951 TREATMENT OF HEARTBURN ASSOCIATED WITH NON-EROSIVE GASTROESOPHAGEAL REFLUX DISEASE (GERD) FOR 4 WEEKS

U-952 USE AS AN ANALGESIC

U-953 METHOD OF TREATING OPHTHALMIC INFLAMMATION AND INFECTION

U-954 CHRONIC MANAGEMENT OF HYPERURICEMIA IN PATIENTS WITH GOUT. NOT RECOMMENDED FOR THE TREATMENT OF ASYMPTOMATIC HYPERURICEMIA

U-955 PROPHYLACTIC TREATMENT OF MIGRAINE

U-956 TREATMENT OF PATIENTS WITH H. PYLORI INFECTION AND DUODENAL ULCER DISEASE

U-957 A METHOD OF TREATING CANCER IN A PATIENT COMPRISING ADMINISTERING Ixabepilone OR PHARMACEUTICAL COMPOSITIONS COMPRISING IXABEPILONE

U-958 METHOD OF TREATING PATIENT COMPRISING MIXING FIRST AND SECOND VIALS OF PRODUCT COMPRISING LYOPHILIZED IXABEPILONE TO PROVIDE AN EPOPHILONE ANALOG SOLUTION, DILUTING SOLUTION WITH A SUITABLE DILUENT TO PREPARE INTRAVENOUS FORMULATION FOR PT

U-959 METHOD OF TREATING CANCER, IV ADMIN, LYOPHILIZED IXABEPILONE DILUTED, EVERY WEEK OR 3 WEEKS; LYOPHILIZED IXABEPILONE WITH SOLVENT (DEHYDRATED ETHANOL) DILUTED TO CONCENTRATION OF 0.1MG/ML TO 0.9MG/ML

U-960 METHOD OF TREATING CANCER IN A PATIENT COMPRISING INTRAVENOUSLY ADMINISTERING TO THE PATIENT IXABEPILONE DILUTED IN A PARENTERAL DILUENT

U-961 METHOD OF TREATING BREAST CANCER BY ADMINISTERING IXABEPILONE; A METHOD OF TREATING A CANCER RESPONSIBLE TO MICROTUBULE STABILIZATION BY ADMINISTERING IXABEPILONE

U-962 SYMBYAX IS INDICATED FOR THE ACUTE TREATMENT OF TREATMENT RESISTANT DEPRESSION IN ADULTS

U-963 PROZAC AND OLANZAPINE IN COMBINATION FOR THE ACUTE TREATMENT OF TREATMENT RESISTANT DEPRESSION IN ADULTS

U-964 ZYPREXA ZYDIS AND FLUOXETINE IN COMBINATION FOR THE ACUTE TREATMENT OF TREATMENT RESISTANT DEPRESSION IN ADULTS

U-965 USE OF IXABEPILONE IN COMBINATION WITH CAPECITABINE IN TREATMENT OF METASTASIS BREAST CANCER

U-966 TREATMENT OF ASTHMA (MAINTENANCE AND PROPHYLACTIC THERAPY)

U-967 A METHOD OF REVERSING SOFT-TISSUE ANESTHESIA I.E. ANESTHESIA OF THE LIP AND TONGUE, AND THE ASSOCIATED FUNCTIONAL DEFICITS RESULTING FROM AN INTRACRANIAL SUBMUCOSAL INJECTION OF A LOCAL ANESTHETIC

U-968 A METHOD FOR IMPROVING GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

U-969 TREATMENT OF MIGRAINE

U-970 TOPICAL TREATMENT OF LICE INFESTATIONS

U-971 INDICATED FOR THE ACUTE TREATMENT OF ADULTS WITH SCHIZOPHRENIA

U-972 MONOTHERAPY OR AS ADJUNCTIVE THERAPY TO LITHIUM OR VALPROATE FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER

U-973 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHO ARE ALREADY TREATED WITH PIOGLITAZONE AND METFORMIN OR WHO HAVE INADEQUATE GLYCEMIC CONTROL ON PIOGLITAZONE OR METFORMIN ALONE

U-974 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES WHO ARE ALREADY TREATED WITH A PIOGLITAZONE AND METFORMIN

U-975 TREATMENT OF PULMONARY HYPERTENSION

U-976 IMPROVEMENT OF GLYCEMIC CONTROL IN INDIVIDUALS WITH TYPE 2 DIABETES
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-977 TREATMENT OF ACUTE, UNCOMPLICATED MALARIA INFECTION DUE TO PLASMODIUM FALCIPARUM IN PATIENTS OF 5KG BODYWEIGHT AND ABOVE

U-978 METHOD OF TREATING HYPONATREMIA

U-979 RELIEF OF MUSCLE SPASM

U-980 NONSTEROIDAL ANTI-INFLAMMATORY DRUG INDICATED FOR RELIEF OF MILD TO MODERATE ACUTE PAIN

U-981 MANAGEMENT OF MILD TO MODERATE PAIN, MANAGEMENT OF MODERATE TO SEVERE PAIN AS AN ADJUNCT TO OPIOID ANALGESICS, REDUCTION IN FEVER THROUGH ANTI-INFLAMMATORY, ANALGESIC, AND ANTIPYRETIC ACTIVITY

U-982 A METHOD OF TREATING OSTEOPOROSIS

U-983 METHOD OF TREATING OSTEOPOROSIS IN A POST-MENOPAUSAL WOMAN AT RISK FOR FRACTURE

U-984 METHOD FOR THE TREATMENT OF A WOMAN WITH OSTEOPOROSIS AND AT RISK FOR BONE FRACTURE

U-985 TREATMENT OF MACULAR EDEMA FOLLOWING BRANCH RETINAL VEIN OCCLUSION (BRVO) OR CENTRAL RETINAL VEIN OCCLUSION (CRVO)

U-986 TREATMENT OF PATIENTS INFECTED WITH PEDICULUS HUMANUS CAPITIS (HEAD LICE AND THEIR OVA) OF THE SCALP HAIR

U-987 TREATMENT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS WITH CHRONIC KIDNEY DISEASE ON DIALYSIS

U-988 TREATMENT OF RHINITIS COMPRISING THE NASAL APPLICATION OF A PHARMACEUTICAL FORMULATION AS CLAIMED IN US PATENT 7541350

U-989 FOR REDUCING BLOOD PHENYLALANINE LEVELS IN A HUMAN SUFFERING FROM HYPERPHENYLALANINEMIA

U-990 TREATMENT OF PROTOZOAL INFECTION

U-991 TREATMENT OR PROPHYLAXIS OF THROMBOSIS OR EMBOLISMS

U-992 REDUCTION OF THE RISK OF CARDIOVASCULAR HOSPITALIZATION

U-993 METHOD OF TREATING INFERTILITY

U-994 METHOD OF TREATMENT OF OSTEOPOROSIS WHEREIN THE OSTEOPOROSIS IS STEROID-INDUCED

U-995 METHOD FOR TREATING TYPE II DIABETES BY ADMINISTERING SAXAGLIPTIN

U-996 AN ADJUNCTIVE THERAPY TO DIET TO REDUCE ELEVATED TOTAL CHOLESTEROL (TC), LOW-DENSITY LIPOPROTEIN CHOLESTEROL, APOLIPOPROTEIN B, TRIGLYCERIDES, AND TO INCREASE HDL-C IN ADULT PATIENTS WITH PRIMARY HYPERLIPIDEMIA OR MIX DYSLIPIDEMIA

U-997 TREATMENT OF MAJOR DEPRESSIVE DISORDER BY DOSING AT INTERVALS OF 24 HOURS

U-998 ADJUNCTIVE THERAPY TO DIET TO REDUCE ELEVATED TOTAL CHOLESTEROL, LOW-DENSITY LIPOPROTEIN CHOLESTEROL, APOLIPOPROTEIN B, TRIGLYCERIDES AND TO INCREASE HDL-C IN ADULT PATIENTS WITH PRIMARY HYPERLIPIDEMIA OR MIXED DYSLIPIDEMIA

U-999 TREATMENT OF CHRONIC HEPATITIS B IN ADULT PATIENTS

U-1000 ADJUNCTIVE THERAPY TO DIET IN PATIENTS WITH HYPERLIPIDEMIAS

U-1001 METHOD FOR DELIVERING DRUG TO LUNG OF MAMMAL, COMPRISING ADMINISTERING DRUG PRODUCT BY INHALATION. TREATING A MAMMAL HAVING A CONDITION CAPABLE OF TREATMENT BY INHALATION, COMPRISING ADMINISTERING TO THE LUNG THE DRUG PRODUCT BY INHALATION

U-1002 METHOD OF TREATING INFLAMMATORY CONDITIONS

U-1003 A METHOD OF MYOCARDIAL PERFUSION IMAGING AND INCREASING CORONARY BLOOD FLOW

U-1004 TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA

U-1005 METHOD OF TREATING A STAPHYLOCOCCAL INFECTION

U-1006 NEW COMBINATION PRODUCT FOR THE EARLY TREATMENT OF RECURRENT HERPES LABIALIS (COLD SORES) TO REDUCE THE LIKELIHOOD OF ULCERATIVE COLD SORES AND TO SHORTEN THE LESION HEALING TIME IN ADULTS AND ADOLESCENTS (12 YEARS OF AGE AND OLDER)

U-1007 METHOD OF TREATING GOUT FLARES

U-1008 APPLICATION OF ANTISEPTIC WITH MOISTURIZERS FOR SURGICAL AND HEALTHCARE PERSONNEL SKIN DISINFECTION

U-1009 METHOD FOR ADMINISTRATION OF TESTOSTERONE
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PATENT AND EXCLUSIVITY TERMS

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PATENT USE

U-1010 TO REDUCE BLOOD PHENYLALANINE LEVELS IN PATIENTS WITH HYPERPHENYLALANINEMIA DUE TO TETRA HYDROBIOPTERIN RESPONSIVE PHENYLKETONURIA. KUVAN SHOULD BE TAKEN ORALLY WITH FOOD TO INCREASE ABSORPTION

U-1011 USE OF GRANISETRON TRANSDERMAL SYSTEM TO TREAT/PREVENT CHEMOTHERAPY INDUCED NAUSEA AND VOMITING

U-1012 METHOD FOR TREATING INSOMNIA WHILE REDUCING THE RISK OF AN ADVERSE DRUG INTERACTION

U-1013 METHOD OF USING RIBAVIRIN IN COMBINATION WITH PEGYLATED INTERFERON ALPHA-2B TO TREAT PATIENTS WITH CHRONIC HEPATITIS C

U-1014 METHOD OF USING RIBAVIRIN IN COMBINATION WITH INTERFERON ALPHA-2B (PEGYLATED AND NONPEGYLATED) TO TREAT PATIENTS WITH CHRONIC HEPATITIS C

U-1015 TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA

U-1016 IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT-EXPERIENCED ADULT PATIENTS, WHO HAVE EVIDENCE OF VIRAL REPLICATION AND HIV-1 STRAINS RESISTANT TO AN NNRTI AND OTHER ANTIRETROVIRAL AGENTS

U-1017 A METHOD OF TREATING NASAL AND NON-NASAL SYMPTOMS OF SEASONAL ALLERGIC RHINITIS

U-1018 TREATMENT OF PULMONARY HYPERTENSION BY INHALATION

U-1019 TREATMENT OF PULMONARY HYPERTENSION

U-1020 METHOD OF USING COLCHICINE FOR THE PROPHYLAXIS OF GOUT FLARES

U-1021 SHORT-TERM TREATMENT (4-8 WEEKS) OF ACTIVE BENIGN GASTRIC ULCER

U-1022 FOR THE PREPARATION OF SKIN PRIOR TO SURGERY; HELPS REDUCE BACTERIA THAT CAN POTENTIALLY CAUSE SKIN INFECTION

U-1023 TREATMENT OF ATROPHIC VAGINITIS DUE TO MENOPAUSE

U-1024 REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH GLAUCOMA OR OCULAR HYPERTENSION WHO REQUIRE ADJUNCTIVE OR REPLACEMENT THERAPY DUE TO INADEQUATELY CONTROLLED IOP

U-1025 TREATING FREQUENT HEARTBURN

U-1026 A METHOD OF TREATING HUMAN SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS.

U-1027 REDUCTION OF ELEVATED PLASMA STEROL AND/OR STANOL LEVELS IN A MAMMAL

U-1028 A METHOD OF DISTRIBUTING SODIUM OXYBATE UNDER CONTROL OF A CENTRAL PHARMACY

U-1029 METHOD FOR TREATING ACUTE ELEVATIONS OF BLOOD PRESSURE IN HUMAN SUBJECT IN NEED THEREOF

U-1030 IMPROVEMENT OF WALKING IN PATIENTS WITH MULTIPLE SCLEROSIS (MS)

U-1031 IMPROVE RESPIRATORY SYMPTOMS IN CYSTIC FIBROSIS IN PATIENTS WITH PSEUDOMONAS AERUGINOSA

U-1032 USE OF ROSUVASTATIN CALCIUM FOR THE PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE IN INDIVIDUALS WITHOUT CLINICALLY EVIDENT CORONARY HEART DISEASE BUT WITH INCREASED RISK FACTORS

U-1033 TOPICAL TREATMENT OF ACNE VULGARIS

U-1034 TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN ADULTS

U-1035 NONSTERoidal ANTI-INFLAMMATory DRUG INDICATED FOR RELIEF OF MILD TO MODERATE ACUTE PAIN

U-1036 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-4 INHIBITOR IN COMBINATION WITH INSULIN

U-1037 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-IV INHIBITOR IN COMBINATION WITH A PPAR-AM AND A PPAR-GAMMA AGONIST

U-1038 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-4 INHIBITOR IN COMBINATION WITH METFORMIN AND A PPAR-GAMMA AGONIST

U-1039 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL PEPTIDASE-4 INHIBITOR IN COMBINATION WITH METFORMIN

U-1040 INHIBITION OF THROMBIN IN A PATIENT

U-1041 TREATMENT OF DISORDERS RESPONSIVE TO GROWTH HORMONE

U-1042 METHOD FOR STIMULATING CORONARY VASODILATION FOR PURPOSES OF IMAGING THE HEART
PATENT AND EXCLUSIVITY TERMS

U-1043 MANAGEMENT OF MODERATE TO SEVERE PAIN

U-1044 TOPICAL TREATMENT OF SCALP PSORIASIS

U-1045 MAINTENANCE TREATMENT IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NSCLC WHO HAVE NOT PROGRESSED ON 1ST-LINE TREATMENT WITH PLATINUM-BASED CHEMOTHERAPY

U-1046 MAINTENANCE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NSCLC WHOSE DISEASE HAS NOT PROGRESSED AFTER FOUR CYCLES PLATINUM-BASED CHEMOTHERAPY

U-1047 TREATMENT OF BIOPSY-CONFIRMED, PRIMARY SUPERFICIAL BASAL CELL CARCINOMA (SBCC)

U-1048 WORKS THROUGH THE INDUCTION OF INTERFERON AND OTHER CYTOKINES

U-1049 PROPHYLAXIS OF ORGAN REJECTION IN ADULT PATIENTS AT LOW-MODERATE IMMUNOLOGIC RISK RECEIVING A RENAL TRANSPLANT

U-1050 USE OF METAXALONE FOR TREATMENT OF MUSCULOSKELETAL CONDITIONS

U-1051 TREATMENT OF OROPHARYNGEEAL CANDIDIASIS

U-1052 RELIEF OF SIGNS AND SYMPTOMS OF ARTHRITIS AND RISK-REDUCTION OF NSAID-ASSOCIATED GASTRIC ULCER

U-1053 RISK-REDUCTION OF NSAID-ASSOCIATED GASTRIC ULCER

U-1054 ONYCHOMYCOSIS OF THE TOENAIL CAUSED BY TRICOPHYTON RUBRUM OR TRICOPHYTON MENTAGROPHYTES, ONCE DAILY USE FOR 12 CONSECUTIVE WEEKS

U-1055 AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHO ARE ALREADY TREATED WITH A THIAZOLIDINEDIONE (TZD) AND METFORMIN OR WHO HAVE INADEQUATE GLYCEMIC CONTROL ON A TZD OR METFORMIN ALONE

U-1056 TREATMENT OF PAIN USING A NASAL SPRAY OF KETOROLAC TROMETHAMINE

U-1057 TREATMENT OF INFLAMMATION AND PAIN USING A NASAL SPRAY OF KETOROLAC TROMETHAMINE

U-1058 USE OF THALIDOMIDE IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA

U-1059 ADJUNCTIVE THERAPY TO DIET TO PATIENTS WITH HYPERTRIGLYCERIDEMIA

U-1060 ADJUNCTIVE THERAPY TO DIET TO PATIENTS WITH ELEVATED CHOLESTEROL AND/OR LIPID LEVELS

U-1061 ADJUNCTIVE THERAPY TO DIET TO PATIENTS WITH MIXED DYSLIPIDEMIA

U-1062 ADMINISTRATION OF APPROVED PRODUCT FOR TREATMENT OF ALZHEIMER'S DISEASE

U-1063 TREATMENT OF ONLY INFLAMMATORY LESIONS (PAPULES AND PUSTULES) OF ROSacea

U-1064 TREATMENT OF BIPOLAR DISORDER AND SCHIZOPHRENIA

U-1065 METHOD OF TREATING ANDROGEN RESPONSIVE OR MEDICATED CONDITION IN A MAMMAL BY ADMINISTERING A SAFE & EFFECTIVE AMOUNT OF DUTASTERIDE OR A PHARMACEUTICALLY ACCEPTABLE SOLVATE THEREOF.. CONDITIONS INCLUDE BENIGN PROSTATIC HYPERPLASIA

U-1066 METHOD OF TREATING AN ANDROGEN RESPONSE OR MEDIATED DISEASE IN A MAMMAL BY ADMINISTERING AN EFFECTIVE ANDROGEN RESPONSIVE OR MEDICATED DISEASE AMOUNT OF DUTASTERIDE..CONDITIONS INCLUDE BENIGN PROSTATIC HYPERPLASIA

U-1067 TREATMENT OF CANCER

U-1068 TREATMENT OF ASTHMA

U-1069 A METHOD OF TREATING A PATIENT WITH A PRESCRIPTION DRUG USING AN EXCLUSIVE COMPUTER DATABASE IN A COMPUTER SYSTEM FOR DISTRIBUTION

U-1070 A METHOD TO CONTROL ABUSE OF A SENSITIVE DRUG BY CONTROLLING WITH A COMPUTER PROCESSOR THE DISTRIBUTION OF THE SENSITIVE DRUG VIA AN EXCLUSIVITY CENTRAL PHARMACY THAT MAINTAINS A CENTRAL DATABASE

U-1071 METHOD OF TREATING BLADDER DY HyFUNCTION WITH ONCE A DAY TROSPiUM SALT FORMULATION

U-1072 THE MANAGEMENT OF MODERATE TO SEVERE CHRONIC PAIN IN PATIENTS REQUIRING A CONTINUOUS, AROUND-THE-CLOCK OPIOID ANALGESIC FOR AN EXTENDED PERIOD OF TIME

U-1073 USE FOR THE TREATMENT OF ASTHMA AND COPD

U-1074 USE OF EXENATIDE MAY RESULT IN REDUCTION IN BODY WEIGHT

U-1075 USE FOR THE TREATMENT OF ASTHMA

U-1076 REDUCE CHRONIC SEVERE DROOLING (I.E., SIALORRHEA) IN PATIENTS WITH NEUROLOGIC CONDITIONS ASSOCIATED WITH PROBLEM DROOLING

U-1077 PRETREATMENT OF PATIENTS WITH VITAMIN B12 AND FOLIC ACID PRIOR TO PEMETREXED
PATENT AND EXCLUSIVITY TERMS

PATENT USE

DISODIUM ADMINISTRATION

U-1078 TREATMENT OF ACNE

U-1079 REVLIMID (LENALIDOMIDE) IS INDICATED FOR THE TREATMENT OF PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA IN MYELODYSPLASTIC SYNDROMES (MDS)

U-1080 METHOD TO TREAT PULMONARY HYPERTENSION BY ADMINISTERING AMBRISENTAN TO A PATIENT

U-1081 LUMIGAN IS A PROSTAGLANDIN ANALOG INDICATED FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA OR OCULAR HYPERTENSION

U-1082 USE OF A COMBINATION OF TOBRAMYCIN AND DEXAMETHASONE TO TREAT OCULAR INFLAMMATION WHERE AN INFECTION OR RISK OF INFECTION EXISTS

U-1083 ACUTE TREATMENT OF MIGRAINE ATTACKS, WITH OR WITHOUT AURA, AND THE TREATMENT OF CLUSTER HEADACHE EPISODES

U-1084 RELIEF OF THE INFLAMMATORY AND PRURITIC MANIFESTATIONS OF CORTICOSTEROID RESPONSIVE DERMATOSES IN PATIENTS 12 YEARS OF AGE OR OLDER

U-1085 METHOD FOR TREATING IRRITABLE BOWEL SYNDROME AND METHOD FOR TREATING ABDOMINAL DISCOMFORT ASSOCIATED WITH IRRITABLE BOWEL SYNDROME

U-1086 TREATMENT OF AUTOIMMUNE DISEASE

U-1087 DETECTION OF NON-MUSCLE INVASIVE PAPILLARY CANCER OF THE BLADDER BY PHOTODYNAMIC CYSTOSCOPY

U-1088 RELIEF OF MUSCLE SPASM

U-1089 INHIBITION OF THROMBIN

U-1090 LO LOESTRIN FE IS INDICATED FOR THE PREVENTION OF PREGNANCY IN WOMEN WHO ELECT TO USE ORAL CONTRACEPTIVES AS A METHOD OF CONTRACEPTION

U-1091 ASSESSMENT OF BRONCHIAL HYPERRESPONSIVENESS IN PATIENTS 6 YEARS OF AGE OR OLDER WHO DO NOT HAVE CLINICALLY APPARENT ASTHMA

U-1092 TREATMENT OF BREAST CANCER

U-1093 TREATMENT OF PSEUDOBULBAR AFFECT

U-1094 MANAGEMENT OF CHRONIC MUSCULOSKELETAL PAIN

U-1095 METHOD OF TREATING OCULAR INFLAMMATION

U-1096 TREATMENT OF PATIENTS WITH METASTATIC BREAST CANCER

U-1097 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHEN TREATMENT WITH BOTH SAXAGLIPTIN AND METFORMIN IS APPROPRIATE

U-1098 METHOD OF TREATING HYPERPARATHYROIDISM; METHOD OF TREATING HYPERCALCEMIA

U-1099 TREATMENT OF PAIN, INCLUDING NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY, POSTHERPETIC NEURALGIA, AND FIBROMYALGIA

U-1100 REDUCTION OF EXCESS ABDOMINAL FAT IN HIV-INFECTED PATIENTS WITH LIPODYSTROPHY

U-1101 METHOD OF TREATING EXCESSIVE DAYTIME SLEEPINESS IN PATIENTS WITH NARCOLEPSY

U-1102 METHOD OF TREATING CATAPLEXY IN PATIENTS WITH NARCOLEPSY

U-1103 TESTOSTERONE REPLACEMENT THERAPY IN MALES FOR CONDITIONS ASSOCIATED WITH A DEFICIENCY OR ABSENCE OF ENDOGENOUS TESTOSTERONE

U-1104 USE OF TRAMADOL FOR THE MANAGEMENT OF MODERATE TO MODERATELY SEVERE CHRONIC PAIN

U-1105 TOPICAL TREATMENT OF HEAD LICE INFESTATION IN PATIENTS FOUR (4) YEARS OF AGE AND OLDER

U-1106 TREATING HYPERTRIGLYCERIDEMIAS WITH REDUCTION OF FOOD EFFECT

U-1107 TREATING HYPERCHOLESTEROLEMIAS WITH REDUCTION OF FOOD EFFECT

U-1108 TREATING TYPE 2 DIABETES MELLITUS WITH EXENATIDE BY STIMULATING INSULIN RELEASE

U-1109 TREATMENT OF CUTANEOUS MANIFESTATIONS OF ERYTHEMA NODOSUM LEPROSUM (ENL) IN CONNECTION WITH A SPECIAL PROGRAM APPROVED BY FDA CALLED "SYSTEM FOR THALIDOMIDE EDUCATION AND PRESCRIBING SAFETY" (S.T.E.P.S.)

U-1110 METHOD OF TREATING A PATIENT WITH A PRESCRIPTION DRUG USING A COMPUTER DATABASE IN A COMPUTER SYSTEM FOR DISTRIBUTION

U-1111 NONSTEROIDAL ANTI-INFLAMMATORY DRUG INDICATED FOR RELIEF OF MILD TO MODERATE ACUTE PAIN
PATENT USE

U-1112 METHOD OF MR IMAGING OF A MAMMAL
U-1113 TREATMENT AND PROPHYLAXIS OF INFLUENZA
U-1114 TREATMENT WITH GABAPENTIN, INCLUDING TREATMENT OF NEUROPATHIC PAIN, INCLUDING NEUROPATHIC PAIN ASSOCIATED WITH POSTHERPETIC NEURALGIA
U-1115 TREATMENT TO REDUCE THE RISK OF COPD EXACERBATIONS IN PATIENTS WITH SEVERE COPD ASSOCIATED WITH CHRONIC BRONCHITIS AND A HISTORY OF EXACERBATIONS
U-1116 METHOD OF ADMINISTERING COLCHICINE TO FAMILIAL MEDITERRANEAN FEVER PATIENTS
U-1117 TREATMENT OF BREAST CANCER
U-1118 USE FOR THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA
U-1119 CONTRAST AGENT FOR MAGNETIC RESONANCE IMAGING
U-1120 TO REDUCE GASTROINTESTINAL SIDE EFFECTS ADMINISTER WITH A MEAL; AS STARTING DOSE ADMINISTER ONCE DAILY WITH EVENING MEAL
U-1121 METHOD OF TREATING TRAVELER'S DIARRHEA
U-1122 TREATMENT OF SECONDARILY INFECTED TRAUMATIC SKIN LESIONS DUE TO S. AUREUS AND S. PYOGENES
U-1123 TREATMENT OF ALCOHOL DEPENDENCE
U-1124 PREVENTION OF RELAPSE TO OPIOID DEPENDENCE, FOLLOWING OPIOID DETOXIFICATION
U-1125 METHOD FOR THE DETECTION OF NEUROENDOCRINE TUMORS
U-1126 USE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO HAVE RECEIVED PRIOR CHEMOTHERAPY CONTAINING DOCETAXEL
U-1127 TREATMENT OF PATENT DUCTUS ARTERIOSUS
U-1128 TREATMENT OF CHRONIC HEPATITIS C (CHC) GENOTYPE 1 INFECTION IN COMBINATION WITH PEGINTERFERON ALFA AND RIBAVIRIN IN ADULT PATIENTS (>=18 YEARS OF AGE) WITH COMPENSATED LIVER DISEASE
U-1129 TREATMENT OF HYPERCHOLESTEROLEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN
U-1130 SECONDARY PREVENTION OF CARDIOVASCULAR EVENTS BY DOSING ONCE PER DAY IN THE EVENING OR A NIGHT WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN
U-1131 TREATMENT OF HYPERTRIGLYCERIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN
U-1132 TREATMENT OF HYPERCHOLESTEROLEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-1133 SECONDARY PREVENTION OF CARDIOVASCULAR EVENTS BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-1134 TREATMENT OF HYPERTRIGLYCERIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-1135 TREATMENT OF HYPERCHOLESTEROLEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, THROUGH REDUCTION OF LDL-C, TC, TG, LP(A) AND INCREASE OF HDL-C
U-1136 SECONDARY PREVENTION OF CARDIOVASCULAR EVENTS BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, THROUGH REDUCTION OF LDL-C, TC, TG, LP(A), AND INCREASE OF HDL-C
U-1137 TREATMENT OF HYPERTRIGLYCERIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, THROUGH REDUCTION OF LDL-C, TC, TG, LP(A), AND INCREASE OF HDL-C
U-1138 TREATMENT OF PRIMARY AND MIXED DYSLIPIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-1139 REDUCTION IN RISK OF RECURRENT NONFATAL MYOCARDIAL INFARCTION BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-1140 REDUCTION IN ELEVATED TC AND LDL-C BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-1141 REDUCTION IN TG BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
U-1142 TREATMENT OF PRIMARY AND MIXED DYSLIPIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-1143 UNL-1143 REDUCTION IN RISK OF RECURRENT NONFATAL MYOCARDIAL INFARCTION BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN

U-1144 UNL-1144 REDUCTION IN ELEVATED TC AND LDL-C BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN

U-1145 UNL-1145 REDUCTION IN TG BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN

U-1146 UNL-1146 REDUCTION IN TG WITH REDUCED FLUSHING BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT

U-1147 UNL-1147 TREATMENT OF PRIMARY AND MIXED DYSLIPIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, THROUGH REDUCTION OF LDL-C, TC, TG, LP(A), AND INCREASE OF HDL-C

U-1148 UNL-1148 REDUCTION IN RISK OF RECURRENT NONFATAL MYOCARDIAL INFARCTION BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, THROUGH REDUCTION OF LDL-C, TC, TG, LP(A), AND INCREASE OF HDL-C

U-1149 UNL-1149 TREATMENT OF HYPERTRIGLYCERIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, WITH PRETREATMENT WITH A FLUSH INHIBITING AGENT SUCH AS ASPIRIN

U-1150 UNL-1150 TREATMENT OF HYPERCHOLESTEROLEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, THROUGH REDUCTION IN TOTAL-C, LDL-C, TG, LP(A), AND INCREASE OF HDL-C

U-1151 UNL-1151 TREATMENT OF HYPERTRIGLYCERIDEMIA BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT, THROUGH REDUCTION IN TOTAL-C, LDL-C, LP(A), AND INCREASE OF HDL-C

U-1152 UNL-1152 CYANOCOBALAMIN ADMINISTRATION THROUGH NASAL INFUSION

U-1153 UNL-1153 IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, IS INDICATED FOR THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) INFECTION IN ANTIRETROVIRAL TREATMENT-NAIVE ADULT PATIENTS, AS SET FORTH IN THE LABELING, INCLUDING I&U SECTION

U-1154 UNL-1154 TREATMENT OF PROTEIN KINASE RELATED DISORDERS, SUCH AS GASTROINTESTINAL STROMAL TUMORS, RENAL CELL CARCINOMA AND ADVANCED Pancreatic NEUROENDOCRINE TUMORS, WITH SUNITINIB

U-1155 UNL-1155 USE OF THALIDOMIDE IN TREATMENT OF CUTANEOUS MANIFESTATIONS OF ERYTHEMA NODOSUM LEPROSUM (ENL)

U-1156 UNL-1156 TO REDUCE BLOOD PHENYLALANINE (PHE) LEVELS IN PATIENTS WITH HYPERPHENYLALANINEMIA (HPA)

U-1157 UNL-1157 RELIEF OF SYMPTOMS ASSOCIATED WITH RESPIRATORY ALLERGIES IN ADULTS AND CHILDREN 2 YEARS OF AGE AND OLDER AND FOR THE RELIEF OF SYMPTOMS ASSOCIATED WITH HIVES (URTICARIA) IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER

U-1158 UNL-1158 RELIEF OF SYMPTOMS ASSOCIATED WITH RESPIRATORY ALLERGIES AND FOR THE RELIEF OF SYMPTOMS ASSOCIATED WITH HIVES (URTICARIA) IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER

U-1159 UNL-1159 RELIEF OF SYMPTOMS ASSOCIATED WITH RESPIRATORY ALLERGIES, SWELLING OF THE NASAL PASSAGES AND SINUS CONGESTION AND PRESSURE IN ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

U-1160 UNL-1160 RELIEF OF SYMPTOMS ASSOCIATED WITH RESPIRATORY ALLERGIES AND FOR THE RELIEF OF SYMPTOMS ASSOCIATED WITH HIVES (URTICARIA) IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER

U-1161 UNL-1161 FOR THE TREATMENT AND PROPHYLAXIS OF GOUT FLARES & THE TREATMENT OF FAMILIAL MEDITERRANEAN FEVER

U-1162 UNL-1162 TREATMENT OF SEBORRHEIC DERMATITIS OF THE SCALP

U-1163 UNL-1163 METHOD OF TREATING THROMBOSIS

U-1164 UNL-1164 METHOD OF TREATING AN ARGATROBAN TREATABLE CONDITION

U-1165 UNL-1165 USE FOR THE TREATMENT OF MULTIPLE MYELOMA

U-1166 UNL-1166 A METHOD FOR TREATMENT OF GOUT FLARES DURING PROPHYLAXIS

U-1167 UNL-1167 PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT)

U-1168 UNL-1168 THE LONG TERM, ONCE-DAILY MAINTENANCE BRONCHODILATOR TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA

U-1169 UNL-1169 MANAGEMENT OF BREAKTHROUGH PAIN IN CANCER PATIENTS 18 YEARS OF AGE AND OLDER WHO ARE RECEIVING AND TOLERANT TO OPIOID THERAPY FOR THEIR UNDERLYING PERSISTENT
PATENT USE

U-1170 TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER

U-1171 REDUCTION OF THE RATE OF THROMBOTIC EVENTS IN PATIENTS WITH ACUTE CORONARY SYNDROME

U-1172 TO REDUCE ELEVATED TOTAL-C, APO B, AND NON-HDL-C IN PATIENTS WITH PRIMARY HYPERLIPIDEMIA BY ADMINISTRATION OF EZETIMIBE IN COMBINATION WITH A STATIN

U-1173 TO REDUCE ELEVATED TOTAL-C, LDL-C, APO B AND NON-HDL-C IN PATIENTS WITH PRIMARY HYPERLIPIDEMIA BY ADMINISTRATION OF EZETIMIBE ALONE OR IN COMBINATION WITH A STATIN OR WITH FENOFOBIRATE

U-1174 ADMINISTRATION OF REMODULIN DILUTED FOR INTRAVENOUS INFUSION WITH STERILE WATER FOR INJECTION, 0.9% SODIUM CHLORIDE INJECTION, OR FLOLAN STERILE DILUENT FOR INJECTION PRIOR TO ADMINISTRATION

U-1175 REDUCTION OF CARDIAC TISSUE DAMAGE ASSOCIATED WITH MYOCARDIAL INFARCTION

U-1176 TREATMENT OR PREVENTION OF STROKE

U-1177 REDUCTION OF CARDIAC TISSUE DAMAGE ASSOCIATED WITH MYOCARDIAL INFARCTION

U-1178 RELIEF OF MODERATE TO SEVERE CHRONIC PAIN

U-1179 TREATMENT OF A CANCER MEDIATED BY AN ANAPLASTIC LYMPHOMA KINASE (ALK)

U-1180 TREATMENT OF THE FOLLOWING INFECTIONS: COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS AND STAPHYLOCOCCUS AUREUS BLOODSTREAM INFECTIONS (BACTEREMIA) INCLUDING THOSE WITH RIGHT-SIDED INFECTIVE ENDOCARDITIS

U-1181 A METHOD OF TREATING OR PREVENTING OCULAR PAIN IN A PATIENT

U-1182 TREATMENT OF CYCLIC HEAVY MENSTRUAL BLEEDING

U-1183 A METHOD FOR ADMINISTERING FOLLICLE STIMULATING HORMONE (FSH) FOR OVARIAN FOLLICLE OR TESTICULAR STIMULATION IN THE HUMAN

U-1184 TREATMENT OF ERECTILE DYSFUNCTION AND THE SIGNS AND SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA

U-1185 TREATMENT OF OPIOID-INDUCED CONSTIPATION

U-1186 ADMINISTRATION OF AN INHALABLE POWDER COMPRISING TIOTROPIUM VIA DEVICE

U-1187 METHOD OF TREATING OR PREVENTING ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA (HAE)

U-1188 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND SIMVASTATIN IS APPROPRIATE

U-1189 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND SIMVASTATIN IS APPROPRIATE, IN COMBINATION WITH METFORMIN

U-1190 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND SIMVASTATIN IS APPROPRIATE, IN COMBINATION WITH INSULIN

U-1191 METHOD OF TREATING TYPE 2 DM IN Pts FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND SIMVASTATIN IS APPROPRIATE, IN COMBO WITH AN AGENT ACTING ON AN ATP-DEPENDENT CHANNEL IN BETA CELLS SUCH AS A SULFONYLUREA (INCL GLIPIZIDE, GLIMEPIRIDE & GLYBURIDE)

U-1192 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND SIMVASTATIN IS APPROPRIATE, IN COMBINATION WITH A SULFONYLUREA (SUCH AS GLIPIZIDE, GLIMEPIRIDE AND GLYBURIDE)

U-1193 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND SIMVASTATIN IS APPROPRIATE, IN COMBINATION WITH A PPAR-GAMMA AGONIST (SUCH AS PIOGLITAZONE AND ROSIGLITAZONE)

U-1194 METHOD FOR TREATING INSOMNIA

U-1195 PREVENTION AND TREATMENT OF SECONDARY HYPERPARATHYROIDISM ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD) STAGE 5, WHICH MAY RESULT IN RENAL OSTEODYSTROPHY, WHILE AVOIDING HYPERPHOSPHATEMIA

U-1196 RELIEF OF SIGNS AND SYMPTOMS OF RHEUMATOID ARTHRITIS AND OSTEOARTHRITIS AND TO DECREASE RISK OF DEVELOPING UPPER GASTROINTESTINAL ULCERS IN PATIENTS WHO ARE TAKING IBUPROFEN FOR THOSE INDICATIONS

U-1197 METHOD OF TREATMENT OF CHILDREN WITH CENTRAL PREOCIOUS PUBERTY

U-1198 RECTIV IS A NITRATE VASODILATOR INDICATED FOR THE TREATMENT OF MODERATE TO SEVERE PAIN ASSOCIATED WITH CHRONIC ANAL FISSURE
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-1199 TREATMENT AND PREVENTION OF POSTMENOPAUSAL OR GLUCOCORTICOID-INDUCED OSTEOPOROSIS AND TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS

U-1200 REDUCING THE RISK OF STROKE AND SYSTEMIC EMBOLISM

U-1201 FOR THE TREATMENT OF INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS

U-1202 METHOD FOR RELIEVING OR TREATING CONSTIPATION IN A PATIENT WITH IRRITABLE BOWEL SYNDROME

U-1203 METHOD FOR RELIEVING OR TREATING CONSTIPATION IN A HUMAN CONSTIPATED PATIENT

U-1204 TREATMENT OF UVEITIS

U-1205 TREATMENT OF MACULAR EDEMA

U-1206 DELIVERING AN OCULAR IMPLANT AS DESCRIBED IN THE DOSAGE AND ADMINISTRATION SECTION OF THE APPROVED LABELING OF OZURDEX

U-1207 INFANT USE AGED 1 MONTH TO LESS THAN ONE YEAR, GERD AND EROSIIVE ESOPHAGITIS

U-1208 TREATMENT OF HYPOTRICHOSIS OF THE EYELASHES BY INCREASING THEIR GROWTH INCLUDING LENGTH, THICKNESS AND DARKNESS

U-1209 TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION IN ADULT PATIENTS, AND TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION IN PEDIATRIC PATIENTS 3 YEARS OF AGE AND OLDER

U-1210 USE OF REVLIMID (LENALIDOMIDE) WHILE PREVENTING THE EXPOSURE OF A FETUS OR OTHER CONTRAINDICATED INDIVIDUAL TO REVLIMID (LENALIDOMIDE)

U-1211 USE OF REVLIMID (LENALIDOMIDE) TO INHIBIT THE SECRETION OF PRO-INFLAMMATORY CYTOKINES, INCLUDING TUMOR NECROSIS FACTOR ALPHA

U-1212 USE OF REVLIMID (LENALIDOMIDE) FOR THE TREATMENT OF MULTIPLE MYELOMA AND TRANSFUSION-DEPENDENT ANEMIA IN MYELODYSPLASTIC SYNDROMES (MDS)

U-1213 TOPICAL TREATMENT OF SEBORRHEIC DERMATITIS IN IMMUNOCOMPETENT PATIENTS 12 YEARS OF AGE AND OLDER

U-1214 METHOD FOR RELIEVING CONSTIPATION IN A HUMAN PATIENT THAT COMPRISSES ADMINISTERING TO THE PATIENT A DOSAGE UNIT COMPRISING (I) 24MCG +/- 10% OF A DRUG SUBSTANCE AND (II) A PHARMACEUTICALLY SUITABLE EXCIPIENT

U-1215 USE OF REVLIMID (LENALIDOMIDE) FOR THE TREATMENT OF TRANSFUSION-DEPENDENT ANEMIA IN MYELODYSPLASTIC SYNDROMES (MDS)

U-1216 USE OF REVLIMID (LENALIDOMIDE) FOR THE TREATMENT OF MULTIPLE MYELOMA

U-1217 METHOD OF INCREASING HAIR GROWTH

U-1218 METHOD OF STIMULATING HAIR GROWTH

U-1219 METHOD OF INCREASING THE NUMBER OF HAIRS

U-1220 TREATMENT OF RENAL CELL CARCINOMA

U-1221 TO STIMULATE THE IMMUNE SYSTEM TO INDUCE T CELL PROLIFERATION

U-1222 TO INHIBIT THE PROLIFERATIVE ACTIVITY OF NEOPLASTIC CELLS

U-1223 METHOD FOR TREATING TYPE 2 DIABETES USING A SUSTAINED-RELEASE COMPOSITION CONTAINING EXENATIDE

U-1224 REDUCTIONS IN BODY WEIGHT ARE OBSERVED WITH EXENATIDE

U-1225 ACCELERATING THE TIME TO UPPER AND LOWER GASTROINTESTINAL RECOVERY FOLLOWING PARTIAL LARGE OR SMALL BOWEL RESECTION SURGERY WITH PRIMARY ANASTOMOSIS

U-1226 A METHOD OF PROVIDING A PREDETERMINED CONCENTRATION OF NITRIC OXIDE TO A PATIENT

U-1227 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND METFORMIN HCL EXTENDED RELEASE IS APPROPRIATE

U-1228 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS FOR WHOM TREATMENT WITH BOTH SITAGLIPTIN AND METFORMIN HCL EXTENDED RELEASE IS APPROPRIATE ALONE OR IN COMBINATION WITH INSULIN

U-1229 TREATMENT OF MILDLY TO MODERATELY ACTIVE ULCERATIVE COLITIS IN MALE PATIENTS

U-1230 A METHOD OF PROVIDING NITRIC OXIDE THERAPY TO A PATIENT

U-1231 TREATMENT OF MODERATE-TO-SEVERE PRIMARY RESTLESS LEG SYNDROME IN ADULTS

U-1232 USE AS ANTICOAGULANT IN PTS W/ UNSTABLE ANGINA UNDERGOING PTCA; W/ PROVISIONAL USE OF GLYCOPROTEIN IIB/III A INHIBITOR, AS ANTICOAGULANT IN PTS UNDERGOING PCI AND FOR PTS W/, OR AT RISK OF, HIT/HITTS UNDERGOING PCI. INTENDED FOR USE
PATENT AND EXCLUSIVITY TERMS

PATENT USE

W/ASPIRIN

U-1233 TREATMENT OF CHRONIC HEPATITIS C (CHC) GENOTYPE 1 INFECTION, ADMINISTERED WITH FOOD
U-1234 FOR REDUCING TOTAL CHOLESTEROL (TOTAL-C), LDL-C, APO-LIPOPROTEIN B, OR TOTAL TRIGLYCERIDES, AND TREATING HYPERTRIGLYCERIDEMIA
U-1235 REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH GLAUCOMA OR OCULAR HYPERTENSION
U-1236 USE OF THALOMID (THALIDOMIDE) FOR THE TREATMENT OF MULTIPLE MYELOMA
U-1237 COMBO W/ OTHER ANTIRETROVIRALS FOR TX OF HIV-1 IN ANTIRETROVIRAL TX-EXPERIENCED PT 6 YEARS UP, WHO HAVE EVIDENCE OF VIRAL REPLICATION AND HIV-1 STRAINS RESISTANT TO NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR AND OTHER ANTIRETROVIRALS
U-1238 TREATMENT OF ANEMIA DUE TO CHRONIC KIDNEY DISEASE
U-1239 MAGNETIC RESONANCE IMAGING OF THE LIVER
U-1240 TREATMENT OF HEAVY MENSTRUAL BLEEDING IN WOMEN WITHOUT ORGANIC PATHOLOGY WHO CHOOSE TO USE AN ORAL CONTRACEPTIVE AS THEIR METHOD OF CONTRACEPTION
U-1241 MANAGEMENT OF MODERATE TO SEVERE PAIN BY ORALLY ADMINISTERING AN INTACT COMPOSITION AS CLAIMED
U-1242 PREVENTION OF RESPIRATORY DISTRESS (RDS) IN PREMATURE INFANTS
U-1243 WITH DRY HANDS, GENTLY REMOVE THE SUPRENZA (PHENTERMINE HYDROCHLORIDE ODT) TABLET FROM THE BOTTLE. IMMEDIATELY PLACE THE SUPRENZA TABLET ON TOP OF THE TONGUE WHERE IT WILL DISSOLVE, THEN SWALLOW WITH OR WITHOUT WATER
U-1244 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A Dipeptidyl Peptidase-4 INHIBITOR IN COMBINATION WITH Sulfoneyurea
U-1245 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A Dipeptidyl Peptidase-4 INHIBITOR IN COMBINATION WITH PIOGLITAZONE
U-1246 SINGLE DOSE ADMINISTRATION INTO THE SURGICAL SITE TO PRODUCE POSTSURGICAL ANALGESIA
U-1247 MANAGEMENT OF POSTHERPETIC NEURALGIA (PHN) IN ADULTS
U-1248 USE OF TOPICAL DICLOFENAC ON THE KNEE AND A SECOND TOPICAL MEDICATION ON THE SAME KNEE
U-1249 TREATMENT OF MALE PATIENT HAVING A DISEASE OR CONDITION RESPONSIVE TO A TERATOGENIC DRUG
U-1250 TREATMENT OF PAIN, INCLUDING NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY OR SPINAL CORD INJURY, POSTHERPETIC NEURALGIA, AND FIBROMYALGIA
U-1251 A METHOD OF CONTROLLING POSTOPERATIVE OCULAR PAIN AND BURNING/STINGING IN A PATIENT
U-1252 METHOD FOR CHRONIC WEIGHT MANAGEMENT BY DECREASING FOOD INTAKE
U-1253 METHOD FOR CHRONIC WEIGHT MANAGEMENT BY INDUCING SATIETY
U-1254 METHOD FOR CHRONIC WEIGHT MANAGEMENT BY CONTROLLING WEIGHT GAIN
U-1255 METHOD FOR CHRONIC WEIGHT MANAGEMENT BY TREATING OBESITY
U-1256 TREATMENT OF SEBORRHEIC DERMATITIS
U-1257 TREATMENT OF OPHTHALMIC DISORDERS
U-1258 VISUALIZATION DURING VITRECTOMY PROCEDURES
U-1259 PROPHYLAXIS OF HIV-1 INFECTION
U-1260 TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY
U-1261 REDUCTION OF THE RISK OF HOSPITALIZATION FOR ATRIAL FIBRILLATION
U-1262 USE OF QSYMIA (PHENTERMINE AND TOPIRAMATE) FOR WEIGHT MANAGEMENT, INCLUDING, BUT NOT LIMITED TO EFFECTING WEIGHT LOSS, TREATING OBESITY, AND/OR TREATING OVERWEIGHT
PATENT USE

U-1263 TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) OR CHRONIC BRONCHITIS

U-1264 TREATMENT OF A RESPIRATORY DISEASE

U-1265 PATENTED METHOD OF USING REPAGLINIDE IN COMBINATION WITH METFORMIN AS INDICATED FOR IMPROVING GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

U-1266 METHOD OF TREATING MIDDLE-OF-THE-NIGHT INSOMNIA

U-1267 TREATMENT OF RHEUMATOID ARTHRITIS BY DELAYED RELEASE FORMULATION OF 1MG OR 2MG OF PREDNISONE

U-1268 TREATMENT OF PULMONARY, GASTROINTESTINAL AND/OR RHEUMATOLOGICAL DISEASES OR CONDITIONS BY USE OF DELAYED RELEASE FORMULATIONS OF 1MG OR 2MG PREDNISONE

U-1269 TREATMENT OF RHEUMATOLOGIC, ALLERGIC, PULMONARY, GASTROINTESTINAL, DERMATOLOGIC DISEASES OR CONDITIONS BY THE USE OF A DELAYED RELEASE 5MG PREDNISONE TABLET

U-1270 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH INSULIN (WITH OR WITHOUT METFORMIN AND/OR PIOGLITAZONE)

U-1271 TREATMENT OF ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME-NEGATIVE (PH-) ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN SECOND OR GREATER RELAPSE OR WHOSE DISEASE HAS PROGRESSED FOLLOWING TWO OR MORE ANTI-LEUKEMIA THERAPIES

U-1272 TREATMENT OF SIGNS AND SYMPTOMS OF PARKINSON’S DISEASE BY APPLICATION OF CLAIMED TRANSDERMAL SYSTEM

U-1273 TREATMENT OF RESTLESS LEGS SYNDROME BY APPLICATION OF CLAIMED TRANSDERMAL DELIVERY SYSTEM

U-1274 TREATMENT OF EXOCRINE PANCREATIC INSUFFICIENCY DUE TO CYSTIC FIBROSIS OR OTHER CONDITIONS

U-1275 TREATMENT OF CHRONIC HEPATITIS B IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER

U-1276 MANAGEMENT OF NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY

U-1277 METHOD OF INCREASING EYELASH GROWTH INCLUDING LENGTH, THICKNESS, DARKNESS AND/OR NUMBER OF EYELASHES BY ADMINISTERING BIMATOPROST TO AN EYELID MARGIN

U-1278 METHOD OF TREATING IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN ADULTS

U-1279 TREATMENT OF HIV INFECTION USING A COMPOSITION CONTAINING A PHARMACOKINETIC ENHANCER THAT INHIBITS CYTOCHROME P450 MONOOXYGENASE

U-1280 USE OF A CALCIPOTRIENE CONTAINING FOAM FOR THE TREATMENT OF PSORIASIS

U-1281 THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO HAVE PREVIOUSLY RECEIVED DOCETAXEL

U-1282 PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING

U-1283 A METHOD OF TREATING CHRONIC MYELOGENOUS LEUKEMIA

U-1284 A METHOD OF TREATING A NEOPLASM

U-1285 TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS

U-1286 A METHOD OF REDUCING THE RISK OF PULMONARY EDEMA IN PATIENTS IN NEED OF TREATMENT WITH INHALED NITRIC OXIDE

U-1287 METHOD OF REDUCING TG LEVELS IN PATIENT SUFFERING FROM SEVERE HYPERTRIGLYCERIDEMIA

U-1288 TREATMENT OF ERECTILE DYSFUNCTION BY ADMINISTERING A FILM-COATED TABLET

U-1289 MANAGEMENT OF MODERATE TO SEVERE ACUTE PAIN

U-1290 TREATMENT OF LUNG CANCER

U-1291 TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA (APL) IN PATIENTS WHOSE APL IS CHARACTERIZED BY THE PRESENCE OF THE (15;17) TRANSLOCATION OR PML/RAR-ALPHA GENE EXPRESSION

U-1292 TREATMENT OF DISEASES OR CONDITIONS BY THE USE OF A DELAYED RELEASE 1, 2, OR 5 MG PREDNISONE TABLET

U-1293 A METHOD OF LOWERING INTRAOCULAR PRESSURE IN A PATIENT WITH OPEN ANGLE GLAUCOMA OR OCULAR HYPERTENSION

U-1294 METHOD OF TREATING GLAUCOMA IN A PATIENT

U-1295 A METHOD OF TREATING A PATIENT WITH GLAUCOMA OR OCULAR HYPERTENSION
PATENT AND EXCLUSIVITY TERMS

U-1296 USE OF PEMETREXED WITH PRIOR AND/OR REPEATED VITAMIN B12 AND FOLIC ACID ADMINISTRATION

U-1297 TREATMENT OF PULMONARY ARTERIAL HYPERTENSION BY INHIBITING ENDOTHELIN RECEPTORS

U-1298 ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL SEIZURES

U-1299 TREATMENT OF PATIENTS WITH LEUKEMIA INCLUDING CHRONIC MYELOID/MYELOGENOUS LEUKEMIA (CML)

U-1300 TREATMENT OF PATIENTS WITH TYROSINE KINASE INHIBITOR (TKI) RESISTANT OR INTOLERANT CHRONIC MYELOID/MYELOGENOUS LEUKEMIA (CML)

U-1301 TREATMENT OF DEEP VEIN THROMBOSIS (DVT)

U-1302 TREATMENT OF PULMONARY EMBOLISM (PE)

U-1303 REDUCTION IN THE RISK OF RECURRENCE OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM

U-1304 USE OF ONCE-A-DAY AMOXICILLIN PRODUCT TO TREAT TONSILLITIS AND/OR PHARYNGITIS SECONDARY TO STREPTOCOCCUS PYOGENES

U-1305 TREATMENT OF HIV-1 INFECTION IN ADULT PATIENTS, AND TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 3 YEARS OF AGE AND OLDER, CO-ADMINISTERED WITH RITONAVIR (PREZISTA/RITONAVIR) AND WITH OTHER ANTIRETROVIRAL AGENTS

U-1306 TREATMENT OF THROMBOCYTOPENIA IN PATIENTS WITH CHRONIC HEPATITIS C TO ALLOW THE INITIATION AND MAINTENANCE OF INTERFERON-BASED THERAPY

U-1307 IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT-NAIVE ADULT PATIENTS WITH HIV-1 RNA LESS THAN OR EQUAL TO 100,000 AT THE START OF THERAPY

U-1308 MULTIPLE MYELOMA

U-1309 BONE METASTASES

U-1310 FOR THE MAINTENANCE OF REMISSION OF ULCERATIVE COLITIS

U-1311 METHOD OF TREATING CYSTIC FIBROSIS

U-1312 USE FOR THE TREATMENT OF HYPERGLYCEMIA

U-1313 AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

U-1314 USE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

U-1315 THE LONG TERM TREATMENT OF PROPHYLACTIC MANAGEMENT OF OCULAR HYPERTENSION AND GLAUCOMA

U-1316 A DOSING REGIMEN FOR THE TREATMENT OF HYPERCHOLESTEROLEMIA AND HYPERLIPIDEMIA IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA USING AT LEAST THREE STEP-WISE INCREASING DOSES

U-1317 TREATMENT OF HYPERCHOLESTEROLEMIA, HYPERLIPIDEMIA AND HYPERLIPOPROTEINEMIA IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA

U-1318 TREATMENT OF HYPERCHOLESTEROLEMIA BY DECREASING THE AMOUNT OR ACTIVITY OF MICROSOMAL TRIGLYCERIDE TRANSFER PROTEIN IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA

U-1319 SYMPTOMATIC RELIEF OF NON-INFECTIOUS DIARRHEA

U-1320 TREATMENT OF ADULT PATIENTS WITH SHORT BOWEL SYNDROME WHO ARE DEPENDENT ON PARENTERAL SUPPORT

U-1321 TREATMENT OF PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS

U-1322 METHOD OF REDUCING OCULAR HYPERTENSION

U-1323 REDUCING THE RISK OF STROKE

U-1324 MANAGEMENT OF CYSTIC FIBROSIS PATIENTS

U-1325 INDUCTION OF REMISSION IN PATIENTS WITH ACTIVE, MILD TO MODERATE ULCERATIVE COLITIS

U-1326 METHOD OF INDUCING CONTRACEPTION IN A FEMALE OF REPRODUCTIVE AGE WHO HAS NOT YET REACHED PREMENOPAUSE

U-1327 METHOD FOR TREATING ACUTE MIGRAINE IN ADULTS, WITH OR WITHOUT AURA, COMPRISING IONTOPHORETIC TRANSDERMAL DELIVERY OF SUMATRIPTAN OR A SALT THEREOF, USING A FLOWABLE HYDROGEL FORMULATION
PATENT USE

U-1328 METHOD FOR TREATING ACUTE MIGRAINE IN ADULTS, WITH OR WITHOUT AURA, COMPRISING IONTOPHORETIC TRANSDERMAL DELIVERY OF SUMATRIPTAN OR A SALT THEREOF

U-1329 TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER

U-1330 METHODS OF TREATING LIPID METABOLISM AND GLYCOMETABOLISM DISORDERS COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH AN INSULIN SECRETION ENHANCER

U-1331 METHODS OF REDUCING THE AMOUNT OF ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH AN INSULIN SECRETION ENHANCER

U-1332 METHODS OF REDUCING THE SIDE EFFECTS OF ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH AN INSULIN SECRETION ENHANCER

U-1333 METHODS OF LOWERING ELEVATED POST PRANDIAL BLOOD GLUCOSE LEVELS COMPRISING ADMINISTERING A DIPEPTIDYL PEPTIDASE INHIBITOR

U-1334 METHODS OF TREATING DIABETES COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH AN INSULIN SECRETION ENHANCER

U-1335 METHODS OF MODIFYING GLUCOSE METABOLISM AND TREATING DIABETES COMPRISING ADMINISTERING A DIPEPTIDYL PEPTIDASE INHIBITOR AND ONE OR MORE OTHER THERAPEUTIC AGENTS SUCH AS METFORMIN

U-1336 METHODS OF TREATING DIABETES COMPRISING ADMINISTERING A DIPEPTIDYL PEPTIDASE INHIBITOR AND METFORMIN

U-1337 METHOD OF TREATING DIABETES COMPRISING ADMINISTERING ALOGLIPTIN

U-1338 METHOD OF TREATING DIABETES COMPRISING ADMINISTERING A COMPOUND SUCH AS ALOGLIPTIN

U-1339 METHODS OF TREATING DIABETES COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH A BIGUANIDE SUCH AS METFORMIN

U-1340 METHODS OF TREATING LIPID METABOLISM DISORDERS COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH A BIGUANIDE SUCH AS METFORMIN

U-1341 METHODS OF TREATING GLYCOMETABOLISM DISORDERS COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH A BIGUANIDE SUCH AS METFORMIN

U-1342 METHODS OF REDUCING THE AMOUNT OF ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH A BIGUANIDE SUCH AS METFORMIN

U-1343 METHODS OF REDUCING THE SIDE EFFECTS OF ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH A BIGUANIDE SUCH AS METFORMIN

U-1344 METHODS OF REDUCING THE SIDE EFFECTS OF ACTIVE COMPONENTS ADMINISTERED TO A DIABETIC PATIENT COMPRISING ADMINISTERING AN INSULIN SENSITIVITY ENHANCER SUCH AS PIOGLITAZONE IN COMBINATION WITH AN INSULIN PREPARATION

U-1345 USE IN RELIEVING OR PREVENTING CONSTIPATION IN A HUMAN PATIENT WITH A DOSAGE UNIT COMPRISING 24MICROG +/- 10% OF A DRUG SUBSTANCE AND A PHARMACEUTICALLY SUITABLE EXCIPIENT

U-1346 USE OF FEBUXOSTAT FOR THE MANAGEMENT OF HYPERURICEMIA IN PATIENTS SUFFERING FROM GOUT AND, WHEN USED WITH THEOPHYLLINE WITHOUT THE NEED FOR DOSE ADJUSTMENT OF THEOPHYLLINE

U-1347 TREATMENT OF A SKIN DISORDER

U-1348 TREATMENT OF OSTEOARTHRITIS

U-1349 TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS

U-1350 TREATMENT OF ANKYLOSING SPONDYLITIS

U-1351 TREATMENT OF ACUTE PAIN

U-1352 TREATMENT OF PRIMARY DYSMENORRHEA

U-1353 ADJUNCTIVE THERAPY TO LIPID-LOWERING MEDICATIONS AND DIET TO REDUCE LOW DENSITY LIPOPROTEIN-CHOLESTEROL, APOLIPOPROTEIN B, TOTAL CHOLESTEROL, AND NON-HIGH DENSITY LIPOPROTEIN CHOLESTEROL IN PTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA
PATENT USE

U-1354 INHIBITION OF PREMATURE LH SURGES IN WOMEN UNDERGOING CONTROLLED OVARIAN HYPERSTIMULATION WITH FSH

U-1355 MAINTENANCE TREATMENT OF ASTHMA AS PROPHYLACTIC THERAPY IN ADULT AND ADOLESCENT PATIENTS 12 YEARS OF AGE AND OLDER. PATENT CLAIMS METHOD FOR TREATING A RESPIRATORY DISEASE IN A CHILD

U-1356 TREATMENT OF NASAL SYMPTOMS ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER. TREATMENT OF NASAL SYMPTOMS ASSOCIATED WITH PERENNIAL ALLERGIC RHINITIS IN ADULTS AND ADOLESCENTS 12 YEARS OF AGE AND OLDER

U-1357 TREATMENT OF SYMPTOMS ASSOCIATED WITH SEASONAL AND PERENNIAL ALLERGIC RHINITIS IN ADULTS AND ADOLESCENTS 12 YEARS OF AGE AND OLDER. PATENT CLAIMS METHODS FOR TREATING A RESPIRATORY DISEASE IN A CHILD

U-1358 TREATMENT OF BACTERIAL INFECTIONS IN THE NASAL PASSAGE OF ADULT PATIENTS AND HEALTH CARE WORKERS WITH METHICILLIN RESISTANT S. AUREUS

U-1359 USE OF POMALIDOMIDE TO INHIBIT THE SECRETION OF PRO-INFLAMMATION CYTOKINES, INCLUDING TUMOR NECROSIS FACTOR ALPHA

U-1360 USE OF POMALIDOMIDE FOR THE TREATMENT OF MULTIPLE MYELOMA

U-1361 USE OF POMALIDOMIDE WHILE PREVENTING THE EXPOSURE OF A FETUS OR OTHER CONTRAINDICATED INDIVIDUAL TO POMALIDOMIDE

U-1362 TREATMENT OF DISEASES OR CONDITIONS BY THE USE OF A DELAYED-RELEASE 1, 2, OR 5MG PREDNISONE TABLET

U-1363 A METHOD OF TREATING OR PREVENTING OCULAR PAIN AND BURNING/STINGING FOLLOWING CORNEAL SURGERY

U-1364 MAINTENANCE TREATMENT OF MAJOR DEPRESSIVE DISORDER (MDD)

U-1365 PROPHYLAXIS OF ALLOGRAFT REJECTION IN ADULT PATIENTS RECEIVING A LIVER TRANSPLANT

U-1366 TREATMENT OF INFERTILITY THROUGH INDUCTION OF OVULATION AND PREGNANCY TO ANOVULATORY INFERTILE WOMEN

U-1367 METHOD OF ADMINISTERING FSH FOR THE TREATMENT OF INFERTILITY THROUGH INDUCTION OF OVULATION AND PREGNANCY IN ANOVULATORY INFERTILE WOMEN

U-1368 TREATMENT OF SOLID EXCRETORY SYSTEM TUMORS; ADVANCED RENAL CELL CARCINOMA (RCC), AFTER FAILURE OF TREATMENT WITH SUNITINIB OR SORAFENIB

U-1369 TREATMENT OF VAGINAL SYMPTOMS OF UROGENITAL ATROPHY BY ORALLY ADMINISTERING OSPEMIFENE WITH FOOD TO ENHANCE BIOAVAILABILITY OF OSPEMIFENE

U-1370 TREATMENT OF DYSPAREUNIA ASSOCIATED WITH MENOPAUSE

U-1371 REDUCTION OF INTRAOCULAR PRESSURE IN PATIENTS WITH ELEVATED INTRAOCULAR PRESSURE OR GLAUCOMA

U-1372 ADMINISTRATION WITHOUT FOOD FOR TREATMENT OF HIV-1 INFECTION

U-1373 METHOD OF TREATING ACETAMINOPHEN OVERDOSE WITH ACETYLCYSTEINE SOLUTIONS

U-1374 TREATMENT OF PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (PH+CML)

U-1375 ADASUVE IS A TYPICAL ANTIPSYCHOTIC INDICATED FOR THE ACUTE TREATMENT OF AGITATION ASSOCIATED WITH SCHIZOPHRENIA OR BIPOLAR I DISORDER IN ADULTS

U-1376 TREATMENT OF INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS

U-1377 IMPROVE RESPIRATORY SYMPTOMS IN CYSTIC FIBROSIS IN PATIENTS WITH PSEUDOMONAS AERUGINOSA

U-1378 TREATMENT OF A NITROGEN METABOLISM DISORDER

U-1379 IMPROVEMENT OF GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHO HAVE ONE OR MORE SPECIFIED CARDIOVASCULAR RISK FACTORS

U-1380 IMPROVEMENT OF GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHO HAVE ONE OR MORE SPECIFIED CARDIOVASCULAR RISK FACTORS WHEREIN THE PATIENT HAS CARDIOVASCULAR DISEASE

U-1381 USE OF PRASUGREL AND ASPIRIN IN PATIENTS REQUIRING THE REDUCTION OF THROMBOTIC CARDIOVASCULAR EVENTS

U-1382 TREATMENT OF NAUSEA AND VOMITING OF PREGNANCY IN WOMEN WHO DO NOT RESPOND TO CONSERVATIVE MANAGEMENT

U-1383 DOSAGE ADJUSTMENT OF A NITROGEN SCAVENGING DRUG IN THE TREATMENT OF A UREA CYCLE
PATENT USE

U-1384 METHOD OF TREATING MULTIPLE SCLEROSIS

U-1385 METHOD OF TREATING AN AUTOIMMUNE DISEASE SELECTED FROM AUTOIMMUNE POLYARThRITIS AND MULTIPLE SCLEROSIS BUT NOT TREATING PSORiATIC ARTHRiTIS

U-1386 A METHOD OF INCREASING THE TESTOSTERONE BLOOD LEVEL OF A PERSON IN NEED THEREOF

U-1387 REDUCTION IN RISK OF HOSPITALIZATION IN PATIENTS WITH A HISTORY OF PAROXYSMAL OR PERSISTENT AF WITHOUT SEVERE HEART FAILURE AND WITH ONE OR MORE RISK FACTORS BY ADMINISTRATION TWICE A DAY WITH MORNING AND EVENING MEALS

U-1388 TREATMENT OF PATIENTS WITH A HISTORY OF PAROXYSMAL OR PERSISTENT AF WITHOUT SEVERE HEART FAILURE AND WITH ONE OR MORE RISK FACTORS BY ADMINISTRATION TWICE A DAY WITH MORNING AND EVENING MEALS

U-1389 ELLA IS A PROGESTERONE AGONIST/ANTAGONIST EMERGENCY CONTRACEPTION INDICATED FOR THE PREVENTION OF PREGNANCY FOLLOWING UNPROTECTED INTERCOURSE OR A KNOWN OR SUSPECTED CONTRACEPTIVE FAILURE. ELLA CAN BE TAKEN WITH OR WITHOUT FOOD

U-1390 A METHOD OF INCREASING THE TESTOSTERONE BLOOD LEVEL OF AN ADULT MALE SUBJECT IN NEED THEREOF

U-1391 METHOD FOR TREATING OPIOID-INDUCED CONSTIPATION

U-1392 METHOD OF RELIEVING OR PREVENTING CONSTIPATION IN A HUMAN PATIENT WITH OPIOID-INDUCED CONSTIPATION

U-1393 METHOD FOR RELIEVING OR TREATING CONSTIPATION IN A PATIENT WITH OPIOID-INDUCED CONSTIPATION

U-1394 METHOD FOR RELIEVING CONSTIPATION IN A PATIENT WITH OPIOID-INDUCED CONSTIPATION THAT COMPRISSES ADMINISTERING TO THE PATIENT A DOSAGE UNIT COMPRISING (I) 24MICROG +/- 10% OF A DRUG SUBSTANCE AND (II) A PHARMACEUTICALLY SUITABLE EXCIPIENT

U-1395 USE IN RELIEVING OR PREVENTING CONSTIPATION IN A PATIENT WITH OPIOID-INDUCED CONSTIPATION WITH A DOSAGE UNIT COMPRISING 24MICROG +/- 10% OF A DRUG SUBSTANCE AND A PHARMACEUTICALLY SUITABLE EXCIPIENT

U-1396 TREATMENT OF ADVANCED HORMONE RECEPTOR POSITIVE, HER2-NEGATIVE BREAST CANCER IN COMBINATION WITH EXEMESTANE AFTER FAILURE OF TREATMENT WITH LETROZOLE OR ANASTROZOLE

U-1397 USE AS AN ANTISEPTIC FOR THE PREPARATION OF A PATIENT'S SKIN PRIOR TO SURGERY

U-1398 METHOD OF TREATING CHRONIC HEPATITIS C

U-1399 MANAGEMENT OF NEPHROPATHIC CYSTINOSIS BY ADMINISTERING A TOTAL DAILY DOSE IN TWO DIVIDED DOSES

U-1400 FOR THE TREATMENT OF PRIMARY HYPERLIPIDEMIA, MIXED HYPERLIPIDEMIA OR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA

U-1401 INDICATED FOR LONG-TERM, ONCE-DAILY MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PTS WITH COPD, INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA, ALSO TO REDUCE EXACERBATIONS OF COPD IN PTS WITH A HISTORY OF EXACERBATIONS

U-1402 FOR USE IN THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) AND/OR INDOLENT B-CELL NON-HODGKIN LYMPHOMA (NHL)

U-1403 FIRST-LINE TREATMENT OF METASTATIC NON SMALL-CELL LUNG CANCER (NSCLC) WITH EGFR EXON 19 DELETIONS OR EXON 21 (L858R) SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST

U-1404 METHOD FOR TREATING CONSTIPATION IN A PATIENT WITH OPIOID-INDUCED CONSTIPATION BY OPENING CIC CHANNELS

U-1405 THERAPEUTIC TREATMENT OF BONE METASTASES

U-1406 TREATMENT OF MELANOMA

U-1407 TREATMENT OF NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (PH + CML)

U-1408 TREATMENT OF PLAQUE PSORIASIS IN PATIENTS 18 YEARS OF AGE OR OLDER

U-1409 TREATMENT OF HIV-1 BY ONCE DAILY ADMINISTRATION

U-1410 TREATMENT OF CORTICOSTEROID-RESPONSIVE DERMATOSES

U-1411 THIS DRUG IS ADMINISTERED BY SUBLINGUAL ROUTE TO HUMANS FOR MAINTENANCE TREATMENT OF OPIOID DEPENDENCE
**PATENT USE**

U-1412 TREATMENT OF ATOPIC DERMATITIS

U-1413 ADMINISTRATION OF REMODULIN DILUTED FOR INTRAVENOUS INFUSION WITH FLOLAN STERILE DILUENT FOR INJECTION PRIOR TO INFUSION

U-1414 USE OF REVLIMID (LENALIDOMIDE) FOR THE TREATMENT OF MANTLE CELL LYMPHOMA (MCL)

U-1415 TREATING A PATIENT HAVING A CONDITION SUSCEPTIBLE TO TREATMENT WITH METHYLPHENIDATE, SUCH AS ADHD, BY ADMINISTERING THE FORMULATION RECITED IN CLAIMS 1 OR 2

U-1416 USE OF FENOFIBRATE FOR REDUCING ELEVATED TOTAL CHOLESTEROL (TOTAL-C), LDL-C, APO-LIPROTEIN B, OR TOTAL TRIGLYCERIDES

U-1417 USE FOR TREATMENT OF HELICOBACTER INFECTIONS

U-1418 TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAFV600E MUTATION AS DETECTED BY AN FDA APPROVED TEST

U-1419 TREATMENT OF ACUTE CYANIDE POISONING THAT IS JUDGED TO BE LIFE THREATENING

U-1420 METHOD OF ONCE A DAY ADMINISTRATION

U-1421 SUBLINGUAL ADMINISTRATION OF A PHARMACEUTICAL COMPOSITION COMPRISING BUPRENORPHINE

U-1422 METHOD OF TREATING PATIENTS NEEDING AN IRON SUPPLEMENT

U-1423 AMYVID IS A RADIOACTIVE DIAGNOSTIC AGENT FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING OF THE BRAIN TO ESTIMATE BETA-AMYLOID NEURITIC PLAQUE DENSITY IN ADULT PATIENTS WITH COGNITIVE IMPAIRMENT

U-1424 LONG-TERM, ONCE DAILY MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PTS WITH COPD, INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA, ALSO TO REDUCE EXACERBATIONS OF COPD IN PATIENTS WITH A HISTORY OF EXACERBATIONS

U-1425 SUBLINGUAL ADMINISTRATION OF A PHARMACEUTICAL COMPOSITION COMPRISING BUPRENORPHINE AND NALOXONE

U-1426 USE FOR TREATMENT OF DIAPER DERMATITIS COMPLICATED BY CANDIDIASIS

U-1427 ALKYLATING DRUG INDICATED FOR THE TOPICAL TREATMENT OF STAGE IA AND IB MYCOSIS FUNGOIDES-TYPE CUTANEOUS T-CELL LYMPHOMA IN PATIENTS WHO HAVE RECEIVED PRIOR SKIN DIRECTED THERAPY

U-1428 TOPICAL TREATMENT OF FACIAL ERYTHEMA OF ROSACEA

U-1429 TREATMENT OF PATIENTS WITH BREAST CANCER WHOSE TUMORS OVEREXPRESS THE HER2 RECEPTOR

U-1430 TREATMENT OF ALLERGIC RHINITIS, INCLUDING SEASONAL AND PERENNIAL ALLERGIC RHINITIS

U-1431 METHOD OF TREATING HYPERGLYCEMIA TO IMPROVE GLYCEMIC CONTROL IN A PATIENT BY ORAL ADMIN OF ONCE A DAY OSMOTIC DOSAGE FORM OF GLIPIZIDE WITH POLYETHYLENE OXIDE, HYDROXYPROPYLMETHYLCELULOSE, CELLULOSE ACETATE, AND SODIUM CHLORIDE

U-1432 METHOD OF TREATMENT OF IRON-RELATED CONDITIONS WITH AT LEAST 0.6 GRAMS OF ELEMENTAL IRON VIA AN IRON CARBOHYDRATE COMPLEX

U-1433 IMPROVEMENTS OF GLYCEMIC CONTROL IN INDIVIDUALS WITH TYPE 2 DIABETES WHO HAVE ONE OR MORE SPECIFIED CARDIOVASCULAR RISK FACTORS

U-1434 TREATMENT OF PANCREATIC CANCER

U-1435 COMBINATION USE OF TOPICAL DICLOFENAC ON THE KNEE AND ADMINISTRATION OF AN ORAL NSAIAD

U-1436 USE OF TOPICAL DICLOFENAC ON THE KNEE AND A SECOND TOPICAL AGENT SELECTED FROM SUNSCREEN AND INSECT REPELLENT

U-1437 ADMINISTRATION OF REMODULIN DILUTED FOR INTRAVENOUS INFUSION WITH STERILE DILUENT FOR FLOLAN OR STERILE DILUENT FOR EPOPROSTENOL SODIUM PRIOR TO ADMINISTRATION

U-1438 ZINGO INTRADERMAL INJECTION SYSTEM IS A DRUG DELIVERY SYSTEM THAT IS CAPABLE OF DELIVERING FINE DRY POWDERED LIDOCAINE HYDROCHLORIDE MONOHYDRATE FOR LOCAL ANESTHETIC ACTION

U-1439 METHOD OF TREATING AN AFFECTIVE DISORDER SUCH AS DEPRESSION

U-1440 USE OF INGENOL MEBUTATE TO TREAT ACTINIC KERATOSIS

U-1441 A METHOD OF TREATING OR REDUCING OCULAR PAIN AND BURNING/STINGING
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-1442 SUBCUTANEOUS INJECTION OF METHOTREXATE
U-1443 ACCELERATING THE TIME TO UPPER AND LOWER GASTROINTESTINAL RECOVERY FOLLOWING SURGERIES THAT INCLUDE PARTIAL BOWEL RESECTION WITH PRIMARY ANASTOMOSIS
U-1444 A DOSING REGIMEN OF AGGRASTAT (TIROFIBAN HYDROCHLORIDE) (25MCG/KG FOLLOWED BY 0.15MCG/KG/MIN INFUSION) TO REDUCE THE RATE OF THROMBOTIC CORONARY EVENTS ASSOCIATED WITH ACUTE CORONARY SYNDROME (ACS) IN PATIENTS WITH NON-ST ELEVATION ACS
U-1445 METHOD OF TREATING PULMONARY ARTERIAL HYPERTENSION BY ADMINISTERING A PHARMACEUTICAL COMPOSITION COMPRISING MACITENTAN AND A POLYSORBATE, WHEREIN THE POLYSORBATE REPRESENTS 0.1 TO 1% OF THE WEIGHT OF SAID PHARMACEUTICAL COMPOSITION
U-1446 METHOD OF TREATING PULMONARY HYPERTENSION COMPRISING ADMINISTERING MACITENTAN IN COMBINATION WITH A COMPOUND HAVING PHOSPHODIESTERASE-5 INHIBITORY PROPERTIES
U-1447 TREATING PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIA
U-1448 TREATING SEVERE HYPERTRIGLYCERIDEMIA
U-1449 METHOD OF ALLEVIATING A SKIN CONDITION
U-1450 TREATMENT OF ALLERGIC RHINITIS SYMPTOMS
U-1451 APPROVED INDICATIONS: APTIOM (ESLICARBAZEPINE ACETATE) IS INDICATED AS ADJUNCTIVE TREATMENT OF PARTIAL-ONSET SEIZURES AND APPROVED IN PATIENTS WITH EPILEPSY. PATENT CLAIMS: IN A METHOD OF TREATING A SUBJECT AFFLICTED WITH EPILEPSY
U-1452 METHOD FOR CHRONIC WEIGHT MANAGEMENT
U-1453 A METHOD OF TREATING HYPOXIC RESPIRATORY FAILURE BY VERIFYING GAS INFORMATION OF NITRIC OXIDE PRIOR TO DELIVERY TO PATIENT
U-1454 PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS
U-1455 TREATMENT OF PERIANAL WARTS
U-1456 TREATMENT OF MANTLE CELL LYMPHOMA
U-1457 A METHOD OF PURGING A NITRIC OXIDE DELIVERY SYSTEM
U-1458 A METHOD OF REDUCING INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA OR OCULAR HYPERTENSION
U-1459 TREATMENT OF CARCINOMA OF THE THYROID
U-1460 TREATMENT OF HERPES LABIALIS
U-1461 A METHOD OF GENERATING AN INJECTABLE FOAM OF CONTROLLED DENSITY AND BUBBLE SIZE
U-1462 A METHOD OF USING A SCLEROSING AGENT FOR THE TREATMENT OF INCOMPETENT GREAT SAPHENOUS VEINS, ACCESSORY SAPHENOUS VEINS AND VISIBLE VARicosITIES OF THE GREAT SAPHENOUS (GSV) SYSTEM ABOVE AND BELOW THE KNEE
U-1463 A METHOD OF INTRAVENOUS INJECTION USING ULTRASOUND GUIDANCE, ADMINISTERED VIA A SINGLE CANNULA INTO THE LUMEN OF THE TARGET INCOMPETENT TRUNK VEINS OR BY DIRECT INJECTION INTO VARicosITIES
U-1464 TREATMENT OF OPIOID DEPENDENCE/SUBLINGUAL OR BUCCAL APPLICATION
U-1465 USE OF THALIDOMIDE WHILE PREVENTING THE EXPOSURE OF A FETUS OR OTHER CONTRAINDIcATED INDIVIDUAL TO THALIDOMIDE
U-1466 RELIEF OF SYMPTOMS ASSOCIATED WITH RESPIRATORY ALLERGIES ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER
U-1467 METHOD OF TREATING HEPATITIS C
U-1468 CONTROL OF PHOSPHOROUS LEVELS IN PATIENTS
U-1469 USE OF PHOSLYRA FOR REDUCTION OF SERUM PHOSPHOROUS IN PATIENTS
U-1470 FOR THE TREATMENT OF HEPATITIS C
U-1471 A METHOD FOR TREATING CARDIOVASCULAR DISEASE COMPRISING ADMINISTERING A RECONSTITUTED LYOPHILIZED PHARMACEUTICAL COMPOSITION COMPRISING EPOPROSTENOL, ARGinine AND SODIUM HYDROxIDE.
U-1472 INTENSIVE CARE UNIT SEDATION, INCLUDING SEDATION OF NON-INTUBATED PATIENTS PRIOR TO AND/OR DURING SURGICAL AND OTHER PROCEDURES
U-1473 MANAGEMENT OF RISK OF DRONEDARONE/BETA-BLOCKER INTERACTION IN PATIENTS IN SINUS
PATENT USE

U-1474  A METHOD FOR THE TREATMENT OF A PATIENT SUFFERING FROM A DISEASE TREATABLE WITH ROTIGOTINE, COMPRISING APPLYING THE CLAIMED TRANSDERMAL DELIVERY SYSTEM (TDS) TO THE SKIN OF THE PATIENT

U-1475  USE OF ORENITRAM FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH) (WHO GROUP 1).

U-1476  INDICATED FOR THE LONG-TERM, ONCE-DAILY, MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA.

U-1477  USE OF TOPICAL DICLOFENAC ON THE KNEE AND A SECOND TOPICAL PRESCRIPTION MEDICATION ON THE SAME KNEE

U-1478  METHOD OF REDUCING TG LEVELS IN PATIENT ON STATIN THERAPY SUFFERING FROM SEVERE HYPERTRIGLYCERIDEMIA

U-1479  INCREASE TEAR PRODUCTION TO TREAT PATIENTS WITH KERATOCONJUNCTIVITIS SICCA (DRY EYE).

U-1480  TREATMENT OF ADVANCED RENAL CELL CARCINOMA

U-1481  REDUCTION IN RISK OF OVERT HEPATIC ENCEPHALOPATHY (HE) RECURRENT

U-1482  DICLOFENAC POTASSIUM FOR RELIEF OF MILD TO MODERATE ACUTE PAIN

U-1483  INCREASE TEAR PRODUCTION IN PATIENTS WITH KERATOCONJUNCTIVITIS SICCA (DRY EYE).

U-1484  COMBINATION PRODUCT FOR THE EARLY TREATMENT OF RECURRENT HERPES LABIALIS (COLD SORES) TO REDUCE THE LIKELIHOOD OF ULCERATIVE COLD SORES AND TO SHORTEN THE LESION HEALING TIME IN ADULTS AND CHILDREN (6 YEARS OF AGE AND OLDER)

U-1485  TREATING A SUBJECT UNDERGOING ABDOMINAL SURGERY BY ADMINISTERING ALVIMOPAN TO ACCELERATE THE TIME TO UPPER AND LOWER GASTROINTESTINAL RECOVERY FOLLOWING SURGERIES THAT INCLUDE PARTIAL BOWEL RESECTION WITH PRIMARY ANASTOMOSIS

U-1486  TREATMENT OF NON-24-HOUR SLEEP-WAKE DISORDER

U-1487  METHOD OF INCREASING EYELASH GROWTH

U-1488  USE OF TOPICAL DICLOFENAC FOR TREATING PAIN

U-1489  USE OF TOPICAL DICLOFENAC ON A JOINT FOR TREATING OSTEOARTHRITIS

U-1490  FOR USE IN PATIENTS HAVING SYMPTOMATIC OR PROGRESSIVE MEDULLARY THYROID CANCER, WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC DISEASE

U-1491  TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA

U-1492  TREATMENT OF IRRITABILITY ASSOCIATED WITH AUTISTIC DISORDER

U-1493  METHOD FOR PREVENTING ITCHING ASSOCIATED WITH ALLERGIC CONJUNCTIVITIS

U-1494  SUBLINGUAL OR BUCCAL ADMINISTRATION OF A PHARMACEUTICAL COMPOSITION COMPRISING BUPRENORPHINE ANDNALOXONE

U-1495  RISK REDUCTION OF REBLEEDING IN PTS FOLLOWING THERAPEUTIC ENDOSCOPY FOR ACUTE BLEEDING GASTRIC OR DUODENAL ULCERS IN ADULTS.

U-1496  METHOD TO TREAT HEMANGIOMA.

U-1497  NEURACEQ IS A RADIOACTIVE DIAGNOSTIC AGENT FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING OF THE BRAIN TO ESTIMATE P-AMYLOID NEURITIC PLAQUE DENSITY IN ADULT PATIENTS WITH COGNITIVE IMPAIRMENT

U-1498  METHOD OF TREATING PATIENTS WITH GASTRIC RETENTIVE DOSAGE FORM

U-1499  MANAGEMENT OF ACUTE PAIN IN PATIENTS REQUIRING OPIOID ANALGESIA

U-1500  TESTOSTERONE REPLACEMENT THERAPY IN ADULT MALES FOR CONDITIONS ASSOCIATED WITH A DEFICIENCY OR ABSENCE OF ENDOGENOUS TESTOSTERONE; PRIMARY HYPOGONADISM (CONGENITAL OR ACQUIRED); HYPOGONADOTROPIC HYPOGONADISM (CONGENITAL OR ACQUIRED).

U-1501  PROPHYLAXIS OF DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM

U-1502  PROPHYLAXIS OF PULMONARY EMBOLISM

U-1503  METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH METFORMIN

U-1504  USE OF OTEZLA (APREMILAST) FOR INHIBITING PDE4

U-1505  USE OF OTEZLA (APREMILAST) FOR THE TREATMENT OF PSORIATIC ARTHRITIS
PATENT USE

U-1506 TREATMENT OF PATIENTS WITH GASTROINTESTINAL STROMAL TUMOR (GIST), INCLUDING BUT NOT LIMITED TO PATIENTS PREVIOUSLY TREATED WITH IMATINIB AND PATIENTS WITH GIST HAVING RESISTANCE TO A KIT TYROSINE KINASE INHIBITOR

U-1507 TO MAINTAIN HEALING OF EE AND RELIEF OF HEARTBURN

U-1508 MANAGEMENT OF PAIN SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG TERM OPIOID TREATMENT BY ORALLY ADMINISTERING A PLURALITY OF COMPOSITE SUBUNITS AS CLAIMED

U-1509 TREATMENT OF FREQUENT HEARTBURN BY ADMINISTERING A GASTRIC ACID REDUCER

U-1510 MANAGEMENT OF PAIN SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG TERM OPIOID TREATMENT BY ORALLY ADMINISTERING AN INTACT COMPOSITION AS CLAIMED.

U-1511 TREATMENT OF HYPERTRIGLYCERIDEMIA

U-1512 REDUCTION OF THROMBOTIC CARDIOVASCULAR EVENTS

U-1513 TREATMENT OF HIV-1 INFECTION IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS

U-1514 MANAGEMENT OF BREAKTHROUGH PAIN IN PATIENTS WITH CANCER BY BUCCAL OR SUBLINGUAL ADMINISTRATION OF FENTANYL

U-1515 METHOD OF TREATING IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN ADULT PATIENTS.

U-1516 METHOD OF TREATING CHRONIC IDIOPATHIC CONSTIPATION IN ADULT PATIENTS.

U-1517 TREATMENT OF BACTERIAL INFECTIONS USING A TWO-DOSE REGIMEN OF DALBAVANCIN.

U-1518 MAINTAINING PUPIL SIZE BY PREVENTING INTRAOPERATIVE MIOSIS AND REDUCING POSTOPERATIVE OCULAR PAIN

U-1519 METHOD FOR THE LONG TERM TREATMENT OF CHRONIC CONSTIPATION IN A HUMAN SUBJECT WITH IRRITABLE BOWEL SYNDROME

U-1520 METHOD FOR THE LONG TERM TREATMENT OF CHRONIC CONSTIPATION IN A HUMAN SUBJECT

U-1521 MAINTENANCE TREATMENT OF OPIOID DEPENDENCE

U-1522 TREATMENT OF TYPE 2 DIABETES MELLITUS IN A PATIENT, WHEREIN GLYCEMIC CONTROL (HBA1C < 7.0%) IS NOT ACHIEVABLE USING ONE OR MORE OF INSULIN, METFORMIN, PIOGLITAZONE, OR ROSIGLITAZONE

U-1523 METHOD OF INDUCING TOPICAL ANESTHESIA IN THE EYE

U-1524 REDUCTION OF ELEVATED INTRAOCULAR PRESSURE

U-1525 METHOD OF TREATING EXCESSIVE DAYTIME SLEEPINESS IN PATIENTS WITH NARCOLEPSY

U-1526 THE TREATMENT OF PATIENTS WITH TRAVELERS' DIARRHEA (TD) OR THE REDUCTION IN RISK OF OVERT HEPATIC ENCEPHALOPATHY (HE) RECURRENT.

U-1527 FOR THE TREATMENT OF OVERACTIVE BLADDER (OAB) WITH SYMPTOMS OF URGE URINARY INCONTINENCE, URGENCY, AND URINARY FREQUENCY

U-1528 A METHOD OF LOWERING INTRAOCULAR PRESSURE

U-1529 ADJUNCTIVE TREATMENT OF MAJOR DEPRESSIVE DISORDER (MDD)

U-1530 USE OF ARIPIPRAZOLE IN EXTENDED RELEASE INJECTABLE SUSPENSION

U-1531 METHOD FOR TRANSDERMAL DELIVERY OF TESTOSTERONE

U-1532 METHOD OF TREATING EXCESSIVE DAYTIME SLEEPINESS AND/OR CATAPLEXY IN NARCOLEPSY PATIENTS WITH SODIUM OXYBATE WHEN DIVALPROEX SODIUM IS CONCOMITANTLY ADMINISTERED.

U-1533 PULMONARY ADMINISTRATION OF PARTICLES COMPRISING A DIKETOPIPERAZINE AND INSULIN.

U-1534 ADMINISTRATION OF A COMPOSITION COMPRISING INSULIN COMPLEXED WITH A DIKETOPIPERAZINE.

U-1535 ADMINISTRATION OF A COMPOSITION COMPRISING INSULIN COMPLEXED WITH MICROPARTICLES OF A DIKETOPIPERAZINE.

U-1536 ADMINISTRATION OF A COMPOSITION COMPRISING A DIKETOPIPERAZINE AND INSULIN.

U-1537 TREATMENT OF A PATIENT HAVING DIABETES MELLITUS WITH A PRANDIAL RAPID ACTING INSULIN.

U-1538 ADMINISTRATION OF FDKP MICROPARTICLES COMPRISING INSULIN.

U-1539 PULMONARY ADMINISTRATION OF AN INSULIN COMPOSITION COMPRISING FDKP AT THE BEGINNING OF A MEAL TO A PATIENT ALSO BEING TREATED WITH A LONG-ACTING INSULIN.

U-1540 BUTRANS IS A PARTIAL OPIOID AGONIST PRODUCT INDICATED FOR THE MANAGEMENT OF PAIN
PATENT USE

SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG TERM OPIOID TREATMENT FOR WHICH ALTERNATIVE TREATMENT OPTIONS ARE INADEQUATE.

U-1541 TREATMENT OF PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX (TSC) WHO HAVE SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) THAT REQUIRES THERAPEUTIC INTERVENTION BUT CANNOT BE CURATIVELY RESECTED.

U-1542 FOR USE IN THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA AND/OR NON-HODGKIN'S LYMPHOMA

U-1543 TREATMENT OF A PATIENT BY ADMINISTERING THE FORMULATION RECITED IN CLAIM 1 OR CLAIM 23

U-1544 TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA (PTCL).

U-1545 A METHOD OF TRANSDERMALLY DELIVERING TESTOSTERONE

U-1546 FOR USE IN THE TREATMENT OF MALIGNANT HYPERTHERMIA IN CONJUNCTION WITH APPROPRIATE SUPPORTIVE MEASURES AND FOR THE PREVENTION OF MALIGNANT HYPERTHERMIA IN PATIENTS AT HIGH RISK.

U-1547 TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), CHRONIC BRONCHITIS OR EMPHYSEMA

U-1548 FOR THE LONG-TERM, ONCE-DAILY MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH COPD, INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA, ALSO TO REDUCE EXACERBATIONS OF COPD IN PATIENTS WITH A HISTORY OF EXACERBATIONS

U-1549 FOR THE TREATMENT OF PATIENTS WITH RELAPSED CHRONIC LYMPHOCYTIC LEUKEMIA

U-1550 METHOD OF TREATING METASTATIC PAPILLARY RENAL CELL CARCINOMA WITH TEMSIROLIMUS.

U-1551 METHOD OF TREATING PAPILLARY RENAL CELL CARCINOMA WITH TEMSIROLIMUS, IN THE ABSENCE OF INTERFERON ALPHA.

U-1552 FOR HEALING OF ALL GRADES OF EROSIIVE ESOPHAGITIS (EE)

U-1553 TO MAINTAIN HEALING OF EE AND RELIEF OF HEARTBURN

U-1554 FOR THE TREATMENT OF HEARTBURN ASSOCIATED WITH SYMPTOMATIC NON-EROSIVE GASTROESOPHAGEAL DISEASE (GERD)

U-1555 MANAGEMENT OF MODERATE TO SEVERE PAIN SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG-TERM OPIOID TREATMENT AND FOR WHICH ALTERNATIVE TREATMENT OPTIONS ARE INADEQUATE.

U-1556 MANAGEMENT OF PAIN SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG-TERM OPIOID TREATMENT AND FOR WHICH ALTERNATIVE TREATMENT OPTIONS ARE INADEQUATE

U-1557 A METHOD OF TESTOSTERONE REPLACEMENT THERAPY COMPRISING THE STEP OF NASALLY ADMINISTERING TO A PATIENT IN NEED OF SUCH TREATMENT AN EFFECTIVE AMOUNT OF TESTOSTERONE GEL FORMULATION.

U-1558 FOR THE TREATMENT OF PATIENTS WITH RELAPSED FOLLICULAR B-CELL NON-HODGKIN LYMPHOMA OR [RELAPSED] SMALL LYMPHOCYTIC LYMPHOMA

U-1559 INDICATED FOR THE ONCE-DAILY MAINTENANCE TREATMENT OF ASThma AS PROPHYLACTIC THERAPY IN PATIENTS AGED 12 YEARS OF AGE AND OLDER

U-1560 A METHOD OF DISRUPTING LEUKOCYTE FUNCTION, INCLUDING AS AN INHIBITOR OF PI3KDELTA KINASE

U-1561 USE OF OTEZLA (APREMILAST) FOR THE TREATMENT OF PSORIATIC ARTHRITIS

U-1562 TREATMENT OF PATIENTS WITH HEPATIC ENCEPHALOPATHY (HE)

U-1563 A METHOD OF TRANSDERMAL ADMINISTRATION OF A PHYSIOLOGICALLY ACTIVE AGENT TO A SUBJECT.

U-1564 A METHOD OF TREATING GAUCHER'S DISEASE

U-1565 METHOD OF TREATING, AS INITIAL LOADING DOSE FOR MONOTHERAPY OR ADJUNCTIVE THERAPY, PARTIAL ONSET-SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS OR OLDER WHEN ORAL ADMINISTRATION IS TEMPORARILY NOT FEASIBLE

U-1566 METHOD OF TREATING, AS MONOTHERAPY OR ADJUNCTIVE THERAPY, PARTIAL-ONSET SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS AND OLDER

U-1567 METHOD OF TREATING, AS INITIAL LOADING DOSE FOR MONOTHERAPY OR ADJUNCTIVE THERAPY, PARTIAL ONSET-SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS OR OLDER

U-1568 METHOD OF TREATING, AS MONOTHERAPY OR ADJUNCTIVE THERAPY, PARTIAL-ONSET SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS AND OLDER WHEN ORAL ADMINISTRATION IS
PATENT USE

U-1569 TREATMENT OF BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS

U-1570 TREATMENT OF BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS USING A SINGLE DOSE

U-1571 TREATMENT OF GAUCHER DISEASE TYPE 1

U-1572 TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION.

U-1573 USE OF RUXOLITINIB (JAKAFI) FOR INHIBITING JANUS ASSOCIATED KINASES (JAKS) JAK1 AND/OR JAK2.

U-1574 A METHOD OF CATALYZING THE HYDROLYSIS OF GLUCOCEREBROSIDE TO GLUCOSE AND CERAMIDE.

U-1575 PATIENTS WITH SEVERE APLASTIC ANEMIA WHO HAVE HAD AN INSUFFICIENT RESPONSE TO IMMUNOSUPPRESSIVE THERAPY

U-1576 TREATMENT OF LEUKEMIA

U-1577 CONTROL OF SERUM PHOSPHOROUS LEVELS

U-1578 TREATMENT OF ACUTE OTITIS MEDIA

U-1579 USE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

U-1580 USE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO HAD RECEIVED PRIOR DOCETAXEL CHEMOTHERAPY IN COMBINATION WITH DABRAFENIB FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA.

U-1581 TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA

U-1582 FOR CHRONIC WEIGHT MANAGEMENT FOR TREATING OVERWEIGHT OR OBESITY

U-1583 USE OF NALTREXONE AND BUPROPION IN A LAYERED FORMULATION FOR CHRONIC WEIGHT MANAGEMENT FOR AFFECTING WEIGHT LOSS

U-1584 USE OF NALTREXONE AND BUPROPION BASED ON AN ESCALATING DOSE SCHEDULE

U-1585 FOR EFFECT ON BLOOD GLUCOSE PARAMETERS IN PATIENTS WITH INSULIN RESISTANCE

U-1586 SINGLE-DOSE INFILTRATION INTO THE SURGICAL SITE TO PRODUCE POSTSURGICAL ANALGESIA.

U-1587 THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (CRPC).

U-1588 METHOD OF USE FOR REDUCING BLOOD PHENYLALANINE LEVELS IN A HUMAN SUFFERING FROM HYPERPHENYLALANINEMIA

U-1589 KUVAN IS INDICATED TO REDUCE BLOOD PHENYLALANINE LEVELS IN PATIENTS WITH HYPERPHENYLALANINEMIA

U-1590 TREATMENT OF ASTHMA IN PATIENTS AGED 12 YEARS AND OLDER

U-1591 TO REDUCE SERUM PHOSPHATE IN PATIENTS WITH END STAGE RENAL DISEASE

U-1592 MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD, INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA, AND REDUCTION OF EXACERBATIONS IN COPD PATIENTS.

U-1593 DILATION OF THE PUPIL

U-1594 USE OF OTEZLA (APREMILAST) FOR THE TREATMENT OF PSORIASIS

U-1595 LAMICTAL IS AN ANTIEPILEPTIC DRUG (AED) INDICATED FOR: EPILEPSY-ADJUNCTIVE THERAPY IN PATIENTS GREATER THAN OR EQUAL TO 2 YEARS OF AGE: (1.1) PARTIAL SEIZURES PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

U-1596 TREATMENT OF DIABETIC MACULAR EDEMA

U-1597 METHOD OF ADMINISTRATION OF CONTROLLED RELEASE OXYMORPHONE

U-1598 MANAGEMENT OF MILD TO MODERATE PAIN, MANAGEMENT OF MODERATE TO SEVERE PAIN AS AN ADJUNCT TO OPIOID ANALGESICS, REDUCTION IN FEVER THROUGH ANTI INFLAMMATORY, ANALGESIC, AND ANTIPYRETIC ACTIVITY

U-1599 DOSAGE MODIFICATION FOLLOWING ELEVATED LIVER ENZYMES IN TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

U-1600 DOSE ESCALATION OVER 14 DAYS FOR TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

U-1601 METHOD OF ADMINISTERING PIRFENIDONE CAPSULES TO TREAT A FIBROTIC CONDITION
PATENT AND EXCLUSIVITY TERMS

U-1603 METHOD FOR ADMINISTERING PIRFENIDONE TO REDUCE DRUG INTERACTIONS WITH FLUVOXAMINE

U-1604 METHOD FOR ADMINISTERING PIRFENIDONE TO REDUCE DRUG INTERACTIONS WITH A STRONG INHIBITOR OF CYPIA2

U-1605 METHOD FOR ADMINISTERING PIRFENIDONE TO AVOID REDUCED EFFICACY BY DISCONTINUING SMOKING OR BY DISCONTINUING OR AVOIDING ANOTHER STRONG CYPIA2 INDUCER

U-1606 METHOD FOR ADMINISTERING PIRFENIDONE WHILE AVOIDING OR DISCONTINUING CONCOMITANT USE OF A MODERATE TO STRONG INHIBITOR OF BOTH CYPIA2 AND ANOTHER CYP ENZYME INVOLVED IN PIRFENIDONE METABOLISM

U-1607 METHOD OF ADMINISTERING A DOSAGE FORM THAT INCLUDES A GRANULATE FORMULATION OF PIRFENIDONE TO TREAT A FIBROTIC CONDITION

U-1608 DOSE ESCALATION OVER 14 DAYS FOR TREATMENT OF A FIBROSIS CONDITION

U-1609 CONTINUED DOSING OR DOSAGE MODIFICATION FOLLOWING ELEVATED LIVER ENZYMES IN TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

U-1610 CONTINUED DOSING OR DOSAGE MODIFICATION FOLLOWING ELVATED LIVER ENZYMES IN USE OF PIRFENIDONE

U-1611 METHOD FOR ADMINISTERING PIRFENIDONE TO AVOID REDUCED EFFICACY BY DISCONTINUING SMOKING OR BY DISCONTINUING A STRONG CYPIA2 INDUCER

U-1612 METHOD FOR ADMINISTERING PIRFENIDONE TO AVOID REDUCED EFFICACY BY AVOIDING SMOKING OR BY AVOIDING ANOTHER STRONG CYPIA2 INDUCER

U-1613 DOSAGE MODIFICATION IN TREATMENT WITH PIRFENIDONE TO REDUCE DRUG INTERACTIONS WITH CIPROFLOXACIN

U-1614 USE OF TOPICAL DICLOFENAC SODIUM FOR TREATING PAIN

U-1615 FOR THE TREATMENT OF PATIENTS WITH CLL, FL, OR SLL

U-1616 NASAL ADMINISTRATION OF A TESTOSTERONE GEL TO A PATIENT TO TREAT THE PATIENT FOR A CONDITION ASSOCIATED WITH A DEFICIENCY OR ABSENCE OF ENDOGENOUS TESTOSTERONE

U-1617 METHOD OF TREATING MEDULLARY THYROID CANCER

U-1618 A METHOD OF TREATING A PATIENT SUFFERING FROM A PAIN ASSOCIATED SLEEP DISTURBANCE COMPRISING ADMINISTERING A LIQUID COMPOSITION FORMULATED INSIDE A SOFT GEL CAPSULE, AS CLAIMED, TO THE PATIENT

U-1619 TREATMENT OF IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA (ITP)

U-1620 METHOD OF TREATMENT OF IRON-RELATED CONDITIONS WITH AT LEAST 0.6 GRAMS OF ELEMENTAL IRON VIA AN IRON CARBOHYDRATE COMPLEX, WITH A SUBSTANTIALLY NON-IMMUNOGENIC CARBOHYDRATE COMPONENT, IN ABOUT 15 MINUTES OR LESS.

U-1621 PULMONARY ADMINISTRATION OF A COMPOSITION COMPRISING INSULIN BOUND TO A COMPLEXING AGENT.

U-1622 FOR THE TREATMENT OF POLYCYTHEMIA VERA

U-1623 USE OF EXENATIDE MAY RESULT IN REDUCTION IN APPETITE.

U-1624 TREATMENT OF UNRESECTABLE HEPATOCELLULAR CARCINOMA, ADVANCED RENAL CELL CARCINOMA, OR DIFFERENTIATED THYROID CARCINOMA.

U-1625 METHOD OF TREATING SCHIZOPHRENIA BY ADMINISTERING ILOPERIDONE TO A PATIENT BY REDUCING THE DOSE IN PATIENTS WHO ARE POOR METABOLIZERS OF CYP2D6

U-1626 A METHOD OF TREATING OR PREVENTING OCULAR PAIN AND BURNING

U-1627 TREATMENT OF ACUTE UNCOMPLICATED INFLUENZA IN ADULTS

U-1628 METHOD OF TREATING DISORDERS WITH AN ETIOLOGY COMPRISING OR ASSOCIATED WITH EXCESS GH-SECRETION

U-1629 METHOD OF TREATING ACMEGALY

U-1630 TREATMENT IN COMBINATION WITH A CORTICOID SUCH AS PRENISONE OF PROSTATE CANCER PREVIOUSLY TREATED WITH DOCETAXEL

U-1631 TREATMENT OF INFLAMMATORY LESIONS OF ROSACEA.

U-1632 TREATMENT OF SCHIZOPHRENIA, WITH EFFICACY IN TREATING ACUTE EPISODES OF SCHIZOPHRENIA

U-1633 USE OF ARIPIPRAZOLE IN EXTENDED RELEASE INJECTABLE SUSPENSION IN TREATING ACUTE EPISODES OF SCHIZOPHRENIA

U-1634 TREATMENT OF BRCA MUTATED OVARIAN CANCER USING PARP INHIBITOR
U-1635 USE OF RITONAVIR AS A POTENT CYP3A INHIBITOR TO INCREASE PLASMA DRUG CONCENTRATION OF PARITAPREVIR AND OVERALL DRUG EXPOSURE FOR TREATMENT OF HCV INFECTION
U-1636 USE OF DASABUVIR TO INHIBIT VIRAL REPLICATION FOR THE TREATMENT OF HCV INFECTION.
U-1637 TREATMENT OF HCV INFECTION USING PARITAPREVIR, OMBITASVIR, RITONAVIR, AND DASABUVIR WITH RIBAVIRIN.
U-1638 TREATMENT OF HCV INFECTION USING PARITAPREVIR.
U-1639 USE OF NALTREXONE AND BUPROPION IN EXTENDED-RELEASE FORM FOR CHRONIC WEIGHT MANAGEMENT FOR TREATING OVERWEIGHT OR OBESITY
U-1640 TREATMENT OF MODERATE TO SEVERE CHRONIC PAIN BY ADMINISTERING AN INTACT COMPOSITION AS CLAIMED
U-1641 MEMANTINE HCL/DONEPEZIL HCL COMBINATION FOR THE TREATMENT OF MODERATE TO SEVERE DEMENTIA OF THE ALZHEIMER'S TYPE
U-1642 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS WITH SEVERE CHRONIC RENAL IMPAIRMENT AND FOR WHOM METFORMIN THERAPY IS INAPPROPRIATE BY ADMINISTERING LINAGLIPTIN
U-1643 TREATING CUSHING'S SYNDROME
U-1644 TREATMENT OF OVERACTIVE BLADDER BY APPLICATION OF OXYBUTYNIN CHLORIDE GEL TO SKIN
U-1645 TREATMENT OF PARKINSON'S DISEASE, POST-ENCEPHALITIC PARKINSONISM, AND PARKINSONISM THAT MAY FOLLOW CARBON MONOXIDE INTOXICATION OR MANGANESE INTOXICATION
U-1646 TREATMENT OF POST-ENCEPHALITIC PARKINSONISM, AND PARKINSONISM THAT MAY FOLLOW CARBON MONOXIDE INTOXICATION OR MANGANESE INTOXICATION
U-1647 TREATMENT OF PARKINSONISM THAT MAY FOLLOW CARBON MONOXIDE INTOXICATION OR MANGANESE INTOXICATION
U-1648 TREATMENT OF PATIENTS WITH PARKINSON'S DISEASE, POST-ENCEPHALITIC PARKINSONISM, AND PARKINSONISM THAT MAY FOLLOW CARBON MONOXIDE INTOXICATION OR MANGANESE INTOXICATION
U-1649 TREATMENT OF POST-ENCEPHALITIC PARKINSONISM
U-1650 TREATMENT OF WALDENSTROM'S MACROGLOBULINEMIA
U-1651 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH EMPAGLIFLOZIN
U-1652 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH EMPAGLIFLOZIN AND METFORMIN
U-1653 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH EMPAGLIFLOZIN (WITH OR WITHOUT METFORMIN)
U-1654 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH EMPAGLIFLOZIN (WITH OR WITHOUT INSULIN OR A SULFONYLUREA)
U-1655 A METHOD TO ACCELERATE THE TIME TO GASTROINTESTINAL RECOVERY BY ADMINISTERING ABOUT 12 MG OF ALVIMOPAN TO THE PATIENT FROM ABOUT 30 TO 60 MINUTES PRIOR TO SURGERY
U-1656 METHOD OF IRON ADMINISTRATION TO TREAT PATIENTS IN NEED OF IRON REPLACEMENT
U-1657 METHOD FOR PROVIDING POST COITAL CONTRACEPTION TO A WOMAN BY ADMINISTERING ABOUT 30 MG OF ULIPRISTAL ACETATE WITHIN ABOUT 120 HOURS AFTER INTERCOURSE, WHEREIN THE WOMAN IS OVERWEIGHT HAVING A BMI OF 25 TO 29.99
U-1658 TREATMENT OF ER-POSITIVE, HER2-NEGATIVE ADVANCED BREAST CANCER IN COMBINATION WITH LETROZOLE AS INITIAL ENDOCRINE-BASED THERAPY FOR METASTATIC DISEASE IN POSTMENOPAUSAL WOMEN
U-1659 MANAGEMENT OF PAIN
U-1660 TREATMENT OF HIV-1 INFECTION IN ADULTS WITH NO DARUNAVIR RESISTANCE-ASSOCIATED SUBSTITUTIONS
U-1661 RISK-REDUCTION OF NSAID-ASSOCIATED GASTRIC ULCERS IN PATIENTS ALSO TAKING LOW DOSE ASPIRIN
U-1662 A METHOD OF TREATING OCULAR PAIN
PATENT USE

U-1663 TREATMENT OF HIV-1 INFECTION
U-1664 TREATMENT OF BACTERIAL VAGINOSIS WITH METRONIDAZOLE GEL
U-1665 METHOD OF TREATING ATTENTION DEFICIT HYPERACTIVITY DISORDER BY ADMINISTERING THE COMPOSITION OF CLAIM 1
U-1666 PALLIATIVE TREATMENT OF PROSTATE CANCER
U-1667 TREATMENT OF ALLERGIC RHINITIS, INCLUDING SEASONAL ALLERGIC RHINITIS
U-1668 METHOD OF TREATING DEPRESSION OR MAJOR DEPRESSIVE DISORDER
U-1669 TREATMENT OF MULTIPLE MYELOMA, IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE
U-1670 NATROBA TOPICAL SUSPENSION IS A PEDICULICIDE INDICATED FOR THE TOPICAL TREATMENT OF HEAD LICE INFESTATION IN PATIENTS SIX (6) MONTHS OF AGE AND OLDER.
U-1671 TREATMENT OF OCULAR ITCHING ASSOCIATED WITH CONJUNCTIVITIS
U-1672 TREATMENT OF COMPLICATED INTRA-ABDOMINAL INFECTION
U-1673 TREATMENT OF COMPLICATED URINARY TRACT INFECTION, INCLUDING PYELONEPHRITIS
U-1674 DOSAGE MODIFICATION TO REDUCE RISKS ASSOCIATED WITH QT PROLONGATION NOT INDUCED BY OTHER DRUGS DURING TREATMENT WITH ILOPERIDONE
U-1675 USE OF TROKENDI XR FOR THE TREATMENT OF EPILEPSY
U-1676 METHODS FOR TREATING BACTERIAL INFECTIONS
U-1677 TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS (IPF)
U-1678 FOR THE TREATMENT OF PATIENTS WITH CLL, FL, OR SLL
U-1679 TREATMENT OF ACUTE OTITIS EXTERNA
U-1680 TREATMENT OF OCULAR ITCHING ASSOCIATED WITH ALLERGIC CONJUNCTIVITIS
U-1681 TREATMENT OF PATIENTS WITH PROGRESSIVE NEUROENDOCRINE TUMORS OF Pancreatic Origin (PNET) THAT ARE UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC
U-1682 TREATMENT OF BACTERIAL VAGINOSIS
U-1683 TREATMENT FOR CHRONIC LYMPHOCYTIC LEUKEMIA WITH 17P DELETION
U-1684 TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA
U-1685 DOSAGE MODIFICATION TO REDUCE THE RISK ASSOCIATED WITH QT PROLONGATION NOT INDUCED BY OTHER DRUGS DURING TREATMENT WITH ILOPERIDONE
U-1686 A METHOD TO REDUCE WITHDRAWAL SYMPTOMS, INCLUDING NICOTINE CRAVING, ASSOCIATED WITH SMOKING CESSATION
U-1687 TREATMENT OF HCV INFECTION USING OMBITASVIR
U-1688 METHOD FOR CHRONIC WEIGHT MANAGEMENT BY TREATING OBESITY IN AN INDIVIDUAL WHO DOES NOT HAVE SEVERE RENAL IMPAIRMENT OR ESRD
U-1689 METHOD FOR CHRONIC WEIGHT MANAGEMENT BY INDUCING SATIETY IN AN INDIVIDUAL WHO DOES NOT HAVE SEVERE RENAL IMPAIRMENT OR ESRD
U-1690 METHOD FOR REDUCTION OF SUBMENTAL FAT
U-1691 INDICATED FOR THE ONCE-DAILY INHALED TREATMENT FOR ASTHMA IN ADULTS AGED 18 YEARS AND OLDER
U-1692 METHOD FOR CHRONIC WEIGHT MANAGEMENT BY DECREASING FOOD INTAKE IN AN INDIVIDUAL WHO DOES NOT HAVE SEVERE RENAL IMPAIRMENT OR ESRD
U-1693 METHOD OF TREATING ADHD IN CHILDREN 6 YEARS OF AGE AND OLDER AND ADOLESCENTS
U-1694 A METHOD FOR TREATING HEART FAILURE IN A HUMAN USING A CRYSTALLINE FORM OF IVABRADINE HYDROCHLORIDE
U-1695 METHOD FOR TREATING THYROID CARCINOMA INCLUDING DIFFERENTIATED THYROID CANCER
U-1696 TREATMENT OF UNRESECTABLE HEPATOCELLULAR CARCINOMA
U-1697 PULMONARY ADMINISTRATION OF A COMPOSITION COMPRISING INSULIN BOUND TO A DIKETOPIPERAZINE.
U-1698 PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS
U-1699 A METHOD FOR TREATING ACUTE LYMPHOBLASTIC LEUKEMIA
U-1700 A METHOD FOR TREATING PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA
PATENT USE

U-1701 A METHOD FOR TREATING LEUKEMIA RESULTING FROM A MUTATION IN THE BCR-ABL KINASE DOMAIN
U-1702 TREATMENT OF COPD
U-1703 TREATMENT OF RESPIRATORY COMPLAINTS
U-1704 USE FOR TREATMENT IN PATIENTS WITH DIABETES
U-1705 USE FOR TREATMENT IN PATIENTS WITH HYPERGLYCEMIA
U-1706 TREATMENT OF TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE WHEREIN THE COMBINED THERAPEUTIC EFFECT IS GREATER THAN THE ADDITIVE EFFECT OF ADMINISTERING EACH AGENT ALONE
U-1707 TREATMENT OF IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) IN ADULTS AND SYMPTOMS THEREOF.
U-1708 TREATMENT OF IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) IN ADULTS.
U-1709 TREATMENT OF IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) WITH VIBERZI (ELUXADOLINE).
U-1710 TREATMENT OF NON-24-HOUR SLEEP-WAKE DISORDER BY AVOIDING THE USE OF TASIMELTEON IN COMBINATION WITH FLUVOXAMINE
U-1711 FOR THE TREATMENT OF PATIENTS WITH CLL, FL OR SLL
U-1712 MEKINIST IN COMBINATION WITH DABRAFENIB FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA
U-1713 TAFINLAR IN COMBINATION WITH TRAMETINIB FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA
U-1714 TREATMENT OF THROMBOCYTOPENIA IN ADULT AND PEDIATRIC PATIENTS 6 YEARS AND OLDER WITH CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA (ITP)
U-1715 P2Y12 PLATELET INHIBITOR FOR USE AS ADJUNCT TO PERCUTANEOUS CORONARY INTERVENTION TO REDUCE RISK OF VARIOUS DISEASES/CONDITIONS IN PATIENTS NOT TREATED WITH A P2Y12 PLATELET INHIBITOR AND NOT GIVEN A GLYCOPROTEIN IIB/IIIb INHIBITOR
U-1716 TREATMENT OF COUGH AND SYMPTOMS ASSOCIATED WITH UPPER RESPIRATORY ALLERGIES OR A COMMON COLD WITH CODEINE PHOSPHATE AND CHLORPHENIRAMINE MALEATE ORALLY ADMINISTERED EXTENDED RELEASE TABLETS
U-1717 METHOD OF TREATING CYSTIC FIBROSIS IN PATIENTS WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE
U-1718 METHOD OF TREATING CYSTIC FIBROSIS IN PATIENTS WHO HAVE THE F508DEL MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE.
U-1719 ACUTE TREATMENT OF MIGRAINE
U-1720 METHOD OF PROVIDING A THERAPEUTICALLY EFFECTIVE AND STABLE MEDIAN BLOOD PLASMA LEVEL OF LEVODOPA
U-1721 USE OF RUXOLITINIB (JAKAFI) FOR BLOCKING SIGNAL TRANSDUCTION OF JANUS ASSOCIATED KINASES (JAKs) JAK1 AND/OR JAK2
U-1722 TREATMENT OF BASAL CELL CARCINOMA
U-1723 TREATMENT OF HEART FAILURE
U-1724 METHOD OF INHIBITING HEPATITIS C VIRUS
U-1725 METHOD OF INHIBITING HEPATITIS C VIRUS WITH DAKLINZA AND AT LEAST ONE ADDITIONAL COMPOUND HAVING ANTI-HCV ACTIVITY
U-1726 REDUCTION IN RISK OF HOSPITALIZATION IN PATIENTS WITH CORONARY HEART DISEASE AND A HISTORY OF PAROXYSMAL OR PERSISTENT AF AND WITH ONE OR MORE RISK FACTORS BY ADMINISTRATION TWICE A DAY WITH MORNING AND EVENING MEALS
U-1727 TOPICAL TREATMENT OF INFLAMMATORY PAPULES AND PUSTULES OF MILD TO MODERATE ROacea
U-1728 REDUCTION IN RISK OF HOSPITALIZATION IN PATIENTS WITH STABLE NYHA CLASS III HEART FAILURE AND A HISTORY OF PAROXYSMAL OR PERSISTENT AF AND WITH ONE OR MORE RISK FACTORS BY ADMINISTRATION TWICE A DAY WITH MORNING AND EVENING MEALS
U-1729 REDUCE THE RISK OF RECURRENT DEEP VEIN THROMBOSIS (DVT)
U-1730 REDUCE THE RISK OF RECURRENT PULMONARY EMBOLISM
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-1731 TEMPORARY RELIEF OF MINOR ACHES AND PAINS

U-1732 TEMPORARY REDUCTION OF FEVER

U-1733 TREATMENT/PREVENTION OF CARDIOVASCULAR DISEASE

U-1734 USE OF FLIBANSERIN OR A PHARMACEUTICALLY ACCEPTABLE ACID ADDITION SALTF THEREOF TO TREAT HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD)

U-1735 METHODS OF TREATING PAIN, INFLAMMATION AND/OR FEVER WITH INTRAVENOUS IBUPROFEN SUCH THAT MEAN ARTERIAL BLOOD PRESSURE DOES NOT INCREASE THE DOSAGE INTERVAL

U-1736 TREATMENT OF THROMBOCYTOPENIA IN ADULT AND PEDIATRIC PATIENTS 1 YEAR AND OLDER WITH CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA (ITP)

U-1737 METHOD OF TREATING SCHIZOPHRENIA BY ADMINISTERING ILOPERIDONE TO A PATIENT BY REDUCING THE DOSE IN PATIENTS WHO ARE BEING TREATED WITH FLUOXETINE

U-1738 TREATMENT OF IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) WITH VIBERZI (ELUXADOLINE)

U-1739 MANAGEMENT OF PAIN SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG-TERM OPIOID TREATMENT, INCLUDING NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY

U-1740 IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT-NAIVE PATIENTS WITH HIV-1 RNA LESS THAN OR EQUAL TO 100,000 AT THE START OF THERAPY

U-1741 PREVENTION OF DELAYED NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY

U-1742 ROLAPITANT IS APPROVED FOR THE PREVENTION OF DELAYED NAUSEA AND EMESIS ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY

U-1743 FOR THE PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH CHEMOTHERAPY

U-1744 FOR THE PREVENTION OF POST-OPERATIVE NAUSEA AND VOMITING

U-1745 FOR THE TREATMENT OF PATIENTS WITH WALDENSTROM'S MACROGLOBULINEMIA

U-1746 MONOTHERAPY OR ADJUNCTIVE THERAPY FOR TREATMENT OF PARTIAL-ONSET SEIZURES AND APPROVED IN PATIENTS WITH EPILEPSY

U-1747 FOR CLAIMS 1-3, 6-13, 16-24 AND 26-32: METHOD OF TREATING ADHD

U-1748 FOR CLAIMS 1-4, 6-14, 16-24 AND 26-32: METHOD OF TREATING ADHD IN CHILDREN 6 YEARS OF AGE AND OLDER AND ADOLESCENTS

U-1749 ACUTE TREATMENT OF MANIC AND MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER

U-1750 TREATMENT OF SCHIZOPHRENIA AND/OR ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER WITH CARIPRAZINE

U-1751 TREATMENT OF PATIENTS WITH METASTATIC COLORECTAL CANCER WHO HAVE BEEN PREVIOUSLY TREATED WITH FLUOROPYRIMIDINE-, OXALIPLATIN- AND IRINOTECAN-BASED CHEMOTHERAPY, AN ANTI-VEGF BIOLOGICAL THERAPY, AND IF RAS WILD-TYPE, AN ANTI-EGFR THERAPY

U-1752 PROPHYLAXIS OF ORGAN REJECTION

U-1753 TREATMENT OF HCV INFECTION USING DASABUVIR

U-1754 FOR THE TREATMENT OF PULMONARY HYPERTENSION (PAH) IN COMBINATION WITH TADALAFIL

U-1755 FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 (L858R) SUBSTITUTION MUTATIONS

U-1756 METHODS OF TREATING PAIN, INFLAMMATION AND/OR FEVER IN A CRITICALLY ILL PATIENT WITH INTRAVENOUS IBUPROFEN IN NEED THEREOF

U-1757 INHIBITION ON PI3K KINASE

U-1758 METHOD OF TREATING ALLERGIC REACTION VIA INJECTION

U-1759 METHOD OF REVERSING THE ANTICOAGULANT EFFECT OF DABIGATRAN USING IDARUCIZUMAB

U-1760 RISK-REDUCTION OF NSAID GASTRIC ULCER IN PATIENTS REQUIRING CHRONIC NSAID TREATMENT

U-1761 PLAQUE PSORIASIS

U-1762 USE OF BELVIQ (LORCASERIN HYDROCHLORIDE) FOR CHRONIC WEIGHT MANAGEMENT IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED A GREATER THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT
PATENT USE

U-1763 USE OF BELVIQ (LORCASERIN HYDROCHLORIDE) FOR CHRONIC WEIGHT MANAGEMENT BY DECREASING FOOD INTAKE IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED GREATER THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT

U-1764 USE OF BELVIQ (LORCASERIN HYDROCHLORIDE) FOR CHRONIC WEIGHT MANAGEMENT BY INDUCING SATIETY IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED A GREATER THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT

U-1765 USE OF BELVIQ (LORCASERIN HYDROCHLORIDE) FOR CHRONIC WEIGHT MANAGEMENT BY TREATING OBESITY IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED A GREATER THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT

U-1766 TREATMENT OF HYPERKALEMIA

U-1767 USE OF CALCIPOTRIENE FOAM FOR THE TOPICAL TREATMENT OF PLAQUE PSORIASIS IN PATIENTS AGED 18 YEARS AND OLDER

U-1768 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN

U-1769 TREATMENT OF PAIN BY TRANSMUCOSAL DELIVERY OF BUPRENORPHINE

U-1770 TREATMENT OF SCHIZOPHRENIA WITH IMPROVEMENT IN NEGATIVE SYMPTOMS AND/OR COGNITIVE DYSFUNCTION OF SCHIZOPHRENIA

U-1771 ADMINISTRATION OF REMODULIN DILUTED FOR INTRAVENOUS INFUSION WITH STERILE WATER FOR INJECTION OR 0.9% SODIUM CHLORIDE INJECTION PRIOR TO ADMINISTRATION

U-1772 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH EMPAGLIFLOZIN

U-1773 LONG-TERM MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

U-1774 USE OF A LOTION CONTAINING HALOBETASOL PROPIONATE FOR THE TREATMENT OF CORTICOSTEROID-RESONSIVE DERMATOSES INCLUDING PSORIASIS

U-1775 USE OF A LOTION CONTAINING HALOBETASOL PROPIONATE FOR THE TREATMENT OF CORTICOSTEROID-RESPONSIVE DERMATOSES INCLUDING PSORIASIS

U-1776 METHOD OF USING COBIMETINIB FOR THE TREATMENT OF MELANOMA

U-1777 TREATMENT OF PATIENTS WITH METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) T790M MUTATION-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC), WHO HAVE PROGRESSED ON OR AFTER EGFR TKI THERAPY

U-1778 METHOD FOR TREATING MULTIPLE MYELOMA

U-1779 METHOD FOR TREATING MULTIPLE MYELOMA WITH ONE OR MORE OTHER THERAPEUTIC AGENTS

U-1780 METHOD FOR TREATING CANCER, INCLUDING MULTIPLE MYELOMA

U-1781 RISK-REDUCTION OF NSAID-ASSOCIATED GASTRIC ULCER IN PATIENTS REQUIRING NSAID TREATMENT

U-1782 FOR HEAD LICE INFESTATIONS

U-1783 METHOD OF TREATING FREQUENT HEARTBURN BY ADMINISTERING AN ESOMEPRAZOLE MAGNESIUM AS CLAIMED

U-1784 METHOD OF TREATING FREQUENT HEARTBURN BY ADMINISTERING AN ESOMEPRAZOLE MAGNESIUM TRIHYDRATE AS CLAIMED

U-1785 METHOD OF TREATING FREQUENT HEARTBURN BY ADMINISTERING AN ESOMEPRAZOLE MAGNESIUM FORMULATION AS CLAIMED

U-1786 TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS WHILE MANAGING THE RISK OF TERIFLUONOMIDE AND ROSUVASTATIN INTERACTION BY LIMITING THE ROSUVASTATIN DOSE TO NO MORE THAN 10MG AND/OR ADMINISTERING ABOUT HALF THE NORMAL DOSE

U-1787 TREATMENT OF EXOCRINE PANCREATIC INSUFFICIENCY

U-1788 TREATMENT OF PATIENT HAVING DIABETES MELLITUS VIA ORAL INHALATION OF FDKP MICROPARTICLES COMPRISING INSULIN

U-1789 METHOD OF ADMINISTERING AN ETHANOL-FREE TAXANE LIQUID NANODISPERSION FORMULATION TO A SUBJECT COMBINING THE FORMULATION WITH AN AQUEOUS MEDIUM TO PROVIDE AN ETHANOL-FREE TAXANE DILUTED SOLUTION

U-1790 FOR USE IN TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) AND/OR NON-HODGKIN'S LYMPHOMA

U-1791 EMERGENCY TREATMENT OF ADULT & PEDIATRIC PATIENTS FOLLOWING FLUOROURACIL OR CAPECITABINE OVERDOSE, OR WHO EXHIBIT EARLY-ONSET, SEVERE OR LIFE-THREATENING CARDIAC OR CNS TOXICITY OR UNUSUALLY SEVERE ADVERSE REACTIONS WITHIN 96 HOURS
PATENT USE

U-1792 TREATMENT OF OTIC INFECTION OR INFLAMMATION

U-1793 TREATMENT OF PEDIATRIC PATIENTS WITH OTITIS MEDIA WITH EFFUSION UNDERGOING TYPANOSTOMY TUBE PLACEMENT

U-1794 REVERSAL OF DRUG-INDUCED NEUROMUSCULAR BLOCK

U-1795 REVERSAL OF NEUROMUSCULAR BLOCKAGE INDUCED BY ROCURONIUM BROMIDE OR VECURONIUM BROMIDE

U-1796 TOPICAL TREATMENT OF INFLAMMATORY PAPULES AND PUSTULES OF MILD TO MODERATE ROSACEA

U-1797 METHOD OF TREATING PULMONARY ARTERIAL HYPERTENSION COMPRISING ADMINISTERING A PHARMACEUTICAL COMPOSITION COMPRISING SELEXIPAG

U-1798 METHOD OF TREATING PULMONARY ARTERIAL HYPERTENSION COMPRISING ADMINISTERING SELEXIPAG IN COMBINATION WITH THE ENDOTHELIN RECEPTOR ANTAGONIST MACITENTAN

U-1799 METHOD OF INCREASING GROWTH OF HAIR INCLUDING EYELASHES

U-1800 A METHOD OF TREATING OCULAR PAIN AND/OR ENHANCING OCULAR COMFORT

U-1801 REDUCTION OF SERUM URIC ACID LEVELS

U-1802 TREATMENT OF GOUT

U-1803 TREATMENT OF HYPERURICEMIA

U-1804 ACHIEVING A THERAPEUTIC BENEFIT IN A SUBJECT WITH GOUT

U-1805 USE OF DEXLANSOPRAZOLE IN PATIENTS TAKING CLOPIDOGREL WITHOUT MEANINGFUL CYP2C19 INTERACTIONS

U-1806 COADMINISTERING WITH ALLOPURINOL TO REDUCE SERUM URIC ACID (SUA) BELOW 4 MG/DL; BELOW 6MG/DL IN PATIENTS HAVING URIC ACID DEPOSITS; AND/OR BELOW 6MG/DL WITH SUA INTRADAY CHANGE MORE THAN 50% AND/OR ADVERSE EVENT RATE LESS THAN 15%

U-1807 TREATMENT OF PEDIATRIC PATIENTS 8 TO 17 YEARS OF AGE WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH)

U-1808 USE OF NALTREXONE AND BUPROPION FOR CHRONIC WEIGHT MANAGEMENT FOR TREATING OVERWEIGHT OR OBESITY IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER

U-1809 METHOD OF DRUG DELIVERY VIA THE NASAL CAVITY

U-1810 TREATMENT OF PAIN IN PATIENTS WITH HEPATIC IMPAIRMENT

U-1811 TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E MUTATIONS AFTER CONFIRMING THE PRESENCE OF BRAF V600E MUTATION

U-1812 TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC LIPOSARCOMA

U-1813 TREATMENT OF PATIENTS INFECTED WITH HEPATITIS C VIRUS

U-1814 METHOD OF TREATING GLAUCOMA OR ELEVATED INTRAOCULAR PRESSURE

U-1815 TREATMENT OF PARTIAL-ONSET SEIZURES AS ADJUNCTIVE THERAPY IN PATIENTS WITH EPILEPSY AGED 16 YEARS AND OLDER WITH EPILEPSY

U-1816 Method of treating a urea cycle disorder

U-1817 PEDIATRIC USE AGES 1 MONTH TO 2 YEARS, GERD AND EROSIVE ESOPHAGITIS

U-1818 TREATING HR-POS., HER2-NEG. ADVANCED OR METASTATIC BREAST CANCER WITH PALBOCICLIB IN COMBO WITH LETROZOLE AS INITIAL ENDOCRINE BASED THERAPY IN POSTMENOPAUSAL WOMEN, OR FULVESTRANT IN WOMEN WITH DISEASE PROGRESSION AFTER ENDOCRINE THERAPY

U-1819 MANAGEMENT OF PAIN SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG TERM OPIOID TREATMENT AND FOR WHICH ALTERNATIVE TREATMENT OPTIONS ARE INADEQUATE

U-1820 METHOD OF TREATING PULMONARY ARTERIAL HYPERTENSION BY ADMINISTERING A PHARMACEUTICAL COMPOSITION COMPRISING MACITENTAN AND A POLYSORBATE, WHEREIN THE POLYSORBATE REPRESENTS 0.1 TO 3% OF THE WEIGHT OF SAID PHARMACEUTICAL COMPOSITION

U-1821 METHOD FOR CONTRACEPTION TO A WOMAN COMPRISING ADMINISTERING TO THE WOMAN 30MG OF ULIPRISTAL ACETATE MORE THAN 72 HOURS AND UP TO 120 HOURS AFTER AN UNPROTECTED INTERCOURSE

U-1822 TREATMENT OF SCHIZOPHRENIA OR BIPOLAR DEPRESSION WITH IMPROVEMENT IN ATTENTION FUNCTION IN SCHIZOPHRENIA AND/OR BIPOLAR DISORDER

U-1823 A METHOD OF PROVIDING NITRIC OXIDE THERAPY TO A PATIENT BY COMPENSATING LONG-TERM SENSITIVITY DRIFT OF ELECTROCHEMICAL GAS SENSORS USED IN SYSTEMS FOR
PATENT USE

DELIVERING THERAPEUTIC NITRIC OXIDE TO A PATIENT

U-1824 A METHOD OF PROVIDING NITRIC OXIDE THERAPY TO A PATIENT BY VERIFYING GAS
INFORMATION OF NITRIC OXIDE PRIOR TO DELIVERY TO PATIENT

U-1825 METHOD OF USING VISMODEGIB TO TREAT CANCER IN A MAMMAL

U-1826 TREATMENT OF HR-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-
NEGATIVE ADVANCED OR METASTATIC BREAST CANCER IN COMBINATION WITH PALBOCICLIB IN
WOMEN WITH DISEASE PROGRESSION AFTER ENDOCRINE THERAPY

U-1827 A METHOD OF PROVIDING A SUBJECT WITH THERAPEUTICALLY EFFECTIVE AMOUNT OF RACEMIC
METHYLPHENIDATE BY ORALLY ADMINISTERING TO SAID SUBJECT A SINGLE METHYLPHENIDATE
EXTENDED RELEASE CHEWABLE TABLET ACCORDING TO CLAIM 1

U-1828 INCREASING MEAN ARTERIAL BLOOD PRESSURE IN ADULT PATIENTS WITH HYPOTENSION
ASSOCIATED WITH SEPTIC SHOCK

U-1829 EMERGENCY TREATMENT OF ALLERGIC REACTIONS (TYPE I), INCLUDING ANAPHYLAXIS

U-1830 INDUCTION AND MAINTENANCE OF MYDRIASIS DURING INTRAOCULAR SURGERY

U-1831 METHOD OF TREATING PULMONARY ARTERIAL HYPERTENSION COMPRISING ADMINISTERING A
CRYSTALLINE FORM OF SELEXIPAG

U-1832 IMPROVEMENT IN GLYCEMIC CONTROL IN DIABETES MELLITUS PATIENTS BY USE OF A PEN
INJECTOR WITH A THREADED DRIVE SLEEVE

U-1833 REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA
OR OCULAR HYPERTENSION

U-1834 TREATMENT OF POSTOPERATIVE INFLAMMATION AND PREVENTION OF OCULAR PAIN IN
PATIENTS UNDERGOING CATARACT SURGERY

U-1835 TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WITH 17P DELETION,
AS DETECTED BY AN FDA APPROVED TEST, WHO HAVE RECEIVED AT LEAST ONE PRIOR
THERAPY

U-1836 TREATMENT OF HEREDITARY TYROSINEMIA TYPE 1 (HT-1) IN COMBINATION WITH DIETARY
RESTRICTION OF TYROSINE AND PHENYLALANINE

U-1837 METHOD FOR TREATING TYPE II DIABETES MELLITUS BY ADMINISTERING SAXAGLIPTIN ALONE
OR IN COMBINATION WITH INSULIN, METFORMIN, A THIAZOLIDINEDIONE, GLYBURIDE OR
METFORMIN PLUS A SULFONYLUREA

U-1838 METHOD FOR TREATING TYPE II DIABETES MELLITUS BY ADMINISTERING SAXAGLIPTIN IN
COMBINATION WITH METFORMIN

U-1839 COMPOSITION AND METHOD FOR PROVIDING A REDUCTION IN SIDE EFFECTS FOR HUMAN
PATIENTS IN NEED OF ACETYLCYSTEINE THERAPY

U-1840 TREATMENT OF HCV INFECTION USING PARITAPREVIR, OMBITASVIR, RITONAVIR, AND
DASABUVIR, WITHOUT RIBAVIRIN

U-1841 USE IN THE LONG-TERM, MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS
WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

U-1842 METHOD OF TREATING EPILEPSY

U-1843 TREATMENT OF PSYCHOSIS

U-1844 TREATMENT OF PARKINSON'S DISEASE PSYCHOSIS

U-1845 TREATMENT OF PSYCHOSIS OR A SYMPTOM THEREOF

U-1846 TREATMENT OF A NEURODEGENERATIVE DISEASE OR A SYMPTOM THEREOF

U-1847 METHOD OF TREATING A BACTERIAL INFECTION

U-1848 TREATMENT OF METASTATIC ADENOCARCINOMA OF THE PANCREAS THAT HAS PROGRESSED ON
GEMCITABINE-BASED THERAPY, IN COMBINATION WITH 5-FUOROURACIL AND LEUCOVORIN

U-1849 METHOD OF TREATING PULMONARY HYPERTENSION BY ADMINISTERING TREPROMISTIN OR A
SALT THEREOF BY INHALATION USING A DEVICE

U-1850 METHOD OF ADMINISTERING LEVETIRACETAM

U-1851 A DOSING REGIMEN FOR THE TREATMENT OF HYPERCHOLESTEROLEMIA AND HYPERLIPIDEMIA
IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA USING AT LEAST THREE
STEP-WISE INCREASING DOSES

U-1852 METHOD OF TREATING TYPE 2 DIABETES

U-1853 METHOD OF TREATING TYPE 2 DIABETES MELLITUS BY ADMINISTERING A DIPEPTIDYL
PEPTIDASE-IV INHIBITOR IN COMBINATION WITH METFORMIN AND, OPTIONALLY, A
PATENT USE

SULFONYLUREA

U-1854 TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC)
U-1855 IMPROVEMENT IN GLYCEMIC CONTROL IN DIABETES MELLITUS PATIENTS
U-1856 TREATMENT OF METASTATIC ADENOCARCINOMA OF THE PANCREAS THAT HAS PROGRESSED ON GEMCITABINE-BASED THERAPY, IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN, IN A PATIENT HOMOZYGOUS FOR THE UGT1A1*28 ALLELE
U-1857 TO INCREASE BLOOD PRESSURE IN ADULTS WITH VASODILATORY SHOCK (E.G., POST-CARDIOTOMY OR SEPSIS) WHO REMAIN HYPTENSIVE DESPITE FLUIDS AND CATECHOLAMINES
U-1858 TREATMENT OF PLAQUE PSORIASIS
U-1859 TREATMENT OF SCHIZOPHRENIA, ACUTE TREATMENT OF MANIC AND MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER, ADJUNCTIVE TREATMENT OF MAJOR DEPRESSIVE DISORDER, AND TREATMENT OF IRRITABILITY ASSOCIATED WITH AUTISTIC DISORDER
U-1860 REDUCTION OF THE RATE OF CARDIOVASCULAR DEATH, MYOCARDIAL INFARCTION, AND STROKE IN PATIENTS WITH ACUTE CORONARY SYNDROME OR A HISTORY OF MYOCARDIAL INFARCTION
U-1861 USE OF AN INHALER TO ADMINISTER DRY POWDER MEDICAMENT
U-1862 TREATMENT OF POST-MYOCARDIAL INFARCTION
U-1863 TREATMENT OF STROKE
U-1864 TREATMENT OF MYOCARDIAL INFARCTION
U-1865 TREATMENT OF THROMBOTIC STROKE
U-1866 TREATMENT OF STABLE AND UNSTABLE ANGINA
U-1867 METHOD OF INHIBITING PLATELET AGGREGATION
U-1868 TREATMENT OF ARTERIAL THROMBOTIC COMPLICATIONS SELECTED FROM THE GROUP CONSISTING OF UNSTABLE ANGINA, THROMBOTIC OR EMBOLIC STROKE, TRANSIENT ISCHAEMIC ATTACKS, PERIPHERAL VASCULAR DISEASE AND MYOCARDIAL INFARCTION
U-1869 TREATMENT OF AN ARTERIAL THROMBOTIC COMPLICATION IN A PATIENT WITH CORONARY ARTERY, CEREBROVASCULAR OR PERIPHERAL VASCULAR DISEASE
U-1870 ZINGO IS A POWDER INTRADERMAL SYSTEM THAT IS CAPABLE OF DELIVERING FINE DRY POWDERED LIDOCAINE HYDROCHLORIDE MONOHYDRATE FOR LOCAL ANESTHETIC ACTION
U-1871 TREATMENT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS WITH STAGE 3 OR 4 CHRONIC KIDNEY DISEASE USING CONTROLLED RELEASE, ORAL 25-HYDROXYVITAMIN D
U-1872 USE OF SUSTAINED RELEASE 25-HYDROXYVITAMIN D IN TREATING PATIENTS HAVING 25-HYDROXYVITAMIN D INSUFFICIENCY OR DEFICIENCY
U-1873 ADMINISTRATION OF 25-HYDROXYVITAMIN D3 BY CONTROLLED RELEASE
U-1874 TREATMENT OF FREQUENT HEARTBURN BY ADMINISTERING OMEPRAZOLE ACCORDING TO CLAIMS 1-8
U-1875 TREATMENT OF FREQUENT HEARTBURN BY ADMINISTERING S-OMEPRAZOLE TRIHYDRATE ACCORDING TO CLAIMS 1-3
U-1876 METHOD OF ANESTHETIZING AT LEAST A PORTION OF THE MAXILLARY DENTAL ARCH
U-1877 METHOD OF TREATING PULMONARY HYPERTENSION BY ORALLY ADMINISTERING A FORMULATION OF A PHARMACEUTICALLY ACCEPTABLE SALT OF TREPРОSTИNIL
U-1878 FOR OPIOID DEPENDENCE
U-1879 METHOD OF DIAGNOSING TUMORS USING POSITRON EMISSION TOMOGRAPHY
U-1880 TREATMENT OF SIGNS AND SYMPTOMS OF DRY EYE DISEASE (DED)
U-1881 IMPROVEMENT IN GLYCEMIC CONTROL IN TYPE 2 DIABETES MELLITUS PATIENTS BY USE OF A PEN INJECTOR
U-1882 MANAGEMENT OF MILD TO MODERATE PAIN, MANAGEMENT OF MODERATE TO SEVERE PAIN AS AN ADJUNCT TO OPIOID ANALGESICS, REDUCTION IN FEVER THROUGH ANALGESIC AND ANTIPYRETIC ACTIVITY
U-1883 TREATMENT OF GASTROINTESTINAL STROMAL TUMORS (GIST)
U-1884 USE OF LORCASERIN HYDROCHLORIDE FOR CHRONIC WEIGHT MANAGEMENT IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED A GREATER THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT
U-1885 USE OF LORCASERIN HYDROCHLORIDE FOR CHRONIC WEIGHT MANAGEMENT BY DECREASING FOOD INTAKE IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED A GREATER
THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT

U-1886 USE OF LORCASERIN HYDROCHLORIDE FOR CHRONIC WEIGHT MANAGEMENT BY INDUCING SATIETY IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED A GREATER THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT

U-1887 USE OF LORCASERIN HYDROCHLORIDE FOR CHRONIC WEIGHT MANAGEMENT BY TREATING OBESITY IN PATIENTS ON A REDUCED-CALORIE DIET AND WHO HAVE ACHIEVED A GREATER THAN OR EQUAL TO 5% WEIGHT LOSS BY WEEK 12 OF TREATMENT

U-1888 USE OF CONTROLLED RELEASE 25-HY DroXYVitamin D IN TREATING SECONDARY HYPERPARATHYROIDISM IN PATIENTS HAVING CHRONIC KIDNEY DISEASE

U-1889 TREATMENT OF HCV INFECTION USING DASABUVIR/OMBITASVIR/PARITAPREVIR/RITONAVIR FIXED DOSE COMBINATION

U-1890 OTC USE: ALLERGY SYMPTOM RELIEVER; TEMPORARILY RELIEVES THESE SYMPTOMS DUE TO HAY FEVER OR OTHER UPPER RESPIRATORY ALLERGIES; NASAL CONGESTION, RUNNY NOSE, SNEEZING, ITCHY NOSE, AND (ITCHY WATER EYES (AGES 12 AND UP))

U-1891 TREATMENT OR PREVENTION OF NAUSEA AND VOMITING

U-1892 METHOD OF TREATING LEFT VENTRICULAR DYSFUNCTION

U-1893 METHOD OF TREATING MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR DISORDER IN PEDIATRIC PATIENTS

U-1894 COMBINATION TREATMENT WITH A GLITAZONE FOR IMPROVEMENT OF GLYCEMIC CONTROL IN TYPE 2 DIABETES MELLITUS PATIENTS

U-1895 METHOD OF TREATING PROSTATE CANCER

U-1896 SUPPLEMENT FOR VITAMIN B12 DEFICIENCIES

U-1897 METHOD OF TREATING ACS USING ANGIOLASTY WITH AGGRASTAT (TIROFIBAN HYDROCHLORIDE)

U-1898 METHOD OF INHIBITING PLATELET AGGREGATION WITH AGGRASTAT (TIROFIBAN HYDROCHLORIDE)

U-1899 TREATMENT OF PANCREATIC CANCER THAT HAS PROGRESSED ON GEMCITABINE-BASED THERAPY, IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN

U-1900 TREATMENT OF THE SIGNS AND SYMPTOMS OF DRY EYE DISEASE (DED)

U-1901 TREATMENT OF SCHIZOAFFECTIVE DISORDER AS A MONOTHERAPY AND AS AN ADJUNCT TO MOOD STABILIZERS OR ANTIDEPRESSANTS

U-1902 TREATMENT OR SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE, CARDIOVASCULAR EVENTS, OR CEREBROVASCULAR EVENTS AND RISK-REDUCTION OF ASPIRIN-ASSOCIATED GASTRIC ULCERS

U-1903 USE OF NALOXONE HYDROCHLORIDE FOR EMERGENCY TREATMENT OF KNOWN OR SUSPECTED OPIOID OVERDOSE, AS MANIFESTED BY RESPIRATORY AND/OR CENTRAL NERVOUS SYSTEM DEPRESSION.

U-1904 (I) TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY; (II) RESTORING/INCREASING FUNCTIONAL DYSTROPHIN PROTEIN; OR (III) INDUCING SKIPPING; EACH OF (I)-(III) IN PATIENTS HAVING A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING

U-1905 METHOD OF TREATING A PATIENT HAVING CYSTIC FIBROSIS, THE PATIENT HAVING A R117H MUTATION IN CFTR, USING N-(5-HYDROXY-2,4-DI-TERT-BUTYL-PHENYL)-4-OXO-1H-QUINOLINE-3-CARBOXYLAMIDE

U-1906 METHOD OF TREATING A PATIENT HAVING CYSTIC FIBROSIS, SUCH AS A PATIENT HAVING A G551D MUTATION IN CFTR, USING N-(5-HYDROXY-2,4-DI-TERT-BUTYL-PHENYL)-4-OXO-1H-QUINOLINE-3-CARBOXYLAMIDE

U-1907 USE OF A DELIVERY DEVICE TO ADMINISTER A DOSE OF NALOXONE

U-1908 METHOD OF TREATING CYSTIC FIBROSIS IN A PATIENT, THE PATIENT HAVING THE F508DEL MUTATION IN CFTR, USING IVACAFTOR AND FORM I LUMACAFTOR

U-1909 METHOD OF TREATING CYSTIC FIBROSIS IN A PATIENT, THE PATIENT HAVING THE F508DEL MUTATION IN CFTR, USING IVACAFTOR AND LUMACAFTOR

U-1910 METHOD OF TREATING CYSTIC FIBROSIS IN A PATIENT, THE PATIENT HAVING THE F508DEL MUTATION IN CFTR, USING THE DOSAGE UNIT OF CLAIM 1 OF U.S. PATENT NO. 8,716,338

U-1911 METHOD OF TREATING A PATIENT HAVING CYSTIC FIBROSIS USING IVACAFTOR AND LUMACAFTOR

U-1912 METHOD OF TREATING CYSTIC FIBROSIS IN A PATIENT, THE PATIENT HAVING THE F508DEL MUTATION IN CFTR, USING A DOSAGE UNIT AS DEFINED IN CLAIM 1 OF U.S. PATENT NO.
PATENT AND EXCLUSIVITY TERMS

PATENT USE

9,192,606

U-1913 TREATMENT OF PEDIATRIC PATIENTS WITH BILATERAL OTITIS MEDIA WITH EFFUSION UNDERGOING TYPANOPLASTY TUBE PLACEMENT

U-1914 IN COMBINATION WITH RITUXIMAB, FOR THE TREATMENT OF PATIENTS WITH RELAPSED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

U-1915 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN PATIENTS WITH SEVERE CHRONIC RENAL IMPAIRMENT AND WHO ARE INELIGIBLE FOR METFORMIN THERAPY BY ADMINISTERING LINAGLIPTIN

U-1916 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH CHEMOTHERAPY (CINV)

U-1917 TREATMENT OF EXOCRINE PANCREATIC CANCER THAT HAS PROGRESSED ON GEMCITABINE-BASED THERAPY, IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN

U-1918 TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY IN PATIENTS HAVING A MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING

U-1919 RESTORING AN mRNA READING FRAME TO INDUCE DYSTROPHIN PROTEIN PRODUCTION IN PATIENTS HAVING A MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING

U-1920 USE OF EXTENDED RELEASE ORAL 25-HYDROXYVITAMIN D3 IN TREATING SECONDARY HYPERPARATHYROIDISM IN ADULT PATIENTS HAVING CHRONIC KIDNEY DISEASE STAGE 3 OR STAGE 4

U-1921 MANAGEMENT OF PAIN SEVERE ENOUGH TO REQUIRE DAILY, AROUND-THE-CLOCK, LONG-TERM OPIOID TREATMENT AND FOR WHICH ALTERNATIVE TREATMENT OPTIONS ARE INADEQUATE BY PROVIDING AN ABUSE-DETERRENT ORAL CONTROLLED RELEASE COMBINATION DRUG PRODUCT

U-1922 INTRAVAGINAL PRASTERONE (DEHYDROEPIANDROSTERONE) AT A DAILY DOSE OF 6.5MG FOR THE TREATMENT OF DYSPAREUNIA, A SYMPTOM OF VULVAR AND VAGINAL ATROPHY, DUE TO MENOPAUSE

U-1923 IMPROVEMENT IN GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS INADEQUATELY CONTROLLED BY BASEL INSULIN OR LIXISENATIDE BY USE OF A PEN INJECTOR WITH A THREADED DRIVE SLEEVE

U-1924 KYPROLIS IS INDICATED IN COMBINATION WITH LENALIDOMIDE PLUS DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED ONE TO THREE LINES OF THERAPY

U-1925 USE OF AN AUTO INJECTOR TO ADMINISTER NALOXONE HCL

U-1926 METHOD OF TREATING, REDUCING THE INCIDENCE OF, OR PREVENTING AN ISCHEMIC EVENT IN A PATIENT UNDERGOING PCI BY ADMINISTERING INTRAVENOUSLY 30 UG/KG BOLUS BEFORE PCI AND CONTINUOUS INFUSION OF 4 UG/KG/MIN FOR AT LEAST 2 HOURS OR THE DURATION OF THE PCI

U-1927 TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB

U-1928 RUBRACA IS INDICATED AS MONOTHERAPY FOR THE TREATMENT OF PATIENTS WITH DELETERIOUS BRCA MUTATION (GERMLINE AND/OR SOMATIC) ASSOCIATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH TWO OR MORE CHEMOTHERAPIES.

U-1929 TREATMENT OF DIABETES MELLITUS WITH AN INHALED INSULIN TO IMPROVE GLYCEMIC CONTROL USING A DRY POWDER INHALATION SYSTEM COMPRISING AN INHALER, A CARTRIDGE AND A DRY POWDER MEDICAMENT COMPRISING INSULIN IN A SINGLE INHALATION

U-1930 METHOD OF AEROSOLIZING/DEAGGLOMERATING AN INSULIN DRY POWDER FOR USE IN TREATING DIABETES MELLITUS VIA ORAL INHALATION USING AN INHALER WITH A CARTRIDGE CONTAINING THE INSULIN DRY POWDER.

U-1931 PROPHYLAXIS OR TREATMENT OF VENOUS AND ARTERIAL THROMBOTIC DISEASE

U-1932 METHOD OF TREATING MILD TO MODERATE ATOPIC DERMATITIS.

U-1933 TREATMENT OF POSTOPERATIVE INFLAMMATION AND REDUCTION OF OCULAR PAIN IN PATIENTS WHO HAVE UNDERGONE CATARACT SURGERY

U-1934 TREATMENT OF NON-24-HOUR SLEEP-WAKE DISORDER BY AVOIDING THE USE OF TASIMELTEON IN COMBINATION WITH A STRONG CYPIA2 INHIBITOR

U-1935 REDUCTION OF THE RATE OF CARDIOVASCULAR DEATH, MYOCARDIAL INFARCTION, AND STROKE IN PATIENTS WITH A HISTORY OF MYOCARDIAL INFARCTION

U-1936 TREATMENT OF MYOCARDIAL INFARCTION AND STROKE IN PATIENTS WITH ACUTE CORONARY SYNDROME OR A HISTORY OF MYOCARDIAL INFARCTION

U-1937 TREATMENT OF MYOCARDIAL INFARCTION IN PATIENTS WITH ACUTE CORONARY SYNDROME OR A
U-1938 TREATMENT OF STROKE IN PATIENTS WITH ACUTE CORONARY SYNDROME OR A HISTORY OF MYOCARDIAL INFARCTION

U-1939 ADMINISTRATION ONCE DAILY WITHIN TWO HOURS AFTER WAKING IN THE MORNING FOR IMPROVEMENT OF GLYCEMIC CONTROL IN A TYPE 2 DIABETES PATIENT

U-1940 IMPROVEMENT IN THE APPEARANCE OF MODERATE TO SEVERE CONVEXITY OR FULLNESS ASSOCIATED WITH SUBMENTAL FAT IN ADULTS BY MEANS OF REDUCING SUBMENTAL FAT VOLUME AS DESCRIBED IN THE APPROVED LABELING

U-1941 TREATMENT OF INFANTILE-ONSET SPINAL MUSCULAR ATROPHY

U-1942 TREATMENT OF SPINAL MUSCULAR ATROPHY BY INCREASING EXON-7 INCLUSION IN SMN2 MRNA

U-1943 TREATMENT OF SPINAL MUSCULAR ATROPHY

U-1944 TREATMENT OF SPINAL MUSCULAR ATROPHY BY INHIBITING AN SMN2 PRE-MRNA INTRONIC SPLICING SILENCER SITE

U-1945 IMPROVEMENT IN THE APPEARANCE OF MODERATE TO SEVERE CONVEXITY OR FULLNESS ASSOCIATED WITH REDUCTION IN SUBMENTAL FAT VOLUME AS DESCRIBED IN THE APPROVED LABELING

U-1946 TREATMENT OF SMALL LYMPHOCYTIC LYMPHOMA

U-1947 TREATMENT OF MARGINAL ZONE LYMPHOMA

U-1948 A METHOD FOR TREATING CHRONIC MYELOID LEUKEMIA

U-1949 FOR USE IN THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

U-1950 TREATMENT OF PATIENTS WITH ADVANCED (METASTATIC) NON-SMALL CELL LUNG CANCER WHOSE DISEASE PROGRESSED DURING OR AFTER PLATINUM-BASED CHEMOTHERAPY

U-1951 TREATMENT OF ONYCHOMYCOSIS OF A TOENAIL

U-1952 FOR USE IN THE TREATMENT OF PATIENTS WITH INDOLENT B-CELL NON-HODGKIN LYMPHOMA

U-1953 REDUCE THE RISK OF STROKE IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION WITH ONCE DAILY, RAPID-RELEASE TABLET ADMINISTERED FOR AT LEAST FIVE CONSECUTIVE DAYS

U-1954 TREATMENT OF DEEP VEIN THROMBOSIS WITH ONCE DAILY, RAPID-RELEASE TABLET ADMINISTERED FOR AT LEAST FIVE CONSECUTIVE DAYS

U-1955 TREATMENT OF PULMONARY EMBOLISM WITH ONCE DAILY, RAPID-RELEASE TABLET ADMINISTERED FOR AT LEAST FIVE CONSECUTIVE DAYS

U-1956 FOLLOWING INITIAL 6 MONTHS TREATMENT FOR DEEP VEIN THROMBOSIS (DVT) AND/OR PULMONARY EMBOLISM (PE), REDUCTION IN THE RISK OF RECURRENCE OF DVT AND OF PE WITH ONCE DAILY, RAPID-RELEASE TABLET ADMINISTERED FOR AT LEAST FIVE CONSECUTIVE DAYS

U-1957 PROPHYLAXIS OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM IN PATIENTS UNDERGOING KNEE OR HIP REPLACEMENT SURGERY, WITH ONCE DAILY, RAPID-RELEASE TABLET ADMINISTERED FOR AT LEAST FIVE CONSECUTIVE DAYS

U-1958 FOR THE TREATMENT OF GENOTYPE 1, 2, 3 OR 4 CHRONIC HEPATITIS C VIRUS (HCV) INFECTION AS A COMPONENT OF A COMBINATION ANTIVIRAL TREATMENT REGIMEN WITH RIBAVIRIN

U-1959 TOPICAL TREATMENT OF PERSISTENT FACIAL ERYTHEMA ASSOCIATED WITH ROSACEA IN ADULTS WITH 1% OXYMETAZOLINE HYDROCHLORIDE CREAM

U-1960 USE OF THE ATYPICAL ANTIPSYCHOTIC ASENAPINE FOR TREATMENT OF SCHIZOPHRENIA IN ADULTS

U-1961 USE OF THE ATYPICAL ANTIPSYCHOTIC ASENAPINE FOR TREATMENT OF MANIC OR MIXED EPISODES OF BIPOLAR I DISORDER: ACUTE MONOTHERAPY OF MANIC OR MIXED EPISODES (AGES 10 TO ADULT)

U-1962 USE OF THE ATYPICAL ANTIPSYCHOTIC ASENAPINE FOR TREATMENT OF MANIC OR MIXED EPISODES OF BIPOLAR I DISORDER: MAINTENANCE MONOTHERAPY IN ADULTS

U-1963 USE OF THE ATYPICAL ANTIPSYCHOTIC ASENAPINE FOR TREATMENT OF MANIC OR MIXED EPISODES OF BIPOLAR I DISORDER: AS ADJUNCTIVE TREATMENT TO LITHIUM OR VALPROATE IN ADULTS

U-1964 ELEVATION OF INTRACELLULAR CGMP RESULTING IN INCREASED INTESTINAL FLUID AND ACCELERATED TRANSIT

U-1965 FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH) IN COMBINATION WITH TADALAFIL, WHEREIN THE WEIGHT RATIO OF AMBRISENTAN TO TADALAFIL IS ABOUT 1:2 TO ABOUT 1:3
U-1966 USE OF THE ATYPICAL ANTIPSYCHOTIC ASENAPINE FOR TREATMENT OF MANIC OR MIXED EPISODES OF BIPOLAR I DISORDER: ACUTE MONOTHERAPY OF MANIC OR MIXED EPISODES IN PEDIATRIC PATIENTS AGE 10-17

U-1967 METHOD OF TREATING TYPE 2 DIABETES IN PATIENTS WITH INSUFFICIENT GLYCEMIC CONTROL DESPITE THERAPY WITH ONE OR MORE CONVENTIONAL ANTIHYPERGLYCEMIC AGENTS BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH METFORMIN

U-1968 METHOD OF TREATING TYPE 2 DIABETES IN PATIENTS WHO HAVE NOT BEEN PREVIOUSLY TREATED WITH AN ANTIHYPERGLYCEMIC AGENT BY ADMINISTERING LINAGLIPTIN IN COMBINATION WITH METFORMIN

U-1969 TOPICAL TREATMENT OF ONYCHOMYCOSIS OF THE TOENAIL(S) DUE TO TRICHOPHYTON RUBRUM AND TRICHOPHYTON MENTAGROPHYTES

U-1970 TREATMENT OF ONYCHOMYCOSIS OF A TOENAIL CAUSED BY TRICHOPHYTON RUBRUM OR TRICHOPHYTON MENTAGROPHYTES

U-1971 FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA

U-1972 FOR THE TREATMENT OF PATIENTS WITH INDOLENT B-CELL NON-HODGKIN LYMPHOMA

U-1973 METHOD OF TREATING CYSTIC FIBROSIS USING N-(5-HYDROXY-2,4-DITERT-BUTYL-PHENYL)-4-OXO-1H-QUINOLINE-3-CARBOXAMIDE AND 3-(6-(1,2,2-DIFLUOROBENZO[D][1,3]DIOXOL-5-YL) CYCLOPROPANECARBOXAMIDO)-3-METHYLPYRIDIN-2-YL)BENZOIC ACID

U-1974 TREATMENT OF HALLUCINATIONS AND DELUSIONS ASSOCIATED WITH PARKINSON'S DISEASE PSYCHOSIS

U-1975 METHOD OF INCREASING EYELASH GROWTH WITH BIMATOPROST

U-1976 METHOD FOR TREATING TYPE 2 DIABETES MELLITUS (T2DM) IN PATIENTS WHO HAVE INADEQUATE CONTROL WITH DAPA GLIFLOZIN

U-1977 METHOD FOR TREATING TYPE 2 DIABETES MELLITUS (T2DM) IN PATIENTS WHO ARE READY TREATED WITH DAPA GLIFLOZIN AND SAXAGLIPTIN

U-1978 TREATMENT OF ADVANCED PROSTATE CANCER WITH A REDUCED LIKELIHOOD OF CAUSING A GONADOTROPHIN RELEASING HORMONE AGONIST SIDE-EFFECT

U-1979 THE TREATMENT OF CARCINOID SYNDROME DIARRHEA IN COMBINATION WITH SOMATOSTATIN ANALOG (SSA) THERAPY IN ADULTS INADEQUATELY CONTROLLED BY SSA THERAPY

U-1980 A METHOD OF TREATING NOCTURIA DUE TO NOCTURNAL POLYURIA IN ADULTS

U-1981 IN COMBINATION WITH AN AROMATASE INHIBITOR AS INITIAL ENDOCRINE-BASED THERAPY FOR TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER-2)-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER

U-1982 USE OF REVLMID (LENALIDOMIDE) FOR TREATMENT OF PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA DUE TO LOW-OR INTERMEDIATE-1-RISK MYELODYSPLASTIC SYNDROMES ASSOCIATED WITH A DELETION 5Q ABNORMALITY WITH OR WITHOUT ADDITIONAL CYTOGENETIC ABNORMALITIES

U-1983 USE OF REVLMID (LENALIDOMIDE) FOR THE TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA WHOSE DISEASE HAS RELAPSED OR PROGRESSED AFTER TWO PRIOR THERAPIES, ONE OF WHICH INCLUDED BORTEZOMIB

U-1984 USE OF REVLMID (LENALIDOMIDE) FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA, IN COMBINATION WITH DEXAMETHASONE

U-1985 USE OF REVLMID (LENALIDOMIDE) FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA, AS MAINTENANCE FOLLOWING AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION (AUTO-HSCT)

U-1986 USE OF REVLMID (LENALIDOMIDE) FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA, IN COMBINATION WITH DEXAMETHASONE, WHEREIN THOSE PATIENTS HAVE NOT RECEIVED PREVIOUS TREATMENT FOR MULTIPLE MYELOMA

U-1987 METHOD OF CONTROLLING GLYCEMIA IN DIABETICS BY ADMINISTERING AN INITIAL DOSE OF INSULIN-FDKP WITH A MEAL; DETERMINING BLOOD GLUCOSE LEVEL 1-2 HRS AFTER AND ADMINISTERING A SUPPLEMENTAL DOSE OF INSULIN-FDKP IF POSTPRANDIAL GLUCOSE LEVEL IS >140 MG/DL

U-1988 METHOD TO TREAT INFANTILE HEMANGIOMA

U-1989 INTRAVITREAL TREATMENT OF MACULAR EDEMA FOLLOWING BRANCH RETINAL VEIN OCCLUSION (BRVO) OR CENTRAL RETINAL VEIN OCCLUSION (CRVO)

U-1990 INTRAVITREAL TREATMENT OF DIABETIC MACULAR EDEMA

U-1991 REDUCTION OF MORTALITY IN ACUTE MYOCARDIAL INFARCTION
PATENT USE

U-1992 USE OF TROKENDI XR FOR PROPHYLACTIC TREATMENT OF MIGRAINE
U-1993 ADJUNCTIVE TREATMENT TO LEVODOPA/CARBIDOPA IN PATIENTS WITH PARKINSON’S DISEASE EXPERIENCING “OFF” EPISODES
U-1994 REDUCTION IN RISK OF OVERT HEPATIC ENCEPHALOPATHY (HE) IN ADULTS
U-1995 TREATMENT OF TARDIVE DYSKINESIA
U-1996 IMPROVEMENT OF GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
U-1997 IMPROVEMENT OF GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS IN COMBINATION WITH METFORMIN AND/OR A PPAR-GAMMA AGONIST AND/OR SULFONYLUREA AND/OR INSULIN
U-1998 TREATING HR-POS., HER2-NEG. ADVANCED OR METASTATIC BREAST CANCER WITH PALBOCICLIB IN COMBO WITH AN AROMATASE INHIBITOR AS INITIAL ENDOCRINE BASED THERAPY IN POSTMENOPAUSAL WOMEN OR FULVESTRANT IN WOMEN WITH DISEASE PROGRESSION AFTER ENDOCRINE THERAPY
U-1999 CHRONIC IDIOPATHIC CONSTIPATION
U-2000 MANAGEMENT OF MODERATE TO SEVERE PAIN AS AN ADJUNCT TO OPIOID ANALGESICS
U-2001 USE FOR THE TREATMENT OF ASTHMA IN PATIENTS 6 YEARS OF AGE AND OLDER
U-2002 USE FOR MAINTENANCE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE
U-2003 A METHOD OF POSITIONING AN INTRAUTERINE SYSTEM BY HOLDING AN INSERTER HANDLE WITH ONE HAND, ADVANCING THE INSERTER THROUGH THE CERVIX AND INTO THE UTERUS, AND RETRACTING A SLIDER ON THE HANDLE TO RELEASE THE INTRAUTERINE SYSTEM
U-2004 REPLACEMENT THERAPY FOR ORAL CARBAMAZEPINE IN ADULTS WITH PARTIAL SEIZURES WITH COMPLEX SYMPTOMATOLOGY
U-2005 REPLACEMENT THERAPY FOR ORAL CARBAMAZEPINE IN ADULTS WITH GENERALIZED TONIC-CLONIC SEIZURES
U-2006 REPLACEMENT THERAPY FOR ORAL CARBAMAZEPINE IN ADULTS WITH MIXED SEIZURE PATTERNS THAT INCLUDE PARTIAL SEIZURES WITH COMPLEX SYMPTOMATOLOGY, GENERALIZED TONIC-CLONIC SEIZURES, OR OTHER PARTIAL OR GENERALIZED SEIZURES
U-2007 TREATMENT OF ADULT PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) WHO ARE FLT3 MUTATION-POSITIVE, IN COMBINATION WITH STANDARD CYTARABINE AND DAUNORUBICIN INDUCTION AND CYTARABINE CONSOLIDATION CHEMOTHERAPY
U-2008 TREATMENT OF ADULT PATIENTS WITH AGGRESSIVE SYSTEMIC MASTOCYTOSIS (ASM), SYSTEMIC MASTOCYTOSIS WITH ASSOCIATED HEMATOLOGICAL NEOPLASM (SM-AHN), OR MAST CELL LEUKEMIA (MCL)
U-2009 METHOD OF TREATING POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS AT HIGH RISK FOR FRACTURE.
U-2010 ACUTE TREATMENT OF MIGRAINE BY DELIVERING A POWDERED SUBSTANCE COMPRISING SUMATRIPTAN VIA A BREATH-POWERED DELIVERY DEVICE
U-2011 TREATMENT OF MIGRAINE VIA DELIVERY OF SUMATRIPTAN VIA THE NASAL CAVITY
U-2012 A METHOD FOR TREATING OVARIAN CANCER BY ADMINISTERING RUCAPARIB, WHEREIN THE CANCER IS ASSOCIATED WITH A DELETERIOUS BRCA MUTATION
U-2013 TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)
U-2014 A METHOD OF TREATING SECONDARY HYPERPARATHYROIDISM (SHPT)
U-2015 SODIUM THIOSULFATE INJECTION IS INDICATED FOR SEQUENTIAL USE WITH SODIUM NITRITE FOR THE TREATMENT OF ACUTE CYANIDE POISONING
U-2016 TREATMENT FOR ONYCHOMYCOSIS THAT IS TINEA UNGUIUM
U-2017 TREATMENT OF OPIOID DEPENDENCE
U-2018 MANAGEMENT OF MILD TO MODERATE PAIN, MANAGEMENT OF MODERATE TO SEVERE PAIN AS AN ADJUNCT TO OPIOID ANALGESICS IN A CRITICALLY ILL PATIENT WITH INTRAVENOUS IBUPROFEN IN NEED THEREOF
U-2019 METHOD OF DELIVERING TO A PATIENT WITH DIABETES MELLITUS IN A SINGLE INHALATION, GREATER THAN 75% OF A DRY POWDER DOSE COMPRISING INSULIN AND FUMARYL DIKETOPIPERAZINE USING A HIGH RESISTANCE TO FLOW DRY POWDER INHALER.
U-2020 MEKINIST IS INDICATED, IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-2021 METHOD OF ADMINISTERING LEVETIRACETAM UNDER FASTED CONDITIONS
U-2022 METHOD OF ADMINISTERING LEVETIRACETAM UNDER FED CONDITIONS
U-2023 A METHOD FOR INCREASING THE BIOAVAILABILITY OF GUAIFENESIN IN A SOLUTION CONTAINING 54% TO 66% BY WEIGHT OF PROPYLENE GLYCOL AND GLYCEROL, WHEREIN THE METHOD INCREASES THE CMAX BY AT LEAST 1.5 AND/OR INCREASES THE AUC (0-INF) BY AT LEAST 1.4
U-2024 METHOD FOR TRANSDERMALLY DELIVERING A DRUG TO A USER IN NEED THEREOF
U-2025 TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER
U-2026 TAFINLAR(R) IS INDICATED, IN COMBINATION WITH TRAMETINIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST.
U-2027 TAFINLAR(R) IS INDICATED, IN COMBINATION WITH TRAMETINIB, FOR THE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST.
U-2028 TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS CAUSED BY DESIGNATED SUSCEPTIBLE BACTERIA IN ADULTS
U-2029 PREVENTING CONDITION CHARACTERIZED BY UNDESIRED THROMBOSIS
U-2030 PROPHYLAXIS OF VENOUS THROMBOSIS
U-2031 TAFINLAR IS INDICATED AS A SINGLE AGENT FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST
U-2032 TAFINLAR IS INDICATED, IN COMBINATION WITH TRAMETINIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST.
U-2033 MEKINIST IS INDICATED, AS A SINGLE AGENT OR IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS
U-2034 INHIBITING COAGULATION
U-2035 PROPHYLAXIS OF VENOUS THROMBOEMBOLISM
U-2036 A METHOD OF TREATING PULMONARY HYPERTENSION COMPRISING PARENTERALLY ADMINISTERING A FORMULATION COMPRISING A) 0.1 TO 5% W/V OF TREPROMILIN OR A PHARMACEUTICALLY ACCEPTABLE SALT THEREOF AND B) A CITRATE BUFFER
U-2037 MEKINIST IS INDICATED, AS A SINGLE AGENT OR IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST
U-2038 MEKINIST IS INDICATED, IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH BRAF V600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST
U-2039 TREATMENT OF ADULT PATIENTS WITH CHRONIC HCV INFECTION WHO HAVE GENOTYPE 1, 2, 3, 4, 5, OR 6 INFECTION AND HAVE PREVIOUSLY BEEN TREATED WITH AN HCV REGIMEN CONTAINING AN NS5A INHIBITOR
U-2040 TREATMENT OF ADULT PATIENTS WITH CHRONIC HCV INFECTION WHO HAVE GENOTYPE 1A OR 3 INFECTION AND HAVE PREVIOUSLY BEEN TREATED WITH AN HCV REGIMEN CONTAINING SOFOSSBVIR WITHOUT AN NS5A INHIBITOR
U-2041 TREATMENT OF PARTIAL-ONSET SEIZURES
U-2042 DISCONTINUING ADMINISTRATION OF FLUVOXAMINE TO AVOID DRUG INTERACTIONS WITH PIRFENIDONE AND THEN ADMINISTERING PIRFENIDONE
U-2043 EXTENDED ADJUVANT TREATMENT OF ADULT PATIENTS WITH EARLY STAGE HER2-OVEREXPRESSED/AMPLIFIED BREAST CANCER, TO FOLLOW ADJUVANT TRASTUZUMAB BASE THERAPY
U-2044 DOSE REDUCTION OF PIRFENIDONE BY ABOUT ONE HALF DURING CONCURRENT ADMINISTRATION OF CIPROFLOXACIN AT A DOSE OF 750 MG TWICE DAILY (1500 MG/DAY) TO REDUCE DRUG INTERACTIONS IN TREATMENT OF A FIBROTIC, INFLAMMATORY, OR AUTOIMMUNE DISORDER
U-2045 ADMINISTRATION OF PIRFENIDONE AND AVOIDING CONCURRENT ADMINISTRATION OF CIPROFLOXACIN AT A DOSE OF 750 MG TO REDUCE DRUG INTERACTIONS IN TREATMENT OF A FIBROTIC, INFLAMMATORY, OR AUTOIMMUNE DISORDER
U-2046 ADMINISTERING PIRFENIDONE WHILE AVOIDING CONCOMITANT USE OF A CYPLA2 INHIBITOR THAT IS A MODERATE TO STRONG INHIBITOR OF BOTH CYP1A2 AND ANOTHER CYP ENZYME
PATENT USE

SELECTED FROM CYP2C9, CYP2C19, AND CYP2D6

U-2047 ADMINISTERING PIRFENIDONE CONCURRENTLY WITH FLUVOXAMINE, THE PIRFENIDONE AT A DOSE OF ABOUT 801 MG/DAY TO REDUCE DRUG INTERACTIONS WITH FLUVOXAMINE

U-2048 ADMINISTERING PIRFENIDONE WHILE AVOIDING CO-ADMINISTRATION OF A STRONG CYP1A2 INHIBITOR TO AVOID DRUG INTERACTIONS WITH PIRFENIDONE

U-2049 DISCONTINUING ADMINISTRATION OF A STRONG CYP1A2 INHIBITOR TO AVOID DRUG INTERACTIONS WITH PIRFENIDONE AND THEN ADMINISTERING PIRFENIDONE

U-2050 ADMINISTERING PIRFENIDONE WHILE AVOIDING CO-ADMINISTRATION OF FLUVOXAMINE TO AVOID DRUG INTERACTIONS WITH PIRFENIDONE

U-2051 DISCONTINUING SMOKING TO AVOID REDUCED PIRFENIDONE EFFICACY AND THEN ADMINISTERING PIRFENIDONE

U-2052 DISCONTINUING ADMINISTRATION OF A STRONG CYP1A2 INDUCER TO AVOID REDUCED PIRFENIDONE EFFICACY AND THEN ADMINISTERING PIRFENIDONE

U-2053 ADMINISTERING PIRFENIDONE WHILE AVOIDING CONCOMITANT ADMINISTRATION OF A STRONG INDUCER OF CYP1A2, INCLUDING CIGARETTE SMOKE, TO AVOID REDUCED PIRFENIDONE EFFICACY

U-2054 ADMINISTERING PIRFENIDONE WHILE AVOIDING CONCOMITANT ADMINISTRATION OF A STRONG INDUCER OF CYP1A2 TO AVOID REDUCED PIRFENIDONE EFFICACY

U-2055 DOSING OF AT LEAST 1600 MG/DAY FOLLOWING GRADE 2 LIVER ABNORMALITY IN BIOMARKER AST AND/OR ALT AFTER PIRFENIDONE ADMINISTRATION IN TREATMENT OF IPF

U-2056 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN BIOMARKER AST AND/OR ALT AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING SUB-1600 DG/DAY, FOLLOWING BY ADMINISTERING AT LEAST 1600 MG/DAY IN TREATMENT OF IPF

U-2057 DOSING 2403 MG/DAY PIRFENIDONE FOLLOWING GRADE 2 ABNORMALITY IN BIOMARKER AST AND/OR ALT AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING 2400MG/DAY IN TREATMENT OF IPF

U-2058 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN BIOMARKER AST AND/OR ALT AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING 2403MG/DAY IN TREATMENT OF IPF

U-2059 DOSING AT LEAST 1600 MG/DAY FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION IN TREATMENT OF IPF

U-2060 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS OF LIVER FUNCTION ARE WITHIN NORMAL LIMITS, FOLLOWED BY FULL DAILY DOSE IN TREATMENT OF IPF

U-2061 DOSING AT LEAST 1600 MG/DAY FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT AFTER PIRFENIDONE ADMINISTRATION IN TREATMENT OF IPF

U-2062 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING SUB-1600 MG/DAY DOSE, FOLLOWED BY ADMINISTERING AT LEAST 1600 MG/DAY IN TREATMENT OF IPF

U-2063 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS OF LIVER FUNCTION ARE WITHIN NORMAL LIMITS, FOLLOWED BY ADMINISTERING AT LEAST 1600 MG/DAY IN TREATMENT OF IPF

U-2064 DOSING AT LEAST 1602 MG/DAY FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION

U-2065 FULL DAILY DOSING FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION

U-2066 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING SUB-2400 MG/DAY DOSE, FOLLOWED BY FULL DAILY DOSE

U-2067 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE, FOLLOWED BY ADMINISTERING AT LEAST 1602 MG/DAY

U-2068 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS OF LIVER FUNCTION ARE WITHIN NORMAL LIMITS, FOLLOWED BY FULL DAILY DOSE
U-2069 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING A SUB-1600 MG/DAY DOSE, FOLLOWED BY ADMINISTERING AT LEAST 1602 MG/DAY

U-2070 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN BIOMARKER ALT OR AST AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS OF LIVER FUNCTION ARE WITHIN NORMAL LIMITS, THEN SUB-1600 MG/DAY, THEN AT LEAST 1602 MG/DAY

U-2071 FULL DAILY DOSING FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION IN TREATMENT OF IPF

U-2072 FULL DAILY DOSING FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION IN TREATMENT OF IPF

U-2073 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS ARE WITHIN NORMAL LIMITS, FOLLOWED BY ADMINISTERING FULL DAILY DOSE IN TREATMENT OF IPF

U-2074 DOSE 1602 MG/DAY PIRFENIDONE FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION IN TREATMENT OF IPF

U-2075 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS ARE WITHIN NORMAL LIMITS FOLLOWED BY ADMINISTERING 1602 MG/DAY IN TREATMENT OF IPF

U-2076 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING 801 MG/DAY FOLLOWED BY ADMINISTERING 1602 MG/DAY IN TREATMENT OF IPF

U-2077 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING SUB-2400 MG/DAY DOSE THEN FULL DAY DAILY DOSE IN TREATMENT OF IPF

U-2078 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS ARE WITHIN LIMITS, THEN SUB-2400MG/DAY DOSE, THEN FULL DAILY DOSE IN TREATMENT OF IPF

U-2079 PIRFENIDONE DOSE ESCALATION REGIMEN FOR TREATMENT OF FIBROSIS AS 801 MG/DAY FOR DAYS 1-7 OF THE REGIMEN, 1602 MG/DAY FOR DAYS 8-14 OF THE REGIMEN, AND 2403 MG/DAY FOR AT LEAST DAY 15 OF THE REGIMEN

U-2080 PIRFENIDONE DOSE ESCALATION REGIMEN FOR TREATMENT OF IPF AS 801 MG/DAY FOR DAYS 1-7 OF THE REGIMEN, 1602 MG/DAY FOR DAYS 8-14 OF THE REGIMEN, AND 2403 MG/DAY FOR AT LEAST DAY 15 OF THE REGIMEN

U-2081 DISCONTINUING USE OF A CYP1A2 INHIBITOR THAT IS A MODERATE TO STRONG INHIBITOR OF BOTH CYP1A2 AND ANOTHER CYP ENZYME SELECTED FROM CYP2C9, CYP2C19, AND CYP2D6 AND THEN ADMINISTERING PIRFENIDONE

U-2082 MODIFYING PIRFENIDONE ADMINISTRATION FROM A DOSE OF ABOUT 2400 MG/DAY DOWNWARD BY ABOUT 1600 MG/DAY WHILE CO-ADMINISTERING FLUVOXAMINE TO REDUCE DRUG INTERACTIONS WITH FLUVOXAMINE

U-2083 DOSSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION, BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS ARE WITHIN NORMAL LIMITS, FOLLOWED BY 801 MG/DAY, DOSE, THEN 1602 MG/DAY IN TREATMENT OF IPF

U-2084 TREATMENT OF SEVERE CHRONIC PAIN VIA INTRATHecal INFUSION OF ZICONOTIDE IN PATIENTS ALSO RECEIVING MORPHINE

U-2085 TREATMENT OF NON-24-HOUR SLEEP-WAKE DISORDER BY AVOIDING THE USE OF TASIMELTEON IN COMBINATION WITH RIFAMPIN

U-2086 A METHOD FOR ADMINISTERING ESTRADIOL COMPRISING A MONOLITHIC TRANSDERMAL DRUG DELIVERY SYSTEM CONSISTING OF (I) A BACKING LAYER AND (II) A SINGLE ADHESIVE POLYMER MATRIX LAYER AS CLAIMED IN US PATENT NO. 9730900

U-2087 TREATMENT OF RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA (AML) WITH AN ISOCITRATE DEHYDROGENASE-2 (IDH2) MUTATION

U-2088 TREATMENT OF PARTIAL-ONSET SEIZURES WITH OR WITHOUT SECONDARILY GENERALIZED SEIZURES IN PATIENTS WITH EPILEPSY

U-2089 TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES AS ADJUNCTIVE THERAPY IN PATIENTS WITH EPILEPSY
PATENT USE

U-2090 FOR THE TREATMENT OF ADULTS WITH NEWLY-DIAGNOSED THERAPY-RELATED ACUTE MYELOID LEUKEMIA (T-AML) OR AML WITH MYELODYSPLASIA-RELATED CHANGES (AML-MRC)

U-2091 TREATMENT OF METASTATIC ADENOCARCINOMA OF THE PANCREAS THAT HAS PROGRESSED ON GEMCITABINE-BASED THERAPY, IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN, IN A PATIENT NOT HOMOZYGOUS FOR THE UGT1A1*28 ALLELE

U-2092 METHOD FOR CONFIRMING DOSE DELIVERY

U-2093 TREATMENT OF TYPE II SPINAL MUSCULAR ATROPHY

U-2094 TREATMENT OF TYPE III SPINAL MUSCULAR ATROPHY

U-2095 MITOSOL IS AN ANTIMETABOLITE INDICATED AS AN ADJUNCT TO AB EXTERNO GLAUCOMA SURGERY. IT IS INTENDED FOR TOPICAL APPLICATION TO THE SITE OF GLAUCOMA FILTRATION SURGERY

U-2096 SOTYLIZE IS INDICATED FOR THE MAINTENANCE OF NORMAL SINUS RHYTHM [DELAY IN TIME TO RECURRENCE OF ATRIAL FIBRILLATION/ATRIAL FLUTTER (AFIB/AFL)] IN PATIENTS WITH SYMPTOMATIC AFIB/AFL WHO ARE CURRENTLY IN SINUS RHYTHM

U-2097 TREATMENT OF DMD IN PATIENTS HAVING A MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING

U-2098 INCREASING PRODUCTION OF FUNCTIONAL DYSTROPHIN PROTEIN IN DMD PATIENTS HAVING A MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING

U-2099 INDICATED FOR THE LONG-TERM, ONCE-DAILY, MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING BRONCHITIS AND/OR EMPHYSEMA

U-2100 INDICATED FOR THE ONCE-DAILY TREATMENT OF ASTHMA IN PATIENTS 18 YEARS AND OLDER

U-2101 MAINTENANCE TREATMENT OF RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER, WHO ARE IN A COMPLETE OR PARTIAL RESPONSE TO PLATINUM-BASED CHEMOTHERAPY

U-2102 TREATMENT OF DELETERIOUS OR SUSPECTED DELETERIOUS GERMALINE BRCA-MUTATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH THREE OR MORE PRIOR LINES OF CHEMOTHERAPY BASED ON AN FDA-APPROVED COMPANION DIAGNOSTIC FOR LYNPARZA

U-2103 MAINTENANCE TREATMENT OF BRCA-MUTATED RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER, WHO ARE IN A COMPLETE OR PARTIAL RESPONSE TO PLATINUM-BASED CHEMOTHERAPY

U-2104 TREATMENT OF HYPERURICEMIA ASSOCIATED WITH GOUT IN PATIENTS WHO HAVE NOT ACHIEVED TARGET SERUM URIC ACID LEVELS WITH A MEDICALLY APPROPRIATE DAILY DOSE OF ALLOPURINOL ALONE

U-2105 TREATMENT OF DYSKINESIA IN PATIENTS WITH PARKINSON'S DISEASE RECEIVING IMMEDIATE RELEASE LEVODOPA-BASED THERAPY, WITH OR WITHOUT CONCOMITANT DOPAMINERGIC MEDICATIONS

U-2106 TREATMENT OF DYSKINESIA IN PATIENTS WITH PARKINSON'S DISEASE RECEIVING LEVODOPA-BASED THERAPY, WITH OR WITHOUT CONCOMITANT DOPAMINERGIC MEDICATIONS

U-2107 TREATMENT OF LOCALLY RECURRENT OR METASTATIC, PROGRESSIVE, DIFFERENTIATED THYROID CARCINOMA REFRACTORY TO RADIOACTIVE IODINE TREATMENT

U-2108 TREATMENT OF HORMONE RECEPTOR POSITIVE HER2-NEGATIVE ADVANCED BREAST CANCER IN POSTMENOPAUSAL WOMEN NOT PREVIOUSLY TREATED WITH ENDOCRINE THERAPY

U-2109 CAROSPIR IS INDICATED FOR TREATMENT OF NYHA CLASS III-IV HEART FAILURE AND REDUCED EJECTION FRACTION TO INCREASE SURVIVAL, MANAGE EDEMA, AND TO REDUCE THE NEED FOR HOSPITALIZATION FOR HEART FAILURE

U-2110 METHOD FOR CHRONIC WEIGHT MANAGEMENT IN PATIENTS WITH MODERATE RENAL IMPAIRMENT WHO ARE OBESE, OR OVERWEIGHT AND HAVE AT LEAST ONE WEIGHT RELATED COMORBID CONDITION

U-2111 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIMS 1-5 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIMS 1-5

U-2112 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 6 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 6

U-2113 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN
SECRETAGOGUE AS RECITED IN CLAIM 7 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 7

U-2114 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 9 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 9

U-2115 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 10 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 10

U-2116 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 12 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 12

U-2117 ADJUNCT TO DIET AND EXERCISE TO TREAT GLUCOSE INTOLERANCE IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIMS 14-15 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIMS 14-15

U-2118 ADJUNCT TO DIET AND EXERCISE TO TREAT GLUCOSE INTOLERANCE IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIMS 16-18 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIMS 16-18

U-2119 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 19 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 19

U-2120 TREATMENT OF PATIENTS 18 YEARS OF AGE AND OLDER WITH COMPLICATED URINARY TRACT INFECTIONS CAUSED BY SUSCEPTIBLE MICROORGANISMS

U-2121 TREATMENT OF PARTIAL-ONSET SEIZURES IN A PATIENT SUFFERING FROM OR SUSCEPTIBLE TO ABSENCE SEIZURES

U-2122 USE FOR REDUCING EXACERBATIONS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

U-2123 TREATMENT OF PARTIAL-ONSET SEIZURES IN PATIENTS WITH EPILEPSY WHO HAVE BEEN PREVIOUSLY TREATED WITH OXCARBAZEPINE

U-2124 TREATMENT OF ADULT PATIENTS WITH RELAPSED FOLLICULAR LYMPHOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES

U-2125 THE TREATMENT OF AN INFLAMMATORY DISORDER OF THE RESPIRATORY TRACT BY ONCE-PER-DAY ADMINISTRATION OF A PHARMACEUTICAL FORMULATION COMPRISING FLUTICASONE FUROATE AND A LONG-ACTING BETA2 ADRENORECEPTOR AGONIST

U-2126 USE OF FLUTICASONE FUROATE FOR THE TREATMENT OF AN INFLAMMATORY OR ALLERGIC CONDITION, INCLUDING CHRONIC OBSTRUCTIVE PULMONARY DISEASE

U-2127 INDICATED FOR THE LONG-TERM, ONCE-DAILY, MAINTENANCE TREATMENT OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA

U-2128 METHOD OF INHIBITING THE BINDING OF ACETYLCOLINE TO AN ACETYLCOLINE RECEPTOR IN THE RESPIRATORY TRACT OF A HUMAN, COMPRISING CONTACTING THE RECEPTOR WITH AN EFFECTIVE AMOUNT OF UMECLIDINIUM, VIA INHALATION

U-2129 METHOD OF INHIBITING THE BINDING OF ACETYLCOLINE TO AN ACETYLCOLINE RECEPTOR IN THE RESPIRATORY TRACT OF A HUMAN, COMPRISING CONTACTING THE RECEPTOR WITH AN EFFECTIVE AMOUNT OF UMECLIDINIUM, VIA TOPICAL APPLICATION

U-2130 TREATMENT OF PARTIAL ONSET SEIZURES IN PATIENTS WITH EPILEPSY AGED 16 YEARS AND OLDER WITH EPILEPSY

U-2131 REDUCTION OF ELEVATED INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH GLAUCOMA OR OCULAR HYPERTENSION, WITH COMPARABLE EFFICACY, AND A REDUCTION IN SPECIFIED ADVERSE EVENTS, COMPARED TO BRimonidine 0.2% TID

U-2132 IN COMBINATION WITH FULVESTRANT FOR THE TREATMENT OF WOMEN WITH HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER WITH DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY

U-2133 METHOD OF DELIVERING FLUTICASONE PROPIONATE TO A NASAL AIRWAY

U-2134 THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE BY ONCE-PER-DAY ADMINISTRATION OF A PHARMACEUTICAL FORMULATION COMPRISING FLUTICASONE FUROATE
AND A LONG-ACTING BETA2 ADRENORECEPTOR

U-2135 AS MONOTHERAPY FOR THE TREATMENT OF ADULT PATIENTS WITH HR-POSITIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER WITH DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY AND PRIOR CHEMOTHERAPY IN THE METASTATIC SETTING

U-2136 TREATMENT OF NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY

U-2137 TREATMENT OF POSTHERPETIC NEURALGIA

U-2138 TOPICAL TREATMENT OF ACTINIC KERATOSIS OF THE FACE OR SCALP USING MORE THAN ONE TREATMENT COURSE OF INGENOL MEBUTATE

U-2139 TREATMENT OF TYPE 2 DIABETES MELLITUS IN COMBINATION WITH EXENATIDE

U-2140 METHOD OF TREATING PARTIAL ONSET SEIZURES IN PATIENTS 4 YEARS OF AGE AND OLDER

U-2141 TREATMENT OF CHRONIC HEPATITIS C VIRUS (HCV) GENOTYPE 1, 2, 3, 4, 5, OR 6 AFTER COMPLETION OF INITIAL TREATMENT LASTING AT LEAST 6 MONTHS

U-2142 REDUCTION IN THE RISK OF RECURRENCE OF DEEP VEIN THROMBOSIS (DVT) AND/OR PULMONARY EMBOLISM (PE) IN PATIENTS AT CONTINUED RISK FOR RECURRENT DVT AND/OR AFTER COMPLETION OF INITIAL TREATMENT LASTING AT LEAST 6 MONTHS

U-2143 AFTER COMPLETION OF INITIAL TREATMENT LASTING AT LEAST 6 MONTHS, TO REDUCE THE RISK OF RECURRENCE OF DEEP VEIN THROMBOSIS AND/OR PULMONARY EMBOLISM IN CERTAIN PATIENTS WITH ONCE DAILY, RAPID-RELEASE TABLET ADMINISTERED FOR AT LEAST 5 CONSECUTIVE DAYS

U-2144 REDUCTION OF INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION

U-2145 TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

U-2146 IMPROVEMENT IN GLYCEMIC CONTROL IN DIABETES MELLITUS PATIENTS BY USE OF A PEN INJECTOR WITH A ROTATING DRIVE SLEEVE

U-2147 TREATMENT OF NON-24 HOUR SLEEP-WAKE DISORDER BY ORALLY ADMINISTERING 20MG OF TASIMELTEON ONCE DAILY BEFORE BEDTIME

U-2148 A METHOD OF PROVIDING NITRIC OXIDE THERAPY TO A PATIENT BY MEASURING AND DISPLAYING AN INDICATION OF THE CALCULATED DELIVERY CONCENTRATION OF NITRIC OXIDE AS COMPARED TO THE DESIRED DELIVERY CONCENTRATION OF NITRIC OXIDE

U-2149 TREATMENT OF NON-24 HOUR SLEEP-WAKE DISORDER BY ADMINISTERING TASIMELTEON

U-2150 TREATMENT OF CHRONIC GRAFT-VERSUS-HOST DISEASE

U-2151 METHOD OF TREATING PAIN OR INFLAMMATION WITH AN INJECTABLE CONTROLLED OR SUSTAINED RELEASE FORMULATION OF TRIAMCINOLONE ACETONIDE

U-2152 TREATMENT OF PAIN ASSOCIATED WITH IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) WITH VIBERZI (ELUXADOLINE)

U-2153 REDUCING FASTING PLASMA GLUCOSE IN A HUMAN IN NEED THEREOF USING A SUSTAINED-RELEASE COMPOSITION CONTAINING EXENDIN-4

U-2154 REDUCING FASTING PLASMA GLUCOSE IN A HUMAN IN NEED THEREOF USING A SUSTAINED-RELEASE COMPOSITION CONTAINING EXENDIN-4

U-2155 REDUCING BODY WEIGHT IN A HUMAN IN NEED THEREOF USING A SUSTAINED-RELEASE COMPOSITION CONTAINING EXENDIN-4

U-2156 REDUCING HBA1C IN A HUMAN IN NEED THEREOF USING A SUSTAINED-RELEASE COMPOSITION CONTAINING EXENDIN-4

U-2157 TREATING TYPE 2 DIABETES MELLITUS BY STIMULATING INSULIN RELEASE

U-2158 DECREASING GASTRIC MOTILITY OR DELAYING GASTRIC EMPTYING BY USING A SUSTAINED-RELEASE COMPOSITION

U-2159 TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA/SMALL LYMPHOCYTIC LYMPHOMA

U-2160 MANAGEMENT OF OSTEOARTHRITIS PAIN BY ADMINISTERING 5 MG OF MELOXICAM

U-2161 TREATMENT OF NAUSEA AND VOMITING, INCLUDING THE PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF HIGHLY OR MODERATELY EMETOGENIC CANCER CHEMOTHERAPY

U-2162 FOR CLEANSING THE LARGE INTESTINE AS A PREPARATION FOR COLONOSCOPY

U-2163 TREATMENT OF HR-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER-2)-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER IN COMBINATION WITH PALBOCICLIB OR ABEMACICLIB IN WOMEN WITH DISEASE PROGRESSION AFTER ENDOCRINE THERAPY
PATENT AND EXCLUSIVITY TERMS

U-2164 ZELBORAF IS INDICATED FOR THE TREATMENT OF PATIENTS WITH ERDHEIM-CHESTER DISEASE WITH BRAF V600 M UTATION

U-2165 MANAGEMENT OF OSTEOARTHRITIS PAIN BY ADMINISTERING 10 MG OF MELOXICAM

U-2166 TREATMENT OF MAJOR DEPRESSIVE EPISODES ASSOCIATED WITH BIPOLAR I DISORDER

U-2167 METHOD OF USING A TABLET EMBEDDED WITH A SENSOR THAT COMMUNICATES INFORMATION VIA A SIGNAL THROUGH THE BODY OF A PATIENT TO A RECEIVER

U-2168 METHOD OF USING A LOGIC CIRCUIT TO STABILIZE BATTERY VOLTAGE SUPPLIED TO A SENSOR EMBEDDED WITH A TABLET AND THAT COMMUNICATES INFORMATION VIA A SIGNAL THROUGH THE BODY OF A PATIENT TO A RECEIVER

U-2169 METHOD OF USING A RECEIVER TO IDENTIFY A SIGNAL FROM A TABLET EMBEDDED WITH A SENSOR THAT COMMUNICATES INFORMATION THROUGH THE BODY OF A PATIENT

U-2170 METHOD OF USING A RECEIVER TO RECEIVE A SIGNAL FROM A TABLET EMBEDDED WITH A SENSOR THAT COMMUNICATES INFORMATION THROUGH THE BODY OF A PATIENT

U-2171 ADJUVANT TREATMENT OF ADULT PATIENTS AT HIGH RISK OF RECURRENT RCC FOLLOWING NEPHRECTOMY

U-2172 METHOD TO TREAT SEVERE ALLERGIC EMERGENCIES IN PATIENTS WEIGHING 7.5 TO 15 KG (16.5 TO 33 LBS)

U-2173 TREATING OPIOID DEPENDENCE BY ADMINISTERING BUPRENORPHINE

U-2174 TREATING OPIOID DEPENDENCY BY ADMINISTERING BUPRENORPHINE ONCE PER MONTH

U-2175 TREATING OPIOID DEPENDENCY BY ADMINISTERING BUPRENORPHINE ONCE MONTHLY

U-2176 TREATING OPIOID ADDICTION BY ADMINISTERING BUPRENORPHINE

U-2177 TREATING OPIOID ADDICTION BY SUBCUTANEOUS INJECTION OF BUPRENORPHINE

U-2178 TREATING OPIOID ADDICTION BY ADMINISTERING BUPRENORPHINE COMPOSITION WITH 28 DAY DOSE DURATION

U-2179 IN SITU FORMATION OF SOLID BUPRENORPHINE COMPOSITION

U-2180 TREATING ADDICTION WITH 100 MG OR 300 MG DOSE OF BUPRENORPHINE

U-2181 TREATING OPIOID DEPENDENCY BY SUBCUTANEOUSLY ADMINISTERING BUPRENORPHINE

U-2182 IMPROVEMENT OF GLYCEMIC CONTROL IN TYPE 2 DIABETES MELLITUS PATIENTS

U-2183 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 1 AND 13

U-2184 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 1, 13, AND 14

U-2185 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING A DOSAGE FORM COMPRISING MICRONIZED BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 15 AND 27

U-2186 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING A DOSAGE FORM COMPRISING MICRONIZED BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 15, 27, AND 28

U-2187 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 29 AND 39

U-2188 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 29, 39, AND 40

U-2189 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 41 AND 52

U-2190 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 41, 52, AND 53

U-2191 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 54 AND 64

U-2192 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2
PATENT USE

DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 54, 64, AND 65

U-2193 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING A DOSAGE FORM COMPRISING MICRONIZED BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 66 AND 75

U-2194 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING A DOSAGE FORM COMPRISING MICRONIZED BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 66, 75, AND 76

U-2195 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 77 AND 87

U-2196 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 77, 87, AND 88

U-2197 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 89 AND 99

U-2198 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ORALLY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 89, 99, AND 100

U-2199 TREATMENT OF SCHIZOPHRENIA WITH IMPROVEMENT IN ATTENTION FUNCTION IN SCHIZOPHRENIA

U-2200 COMBINATION TREATMENT WITH INSULIN GLARGINE WITH OR WITHOUT METFORMIN FOR IMPROVEMENT OF GLYCEMIC CONTROL IN TYPE 2 DIABETES MELLITUS PATIENTS

U-2201 TREATMENT OF BIPOLAR DEPRESSION WITH IMPROVEMENT IN ATTENTION FUNCTION IN BIPOLAR DISORDER

U-2202 OZEMPIC IS INDICATED AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

U-2203 A METHOD OF PROVIDING A SUBJECT WITH A THERAPEUTICALLY EFFECTIVE AMOUNT OF RACEMIC METHYLPHENIDATE BY ORALLY ADMINISTERING TO SAID SUBJECT A SINGLE METHYLPHENIDATE EXTENDED RELEASE CHEWABLE TABLET AS CLAIMED

U-2204 TREATING PATIENTS WITH ACUTE PROMYELOCYTIC LEUKEMIA (APL) WHO ARE REFRACTORY TO, OR HAVE RELAPSED FROM, RETINOID AND ANTHRACYCLINE CHEMOTHERAPY, AND WHOSE APL IS CHARACTERIZED BY THE PRESENCE OF THE T(15;17) TRANSLOCATION OR PML/RAR-ALPHA GENE EXPRESSION

U-2205 TREATMENT OF SEBORRHEIC KERATOSES THAT ARE RAISED

U-2206 TREATING OPIOID DEPENDENCY BY ADMINISTERING BUPRENORPHINE

U-2207 TREATING ADDICTION BY SUBCUTANEOUS INJECTION OF BUPRENORPHINE

U-2208 TREATING ADDICTION BY ONCE PER MONTH ADMINISTRATION OF BUPRENORPHINE

U-2209 TREATING OPIOID ADDICTION BY ADMINISTERING BUPRENORPHINE ONCE PER MONTH

U-2210 TREATING OPIOID ADDICTION BY 100 MG OR 300 MG DOSE BUPRENORPHINE

U-2211 TREATING OPIOID ADDICTION BY ADMINISTRATION OF BUPRENORPHINE

U-2212 REDUCING FASTING PLASMA GLUCOSE IN A HUMAN IN NEED THEREOF IN COMBINATION WITH A SUSTAINED-RELEASE COMPOSITION CONTAINING EXENDIN-4

U-2213 REDUCING HBA1C IN A HUMAN IN NEED THEREOF IN COMBINATION WITH A SUSTAINED-RELEASE COMPOSITION CONTAINING EXENDIN-4

U-2214 AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES

U-2215 ERTUGLIFLOZIN IN COMBINATION WITH SITAGLIPTIN AND IN FURTHER COMBINATION WITH METFORMIN AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

U-2216 ERTUGLIFLOZIN AND SITAGLIPTIN IN COMBINATION AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

U-2217 TREATING HIGH OUTPUT SHOCK WITH ANGIOTENSIN II BY INCREASING MEAN ARTERIAL PRESSURE IN PATIENTS TREATED WITH CATECHOLAMINES AND REDUCING CATECHOLAMINE USE

U-2218 MAINTAINING MEAN ARTERIAL PRESSURE OF ABOUT 65 MMHG OR HIGHER WITH ANGIOTENSIN II IN SHOCK PATIENTS TREATED WITH CATECHOLAMINES AND REDUCING CATECHOLAMINE USE
PATENT USE

U-2219  TREATMENT OF CHRONIC SMALL LYMPHOCYTIC LEUKEMIA

U-2220  A METHOD FOR THE DIAGNOSIS OF ADULT GROWTH HORMONE DEFICIENCY BY MEASURING THE LEVEL OF GROWTH HORMONE AFTER ORAL ADMINISTRATION OF MACIMORELIN

U-2221  TREATING REFRACTORY HYPOTENSION WITH ABOUT 20 NG/KG/MIN ANGIOTENSIN II IN A PATIENT RECEIVING VASOPRESSOR

U-2222  RELIEVES REDNESS OF THE EYE DUE TO MINOR EYE IRRITATIONS

U-2223  METHOD OF TREATING ANGINA PECTORIS

U-2224  TREATMENT OF DYSKINESIA AND INCREASING ON TIME WITHOUT TROUBLESOME DYSKINESIA IN PATIENTS WITH PARKINSON'S DISEASE RECEIVING LEVODOPA-BASED THERAPY, WITH OR WITHOUT CONCOMITANT DOPAMINERGIC MEDICATIONS

U-2225  METHOD OF ADMINISTERING A LOCAL ANESTHETIC TO THE MUCOUS MEMBRANES IN PATIENTS WITH HEPATIC IMPAIRMENT

U-2226  METHOD OF ADMINISTERING A LOCAL ANESTHETIC TO THE MUCOUS MEMBRANES IN PATIENTS WITH RENAL IMPAIRMENT

U-2227  METHOD OF ADMINISTERING A LOCAL ANESTHETIC TO THE MUCOUS MEMBRANES IN GERIATRIC PATIENTS

U-2228  TREATMENT OF SMALL LYMPHOCYTIC LEUKEMIA

U-2229  IN COMBINATION WITH TRETINOIN, TREATING ADULTS AND PEDIATRIC PATIENTS 1 YEAR AND OLDER WITH NEWLY-DIAGNOSED LOW-RISK ACUTE PROMYELOCYTIC LEUKEMIA (APL) CHARACTERIZED BY THE PRESENCE OF THE T(15;17) TRANSLOCATION OR PML/RAR-A GENE EXPRESSION

U-2230  IRRITABLE BOWEL SYNDROME WITH CONSTIPATION

U-2231  TREATING REFRACTORY HYPOTENSION WITH ABOUT 5 NG/KG/MIN TO ABOUT 20 NG/KG/MIN ANGIOTENSIN II IN A PATIENT RECEIVING VASOPRESSOR

U-2232  TREATMENT OF PSORIATIC ARTHRITIS USING A DOSAGE TITRATION SCHEDULE

U-2233  TREATMENT OF PSORIATIC ARTHRITIS WITH APREMILAST USING A DOSAGE TITRATION SCHEDULE AND A SECOND ACTIVE AGENT

U-2234  USE OF IVACAFTOR FOR TREATING CYSTIC FIBROSIS IN A PATIENT WITH A MILD TO MODERATE CF PHENOTYPE WITH AT LEAST ONE MUTATION IN THE CFTR GENE THAT IS RESPONSIVE TO IVACAFTOR BASED ON IN VITRO ASSAY DATA

U-2235  USE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC HIGH-RISK CASTRATION-SENSITIVE PROSTATE CANCER

U-2236  REDUCING THE RISK OF PRETERM BIRTH IN WOMEN WITH A SINGLETON PREGNANCY WHO HAVE A HISTORY OF SINGLETON SPONTANEOUS PRETERM BIRTH

U-2237  TREATMENT OF NON-METASTATIC, CASTRATION-RESISTANT PROSTATE CANCER (NM-CRPC)

U-2238  METHOD OF IMPROVING GLYCEMIC CONTROL IN PATIENTS WITH DIABETES MELLITUS BY ADMINISTERING A MIXTURE OF INSULIN DEGludec AND INSULIN ASPART DURING OR AROUND THE TIME OF THE LARGEST MEAL OF THE DAY

U-2239  REDUCTION OF ELEVATED INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH GLAUCOMA OR OCULAR HYPERTENSION, WITH A REDUCTION IN SPECIFIED ADVERSE EVENTS, COMPARED TO BRIMONDINE 0.2% TID

U-2240  REDUCTION OF ELEVATED INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH GLAUCOMA OR OCULAR HYPERTENSION, WITH COMPARABLE EFFICACY TO BRIMONDINE 0.2% TID

U-2241  TREATMENT OF SMALL LYMPHOCYTIC LYMPHOMA WITH 17P DELETION

U-2242  TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA/SMALL LYMPHOCYTIC LYMPHOMA WITH 17P DELETION

U-2243  A METHOD OF TREATING BACTERIAL INFECTIONS IN HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA AND VENTILATOR-ASSOCIATED BACTERIAL PNEUMONIA (HABP/VABP) PATIENTS COMPRISING ADMINISTERING A BACTERICIDALLY EFFECTIVE AMOUNT OF AVIBACTAM SODIUM

U-2244  METHOD OF TREATING A BACTERIAL INFECTION IN HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA AND VENTILATOR-ASSOCIATED BACTERIAL PNEUMONIA (HABP/VABP) PATIENTS COMPRISING ADMINISTERING AN EFFECTIVE AMOUNT OF AVIBACTAM SODIUM

U-2245  TEZACAFTOR AND IVACAFTOR FOR THE TREATMENT OF CYSTIC FIBROSIS IN PATIENTS WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION OR HAVING AT LEAST ONE CFTR GENE MUTATION THAT IS RESPONSIVE TO TEZACAFTOR/IVACAFTOR BASED ON IN VITRO DATA AND/OR CLINICAL EVIDENCE
U-2247 TEZACAFTOR AND IVACAFTOR FOR THE TREATMENT OF PATIENTS WITH A MILD TO MODERATE CLINICAL PHENOTYPE OF CYSTIC FIBROSIS HAVING AT LEAST ONE CFTR GENE MUTATION THAT IS RESPONSIVE TO TEZACAFTOR/IVACAFTOR BASED ON IN VITRO DATA AND/OR CLINICAL EVIDENCE

U-2248 TEZACAFTOR AND IVACAFTOR FOR THE TREATMENT OF CYSTIC FIBROSIS IN PATIENTS WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION OR HETEROZYGOUS FOR THE F508DEL MUTATION AND A SECOND MUTATION THAT IS RESPONSIVE TO TEZACAFTOR/IVACAFTOR

U-2249 MANAGEMENT OF ACUTE PAIN SEVERE ENOUGH TO REQUIRE AN OPIOID ANALGESIC AND FOR WHICH ALTERNATIVE TREATMENTS ARE INADEQUATE

U-2250 DETECTION OF CARCINOMA IN THE BLADDER BY PHOTODYNAMIC CYSTOSCOPY

U-2251 IN COMBINATION WITH AN AROMATASE INHIBITOR AS INITIAL ENDOCRINE-BASED THERAPY FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER

U-2252 THE TREATMENT OF ACUTE OTITIS EXTERNA IN PATIENTS 6 MONTHS OF AGE AND OLDER DUE TO PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS

U-2253 PROPHYLACTIC TREATMENT OF NAUSEA AND VOMITING, INCLUDING PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED CHEMOTHERAPY

U-2254 USE OF POMALIDOMIDE WITH DEXAMETHASONE FOR PATIENTS WITH MULTIPLE MYELOMA AFTER AT LEAST TWO PRIOR THERAPIES INCLUDING LENALIDOMIDE AND A PROTEASOME INHIBITOR AND DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETING THE LAST THERAPY

U-2255 TREATING SECONDARY HYPERPARATHYROIDISM IN CHRONIC KIDNEY DISEASE WITH SUSTAINED RELEASE 25-HYDROXYVITAMIN D TO REDUCE THE PATIENT'S SERUM PARATHYROID HORMONE LEVEL AND THE SUSTAINED RELEASE IS OVER AT LEAST 10 HOURS

U-2256 TREATING SECONDARY HYPERPARATHYROIDISM IN CHRONIC KIDNEY DISEASE WITH SUSTAINED RELEASE 25-HYDROXYVITAMIN D TO REDUCE THE PATIENT'S SERUM PARATHYROID HORMONE LEVEL AND CMAX IS REDUCED COMPARED TO BOLUS IV INJECTION AND IMMEDIATE-RELEASE, ORAL DOSING

U-2257 TREATING SHPT IN CKD WITH SUSTAINED RELEASE CALCIFEDIOL TO REDUCE SERUM PARATHYROID HORMONE LEVEL AND CHANGE IN SERUM CONCENTRATION OF CALCIFEDIOL IN DOSE INTERVAL IS REDUCED COMPARED TO BOLUS IV INJECTION AND IMMEDIATE-RELEASE, ORAL DOSING

U-2258 TREATING SECONDARY HYPERPARATHYROIDISM IN CKD WITH SUSTAINED RELEASE CALCIFEDIOL TO REDUCE THE PATIENT'S SERUM PARATHYROID HORMONE LEVEL AND CMAX24HR/C24HR IS REDUCED COMPARED TO BOLUS IV INJECTION AND IMMEDIATE-RELEASE, ORAL DOSING

U-2259 TREATING SECONDARY HYPERPARATHYROIDISM IN CKD WITH SUSTAINED RELEASE CALCIFEDIOL TO REDUCE THE PATIENT'S SERUM PARATHYROID HORMONE LEVEL AND TMAX IS INCREASED COMPARED TO BOLUS IV INJECTION AND IMMEDIATE-RELEASE, ORAL DOSING

U-2260 METHOD OF REDUCING THE RISK OF PERIPROCEDURAL MYOCARDIAL INFARCTION, AND STENT THROMBOSIS IN A PATIENT UNDERGOING PCI BY ADMINISTERING INTRAVENOUSLY 30 UG/KG BOLUS BEFORE PCI AND THEN A CONTINUOUS INFUSION

U-2261 MODIFIED DOSING REGIMEN FOR THE MANAGEMENT OF MILD TO MODERATE PAIN OR MANAGEMENT OF MODERATE TO SEVERE PAIN AS AN ADJUNCT TO OPIOID ANALGESICS

U-2262 MODIFIED DOSING REGIMEN FOR THE REDUCTION OF FEVER

U-2263 MODIFIED DOSING REGIMEN FOR THE MANAGEMENT OF MODERATE TO SEVERE PAIN WITH ADJUNCTIVE OPIOID ANALGESICS

U-2264 METHODS OF TREATING PAIN, INFLAMMATION, FEVER, PATENT DUCTUS ARTERIOSIS WITH AQUEOUS COMPOSITION

U-2265 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH HEC AND MEC IN ADULT AND PEDIATRIC PATIENTS

U-2266 METHODS OF MAKING AQUEOUS COMPOSITION AND TREATING PAIN, INFLAMMATION, FEVER, PATENT DUCTUS ARTERIOSIS WITH AQUEOUS COMPOSITION

U-2267 METHOD FOR RELIEVING THE PAIN ASSOCIATED WITH POST-HERPETIC NEURALGIA

U-2268 DISCONTINUING A STRONG CYP1A2 INDUCER TO AVOID REDUCED PIRFENIDONE EFFICACY AND THEN ADMINISTERING PIRFENIDONE

U-2269 DOSAGE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION, BY ADMINISTERING SUB-2400MG/DAY DOSE THEN FULL DAILY DOSE IN TREATMENT OF IPF
PATENT USE

U-2270 DOSE MODIFICATION FOLLOWING GRADE 2 ABNORMALITY IN LIVER FUNCTION BIOMARKER AFTER PIRFENIDONE ADMINISTRATION. BY DISCONTINUING PIRFENIDONE UNTIL BIOMARKERS ARE WITHIN NORMAL LIMITS, THEN SUB-2400MG/DAY DOSE, THEN FULL DAILY DOSE IN TREATMENT OF IPF

U-2271 THERAPEUTIC TREATMENT OF PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER, SYMPTOMATIC BONE METASTASES AND NO KNOWN VISCERAL METASTATIC DISEASE

U-2272 TREATMENT OF NASAL POLYPS IN PATIENTS >=18 YEARS OF AGE WHO HAVE HAD ETHMOID SINUS SURGERY USING A CORTICOSTEROID-ELUTING (MOMETASONE FURATE) IMPLANT

U-2273 A METHOD FOR TREATING EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER, WHEREIN THE CANCER IS ASSOCIATED WITH A DELETERIOUS BRCA MUTATION

U-2274 MAINTAINING SERUM 25-HYDROXYVITAMIN D AT A LEVEL OF AT LEAST 30 NG/ML WITH ORAL, SUSTAINED RELEASE 25-HYDROXYVITAMIN D

U-2275 TREATING CYSTIC FIBROSIS PATIENTS AGES 12 AND OLDER, WHO ARE HOMOZYGOUS FOR F508DEL OR HAVE AT LEAST 1 CFTR GENE MUTATION RESPONSIVE TO TEZACAFTOR/IVACAFTOR, WITH TEZACAFTOR AND A SOLID COMPOSITION COMPRISING AMORPHOUS (<30% CRYSTALLINE) IVACAFTOR

U-2276 METHOD OF TREATING CYSTIC FIBROSIS IN A PATIENT AGE 6 OR OLDER HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE USING LUMACAFTOR AND A SOLID COMPOSITION COMPRISING AMORPHOUS (LESS THAN ABOUT 30% CRYSTALLINE) IVACAFTOR

U-2277 IMPROVEMENT IN GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS INADEQUATELY CONTROLLED BY LIXISENATIDE

U-2278 IMPROVEMENT IN GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS INADEQUATELY CONTROLLED BY LIXISENATIDE IN COMBINATION WITH METFORMIN

U-2279 IMPROVEMENT IN GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS INADEQUATELY CONTROLLED BY LIXISENATIDE IN COMBINATION WITH METFORMIN AND A SECOND ORAL ANTIDIABETIC DRUG

U-2280 ADJUNCTIVE TREATMENT OF PATIENTS WITH TSC-ASSOCIATED PARTIAL-ONSET SEIZURES

U-2281 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 1 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 1

U-2282 ADJUNCT TO DIET AND EXERCISE TO TREAT GLUCOSE INTOLERANCE IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 2 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 2

U-2283 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIMS 3-7 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIMS 3-7

U-2284 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 8 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 8

U-2285 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 11 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 11

U-2286 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIM 14 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIM 14

U-2287 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING BROMOCRIPTINE MESYLATE AND A FIRST-PHASE INSULIN SECRETAGOGUE AS RECITED IN CLAIMS 16-19 AND WHEREIN THE EFFECTS ARE AS RECITED IN CLAIMS 16-19

U-2288 TREATMENT OF TYPE 2 DIABETES MELLITUS WITH EXENATIDE AS AN ADD-ON TO BASIL INSULIN OR BASAL INSULIN PLUS METFORMIN THERAPY

U-2289 TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21L858R MUTATIONS
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-2290 METHOD OF TREATING TYPE 2 DIABETES MELLITUS IN A PATIENT WITH RENAL IMPAIRMENT (45 ML/MIN/1.73 M2 <= eGFR < 60 ML/MIN/1.73 M2) BY ONCE DAILY ADMINISTRATION OF 10 MG OR 25 MG OF EMPAGLIFLOZIN

U-2291 REDUCTION OF THROMBOTIC CARDIOVASCULAR EVENTS IN PATIENTS WITH A HISTORY OF MYOCARDIAL INFARCTION (MI) OR WITH PERIPHERAL ARTERIAL DISEASE (PAD)

U-2292 METHOD OF REDUCING THE RISK OF CARDIOVASCULAR DEATH IN ADULT PATIENTS WITH TYPE 2 DIABETES MELLITUS AND CARDIOVASCULAR DISEASE BY ONCE DAILY ADMINISTRATION OF 10 MG OR 25 MG OF EMPAGLIFLOZIN

U-2293 USE IN COMBINATION WITH DEXAMETHASONE IN ADULTS FOR THE PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF CANCER CHEMOTHERAPY, INCLUDING, BUT NOT LIMITED TO, HIGHLY EMETOGENIC CHEMOTHERAPY

U-2294 TREATMENT OF THROMBOCYTOPENIA IN ADULT PATIENTS WITH CHRONIC IMMUNE THROMBOCYTOPENIA (ITP) WHO HAVE HAD AN INSUFFICIENT RESPONSE TO A PREVIOUS TREATMENT

U-2295 TREATMENT OF PARTIAL-ONSET SEIZURES IN PATIENTS 4 YEARS OF AGE AND OLDER

U-2296 TAFINLAR IS INDICATED, IN COMBINATION WITH TRAMETINIB, FOR THE ADJUVANT TREATMENT OF PATIENTS WITH MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST, AND INVOLVEMENT OF LYMHP NODE(S), FOLLOWING COMPLETE RESECTION

U-2297 IMPROVEMENT OF GLYCEMIC CONTROL IN TYPE 2 DIABETES PATIENTS BY ADMINISTERING A STARTING DOSE OF 10 MCG FOR 14 DAYS AND INCREASING TO A MAINTENANCE DOSE OF 20 MCG ON DAY 15

U-2298 TAFINLAR IS INDICATED, IN COMBINATION WITH TRAMETINIB, FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC ANAPLASTIC THYROID CANCER (ATC) WITH BRAF V600E MUTATION AND WITH NO SATISFACTORY LOCOREGIONAL TREATMENT OPTIONS

U-2299 TAFINLAR IS INDICATED AS A SINGLE AGENT FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E MUTATION

U-2300 USE IN COMBINATION WITH THE MUSCARINIC ANTAGONIST SOLIFENACIN SUCINNATE FOR THE TREATMENT OF OVERACTIVE BLADDER (OAB) WITH SYMPTOMS OF URGE URINARY INCONTINENCE, URGENCY, AND URINARY FREQUENCY

U-2301 USE IN COMBINATION WITH DEXAMETHASONE IN ADULTS FOR THE PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF HIGHLY EMETOGENIC CANCER CHEMOTHERAPY

U-2302 MEKINIST IS INDICATED, IN COMBINATION WITH DABRAFENIB, FOR THE ADJUVANT TREATMENT OF PATIENTS WITH MELANOMA WITH BRAF V600E OR V600K MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST, AND INVOLVEMENT OF LYMHP NODE(S), FOLLOWING COMPLETE RESECTION

U-2303 MEKINIST IS INDICATED, IN COMBINATION WITH DABRAFENIB, FOR THE ADJUVANT TREATMENT OF PATIENTS WITH MELANOMA WITH BRAF V600E OR V600K MUTATIONS AND INVOLVEMENT OF LYMHP NODE(S), FOLLOWING COMPLETE RESECTION

U-2304 MEKINIST IS INDICATED, IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH BRAF V600E MUTATION

U-2305 MEKINIST IS INDICATED, IN COMBINATION WITH DABRAFENIB, FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC ANAPLASTIC THYROID CANCER (ATC) WITH BRAF V600E MUTATION AND WITH NO SATISFACTORY LOCOREGIONAL TREATMENT OPTIONS

U-2306 ONCE DAILY TOPICAL TREATMENT OF PERSISTENT FACIAL ERYTHEMA ASSOCIATED WITH ROSACEA IN ADULTS WITH 1% OXYMETAZOLINE HYDROCHLORIDE CREAM

U-2307 TREATMENT OF AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE

U-2308 TREATMENT OF ADULT PATIENTS WITH SHORT BOWEL SYNDROME WHO ARE DEPENDENT ON PARENTERAL SUPPORT

U-2309 USE IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER TO IMPROVE PROCESSING SPEED, AN ASPECT OF COGNITIVE FUNCTION

U-2310 FOR CLEANSING OF THE COLON IN PREPARATION FOR COLONOSCOPY IN ADULTS

U-2311 TREATMENT OF HYPERURICEMIA ASSOCIATED WITH GOUT IN PATIENTS WHO HAVE NOT ACHIEVED TARGET SERUM URIC ACID LEVELS WITH A XANTHINE OXIDASE INHIBITOR ALONE

U-2312 TREATMENT OF HYPERKALEMIA IN ADULTS

U-2313 METHOD OF REDUCING THE RISK OF CARDIOVASCULAR DEATH, NON-FATAL MYOCARDIAL INFARCTION, AND/OR NON-FATAL STROKE IN ADULTS WITH TYPE 2 DIABETES MELLITUS AND
PATENT USE

U-2314 TREATMENT OF THROMBOCYTOPENIA IN AN ADULT PATIENT WITH CHRONIC LIVER DISEASE WHO IS SCHEDULED TO UNDERGO A PROCEDURE USING DOPTELET

U-2315 TREATMENT OF MULTIPLE SCLEROSIS IN THE PEDIATRIC PATIENT POPULATION WITH 0.25 MG FINGOLIMOD

U-2316 TREATMENT OF DYSpareunIA

U-2317 TREATMENT OF A SYMPTOM OF VULVAR AND VAGINAL ATROPHY

U-2318 TREATMENT OF CYSTIC FIBROSIS IN PATIENTS AGED 12 AND OLDER, WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION OR HAVE AT LEAST ONE CFTR GENE MUTATION THAT IS RESPONSIVE TO TEZACAFTOR/IVACAFTOR, WITH TEZACAFTOR AND IVACAFTOR

U-2319 KYPROLIS IS INDICATED IN COMBINATION WITH DEXAMETHASONE OR WITH LENALIDOMIDE PLUS DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED ONE TO THREE LINES OF THERAPY

U-2320 KYPROLIS IS INDICATED AS A SINGLE AGENT FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED ONE OR MORE LINES OF THERAPY

U-2321 A METHOD OF APPLYING TRYPAN BLUE ONTO AN OUTER SURFACE OF THE ANTERIOR LENS CAPSULE TO FACILITATE REMOVAL OF THE LENS SUBSTANCE

U-2322 TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC)

U-2323 TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL), WITH OR WITHOUT 17P DELETION, WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

U-2324 FOR SECONDARY PREVENTION OF CARDIOVASCULAR AND CEREBROVASCULAR EVENTS IN PATIENTS AT RISK OF DEVELOPING ASPIRIN-ASSOCIATED GASTRIC ULCERS

U-2325 EMERGENCY TREATMENT OF ALLERGIC REACTIONS (TYPE 1), INCLUDING ANAPHYLAXIS; A METHOD OF TREATING ALLERGIC REACTION, ANAPHYLAXIS, ANAPHYLACTIC SHOCK, OR COMBINATION THEREOF BY AN INJECTION OF AT LEAST ONE DOSAGE OF THE INJECTABLE LIQUID PHARMACEUTICAL

U-2326 TREATMENT OF NOCTURIA DUE TO NOCTURNAL POLYURIA IN ADULTS

U-2327 TREATMENT OF NOCTURIA DUE TO NOCTURNAL POLYURIA IN ADULTS, COMPRISING MONITORING A PATIENT’S SERUM SODIUM CONCENTRATION

U-2328 METHOD OF USING PLAZOMICIN TO TREAT BACTERIAL INFECTIONS

U-2329 METHOD OF ADMINISTERING A LOCAL ANESTHETIC PRIOR TO PERFORMING A DIAGNOSTIC OR SURGICAL PROCEDURE ON A SUBJECT WITH HEPATIC OR RENAL IMPAIRMENT

U-2330 METHOD OF TREATING MELANOMA

U-2331 INDICATED IN COMBINATION WITH ENCORAFENIB FOR THE TREATMENT OF MELANOMA

U-2332 INDICATED IN COMBINATION WITH ENCORAFENIB FOR THE TREATMENT OF MELANOMA MEDIATED BY A B-RAF PROTEIN KINASE

U-2333 INDICATED IN COMBINATION WITH ENCORAFENIB FOR THE TREATMENT OF MELANOMA WITH A BRAF MUTATION

U-2334 TREATMENT OF MELANOMA WITH A BRAF MUTATION

U-2335 TREATMENT OF MELANOMA

U-2336 TREATMENT OF MELANOMA MEDIATED BY A B-RAF PROTEIN KINASE

U-2337 INDICATED IN COMBINATION WITH BINimetINIB FOR THE TREATMENT OF MELANOMA WITH A BRAF MUTATION

U-2338 MAINTAINING MEAN ARTERIAL PRESSURE OF ABOUT 65 MMHG OR ABOVE WITH ABOUT 1 NG/KG/MIN TO ABOUT 40 NG/KG/MIN ANGIOTENSIN II IN HYPOTENSIVE PATIENTS TREATED WITH VASOPRESSIN OR A VASOPRESSIN ANALOGUE AND REDUCING VASOPRESSIN OR VASOPRESSIN ANALOGUE USE

U-2339 USE OF A PHARMACEUTICAL COMPOSITION COMPRISING LINAGLIPTIN, METFORMIN AND A BASIC AMINO ACID TO TREAT TYPE 2 DIABETES MELLITUS

U-2340 TREATMENT OF POSTOPERATIVE INFLAMMATION

U-2341 METHOD OF RECONSTITUTING A LYOPHILIZED LIPOSOMAL COMPOSITION FOR ADMINISTERING CYTARABINE AND DAUNORUBICIN TO TREAT ADULTS WITH NEWLY-DIAGNOSED THERAPY-RELATED ACUTE MYELOID LEUKEMIA (T-AML) OR AML WITH MYELODYSPLASIA-RELATED CHANGES (AML-
PATENT AND EXCLUSIVITY TERMS

PATENT USE

MRC

U-2342  METHOD OF ADMINISTERING A RECONSTITUTED LIPOSOMAL COMPOSITION CONTAINING CYTARABINE AND DAUNORUBICIN TO TREAT ADULTS WITH NEWLY-DIAGNOSED THERAPY-RELATED ACUTE MYELOID LEUKEMIA (T-AML) OR AML WITH MYELODYSPLASIA-RELATED CHANGES (AML-MRC)

U-2343  TREATMENT OF CYSTIC FIBROSIS IN PATIENTS AGED 12 YEARS AND OLDER, WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION OR HETEROZYGOUS FOR F508DEL AND A SECOND CFTR MUTATION PREDICTED TO BE RESPONSIVE TO TEZACAFTOR/IVACAFTOR, WITH TEZACAFTOR AND IVACAFTOR

U-2344  TREATMENT OF THROMBOCYTOPENIA IN ADULT PATIENTS WITH CHRONIC LIVER DISEASE WHO ARE SCHEDULED TO UNDERGO A PROCEDURE

U-2345  TREATMENT OF PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER (CRPC)

U-2346  TREATMENT OF HUMAN SMALLPOX DISEASE CAUSED BY VARIOLA VIRUS IN ADULTS AND PEDIATRIC PATIENTS WEIGHING AT LEAST 13 KG

U-2347  TREATMENT OF TYPE 2 DIABETES MELLITUS IN A PATIENT WITH RENAL IMPAIRMENT AND FOR WHOM METFORMIN THERAPY IS INAPPROPRIATE BY ADMINISTERING LINAGLIPTIN WITHOUT DOSE ADJUSTMENT

U-2348  A METHOD FOR PREVENTION OF PREGNANCY

U-2349  FOR ONCE-DAILY MAINTENANCE TREATMENT OF ASTHMA AS PROPHYLACTIC THERAPY IN PATIENTS AGED 5 YEARS AND OLDER

U-2350  A METHOD OF TREATING A CANCER CHARACTERIZED BY AN IDH1 MUTATION WHERE THE CANCER IS ACUTE MYELOGENOUS LEUKEMIA (AML)

U-2351  TREATMENT OF ACUTE MYELOID LEUKEMIA (AML) WITH AN IDH1 MUTATION

U-2352  TREATMENT OF HIV-1 INFECTION IN ADULTS WHO HAVE NO PRIOR ANTIRETROVIRAL TREATMENT HISTORY OR ARE VIROLOGICALLY SUPPRESSED ON A STABLE ANTIRETROVIRAL REGIMEN FOR AT LEAST 6 MONTHS

U-2353  TX OF HIV-1 INFECTION USING A COMPOSITION CONTAINING A PK ENHANCER THAT INHIBITS CYTOCHROME P450 MONOOXYGENASES IN ADULTS WHO HAVE NO PRIOR ANTIRETROVIRAL TX HISTORY OR ARE VIROLOGICALLY SUPPRESSED ON A STABLE ANTIRETROVIRAL REGIMEN FOR AT LEAST 6 MONTHS

U-2354  COMBINATION WITH OTHER ANTIRETROVIRALS (ATV) FOR TREATMENT OF HIV-1 IN ATV TREATMENT-EXPERIENCED PATIENTS 2 YEARS AND OLDER WITH EVIDENCE OF VIRAL REPLICATION AND HIV-1 STRAINS RESISTANT TO NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR AND OTHER ATV

U-2355  IN COMBINATION WITH AN AROMATASE INHIBITOR FOR THE TREATMENT OF PRE/PERIMENOPAUSAL OR POSTMENOPAUSAL WOMEN WITH HR-POSITIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER, AS INITIAL ENDOCRINE-BASED THERAPY

U-2356  IN COMBINATION WITH FULVESTRANT FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HR-POSITIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER, AS INITIAL ENDOCRINE BASED THERAPY OR FOLLOWING DISEASE PROGRESSION ON ENDOCRINE THERAPY

U-2357  METHOD OF TREATING ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

U-2358  TREATMENT OF PATIENTS WITH HORMONE RECEPTOR (HR)-NEGATIVE BREAST CANCER WITH DELETERIOUS OR SUSPECTED DELETERIOUS GBRCAM, HER2-NEGATIVE METASTATIC BREAST CANCER, WHO HAVE BEEN TREATED WITH CHEMOTHERAPY IN NEOADJUVANT, ADJUVANT, OR METASTATIC SETTING

U-2359  TREATMENT OF PATIENTS WITH HORMONE RECEPTOR (HR)-POSITIVE BREAST CANCER WHO SHOULD HAVE BEEN TREATED WITH PRIOR ENDOCRINE THERAPY OR BE CONSIDERED INAPPROPRIATE FOR ENDOCRINE THERAPY

U-2360  MANAGEMENT OF MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS

U-2361  METHOD OF ADMINISTERING A GRANULATE FORMULATION OF 5-METHYL-1-PHENYL-2-(1H)-PYRIDONE AS RECITED IN CLAIM 1, TO TREAT IDIOPATHIC PULMONARY FIBROSIS

U-2362  TREATMENT OF HEPATITIS C VIRUS (HCV) GENOTYPE 1, 2, 3, 4, 5, OR 6

U-2363  ADMINISTRATION OF RISPERIDONE

U-2364  TREATMENT OF HIV-1 INFECTION USING A COMPOSITION CONTAINING A PHARMACOKINETIC ENHANCER THAT INHIBITS CYTOCHROME P450 MONOOXYGENASE IN ADULTS WHO HAVE NO PRIOR ANTIRETROVIRAL TREATMENT HISTORY

U-2365  TREATMENT OF HIV-1 INFECTION USING A COMPOSITION CONTAINING A PHARMACOKINETIC ENHANCER THAT INHIBITS CYTOCHROME P450 MONOOXYGENASE IN ADULTS WHO ARE
PATENT AND EXCLUSIVITY TERMS

PATENT USE

Virologically Suppressed on a stable antiretroviral regimen for at least 6 months

U-2366 Treatment of Liver Disease through nutrition for patients under the age of 12

U-2367 Use for patients with parenteral nutrition associated cholestasis or parenteral nutrition associated liver disease

U-2368 Topical treatment of acne vulgaris in patients 9 years of age and older

U-2369 For the treatment of genotype 1, 4, 5 or 6 chronic Hepatitis C virus (HCV) infection

U-2370 For treatment-naive genotype 1 patients with chronic Hepatitis C virus (HCV) infection for a duration of 8-weeks

U-2371 The treatment of Fabry patients

U-2372 A method of reducing left ventricular mass index (LVMI) in a Fabry patient by administering migalastat

U-2373 A method of reducing podocyte globotriaosylceramide (GL-3) in a Fabry patient by administering migalastat

U-2374 Treatment of cystic fibrosis in a patient age 2-5 years who is homozygous for the F508del mutation in the CFTR gene using lumacaftor and ivacaftor

U-2375 Treatment of cystic fibrosis in a patient age 2-5 years who is homozygous for the F508del mutation in the CFTR gene using lumacaftor form I and IVacaftor

U-2376 Treatment of cystic fibrosis in a patient age 2-5 years who is homozygous for the F508del mutation in the CFTR gene using lumacaftor and a solid composition comprising amorphous and less than about 30% crystalline ivacaftor

U-2377 Use of vital dye for facilitating surgical procedures for vitreo-retinal surgery

U-2378 Treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis

U-2379 Use in identification of intraocular membranes to facilitate removal during ophthalmic surgery

U-2380 Treatment of complicated intra-abdominal infections in patients 18 years of age and older

U-2381 Treatment in combination with a GnRH agonist of non-metastatic, castration-resistant prostate cancer (NM-CRPC)

U-2382 Treatment in combination with a GnRH agonist of high risk non-metastatic, castration-resistant prostate cancer (NM-CRPC)

U-2383 Method of controlling glycemia in a diabetic patient with delayed or prolonged food absorption by administering 50 to 75% of a predetermined dose of insulin-FDKP at mealtime, and administering remainder of dose 30-120 minutes after beginning of meal

U-2384 Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes by administering a dosage form comprising micronized bromocriptine and one or more excipients as recited in claims 1 and 10

U-2385 Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes by administering a dosage form comprising micronized bromocriptine and one or more excipients as recited in claims 1, 10 and 11

U-2386 Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes by administering a dosage form comprising bromocriptine and one or more excipients as recited in claims 12 and 19

U-2387 Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes by administering a dosage form comprising bromocriptine and one or more excipients as recited in claims 12, 19 and 20

U-2388 Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes by administering a dosage form comprising bromocriptine and one or more excipients as recited in claims 21 and 28

U-2389 Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes by administering a dosage form comprising bromocriptine and one or more excipients as recited in claims 21, 28, and 29

U-2390 Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes by administering a dosage form comprising bromocriptine and one or more excipients as recited in claims 30 and 41
PATENT USE

U-2391 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 30, 41, AND 42

U-2392 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 43 AND 50

U-2393 ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES BY ADMINISTERING A DOSAGE FORM COMPRISING BROMOCRIPTINE AND ONE OR MORE EXCIPIENTS AS RECITED IN CLAIMS 43, 50 AND 51

U-2394 FOR USE IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN ADULT PATIENTS WITH NO PRIOR ANTIRETROVIRAL TREATMENT HISTORY

U-2395 FOR THE TREATMENT OF HIV-1 INFECTION IN ADULT PATIENTS WITH NO PRIOR ANTIRETROVIRAL TREATMENT HISTORY

U-2396 TREATMENT OF CYSTIC FIBROSIS IN A PATIENT AGE 2-5 YEARS WHO IS HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE USING THE DOSAGE UNIT COMPRISING LUMACAFTOR AS RECITED IN CLAIM 1 OF US PATENT 8716338 AND IVACAFTOR

U-2397 TREATMENT OF CYSTIC FIBROSIS IN A PATIENT AGE 2-5 YEARS WHO IS HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE USING THE DOSAGE UNIT COMPRISING LUMACAFTOR AND IVACAFTOR AS RECITED IN CLAIM 1 OF US PATENT 9192606

U-2398 TOPICAL TREATMENT OF PRIMARY AXILLARY HYPERHIDROSIS IN ADULTS AND PEDIATRIC PATIENTS 9 YEARS OF AGE AND OLDER

U-2399 TREATMENT OF CYSTIC FIBROSIS IN PATIENTS 12 YEARS AND OLDER, WITH A F508DEL OR G551D CFTR GENE MUTATION AND A A455E, 2789+5G-->A, OR 3849+10KBC-->T MUTATION, COMPRISING CONCURRENT COADMINISTRATION OF THE COMPOSITIONS OF CLAIM 1 OF U.S PATENT 10058546

U-2400 REDUCING ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION

U-2401 A METHOD OF TREATINGamyotrophic lateral sclerosis in a patient in need of such treatment, said method comprising administering to said patient an effective amount of a suspension according to claim 1

U-2402 TREATMENT OF SCHIZOPHRENIA BY RAPID AND CONTINUOUS INTRAMUSCULAR INJECTION

U-2403 TREATMENT OF PSORIASIS USING A DOSAGE TITRATION SCHEDULE

U-2404 METHOD OF DELIVERING SUMATRIPTAN TO A NASAL CAVITY

U-2405 A METHOD FOR TREATING A BACTERIAL INFECTION IN INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS PATIENTS 9 YEARS OF AGE AND OLDER COMPRISING ADMINISTERING AN EFFECTIVE AMOUNT OF SARECYCLINE HYDROCHLORIDE

U-2406 A METHOD FOR TREATING A PATIENT 9 YEARS OF AGE AND OLDER SUFFERING FROM AN INFLAMMATORY SKIN DISORDER OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS COMPRISING ADMINISTERING AN EFFECTIVE AMOUNT OF SARECYCLINE HYDROCHLORIDE CRYSTAL SALT

U-2407 A METHOD FOR TREATING ACNE IN INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS PATIENTS 9 YEARS OF AGE AND OLDER COMPRISING ADMINISTERING AN EFFECTIVE AMOUNT OF SARECYCLINE HYDROCHLORIDE CRYSTAL SALT

U-2408 A METHOD FOR TREATING A BACTERIAL INFECTION IN INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS PATIENTS 9 YEARS OF AGE AND OLDER COMPRISING ADMINISTERING AN EFFECTIVE AMOUNT OF SARECYCLINE HYDROCHLORIDE CRYSTAL SALT

U-2409 A METHOD FOR TREATING ACNE IN INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS PATIENTS 9 YEARS OF AGE AND OLDER COMPRISING ADMINISTERING SARECYCLINE HYDROCHLORIDE IN 60 MG, 100 MG OR 150 MG EQUIVALENT DOSES

U-2410 TREATMENT OF ADULT PATIENTS FOR WHOM TREATMENT WITH BOTH AMLODIPINE FOR HYPERTENSION AND CLECOXIB FOR OSTEOARTHRITIS ARE APPROPRIATE

U-2411 TREATMENT OF CYSTIC FIBROSIS IN A PATIENT AGE 12 YEARS OR OLDER WHO IS HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE USING THE TABLET COMPRISING LUMACAFTOR AS RECITED IN CLAIM 1, 19, OR 21 OF U.S. PATENT NO. 10,076,513 AND IVACAFTOR

U-2412 FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) AND/OR SMALL LYMPHOCYTIC LEUKEMIA (SLL)

U-2413 FOR THE TREATMENT OF PATIENTS WITH FOLLICULAR LYMPHOMA (FL)

U-2414 TREATING MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE IN ADULTS AS PART OF A
PATENT USE

COMBINATION DRUG REGIMEN

U-2415 TREATING MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE IN ADULTS AS PART OF A COMBINATION ANTIBACTERIAL DRUG REGIMEN

U-2416 TREATING MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE IN ADULTS WITH CYSTIC FIBROSIS AS PART OF A COMBINATION DRUG REGIMEN

U-2417 TREATING MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE IN NON-CYSTIC FIBROSIS ADULTS AS PART OF A COMBINATION ANTIBACTERIAL DRUG REGIMEN

U-2418 METHOD OF ADMINISTERING TESTOSTERONE ENANTHATE SUBCUTANEOUSLY

U-2419 METHOD OF OPERATING AN INJECTION DEVICE

U-2420 TREATMENT OF CYSTIC FIBROSIS IN PATIENTS AGES 12 AND OLDER, WHO HAVE TWO COPIES OF THE F508DEL MUTATION OR ONE F508DEL MUTATION AND A CFTR MUTATION PREDICTED TO BE RESPONSIVE TO TEZACAFTOR/IVACAFTOR, WITH THE COMPOSITION OF CLAIM 1 OF US 10,081,621

U-2421 USE IN COMBINATION WITH CLOBAZAM FOR THE TREATMENT OF SEIZURES IN PATIENTS WITH DRAVET SYNDROME

U-2422 USE IN COMBINATION WITH CLOBAZAM FOR THE TREATMENT OF SEIZURES IN PATIENTS WITH LENNOX GASTAUT SYNDROME WHO HAVE BEEN PREVIOUSLY TREATED WITH CLOBAZAM

U-2423 USE IN COMBINATION WITH CLOBAZAM FOR THE TREATMENT OF SEIZURES IN PATIENTS WITH DRAVET SYNDROME WHO HAVE BEEN PREVIOUSLY TREATED WITH CLOBAZAM

U-2424 USE IN COMBINATION WITH CLOBAZAM FOR THE TREATMENT OF SEIZURES IN PATIENTS WITH LENNOX GASTAUT SYNDROME

U-2425 USE FOR THE TREATMENT OF CONVULSIVE SEIZURES IN PATIENTS WITH DRAVET SYNDROME

U-2426 USE FOR THE TREATMENT OF CONVULSIVE SEIZURES IN PATIENTS WITH LENNOX GASTAUT SYNDROME

U-2427 USE FOR THE TREATMENT OF DROP SEIZURES IN PATIENTS WITH DRAVET SYNDROME

U-2428 TREATMENT OF PARTIAL-ONSET SEIZURES WITH OR WITHOUT SECONDARILY GENERALIZED SEIZURES IN PATIENTS WITH EPILEPSY 4 YEARS OF AGE AND OLDER

U-2429 TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES AS ADJUNCTIVE THERAPY IN PATIENTS WITH EPILEPSY 12 YEARS OF AGE AND OLDER

U-2430 TREATMENT OF POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN AMYLOIDOSIS

U-2431 TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS

U-2432 LONG-TERM, MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

U-2433 METHOD OF TREATING A BIOLOGICAL RHYTHM DISORDER, SUCH AS INSOMNIA

U-2434 USE IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

U-2435 REDUCTION OF RISK OF MAJOR CARDIOVASCULAR EVENTS (CV DEATH, MI, AND STROKE) IN CHRONIC CAD OR PAD

U-2436 USE IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER TO IMPROVE TREATMENT EMERGENT SEXUAL DYSFUNCTION (TESD) INDUCED BY PRIOR SEROTONIN REUPTAKE INHIBITOR TREATMENT

U-2437 TREATMENT OF ADULT PATIENTS WITH DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE BREAST CANCER SUSCEPTIBILITY GENE (BRCA)-MUTATED (GBRCAM) HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER

U-2438 CARDIOVASCULAR OUTCOMES TRIAL OF LIRAGLUTIDE 1.8 MG IN PATIENTS WITH TYPE 2 DIABETES AND CARDIOVASCULAR DISEASE

U-2439 TREATMENT OF MENOPAUSE SYMPTOMS, INCLUDING VASOMOTOR SYMPTOMS

U-2440 FOR THE MAINTENANCE TREATMENT OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

U-2441 REDUCTION OF RISK OF MAJOR ADVERSE CARDIOVASCULAR EVENTS IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS PATIENTS

U-2442 USE FOR THE TREATMENT OF ATONIC SEIZURES IN PATIENTS WITH LENNOX-GASTAUT SYNDROME

U-2443 USE FOR THE TREATMENT OF ATONIC SEIZURES IN PATIENTS WITH DRAVET SYNDROME
PATENT AND EXCLUSIVITY TERMS

PATENT USE

U-2444 TREATMENT OF SUBJECTS HAVING BACTERIAL SKIN OR SKIN STRUCTURE INFECTION

U-2445 TREATMENT IN COMBINATION WITH AZACITIDINE OR DECITABINE OR LOW-DOSE CYTARABINE OF NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) IN ADULTS WHO ARE AGE 75 YEARS OR OLDER, OR WHO HAVE COMORBIDITIES THAT PRECLUDE USE OF INTENSIVE INDUCTION CHEMOTHERAPY

U-2446 TREATMENT OF ADULT PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL), WITH OR WITHOUT 17P DELETION, WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY

U-2447 TREATMENT OF SEVERE HYPERTRIGLYCERIDEMIA (500 MG/DL) IN ADULT PATIENTS AS AN ADJUNCT TO DIET

U-2448 TREATMENT OF TRAVELERS' DIARRHEA CAUSED BY NON-INVASIVE STRAINS OF ESCHERICHIA COLI IN ADULTS

U-2449 TREATMENT OF BACTERIAL SKIN AND SKIN STRUCTURE INFECTION

U-2450 POSITRON EMISSION TOMOGRAPHY DIAGNOSTIC AGENT IN ADULTS WITH SUSPECTED PROSTATE CANCER RECURRENCE BASED ON ELEVATED BLOOD PROSTATE SPECIFIC ANTIGEN LEVELS FOLLOWING PRIOR TREATMENT

U-2451 TREATMENT OF THROMBOCYTOPENIA IN ADULT AND PEDIATRIC PATIENTS 1 YEAR AND OLDER WITH CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA (ITP)

U-2452 COMBINATION WITH IMMUNOSUPPRESSIVE THERAPY FOR FIRST-LINE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 2 YEARS AND OLDER WITH SEVERE APLASTIC ANEMIA

U-2453 TREATMENT OF FUNGAL INFECTIONS, INCLUDING BLASTOMYCOSIS, HISTOPLASMOsis, AND ASPERGILLOSIS

U-2454 USE FOR THE TREATMENT OF DROP SEIZURES IN PATIENTS WITH LENNOX-GASTAUT SYNDROME

U-2455 USE IN COMBINATION WITH CLOBAZAM FOR TREATMENT OF DROP SEIZURES IN PATIENTS WITH LENNOX GASTAUT SYNDROME

U-2456 TREATMENT OF ACUTE MYELOID LEUKEMIA (AML)

U-2457 REINITIATION OF SCHIZOPHRENIA TREATMENT FOLLOWING A MISSED DOSE MORE THAN 9 MONTHS AGO

U-2458 REINITIATION OF SCHIZOPHRENIA TREATMENT FOLLOWING A MISSED DOSE 4-9 MONTHS AGO

U-2459 TREATMENT OF DYSKINESIA AND DECREASING OFF TIME IN PATIENTS WITH PARKINSON'S DISEASE RECEIVING LEVODOPA-BASED THERAPY, WITH OR WITHOUT CONCOMITANT DOPAMINERGIC MEDICATIONS

U-2460 VISUALIZATION OF VESSELS, BLOOD FLOW AND TISSUE PERFUSION OF CORONARY ARTERY BYPASS GRAFT IN VASCULAR, GASTROINTESTINAL, ORGAN TRANSPLANT, AND PLASTIC, MICRO- AND RECONSTRUCTIVE, INCLUDING MINIMALLY INVASIVE, SURGERY

U-2461 VISUALIZATION OF VESSELS, BLOOD FLOW AND TISSUE PERFUSION OF CARDIOVASCULAR BYPASS GRAFT AND VASCULATURE IN VASCULAR, GASTROINTESTINAL, ORGAN TRANSPLANT, AND PLASTIC, MICRO- AND RECONSTRUCTIVE, INCLUDING MINIMALLY INVASIVE, SURGERY

U-2462 VISUALIZATION OF VESSELS, BLOOD FLOW AND TISSUE PERFUSION OF VESSEL WITH ARTERIOVENOUS MALFORMATION IN VASCULAR, GASTROINTESTINAL, ORGAN TRANSPLANT, AND PLASTIC, MICRO- AND RECONSTRUCTIVE, INCLUDING MINIMALLY INVASIVE, SURGERY

U-2463 VISUALIZATION OF VESSELS, BLOOD FLOW AND TISSUE PERFUSION IN SURGICAL FLAPS IN VASCULAR, GASTROINTESTINAL, ORGAN TRANSPLANT, AND PLASTIC, MICRO- AND RECONSTRUCTIVE, INCLUDING MINIMALLY INVASIVE, SURGERY

U-2464 VISUALIZATION OF VESSELS, BLOOD FLOW AND TISSUE PERFUSION OF TRANSPLANTED ORGAN OR ATTACHED VESSEL IN VASCULAR, GASTROINTESTINAL, ORGAN TRANSPLANT, AND PLASTIC, MICRO- AND RECONSTRUCTIVE, INCLUDING MINIMALLY INVASIVE, SURGERY

U-2465 VISUALIZATION OF VESSELS, BLOOD FLOW AND TISSUE PERFUSION OF VESSEL GRAFT IN VASCULAR, GASTROINTESTINAL, ORGAN TRANSPLANT, AND PLASTIC, MICRO- AND RECONSTRUCTIVE, INCLUDING MINIMALLY INVASIVE, SURGERY

U-2466 VISUALIZATION OF VESSELS, BLOOD FLOW AND TISSUE PERFUSION OF DONOR ORGAN OR ATTACHED VESSEL IN VASCULAR, GASTROINTESTINAL, ORGAN TRANSPLANT, AND PLASTIC, MICRO- AND RECONSTRUCTIVE, INCLUDING MINIMALLY INVASIVE, SURGERY

U-2467 VISUALIZATION OF EXTRAHEPATIC BILIARY DUCT ATTACHED TO DONOR ORGAN IN PATIENTS 12 YEARS AND OLDER

U-2468 VISUALIZATION OF EXTRAHEPATIC BILIARY DUCT ATTACHED TO TRANSPLANTED ORGAN IN PATIENTS 12 YEARS AND OLDER

U-2469 METHOD OF TREATING CANCEROUS SOLID TUMORS
PATENT USE

U-2470  METHOD OF TREATING SOLID TUMORS THAT EXHIBIT AN NTRK GENE FUSION

U-2471  METHOD OF TREATING SOLID TUMORS THAT EXHIBIT AN NTRK FUSION GENE IN A PEDIATRIC PATIENT

U-2472  METHOD OF TREATING NEUROBLASTOMA, GLIOMA, THYROID, AND BREAST CANCER SOLID TUMORS THAT EXHIBIT AN NTRK GENE FUSION

U-2473  METHOD OF TREATING CMN, IFS, HGG, DIPGS, PTC, SOFT TISSUE SARCOMA, AND SPINDLE CELL SARCOMA SOLID TUMORS EXHIBITING AN NTRK GENE FUSION IN A PEDIATRIC PATIENT WITH AN ORAL SOLUTION

U-2474  METHOD OF TREATING SOLID TUMORS THAT EXHIBIT AN NTRK GENE FUSION AFTER SURGICAL RESECTION

U-2475  METHOD OF TREATING SOLID TUMORS THAT EXHIBIT AN NTRK GENE FUSION IN A PEDIATRIC PATIENT

U-2476  USE OF A DELIVERY DEVICE TO DELIVER A DOSE OF NALOXONE

U-2477  TREATMENT OF NON-24 HOUR SLEEP-WAKE DISORDER BY AVOIDING THE USE OF TASIMELTEON IN COMBINATION WITH CYPIA2 STRONG INHIBITORS

U-2478  METHOD FOR THE INDUCTION OF LOCAL ANESTHESIA PRIOR TO PERFORMING A PROCEDURE ON, THROUGH, OR ADJACENT TO THE MUCOUS MEMBRANES

U-2479  METHOD OF ADMINISTERING A LOCAL ANESTHETIC TO THE MUCOUS MEMBRANES