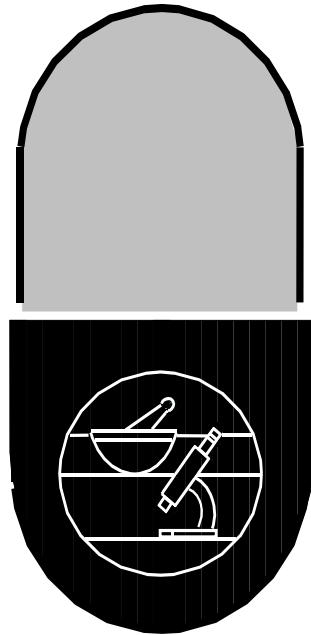


**CUMULATIVE
SUPPLEMENT 1
January 2024**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

44th EDITION

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**

2024

Prepared By
Food and Drug Administration
Office of Medical Products and Tobacco
Center for Drug Evaluation and Research
Office of Generic Drugs
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CONTENTS

PAGE

Contents

1.0	INTRODUCTION.....	v
1.1	HOW TO USE THE CUMULATIVE SUPPLEMENT.....	vi
1.2	CUMULATIVE SUPPLEMENT CONTENT.....	vi
1.3	APPLICANT NAME CHANGES.....	vii
1.4	LEVOTHYROXINE SODIUM.....	viii
1.5	AVAILABILITY OF THE EDITION.....	ix
1.6	REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST.....	x
1.7	CUMULATIVE SUPPLEMENT LEGEND.....	xi
DRUG PRODUCT LISTS		
	Prescription Drug Product List.....	1-1
	OTC Drug Product List.....	2-1
	Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List.....	3-1
	Orphan Products Designations and Approvals List.....	4-1
	Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution.....	5-1
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM		
A.	Patent and Exclusivity Lists.....	A-1
B.	Patent and Exclusivity Terms.....	B-1

**APPROVED DRUG PRODUCTS
with
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44th EDITION

**CUMULATIVE SUPPLEMENT 1
January 2024**

1.0 INTRODUCTION

This Cumulative Supplement is one of a series of monthly updates to the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the List, commonly known as the Orange Book). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; 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; drug products with approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) administered by the Center for Biologics Evaluation and Research; and 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 for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, Discontinued Drug Product, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case, the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

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 for safety or effectiveness reasons or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a

"@" symbol in the 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the next Edition. The current Annual Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity List new additions are indicated by the symbol >A> to the left of Patent Number or Exclusivity Code. The >A> symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

The Patent and Exclusivity List is arranged in alphabetical order by active ingredient name(s) and trade name. The trade name will follow the active ingredient name separated by a dash symbol. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

1.2 CUMULATIVE SUPPLEMENT CONTENT

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the Cumulative Supplement (CS) for several weeks.

The CS monthly update publish goal is by the end of the following month's second work week (e.g., November's supplement will be updated by the end of the second full work week in December).

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
 - Refer to CS Section 1.7 Cumulative Supplement Legend for types of changes

- New Drug Application (NDA) approvals appear in the CS month they were approved.
- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and is current as of the date of publication.

Every effort is made to ensure the Cumulative Supplement is accurate. Applicant holders are requested to inform the FDA Division of Orange Book Publication and Regulatory Assessment (DOB/PRA) of any changes or corrections. The DOB/PRA can be contacted by email at orangebook@fda.hhs.gov.

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each, and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

<u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u>
AKORN OPERATING CO LLC (AKORN)	EPIC PHARMA LLC (EPIC PHARMA LLC)
CADILA HEALTHCARE LTD (CADILA)	ZYDUS LIFESCIENCES LTD (ZYDUS LIFESCIENCES)
GLAXOSMITHKLINE (GLAXOSMITHKLINE)	HALEON US HOLDINGS LLC (HALEON US HOLDINGS)
GLAXOSMITHKLINE CONSUMER HEALTHCARE (GLAXOSMITHKLINE CONS)	HALEON US HOLDINGS LLC (HALEON US HOLDINGS)
GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS US LLC (GLAXOSMITHKLINE CONS)	HALEON US HOLDINGS LLC (HALEON US HOLDINGS)

TARO PHARMACEUTICALS USA INC
(TARO)

TARO PHARMACEUTICALS INC
(TARO)

VERTICE PHARMA MANAGEMENT CORP
(VERTICE)

ENCUBE ETHICALS PRIVATE LTD
(ENCUBE)

1.4 LEVOTHYROXINE SODIUM¹

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 therapeutic equivalence codes may be potentially confusing and inadequate for these drug products. Looking at the Orange Book listing alone for a product identified as a reference listed drug or reference standard, it may be difficult to determine to which therapeutic equivalence code the reference listed drugs and/or reference standard designation corresponds. For example, Unithroid 0.3 mg strength has been assigned the therapeutic equivalence codes AB1, AB2, and AB3 and it is identified as the reference listed drug and reference standard, but it is unclear that the reference listed drug and reference standard designations are associated with the AB1 therapeutic equivalence code.

Accordingly, FDA provides the following chart, which identifies (1) a reference listed drug for each therapeutic equivalence code in the Orange Book and (2) and the reference standard products in the Active Section of the Orange Book.²

- Therapeutic equivalence has been established between products that have the same AB+number therapeutic equivalence code (i.e. AB1, AB2, AB3 or AB4).
- More than one therapeutic equivalence code may apply to some products. One common therapeutic equivalence code indicates therapeutic equivalence between products. For example, Unithroid has been assigned therapeutic equivalence codes AB1, AB2, and AB3 therefore Unithroid tablets are considered therapeutically equivalent to other levothyroxine sodium products of the same strength with these therapeutic equivalence codes.

TE Code	Proprietary Name	Applicant	Strength	Appl No	RLD	RS
AB1	UNITHROID	STEVENS J	0.3MG	N021210	RLD	RS

¹ In previous editions of the Orange Book, FDA provided a chart outlining therapeutic equivalence codes for all .025 mg levothyroxine sodium drug products in the Active Section of the Orange Book. FDA has decided, for ease of review, to revise the chart to identify the NDAs for the reference listed drugs for each therapeutic equivalence code (i.e., AB1, AB2, AB3, and AB4), and their corresponding reference standards, which are identified in 0.2 and 0.3 mg strengths.

² Please consult the Active Section of the Orange Book for information on other strengths.

AB2	SYNTHROID	ABBVIE	0.3MG	N021402	RLD	RS
AB3	LEVOXYL	KING PHARMS	0.2MG	N021301	RLD	RS
AB4	THYRO-TABS	ALVOGEN INC	0.3MG	N021116	RLD	-
AB4	LEVOTHYROXINE SODIUM ³	MYLAN	0.3MG	A076187	-	RS

1.5 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>, has been available on the internet and has become the updated-every-month Orange Book. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: <http://bookstore.gpo.gov>; toll free 866-512-1800.

There are historical lists of Orange Book cumulative supplement product monthly changes at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm>. There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm>. The drug product text files are provided in eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format are updated quarterly.

³ Lloyd's Thyro-Tabs tablets (NDA 021116) (previously known as Levothroid) previously was listed in the Discontinued Drug Product List section of the Orange Book. It is the RLD for therapeutic equivalents identified with the AB4 code. During this time, Mylan's levothyroxine product (ANDA 076187) was selected as the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. It remains 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 Nataline, Principal Consultant, Lachman Consultant Services, Inc., Docket No. FDA-2015-P-0403 (May 27, 2016).

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List,
 Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List,
<https://www.fda.gov/about-fda/reports-manuals-forms/forms>.

The current listing of the Orphan Product Designations and Approvals is available at <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products>.

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (December of the previous Annual Edition) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST COUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES</u>	<u>DEC</u>	<u>MAR</u>	<u>JUN</u>	<u>SEP</u>	<u>DEC</u>
<u>COUNTED</u>	<u>2023</u>	<u>2024</u>	<u>2024</u>	<u>2024</u>	<u>2024</u>

DRUG PRODUCTS LISTED SINGLE SOURCE	23099 2784 (12.1%)
MULTISOURCE	20315 (87.9%)
THERAPEUTICALLY EQUIVALENT	20252 (87.7%)
NOT THERAPEUTICALLY EQUIVALENT	63 (0.3%)
EXCEPTIONS ⁴	46 (0.2%)
NEW MOLECULAR ENTITIES APPROVED	8
NUMBER OF APPLICANTS	1214

1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route of Administration and then by trade name (or established name of the active ingredient, if no trade name exists).

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, Reference Standard symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form, new route(s) of administration, new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

NEWA	New drug product approval
NFTG	New first-time generic approval
CAHN ⁵	Applicant holder firm name has changed

⁴ Amino acid containing products of varying composition (see Introduction, page xx of the List).

⁵ The Cumulative Supplement (CS) currently displays a condensed 20 character collapsed applicant holder firm name and the Electronic Orange Book (EOB) query may display up to a 250-character full applicant holder firm name. An applicant holder firm name change usually changes both the collapsed name and long name. On occasion, only the long name is changed resulting in the CS displaying only the collapsed name for the >D> and >A> action. The new firm long name will display in the EOB query.

CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration
CFTG	Change. A TE Code is added when a first time generic for an innovator is approved.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMKT	Change. RX to OTC marketing status switch.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug
CHRS	Change. Reference Standard
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will appear in the discontinued section in the next edition.

ABACAVIR SULFATE; LAMIVUDINE

TABLET;ORAL

ABACAVIR SULFATE AND LAMIVUDINE

>D>	AB	CIPLA	EQ 600MG BASE;300MG	A 091144	001	Mar 28, 2017	Jan	CHRS
>A>	AB	!	EQ 600MG BASE;300MG	A 091144	001	Mar 28, 2017	Jan	CHRS
>D>		EPZICOM						
>D>	AB	+!	VIIV HLTHCARE EQ 600MG BASE;300MG	N 021652	001	Aug 02, 2004	Jan	DISC
>A>		+ @	EQ 600MG BASE;300MG	N 021652	001	Aug 02, 2004	Jan	DISC
>D>		TABLET, FOR SUSPENSION;ORAL						
>D>		ABACAVIR SULFATE AND LAMIVUDINE						
>D>		+!	MYLAN LABS LTD EQ 60MG BASE;30MG	N 204311	001	Dec 22, 2023	Jan	DISC
>A>		+ @	EQ 60MG BASE;30MG	N 204311	001	Dec 22, 2023	Jan	DISC

ACETAMINOPHEN; BUTALBITAL

TABLET;ORAL

BUTALBITAL AND ACETAMINOPHEN

>A>	AA	QUAGEN	300MG;50MG	A 214305	001	Feb 01, 2024	Jan	NEWA
>A>	AA		325MG;50MG	A 214291	001	Jan 18, 2024	Jan	NEWA

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE;ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

>A>	AA	QUAGEN	300MG;50MG;40MG	A 214288	001	Feb 08, 2024	Jan	NEWA
>D>		TABLET;ORAL						
>A>	AA	QUAGEN	325MG;50MG;40MG	A 214287	001	Jan 18, 2024	Jan	NEWA

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET;ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>D>	AA	SUN PHARM INDS LTD	300MG;30MG	A 085868	001		Jan	DISC
>A>		@	300MG;30MG	A 085868	001		Jan	DISC

ACETAZOLAMIDE

TABLET;ORAL

ACETAZOLAMIDE

>A>		@ TORRENT	125MG	A 213706	001	Jan 26, 2024	Jan	DISC
>A>		@	250MG	A 213706	002	Jan 26, 2024	Jan	DISC

ALBUTEROL SULFATE; BUDESONIDE

AEROSOL, METERED; INHALATION

AIRSUPRA

>A>		+!	ASTRAZENECA EQ 0.09MG BASE/INH;0.08MG/INH	N 214070	001	Jan 10, 2023	Jan	CPOT
>D>		+!	EQ 90MCG BASE/INH;80MCG/INH	N 214070	001	Jan 10, 2023	Jan	CPOT

AMANTADINE HYDROCHLORIDE

SYRUP;ORAL

AMANTADINE HYDROCHLORIDE

>D>		@ ANDA REPOSITORY	50MG/5ML	A 076352	001	Sep 10, 2004	Jan	CAHN
>A>		@ GENUS	50MG/5ML	A 076352	001	Sep 10, 2004	Jan	CAHN

AMCINONIDE

LOTION;TOPICAL

AMCINONIDE

>D>		!	ANDA REPOSITORY 0.1%	A 076329	001	Nov 06, 2002	Jan	CAHN
>A>		!	GENUS 0.1%	A 076329	001	Nov 06, 2002	Jan	CAHN

OINTMENT;TOPICAL

AMCINONIDE

>D>	AB	!	ANDA REPOSITORY 0.1%	A 076096	001	Nov 19, 2002	Jan	CAHN
>A>	AB	!	GENUS 0.1%	A 076096	001	Nov 19, 2002	Jan	CAHN

AMLODIPINE BESYLATE

TABLET;ORAL

AMLODIPINE BESYLATE

>D>	AB	SUN PHARM INDS LTD	EQ 2.5MG BASE	A 077974	001	Jul 09, 2007	Jan	DISC
>A>		@	EQ 2.5MG BASE	A 077974	001	Jul 09, 2007	Jan	DISC
>D>	AB		EQ 5MG BASE	A 077974	002	Jul 09, 2007	Jan	DISC
>A>		@	EQ 5MG BASE	A 077974	002	Jul 09, 2007	Jan	DISC
>D>	AB		EQ 10MG BASE	A 077974	003	Jul 09, 2007	Jan	DISC

TABLET;ORAL
 AMLODIPINE BESYLATE

>A> @ EQ 10MG BASE A077974 003 Jul 09, 2007 Jan DISC

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE;ORAL

ADDERALL XR 10

>D> AB + TAKEDA PHARMS USA 2.5MG;2.5MG;2.5MG;2.5MG N021303 001 Oct 11, 2001 Jan CTEC
 >A> AB1 + 2.5MG;2.5MG;2.5MG;2.5MG N021303 001 Oct 11, 2001 Jan CTEC

ADDERALL XR 15

>D> AB + TAKEDA PHARMS USA 3.75MG;3.75MG;3.75MG;3.75MG N021303 006 May 22, 2002 Jan CTEC
 >A> AB1 + 3.75MG;3.75MG;3.75MG;3.75MG N021303 006 May 22, 2002 Jan CTEC

ADDERALL XR 20

>D> AB + TAKEDA PHARMS USA 5MG;5MG;5MG;5MG N021303 002 Oct 11, 2001 Jan CTEC
 >A> AB1 + 5MG;5MG;5MG;5MG N021303 002 Oct 11, 2001 Jan CTEC

ADDERALL XR 25

>D> AB + TAKEDA PHARMS USA 6.25MG;6.25MG;6.25MG;6.25MG N021303 004 May 22, 2002 Jan CTEC
 >A> AB1 + 6.25MG;6.25MG;6.25MG;6.25MG N021303 004 May 22, 2002 Jan CTEC

ADDERALL XR 30

>D> AB +! TAKEDA PHARMS USA 7.5MG;7.5MG;7.5MG;7.5MG N021303 003 Oct 11, 2001 Jan CTEC
 >A> AB1 +! 7.5MG;7.5MG;7.5MG;7.5MG N021303 003 Oct 11, 2001 Jan CTEC

ADDERALL XR 5

>D> AB + TAKEDA PHARMS USA 1.25MG;1.25MG;1.25MG;1.25MG N021303 005 May 22, 2002 Jan CTEC
 >A> AB1 + 1.25MG;1.25MG;1.25MG;1.25MG N021303 005 May 22, 2002 Jan CTEC

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>D> AB ACTAVIS ELIZABETH 1.25MG;1.25MG;1.25MG;1.25MG A077302 001 Jun 22, 2012 Jan CTEC
 >A> AB1 1.25MG;1.25MG;1.25MG;1.25MG A077302 001 Jun 22, 2012 Jan CTEC
 >D> AB 2.5MG;2.5MG;2.5MG;2.5MG A077302 002 Jun 22, 2012 Jan CTEC
 >A> AB1 2.5MG;2.5MG;2.5MG;2.5MG A077302 002 Jun 22, 2012 Jan CTEC
 >D> AB 3.75MG;3.75MG;3.75MG;3.75MG A077302 003 Jun 22, 2012 Jan CTEC
 >A> AB1 3.75MG;3.75MG;3.75MG;3.75MG A077302 003 Jun 22, 2012 Jan CTEC
 >D> AB 5MG;5MG;5MG;5MG A077302 004 Jun 22, 2012 Jan CTEC
 >A> AB1 5MG;5MG;5MG;5MG A077302 004 Jun 22, 2012 Jan CTEC
 >D> AB 6.25MG;6.25MG;6.25MG;6.25MG A077302 005 Jun 22, 2012 Jan CTEC
 >A> AB1 6.25MG;6.25MG;6.25MG;6.25MG A077302 005 Jun 22, 2012 Jan CTEC
 >D> AB 7.5MG;7.5MG;7.5MG;7.5MG A077302 006 Jun 22, 2012 Jan CTEC
 >A> AB1 7.5MG;7.5MG;7.5MG;7.5MG A077302 006 Jun 22, 2012 Jan CTEC
 >D> AB ANI PHARMS 1.25MG;1.25MG;1.25MG;1.25MG A205401 001 Jan 22, 2019 Jan CTEC
 >A> AB1 1.25MG;1.25MG;1.25MG;1.25MG A205401 001 Jan 22, 2019 Jan CTEC
 >D> AB 2.5MG;2.5MG;2.5MG;2.5MG A205401 002 Jan 22, 2019 Jan CTEC
 >A> AB1 2.5MG;2.5MG;2.5MG;2.5MG A205401 002 Jan 22, 2019 Jan CTEC
 >D> AB 3.75MG;3.75MG;3.75MG;3.75MG A205401 003 Jan 22, 2019 Jan CTEC
 >A> AB1 3.75MG;3.75MG;3.75MG;3.75MG A205401 003 Jan 22, 2019 Jan CTEC
 >D> AB 5MG;5MG;5MG;5MG A205401 004 Jan 22, 2019 Jan CTEC
 >A> AB1 5MG;5MG;5MG;5MG A205401 004 Jan 22, 2019 Jan CTEC
 >D> AB 6.25MG;6.25MG;6.25MG;6.25MG A205401 005 Jan 22, 2019 Jan CTEC
 >A> AB1 6.25MG;6.25MG;6.25MG;6.25MG A205401 005 Jan 22, 2019 Jan CTEC
 >D> AB 7.5MG;7.5MG;7.5MG;7.5MG A205401 006 Jan 22, 2019 Jan CTEC
 >A> AB1 7.5MG;7.5MG;7.5MG;7.5MG A205401 006 Jan 22, 2019 Jan CTEC
 >D> AB ASCENT PHARMS INC 1.25MG;1.25MG;1.25MG;1.25MG A214959 001 Sep 29, 2021 Jan CTEC
 >A> AB1 1.25MG;1.25MG;1.25MG;1.25MG A214959 001 Sep 29, 2021 Jan CTEC
 >D> AB 2.5MG;2.5MG;2.5MG;2.5MG A214959 002 Sep 29, 2021 Jan CTEC
 >A> AB1 2.5MG;2.5MG;2.5MG;2.5MG A214959 002 Sep 29, 2021 Jan CTEC
 >D> AB 3.75MG;3.75MG;3.75MG;3.75MG A214959 003 Sep 29, 2021 Jan CTEC
 >A> AB1 3.75MG;3.75MG;3.75MG;3.75MG A214959 003 Sep 29, 2021 Jan CTEC
 >D> AB 5MG;5MG;5MG;5MG A214959 004 Sep 29, 2021 Jan CTEC
 >A> AB1 5MG;5MG;5MG;5MG A214959 004 Sep 29, 2021 Jan CTEC
 >D> AB 6.25MG;6.25MG;6.25MG;6.25MG A214959 005 Sep 29, 2021 Jan CTEC
 >A> AB1 6.25MG;6.25MG;6.25MG;6.25MG A214959 005 Sep 29, 2021 Jan CTEC
 >D> AB 7.5MG;7.5MG;7.5MG;7.5MG A214959 006 Sep 29, 2021 Jan CTEC
 >A> AB1 7.5MG;7.5MG;7.5MG;7.5MG A214959 006 Sep 29, 2021 Jan CTEC
 >D> AB ELITE LABS INC 1.25MG;1.25MG;1.25MG;1.25MG A212037 001 Dec 11, 2019 Jan CTEC
 >A> AB1 1.25MG;1.25MG;1.25MG;1.25MG A212037 001 Dec 11, 2019 Jan CTEC
 >D> AB 2.5MG;2.5MG;2.5MG;2.5MG A212037 002 Dec 11, 2019 Jan CTEC
 >A> AB1 2.5MG;2.5MG;2.5MG;2.5MG A212037 002 Dec 11, 2019 Jan CTEC
 >D> AB 3.75MG;3.75MG;3.75MG;3.75MG A212037 003 Dec 11, 2019 Jan CTEC
 >A> AB1 3.75MG;3.75MG;3.75MG;3.75MG A212037 003 Dec 11, 2019 Jan CTEC
 >D> AB 5MG;5MG;5MG;5MG A212037 004 Dec 11, 2019 Jan CTEC
 >A> AB1 5MG;5MG;5MG;5MG A212037 004 Dec 11, 2019 Jan CTEC
 >D> AB 6.25MG;6.25MG;6.25MG;6.25MG A212037 005 Dec 11, 2019 Jan CTEC
 >A> AB1 6.25MG;6.25MG;6.25MG;6.25MG A212037 005 Dec 11, 2019 Jan CTEC
 >D> AB 7.5MG;7.5MG;7.5MG;7.5MG A212037 006 Dec 11, 2019 Jan CTEC
 >A> AB1 7.5MG;7.5MG;7.5MG;7.5MG A212037 006 Dec 11, 2019 Jan CTEC

CAPSULE, EXTENDED RELEASE;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>D>	AB	GRANULES	1.25MG;1.25MG;1.25MG;1.25MG	A217027	001	Jan 23, 2023	Jan CTEC
>A>	AB1		1.25MG;1.25MG;1.25MG;1.25MG	A217027	001	Jan 23, 2023	Jan CTEC
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A217027	002	Jan 23, 2023	Jan CTEC
>A>	AB1		2.5MG;2.5MG;2.5MG;2.5MG	A217027	002	Jan 23, 2023	Jan CTEC
>D>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A217027	003	Jan 23, 2023	Jan CTEC
>A>	AB1		3.75MG;3.75MG;3.75MG;3.75MG	A217027	003	Jan 23, 2023	Jan CTEC
>D>	AB		5MG;5MG;5MG;5MG	A217027	004	Jan 23, 2023	Jan CTEC
>A>	AB1		5MG;5MG;5MG;5MG	A217027	004	Jan 23, 2023	Jan CTEC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A217027	005	Jan 23, 2023	Jan CTEC
>A>	AB1		6.25MG;6.25MG;6.25MG;6.25MG	A217027	005	Jan 23, 2023	Jan CTEC
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A217027	006	Jan 23, 2023	Jan CTEC
>A>	AB1		7.5MG;7.5MG;7.5MG;7.5MG	A217027	006	Jan 23, 2023	Jan CTEC
>D>	AB	IMPAX LABS	1.25MG;1.25MG;1.25MG;1.25MG	A076852	001	Feb 16, 2016	Jan CTEC
>A>	AB1		1.25MG;1.25MG;1.25MG;1.25MG	A076852	001	Feb 16, 2016	Jan CTEC
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A076852	002	Feb 16, 2016	Jan CTEC
>A>	AB1		2.5MG;2.5MG;2.5MG;2.5MG	A076852	002	Feb 16, 2016	Jan CTEC
>D>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A076852	003	Feb 16, 2016	Jan CTEC
>A>	AB1		3.75MG;3.75MG;3.75MG;3.75MG	A076852	003	Feb 16, 2016	Jan CTEC
>D>	AB		5MG;5MG;5MG;5MG	A076852	004	Feb 16, 2016	Jan CTEC
>A>	AB1		5MG;5MG;5MG;5MG	A076852	004	Feb 16, 2016	Jan CTEC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A076852	005	Feb 16, 2016	Jan CTEC
>A>	AB1		6.25MG;6.25MG;6.25MG;6.25MG	A076852	005	Feb 16, 2016	Jan CTEC
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A076852	006	Feb 16, 2016	Jan CTEC
>A>	AB1		7.5MG;7.5MG;7.5MG;7.5MG	A076852	006	Feb 16, 2016	Jan CTEC
>D>	AB	LANNETT CO INC	1.25MG;1.25MG;1.25MG;1.25MG	A214403	001	Nov 26, 2021	Jan CTEC
>A>	AB1		1.25MG;1.25MG;1.25MG;1.25MG	A214403	001	Nov 26, 2021	Jan CTEC
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A214403	002	Nov 26, 2021	Jan CTEC
>A>	AB1		2.5MG;2.5MG;2.5MG;2.5MG	A214403	002	Nov 26, 2021	Jan CTEC
>D>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A214403	003	Nov 26, 2021	Jan CTEC
>A>	AB1		3.75MG;3.75MG;3.75MG;3.75MG	A214403	003	Nov 26, 2021	Jan CTEC
>D>	AB		5MG;5MG;5MG;5MG	A214403	004	Nov 26, 2021	Jan CTEC
>A>	AB1		5MG;5MG;5MG;5MG	A214403	004	Nov 26, 2021	Jan CTEC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A214403	005	Nov 26, 2021	Jan CTEC
>A>	AB1		6.25MG;6.25MG;6.25MG;6.25MG	A214403	005	Nov 26, 2021	Jan CTEC
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A214403	006	Nov 26, 2021	Jan CTEC
>A>	AB1		7.5MG;7.5MG;7.5MG;7.5MG	A214403	006	Nov 26, 2021	Jan CTEC
>D>	AB	RHODES PHARMS	1.25MG;1.25MG;1.25MG;1.25MG	A210651	001	May 17, 2019	Jan CTEC
>A>	AB1		1.25MG;1.25MG;1.25MG;1.25MG	A210651	001	May 17, 2019	Jan CTEC
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A210651	002	May 17, 2019	Jan CTEC
>A>	AB1		2.5MG;2.5MG;2.5MG;2.5MG	A210651	002	May 17, 2019	Jan CTEC
>D>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A210651	003	May 17, 2019	Jan CTEC
>A>	AB1		3.75MG;3.75MG;3.75MG;3.75MG	A210651	003	May 17, 2019	Jan CTEC
>D>	AB		5MG;5MG;5MG;5MG	A210651	004	May 17, 2019	Jan CTEC
>A>	AB1		5MG;5MG;5MG;5MG	A210651	004	May 17, 2019	Jan CTEC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A210651	005	May 17, 2019	Jan CTEC
>A>	AB1		6.25MG;6.25MG;6.25MG;6.25MG	A210651	005	May 17, 2019	Jan CTEC
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A210651	006	May 17, 2019	Jan CTEC
>A>	AB1		7.5MG;7.5MG;7.5MG;7.5MG	A210651	006	May 17, 2019	Jan CTEC
>D>	AB	SPECGX LLC	1.25MG;1.25MG;1.25MG;1.25MG	A211547	001	Apr 22, 2019	Jan CTEC
>A>	AB1		1.25MG;1.25MG;1.25MG;1.25MG	A211547	001	Apr 22, 2019	Jan CTEC
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A211547	002	Apr 22, 2019	Jan CTEC
>A>	AB1		2.5MG;2.5MG;2.5MG;2.5MG	A211547	002	Apr 22, 2019	Jan CTEC
>D>	AB		3.125MG;3.125MG;3.125MG;3.125MG	A211546	001	Aug 31, 2023	Jan CTEC
>A>	AB2		3.125MG;3.125MG;3.125MG;3.125MG	A211546	001	Aug 31, 2023	Jan CTEC
>D>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A211547	003	Apr 22, 2019	Jan CTEC
>A>	AB1		3.75MG;3.75MG;3.75MG;3.75MG	A211547	003	Apr 22, 2019	Jan CTEC
>D>	AB		5MG;5MG;5MG;5MG	A211547	004	Apr 22, 2019	Jan CTEC
>A>	AB1		5MG;5MG;5MG;5MG	A211547	004	Apr 22, 2019	Jan CTEC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A211546	002	Aug 31, 2023	Jan CTEC
>A>	AB2		6.25MG;6.25MG;6.25MG;6.25MG	A211546	002	Aug 31, 2023	Jan CTEC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A211547	005	Apr 22, 2019	Jan CTEC
>A>	AB1		6.25MG;6.25MG;6.25MG;6.25MG	A211547	005	Apr 22, 2019	Jan CTEC
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A211547	006	Apr 22, 2019	Jan CTEC
>A>	AB1		7.5MG;7.5MG;7.5MG;7.5MG	A211547	006	Apr 22, 2019	Jan CTEC
>D>	AB		9.375MG;9.375MG;9.375MG;9.375MG	A211546	003	Aug 31, 2023	Jan CTEC
>A>	AB2		9.375MG;9.375MG;9.375MG;9.375MG	A211546	003	Aug 31, 2023	Jan CTEC
>D>	AB		12.5MG;12.5MG;12.5MG;12.5MG	A211546	004	Aug 31, 2023	Jan CTEC
>A>	AB2		12.5MG;12.5MG;12.5MG;12.5MG	A211546	004	Aug 31, 2023	Jan CTEC
>D>	AB	SUN PHARM INDS INC	3.125MG;3.125MG;3.125MG;3.125MG	A215997	001	Sep 27, 2023	Jan CTEC
>A>	AB2		3.125MG;3.125MG;3.125MG;3.125MG	A215997	001	Sep 27, 2023	Jan CTEC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A215997	002	Sep 27, 2023	Jan CTEC
>A>	AB2		6.25MG;6.25MG;6.25MG;6.25MG	A215997	002	Sep 27, 2023	Jan CTEC

CAPSULE, EXTENDED RELEASE;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>D>	AB		9.375MG;9.375MG;9.375MG;9.375MG	A215997	003	Sep 27, 2023	Jan CTEC	
>A>	AB2		9.375MG;9.375MG;9.375MG;9.375MG	A215997	003	Sep 27, 2023	Jan CTEC	
>D>	AB		12.5MG;12.5MG;12.5MG;12.5MG	A215997	004	Sep 27, 2023	Jan CTEC	
>A>	AB2		12.5MG;12.5MG;12.5MG;12.5MG	A215997	004	Sep 27, 2023	Jan CTEC	
>D>	AB	SUN PHARM INDUSTRIES	1.25MG;1.25MG;1.25MG;1.25MG	A211715	001	May 17, 2019	Jan CTEC	
>A>	AB1		1.25MG;1.25MG;1.25MG;1.25MG	A211715	001	May 17, 2019	Jan CTEC	
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A211715	002	May 17, 2019	Jan CTEC	
>A>	AB1		2.5MG;2.5MG;2.5MG;2.5MG	A211715	002	May 17, 2019	Jan CTEC	
>D>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A211715	003	May 17, 2019	Jan CTEC	
>A>	AB1		3.75MG;3.75MG;3.75MG;3.75MG	A211715	003	May 17, 2019	Jan CTEC	
>D>	AB		5MG;5MG;5MG;5MG	A211715	004	May 17, 2019	Jan CTEC	
>A>	AB1		5MG;5MG;5MG;5MG	A211715	004	May 17, 2019	Jan CTEC	
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A211715	005	May 17, 2019	Jan CTEC	
>A>	AB1		6.25MG;6.25MG;6.25MG;6.25MG	A211715	005	May 17, 2019	Jan CTEC	
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A211715	006	May 17, 2019	Jan CTEC	
>A>	AB1		7.5MG;7.5MG;7.5MG;7.5MG	A211715	006	May 17, 2019	Jan CTEC	
>D>	AB	TEVA PHARMS USA	3.125MG;3.125MG;3.125MG;3.125MG	A210876	001	Jan 31, 2022	Jan CTEC	
>A>	AB2		3.125MG;3.125MG;3.125MG;3.125MG	A210876	001	Jan 31, 2022	Jan CTEC	
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A210876	002	Jan 31, 2022	Jan CTEC	
>A>	AB2		6.25MG;6.25MG;6.25MG;6.25MG	A210876	002	Jan 31, 2022	Jan CTEC	
>D>	AB		9.375MG;9.375MG;9.375MG;9.375MG	A210876	003	Jan 31, 2022	Jan CTEC	
>A>	AB2		9.375MG;9.375MG;9.375MG;9.375MG	A210876	003	Jan 31, 2022	Jan CTEC	
>D>	AB		12.5MG;12.5MG;12.5MG;12.5MG	A210876	004	Jan 31, 2022	Jan CTEC	
>A>	AB2		12.5MG;12.5MG;12.5MG;12.5MG	A210876	004	Jan 31, 2022	Jan CTEC	
		MYDAYIS						
>D>	AB	+	TAKEDA PHARMS USA	3.125MG;3.125MG;3.125MG;3.125MG	N022063	001	Jun 20, 2017	Jan CTEC
>A>	AB2	+		3.125MG;3.125MG;3.125MG;3.125MG	N022063	001	Jun 20, 2017	Jan CTEC
>D>	AB	+		6.25MG;6.25MG;6.25MG;6.25MG	N022063	002	Jun 20, 2017	Jan CTEC
>A>	AB2	+		6.25MG;6.25MG;6.25MG;6.25MG	N022063	002	Jun 20, 2017	Jan CTEC
>D>	AB	+		9.375MG;9.375MG;9.375MG;9.375MG	N022063	003	Jun 20, 2017	Jan CTEC
>A>	AB2	+		9.375MG;9.375MG;9.375MG;9.375MG	N022063	003	Jun 20, 2017	Jan CTEC
>D>	AB	+	!	12.5MG;12.5MG;12.5MG;12.5MG	N022063	004	Jun 20, 2017	Jan CTEC
>A>	AB2	+	!	12.5MG;12.5MG;12.5MG;12.5MG	N022063	004	Jun 20, 2017	Jan CTEC

APREMILAST

TABLET;ORAL

APREMILAST

>A>	AB	MANKIND PHARMA	10MG	A211734	001	Feb 07, 2024	Jan NEWA
>A>	AB		20MG	A211734	002	Feb 07, 2024	Jan NEWA
>A>	AB		30MG	A211734	003	Feb 07, 2024	Jan NEWA

ARIPIPRAZOLE LAUROXIL

SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR

ARISTADA INITIO KIT

>D>	+	ALKERMES INC	675MG/2.4ML	N209830	001	Jun 29, 2018	Jan CPOT
>A>	+		675MG/2.4ML (281.25MG/ML)	N209830	001	Jun 29, 2018	Jan CPOT

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE;ORAL

LANORINAL

>D>	AA	!	LANNETT	325MG;50MG;40MG	A086996	002	Oct 11, 1985	Jan CAHN
>A>	AA	!	SANDOZ	325MG;50MG;40MG	A086996	002	Oct 11, 1985	Jan CAHN

ATOMOXETINE HYDROCHLORIDE

CAPSULE;ORAL

ATOMOXETINE HYDROCHLORIDE

>D>	AB	ZYDUS PHARMS USA INC	18MG	A079017	001	Sep 17, 2010	Jan CMS1
>A>	AB		18MG	A079017	001	Sep 16, 2010	Jan CMS1
>D>	AB		25MG	A079017	002	Sep 17, 2010	Jan CMS1
>A>	AB		25MG	A079017	002	Sep 16, 2010	Jan CMS1
>D>	AB		40MG	A079017	003	Sep 17, 2010	Jan CMS1
>A>	AB		40MG	A079017	003	Sep 16, 2010	Jan CMS1
>D>	AB		60MG	A079017	004	Sep 17, 2010	Jan CMS1
>A>	AB		60MG	A079017	004	Sep 16, 2010	Jan CMS1
>D>	AB		80MG	A079017	005	Sep 17, 2010	Jan CMS1
>A>	AB		80MG	A079017	005	Sep 16, 2010	Jan CMS1
>D>	AB		100MG	A079017	006	Sep 17, 2010	Jan CMS1
>A>	AB		100MG	A079017	006	Sep 16, 2010	Jan CMS1

ATORVASTATIN CALCIUM

TABLET; ORAL

ATORVASTATIN CALCIUM

>A>	AB	ANBISON LAB	EQ 10MG BASE	A211886	001	Jan 25, 2024	Jan NEWA
>A>	AB		EQ 20MG BASE	A211886	002	Jan 25, 2024	Jan NEWA
>A>	AB		EQ 40MG BASE	A211886	003	Jan 25, 2024	Jan NEWA
>A>	AB		EQ 80MG BASE	A211886	004	Jan 25, 2024	Jan NEWA
>A>	AB	LAURUS	EQ 10MG BASE	A214513	001	Jan 22, 2024	Jan NEWA
>A>	AB		EQ 20MG BASE	A214513	002	Jan 22, 2024	Jan NEWA
>A>	AB		EQ 40MG BASE	A214513	003	Jan 22, 2024	Jan NEWA
>A>	AB		EQ 80MG BASE	A214513	004	Jan 22, 2024	Jan NEWA

AVACINCAPTAD PEGOL SODIUM

SOLUTION; INTRAVITREAL

IZERVAY

>A>	+	ASTELLAS	EQ 2MG BASE/0.1ML (EQ 2MG BASE/0.1ML)	N217225	001	Aug 04, 2023	Jan CAHN
>D>	+	IVERIC BIO	EQ 2MG BASE/0.1ML (EQ 2MG BASE/0.1ML)	N217225	001	Aug 04, 2023	Jan CAHN

BACLOFEN

INJECTABLE; INTRATHECAL

BACLOFEN

>D>	AP	ACIC PHARMS	0.5MG/ML	A216309	001	Aug 10, 2023	Jan DISC
>A>		@	0.5MG/ML	A216309	001	Aug 10, 2023	Jan DISC
>D>	AP		2MG/ML	A216309	002	Aug 10, 2023	Jan DISC
>A>		@	2MG/ML	A216309	002	Aug 10, 2023	Jan DISC

TABLET; ORAL

BACLOFEN

>A>		RUBICON	15MG	A209102	004	Feb 05, 2024	Jan NEWA
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BERDAZIMER SODIUM

>A> GEL; TOPICAL

>A> ZELSUVMI

>A>	+	LNHC	EQ 10.3% BASE	N217424	001	Jan 05, 2024	Jan NEWA
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BETAMETHASONE DIPROPIONATE

OINTMENT, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

>A>		@ PADAGIS US	EQ 0.05% BASE	A206118	001	Nov 09, 2017	Jan CAHN
>D>		@ PAI HOLDINGS PHARM	EQ 0.05% BASE	A206118	001	Nov 09, 2017	Jan CAHN

BICALUTAMIDE

TABLET; ORAL

BICALUTAMIDE

>D>	AB	BRECKENRIDGE	50MG	A091011	001	Jun 10, 2015	Jan CAHN
>A>	AB	CHARTWELL RX	50MG	A091011	001	Jun 10, 2015	Jan CAHN

BIRCH TRITERPENES

GEL; TOPICAL

FILSUVEZ

>D>	+	AMRYT	10%	N215064	001	Dec 18, 2023	Jan CAHN
>A>	+	CHIESI	10%	N215064	001	Dec 18, 2023	Jan CAHN

BISOPROLOL FUMARATE

TABLET; ORAL

BISOPROLOL FUMARATE

>A>	AB	HARMAN FINOCHEM	5MG	A217617	001	Jan 18, 2024	Jan NEWA
>A>	AB		10MG	A217617	002	Jan 18, 2024	Jan NEWA

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN SULFATE

>D>	AP	TEVA PHARMS USA	EQ 15 UNITS BASE/VIAL	A065033	001	Jun 27, 2000	Jan DISC
>A>		@	EQ 15 UNITS BASE/VIAL	A065033	001	Jun 27, 2000	Jan DISC
>D>	AP		EQ 30 UNITS BASE/VIAL	A065033	002	Jun 27, 2000	Jan DISC
>A>		@	EQ 30 UNITS BASE/VIAL	A065033	002	Jun 27, 2000	Jan DISC

BROMFENAC SODIUM

SOLUTION/DROPS;OPHTHALMIC

>A>		BROMFENAC SODIUM						
>A>	AB	LUPIN LTD	EQ 0.075% ACID	A211239	001	Feb 02, 2024	Jan	NFTG
		BROMSITE						
>D>	+	SUN PHARM	EQ 0.075% ACID	N206911	001	Apr 08, 2016	Jan	CFTG
>A>	AB	+	EQ 0.075% ACID	N206911	001	Apr 08, 2016	Jan	CFTG

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE;INJECTION

>D>		BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE						
>D>	!	SEPTODONT	0.5%;0.0091MG/ML	A077250	001	Sep 27, 2006	Jan	CTNA
>A>		VIVACAINE						
>A>	!	SEPTODONT	0.5%;0.0091MG/ML	A077250	001	Sep 27, 2006	Jan	CTNA

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE;INJECTION

BUPRENORPHINE HYDROCHLORIDE

>D>	AP	AM REGENT	EQ 0.3MG BASE/ML	A078331	001	Mar 27, 2007	Jan	DISC
>A>		@	EQ 0.3MG BASE/ML	A078331	001	Mar 27, 2007	Jan	DISC

BUSPIRONE HYDROCHLORIDE

TABLET;ORAL

BUSPIRONE HYDROCHLORIDE

>A>	AB	AIPING PHARM INC	5MG	A202087	001	Dec 16, 2015	Jan	CAHN
>A>	AB		10MG	A202087	002	Dec 16, 2015	Jan	CAHN
>A>	AB		15MG	A202087	003	Dec 16, 2015	Jan	CAHN
>A>	AB		30MG	A202087	004	Dec 16, 2015	Jan	CAHN
>D>	AB	YILING	5MG	A202087	001	Dec 16, 2015	Jan	CAHN
>D>	AB		10MG	A202087	002	Dec 16, 2015	Jan	CAHN
>D>	AB		15MG	A202087	003	Dec 16, 2015	Jan	CAHN
>D>	AB		30MG	A202087	004	Dec 16, 2015	Jan	CAHN

CARBOPROST TROMETHAMINE

INJECTABLE;INJECTION

CARBOPROST TROMETHAMINE

>A>	AP	ANI PHARMS	EQ 0.25MG BASE/ML	A215901	001	Jan 25, 2024	Jan	NEWA
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CARVEDILOL

TABLET;ORAL

CARVEDILOL

>D>	AB	SUN PHARM INDS LTD	3.125MG	A076989	001	Sep 05, 2007	Jan	DISC
>A>		@	3.125MG	A076989	001	Sep 05, 2007	Jan	DISC
>D>	AB		6.25MG	A076989	002	Sep 05, 2007	Jan	DISC
>A>		@	6.25MG	A076989	002	Sep 05, 2007	Jan	DISC
>D>	AB		12.5MG	A076989	003	Sep 05, 2007	Jan	DISC
>A>		@	12.5MG	A076989	003	Sep 05, 2007	Jan	DISC
>D>	AB		25MG	A076989	004	Sep 05, 2007	Jan	DISC
>A>		@	25MG	A076989	004	Sep 05, 2007	Jan	DISC

CEFAZOLIN SODIUM

INJECTABLE;INJECTION

CEFAZOLIN SODIUM

>A>		QILU	EQ 3GM BASE/VIAL	A203661	003	Jan 24, 2024	Jan	NEWA
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CEFOTAXIME SODIUM

INJECTABLE;INJECTION

CLAFORAN

>A>	+	@	STERIMAX	EQ 500MG BASE/VIAL	N050547	001		Jan	CAHN
>A>	+	@		EQ 1GM BASE/VIAL	N050547	002		Jan	CAHN
>A>	+	@		EQ 2GM BASE/VIAL	N050547	003		Jan	CAHN
>A>	+	@		EQ 10GM BASE/VIAL	N050547	004	Dec 29, 1983	Jan	CAHN
>D>	+	@	VALIDUS PHARMS	EQ 500MG BASE/VIAL	N050547	001		Jan	CAHN
>D>	+	@		EQ 1GM BASE/VIAL	N050547	002		Jan	CAHN
>D>	+	@		EQ 2GM BASE/VIAL	N050547	003		Jan	CAHN
>D>	+	@		EQ 10GM BASE/VIAL	N050547	004	Dec 29, 1983	Jan	CAHN
			CLAFORAN IN DEXTROSE 5% IN PLASTIC CONTAINER						
>A>		@	STERIMAX	EQ 20MG BASE/ML	N050596	002	May 20, 1985	Jan	CAHN
>A>		@		EQ 40MG BASE/ML	N050596	004	May 20, 1985	Jan	CAHN
>D>		@	VALIDUS PHARMS	EQ 20MG BASE/ML	N050596	002	May 20, 1985	Jan	CAHN
>D>		@		EQ 40MG BASE/ML	N050596	004	May 20, 1985	Jan	CAHN

INJECTABLE; INJECTION

CLAFORAN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

>A>	@ STERIMAX	EQ 20MG BASE/ML	N050596	001	May 20, 1985	Jan CAHN
>A>	@	EQ 40MG BASE/ML	N050596	003	May 20, 1985	Jan CAHN
>D>	@ VALIDUS PHARMS	EQ 20MG BASE/ML	N050596	001	May 20, 1985	Jan CAHN
>D>	@	EQ 40MG BASE/ML	N050596	003	May 20, 1985	Jan CAHN

CEFTRIAXONE SODIUM

INJECTABLE; INTRAMUSCULAR, INTRAVENOUS
CEFTRIAXONE

>A>	AP DEVA HOLDING AS	EQ 250MG BASE/VIAL	A210197	001	Jan 12, 2024	Jan NEWA
>A>	AP	EQ 500MG BASE/VIAL	A210197	002	Jan 12, 2024	Jan NEWA
>A>	AP	EQ 1GM BASE/VIAL	A210197	003	Jan 12, 2024	Jan NEWA
>A>	AP	EQ 2GM BASE/VIAL	A210197	004	Jan 12, 2024	Jan NEWA

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL
CETIRIZINE HYDROCHLORIDE

>D>	@ PHARM ASSOC	5MG/5ML	A078412	001	Jun 18, 2008	Jan CMFD
>A>	AA	5MG/5ML	A078412	001	Jun 18, 2008	Jan CMFD

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

>A>	AA HAVIX	500MG	A210961	001	Jan 22, 2024	Jan NEWA
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CICLOPIROX

CREAM; TOPICAL
CICLOPIROX

>D>	AB TARO	0.77%	A076790	001	Apr 12, 2005	Jan CAHN
>A>	AB	0.77%	A076790	001	Apr 12, 2005	Jan CAHN

CITALOPRAM HYDROBROMIDE

TABLET; ORAL
CITALOPRAM HYDROBROMIDE

>A>	AB APOTEX	EQ 10MG BASE	A077046	001	Nov 24, 2004	Jan CAHN
>A>	AB	EQ 20MG BASE	A077046	002	Nov 24, 2004	Jan CAHN
>A>	AB	EQ 40MG BASE	A077046	003	Nov 24, 2004	Jan CAHN
>D>	AB APOTEX INC	EQ 10MG BASE	A077046	001	Nov 24, 2004	Jan CAHN
>D>	@ TARO	EQ 10MG BASE	A077278	001	Mar 22, 2006	Jan CAHN
>A>	@	EQ 10MG BASE	A077278	001	Mar 22, 2006	Jan CAHN
>D>	@	EQ 20MG BASE	A077278	002	Mar 22, 2006	Jan CAHN
>A>	@	EQ 20MG BASE	A077278	002	Mar 22, 2006	Jan CAHN
>D>	@	EQ 40MG BASE	A077278	003	Mar 22, 2006	Jan CAHN
>A>	@	EQ 40MG BASE	A077278	003	Mar 22, 2006	Jan CAHN
>D>	AB TORPHARM	EQ 20MG BASE	A077046	002	Nov 24, 2004	Jan CAHN
>D>	AB	EQ 40MG BASE	A077046	003	Nov 24, 2004	Jan CAHN

CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE

>D>	@ CHARTWELL MOLECULAR	EQ 0.5MG BASE/5ML	A074884	001	Dec 17, 1997	Jan CAHN
>A>	@ NEW HEIGHTS	EQ 0.5MG BASE/5ML	A074884	001	Dec 17, 1997	Jan CAHN

CLINDAMYCIN PHOSPHATE

GEL; VAGINAL
XACIATO

>D>	+! DARE	EQ 2% BASE	N215650	001	Dec 07, 2021	Jan CAHN
>A>	+! ORGANON LLC	EQ 2% BASE	N215650	001	Dec 07, 2021	Jan CAHN

CLOBAZAM

TABLET; ORAL
CLOBAZAM

>D>	AB BRECKENRIDGE	20MG	A209308	002	Oct 22, 2018	Jan DISC
>A>	@	20MG	A209308	002	Oct 22, 2018	Jan DISC

CLONIDINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
CLONIDINE HYDROCHLORIDE

>A>	@ BLUEPHARMA INDUSTRIA	0.1MG	A211433	001	Oct 12, 2018	Jan CAHN
>D>	@ UPSHER SMITH LABS	0.1MG	A211433	001	Oct 12, 2018	Jan CAHN

COBICISTAT

TABLET; ORAL

>A>		COBICISTAT						
>A>	AB	MYLAN LABS LTD	150MG	A209986	001	Feb 07, 2024	Jan	NFTG
		TYBOST						
>D>	+	GILEAD SCIENCES INC	150MG	N203094	001	Sep 24, 2014	Jan	CFTG
>A>	AB	+	150MG	N203094	001	Sep 24, 2014	Jan	CFTG

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYCLOPHOSPHAMIDE

>A>	AP	HIKMA	500MG/VIAL	A216958	001	Dec 18, 2023	Jan	CAHN
>A>	AP		1GM/VIAL	A216958	002	Dec 18, 2023	Jan	CAHN
>A>	AP		2GM/VIAL	A216958	003	Dec 18, 2023	Jan	CAHN
>D>	AP	RK PHARMA	500MG/VIAL	A216958	001	Dec 18, 2023	Jan	CAHN
>D>	AP		1GM/VIAL	A216958	002	Dec 18, 2023	Jan	CAHN
>D>	AP		2GM/VIAL	A216958	003	Dec 18, 2023	Jan	CAHN

SOLUTION; INTRAVENOUS

CYCLOPHOSPHAMIDE

>A>	+	@ BAXTER HLTHCARE CORP	500MG/2.5ML (200MG/ML)	N217651	001	Jun 28, 2023	Jan	CAHN
>A>	+	@	1GM/5ML (200MG/ML)	N217651	002	Jun 28, 2023	Jan	CAHN
>D>	+	@ NEVAKAR INJECTABLES	500MG/2.5ML (200MG/ML)	N217651	001	Jun 28, 2023	Jan	CAHN
>D>	+	@	1GM/5ML (200MG/ML)	N217651	002	Jun 28, 2023	Jan	CAHN

>D> CYSTEINE HYDROCHLORIDE

SOLUTION; INTRAVENOUS

ELCYS

>D>	+	EXELA PHARMA	2500MG/50ML (50MG/ML)	N210660	002	Dec 04, 2023	Jan	DISC
>A>	+	@	2500MG/50ML (50MG/ML)	N210660	002	Dec 04, 2023	Jan	DISC

DACTINOMYCIN

INJECTABLE; INJECTION

COSMEGEN

>D>	AP	+	RECORDATI RARE	0.5MG/VIAL	N050682	001		Jan	DISC
>A>		+	@	0.5MG/VIAL	N050682	001		Jan	DISC
			DACTINOMYCIN						
>D>	AP		EUGIA PHARMA	0.5MG/VIAL	A203385	001	Nov 09, 2017	Jan	CHRS
>A>	AP	!		0.5MG/VIAL	A203385	001	Nov 09, 2017	Jan	CHRS

DAPSONE

GEL; TOPICAL

DAPSONE

>D>	AB		PADAGIS ISRAEL	5%	A215087	001	Oct 31, 2023	Jan	DISC
>A>		@		5%	A215087	001	Oct 31, 2023	Jan	DISC
>D>	AB			7.5%	A212657	001	Nov 01, 2023	Jan	DISC
>A>		@		7.5%	A212657	001	Nov 01, 2023	Jan	DISC

DEOXYCHOLIC ACID

SOLUTION; SUBCUTANEOUS

KYBELLA

>A>	AP	+	ABBVIE	20MG/2ML (10MG/ML)	N206333	001	Apr 29, 2015	Jan	CAHN
>D>	AP	+	KYTERA BIOPHARMS	20MG/2ML (10MG/ML)	N206333	001	Apr 29, 2015	Jan	CAHN

DESLORATADINE

TABLET; ORAL

DESLORATADINE

>A>		@	CHARTWELL RX	5MG	A078364	001	Dec 03, 2010	Jan	CAHN
>D>		@	SANDOZ	5MG	A078364	001	Dec 03, 2010	Jan	CAHN

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

>A>		@	PANGEA	0.25MG	A088149	001	Apr 28, 1983	Jan	CAHN
>D>		@	STRIDES PHARMA	0.25MG	A088149	001	Apr 28, 1983	Jan	CAHN
>A>	AB		ZYDUS PHARMS	0.5MG	A216282	001	Feb 07, 2024	Jan	NEWA
>A>	AB			0.75MG	A216282	002	Feb 07, 2024	Jan	NEWA
>A>	AB			1.5MG	A216282	003	Feb 07, 2024	Jan	NEWA
>A>	AB			2MG	A216283	001	Feb 07, 2024	Jan	NEWA
>A>	AB			4MG	A216282	004	Feb 07, 2024	Jan	NEWA
>A>	AB			6MG	A216282	005	Feb 07, 2024	Jan	NEWA

DEXLANSOPRAZOLE

CAPSULE, DELAYED RELEASE;ORAL
DEXLANSOPRAZOLE

>A>	AB	MYLAN	30MG	A205205	001	Jan 19, 2024	Jan NEWA
>A>	AB		60MG	A205205	002	Jan 19, 2024	Jan NEWA

DEXTROAMPHETAMINE SULFATE

TABLET;ORAL
DEXTROAMPHETAMINE SULFATE

>D>	AA	TRIS PHARMA INC	5MG	A206095	001	Aug 18, 2022	Jan DISC
>A>		@	5MG	A206095	001	Aug 18, 2022	Jan DISC
>D>	AA		10MG	A206095	002	Aug 18, 2022	Jan DISC
>A>		@	10MG	A206095	002	Aug 18, 2022	Jan DISC

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

>D>	AP	HIKMA	5MG/ML	A070311	001	Dec 16, 1985	Jan CPOT
>A>		@	5MG/ML (5MG/ML)	A070311	002	Dec 16, 1985	Jan NEWA
>A>		@	10MG/2ML (5MG/ML)	A070311	003	Dec 16, 1985	Jan NEWA
>A>	AP		50MG/10ML (5MG/ML)	A070311	001	Dec 16, 1985	Jan CPOT

DIPYRIDAMOLE

TABLET;ORAL
DIPYRIDAMOLE

>D>		@ ANDA REPOSITORY	25MG	A040898	001	Apr 23, 2008	Jan CAHN
>D>		@	50MG	A040898	002	Apr 23, 2008	Jan CAHN
>D>		@	75MG	A040898	003	Apr 23, 2008	Jan CAHN
>A>		@ GENUS	25MG	A040898	001	Apr 23, 2008	Jan CAHN
>A>		@	50MG	A040898	002	Apr 23, 2008	Jan CAHN
>A>		@	75MG	A040898	003	Apr 23, 2008	Jan CAHN

DOCETAXEL

SOLUTION; INTRAVENOUS
DOCETAXEL

>A>		+ @ AVYXA HOLDINGS	20MG/2ML (10MG/ML)	N215813	001	Nov 22, 2022	Jan CAHN
>A>		+ @	80MG/8ML (10MG/ML)	N215813	002	Nov 22, 2022	Jan CAHN
>A>		+ @	160MG/16ML (10MG/ML)	N215813	003	Nov 22, 2022	Jan CAHN
>D>		+ @ INGENUS PHARMS LLC	20MG/2ML (10MG/ML)	N215813	001	Nov 22, 2022	Jan CAHN
>D>		+ @	80MG/8ML (10MG/ML)	N215813	002	Nov 22, 2022	Jan CAHN
>D>		+ @	160MG/16ML (10MG/ML)	N215813	003	Nov 22, 2022	Jan CAHN

DOLUTEGRAVIR SODIUM

TABLET;ORAL
TIVICAY

>D>		+ VIIIV HLTHCARE	EQ 10MG BASE	N204790	002	Jun 09, 2016	Jan DISC
>A>		+ @	EQ 10MG BASE	N204790	002	Jun 09, 2016	Jan DISC
>D>		+ @	EQ 25MG BASE	N204790	003	Jun 09, 2016	Jan DISC
>A>		+ @	EQ 25MG BASE	N204790	003	Jun 09, 2016	Jan DISC

DOXERCALCIFEROL

INJECTABLE; INJECTION
DOXERCALCIFEROL

>D>	AP	AMNEAL	2MCG/ML (2MCG/ML)	A208974	001	May 24, 2017	Jan DISC
>A>		@	2MCG/ML (2MCG/ML)	A208974	001	May 24, 2017	Jan DISC
>D>	AP		4MCG/2ML (2MCG/ML)	A208974	002	May 24, 2017	Jan DISC
>A>		@	4MCG/2ML (2MCG/ML)	A208974	002	May 24, 2017	Jan DISC
>D>		@	4MCG/2ML (2MCG/ML)	A208975	001	May 24, 2017	Jan CMFD
>A>	AP		4MCG/2ML (2MCG/ML)	A208975	001	May 24, 2017	Jan CMFD

DOXYCYCLINE HYCLATE

CAPSULE;ORAL
ACTICLATE CAP

>D>		+ @ ALMIRALL	EQ 75MG BASE	N208253	001	Apr 26, 2016	Jan CAHN
>A>		+ @ CHARTWELL RX	EQ 75MG BASE	N208253	001	Apr 26, 2016	Jan CAHN

TABLET;ORAL
ACTICLATE

>D>	AB	+ ALMIRALL	EQ 75MG BASE	N205931	001	Jul 25, 2014	Jan CAHN
>D>	AB	+!	EQ 150MG BASE	N205931	002	Jul 25, 2014	Jan CAHN
>A>	AB	+ CHARTWELL RX	EQ 75MG BASE	N205931	001	Jul 25, 2014	Jan CAHN
>A>	AB	+!	EQ 150MG BASE	N205931	002	Jul 25, 2014	Jan CAHN

DRONEDARONE HYDROCHLORIDE

TABLET; ORAL

>A>		DRONEDARONE HYDROCHLORIDE						
>A>	AB	LUPIN	EQ 400MG BASE	A205904	001	Jan 31, 2024	Jan	NFTG
		MULTAQ						
>D>		+! SANOFI AVENTIS US	EQ 400MG BASE	N022425	001	Jul 01, 2009	Jan	CFTG
>A>	AB	+!	EQ 400MG BASE	N022425	001	Jul 01, 2009	Jan	CFTG

EPLONTERSEN SODIUM

SOLUTION; SUBCUTANEOUS
WAINUA

>A>		+! ASTRAZENECA AB	EQ 45MG BASE/0.8ML (EQ 45MG BASE/0.8ML)	N217388	001	Dec 21, 2023	Jan	CAHN
>D>		+! IONIS PHARMS INC	EQ 45MG BASE/0.8ML (EQ 45MG BASE/0.8ML)	N217388	001	Dec 21, 2023	Jan	CAHN

EPOPROSTENOL SODIUM

INJECTABLE; INJECTION
EPOPROSTENOL SODIUM

>D>	AP1	HONG KONG	EQ 0.5MG BASE/VIAL	A078396	001	Apr 23, 2008	Jan	CAHN
>D>	AP1		EQ 1.5MG BASE/VIAL	A078396	002	Apr 23, 2008	Jan	CAHN
>A>	AP1	MEITHEAL	EQ 0.5MG BASE/VIAL	A078396	001	Apr 23, 2008	Jan	CAHN
>A>	AP1		EQ 1.5MG BASE/VIAL	A078396	002	Apr 23, 2008	Jan	CAHN

ERTAPENEM SODIUM

INJECTABLE; INTRAMUSCULAR, INTRAVENOUS
ERTAPENEM SODIUM

>D>	AP	SUN PHARM	EQ 1GM BASE/VIAL	A209145	001	May 02, 2023	Jan	DISC
>A>		@	EQ 1GM BASE/VIAL	A209145	001	May 02, 2023	Jan	DISC

ETHOSUXIMIDE

CAPSULE; ORAL
ETHOSUXIMIDE

>D>	AB	AKORN	250MG	A040686	001	May 28, 2008	Jan	CAHN
>A>	AB	EPIC PHARMA LLC	250MG	A040686	001	May 28, 2008	Jan	CAHN

FAMOTIDINE

FOR SUSPENSION; ORAL
FAMOTIDINE

>A>	AB	CEROVENE INC	40MG/5ML	A217605	001	Jan 16, 2024	Jan	NEWA
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FEBUXOSTAT

TABLET; ORAL
FEBUXOSTAT

>A>	AB	LUPIN LTD	40MG	A205406	001	Jan 17, 2024	Jan	NEWA
>A>	AB		80MG	A205406	002	Jan 17, 2024	Jan	NEWA

FENOFIBRATE

CAPSULE; ORAL
FENOFIBRATE (MICRONIZED)

>A>	AB	YOUNGTECH PHARMS INC	67MG	A211407	001	Jan 31, 2024	Jan	NEWA
>A>	AB		134MG	A211407	002	Jan 31, 2024	Jan	NEWA
>A>	AB		200MG	A211407	003	Jan 31, 2024	Jan	NEWA

FIDAXOMICIN

TABLET; ORAL
DIFICID

>D>		+! CUBIST PHARMS LLC	200MG	N201699	001	May 27, 2011	Jan	CFTG
>A>	AB	+!	200MG	N201699	001	May 27, 2011	Jan	CFTG
>A>		FIDAXOMICIN						
>A>	AB	ACTAVIS LABS FL	200MG	A208443	001	Jan 16, 2024	Jan	NEWA

FLUOCINOLONE ACETONIDE

OIL; TOPICAL
FLUOCINOLONE ACETONIDE

>D>	AT	TARO	0.01%	A209336	001	May 19, 2016	Jan	CAHN
>A>	AT		0.01%	A209336	001	May 19, 2016	Jan	CAHN

FLUOCINONIDE

CREAM;TOPICAL
FLUOCINONIDE

>D> AB PADAGIS ISRAEL 0.1% A090256 001 Jan 14, 2014 Jan DISC
>A> @ 0.1% A090256 001 Jan 14, 2014 Jan DISC

GEL;TOPICAL
FLUOCINONIDE

>A> @ PADAGIS US 0.05% A209030 001 Jun 19, 2018 Jan CAHN
>D> @ PAI HOLDINGS PHARM 0.05% A209030 001 Jun 19, 2018 Jan CAHN

FLUOXETINE HYDROCHLORIDE

CAPSULE;ORAL
FLUOXETINE HYDROCHLORIDE

>D> AB SUN PHARM INDS LTD EQ 40MG BASE A076990 001 Dec 13, 2004 Jan DISC
>A> @ EQ 40MG BASE A076990 001 Dec 13, 2004 Jan DISC

TABLET;ORAL
FLUOXETINE HYDROCHLORIDE

>D> AB TEVA EQ 10MG BASE A075872 001 Jan 29, 2002 Jan DISC
>A> @ EQ 10MG BASE A075872 001 Jan 29, 2002 Jan DISC
>D> AB EQ 20MG BASE A075872 002 Jan 04, 2019 Jan DISC
>A> @ EQ 20MG BASE A075872 002 Jan 04, 2019 Jan DISC
>D> AB TEVA PHARMS USA EQ 60MG BASE A211051 001 Dec 03, 2018 Jan DISC
>A> @ EQ 60MG BASE A211051 001 Dec 03, 2018 Jan DISC

FLUPHENAZINE HYDROCHLORIDE

TABLET;ORAL
FLUPHENAZINE HYDROCHLORIDE

>A> @ TORRENT 1MG A217094 001 Jan 22, 2024 Jan DISC
>A> @ 2.5MG A217094 002 Jan 22, 2024 Jan DISC
>A> @ 5MG A217094 003 Jan 22, 2024 Jan DISC
>A> @ 10MG A217094 004 Jan 22, 2024 Jan DISC

FLUVOXAMINE MALEATE

TABLET;ORAL
FLUVOXAMINE MALEATE

>A> AB BIONPHARMA 25MG A217917 001 Jan 22, 2024 Jan NEWA
>A> AB 50MG A217917 002 Jan 22, 2024 Jan NEWA
>A> AB 100MG A217917 003 Jan 22, 2024 Jan NEWA

FOSAMPRENAVIR CALCIUM

TABLET;ORAL
FOSAMPRENAVIR CALCIUM

>D> AB MYLAN EQ 700MG BASE A204060 001 Apr 15, 2016 Jan CHRS
>A> AB ! EQ 700MG BASE A204060 001 Apr 15, 2016 Jan CHRS
>D> LEXIVA
>D> AB +! VIIV HLTHCARE EQ 700MG BASE N021548 001 Oct 20, 2003 Jan DISC
>A> + @ EQ 700MG BASE N021548 001 Oct 20, 2003 Jan DISC

GABAPENTIN

SOLUTION;ORAL
GABAPENTIN

>A> AA ANNORA PHARMA 250MG/5ML A217682 001 Jan 17, 2024 Jan NEWA

TABLET;ORAL
GABAPENTIN

>D> AB ACI 600MG A203244 002 Jul 12, 2013 Jan CTEC
>A> AB1 600MG A203244 002 Jul 12, 2013 Jan CTEC
>D> AB 800MG A203244 001 Jul 12, 2013 Jan CTEC
>A> AB1 800MG A203244 001 Jul 12, 2013 Jan CTEC
>D> AB ACTAVIS ELIZABETH 600MG A075694 001 Oct 21, 2004 Jan CTEC
>A> AB1 600MG A075694 001 Oct 21, 2004 Jan CTEC
>D> AB 800MG A075694 002 Oct 21, 2004 Jan CTEC
>A> AB1 800MG A075694 002 Oct 21, 2004 Jan CTEC
>D> AB ALKEM LABS LTD 600MG A206402 001 Dec 23, 2015 Jan CTEC
>A> AB1 600MG A206402 001 Dec 23, 2015 Jan CTEC
>D> AB 800MG A206402 002 Dec 23, 2015 Jan CTEC
>A> AB1 800MG A206402 002 Dec 23, 2015 Jan CTEC
>A> AB1 APOTEX 100MG A077894 001 Oct 10, 2006 Jan CTEC
>A> AB1 300MG A077894 002 Oct 10, 2006 Jan CTEC
>A> AB1 400MG A077894 003 Oct 10, 2006 Jan CTEC
>D> AB APOTEX INC 100MG A077894 001 Oct 10, 2006 Jan CTEC
>D> AB 300MG A077894 002 Oct 10, 2006 Jan CTEC

TABLET;ORAL
GABAPENTIN

>D>	AB		400MG	A077894	003	Oct 10, 2006	Jan CTEC	
>D>	AB	ASCENT PHARMS INC	600MG	A214957	001	Oct 01, 2021	Jan CTEC	
>A>	AB1		600MG	A214957	001	Oct 01, 2021	Jan CTEC	
>D>	AB		800MG	A214957	002	Oct 01, 2021	Jan CTEC	
>A>	AB1		800MG	A214957	002	Oct 01, 2021	Jan CTEC	
>D>	AB	AUROBINDO PHARMA LTD	600MG	A200651	001	Oct 06, 2011	Jan CTEC	
>A>	AB1		600MG	A200651	001	Oct 06, 2011	Jan CTEC	
>D>	AB		800MG	A200651	002	Oct 06, 2011	Jan CTEC	
>A>	AB1		800MG	A200651	002	Oct 06, 2011	Jan CTEC	
>D>	AB	CSPC OUYI	600MG	A207057	001	Oct 26, 2017	Jan CTEC	
>A>	AB1		600MG	A207057	001	Oct 26, 2017	Jan CTEC	
>D>	AB		800MG	A207057	002	Oct 26, 2017	Jan CTEC	
>A>	AB1		800MG	A207057	002	Oct 26, 2017	Jan CTEC	
>D>	AB	GLENMARK PHARMS LTD	600MG	A077662	001	Aug 18, 2006	Jan CTEC	
>A>	AB1		600MG	A077662	001	Aug 18, 2006	Jan CTEC	
>D>	AB		800MG	A077662	002	Aug 18, 2006	Jan CTEC	
>A>	AB1		800MG	A077662	002	Aug 18, 2006	Jan CTEC	
>D>	AB	GRANULES	600MG	A217116	001	Mar 28, 2023	Jan CTEC	
>A>	AB1		600MG	A217116	001	Mar 28, 2023	Jan CTEC	
>D>	AB		800MG	A217116	002	Mar 28, 2023	Jan CTEC	
>A>	AB1		800MG	A217116	002	Mar 28, 2023	Jan CTEC	
>D>	AB	INVAGEN PHARMS	600MG	A202764	001	Oct 16, 2012	Jan CTEC	
>A>	AB1		600MG	A202764	001	Oct 16, 2012	Jan CTEC	
>D>	AB		800MG	A202764	002	Oct 16, 2012	Jan CTEC	
>A>	AB1		800MG	A202764	002	Oct 16, 2012	Jan CTEC	
>D>	AB	IVAX SUB TEVA PHARMS	100MG	A076017	001	Apr 28, 2004	Jan CTEC	
>A>	AB1		100MG	A076017	001	Apr 28, 2004	Jan CTEC	
>D>	AB		300MG	A076017	002	Apr 28, 2004	Jan CTEC	
>A>	AB1		300MG	A076017	002	Apr 28, 2004	Jan CTEC	
>D>	AB		400MG	A076017	003	Apr 28, 2004	Jan CTEC	
>A>	AB1		400MG	A076017	003	Apr 28, 2004	Jan CTEC	
>D>	AB	RISING	600MG	A217995	001	Jul 19, 2023	Jan CTEC	
>A>	AB1		600MG	A217995	001	Jul 19, 2023	Jan CTEC	
>D>	AB		800MG	A217995	002	Jul 19, 2023	Jan CTEC	
>A>	AB1		800MG	A217995	002	Jul 19, 2023	Jan CTEC	
>D>	AB	RUBICON	600MG	A077661	004	Sep 13, 2006	Jan CTEC	
>A>	AB1		600MG	A077661	004	Sep 13, 2006	Jan CTEC	
>D>	AB		800MG	A077661	005	Sep 13, 2006	Jan CTEC	
>A>	AB1		800MG	A077661	005	Sep 13, 2006	Jan CTEC	
>D>	AB	SCIEGEN PHARMS INC	600MG	A205101	001	Feb 04, 2016	Jan CTEC	
>A>	AB1		600MG	A205101	001	Feb 04, 2016	Jan CTEC	
>D>	AB		800MG	A205101	002	Feb 04, 2016	Jan CTEC	
>A>	AB1		800MG	A205101	002	Feb 04, 2016	Jan CTEC	
>D>	AB	SUN PHARM INDS LTD	600MG	A077525	001	Aug 24, 2006	Jan CTEC	
>A>	AB1		600MG	A077525	001	Aug 24, 2006	Jan CTEC	
>D>	AB		800MG	A077525	002	Aug 24, 2006	Jan CTEC	
>A>	AB1		800MG	A077525	002	Aug 24, 2006	Jan CTEC	
>A>	AB2	ZYDUS PHARMS	300MG	A203934	001	Jan 24, 2024	Jan NEWA	
>A>	AB2		600MG	A203934	002	Jan 24, 2024	Jan NEWA	
>D>	AB	ZYDUS PHARMS USA INC	600MG	A078926	001	Feb 11, 2011	Jan CTEC	
>A>	AB1		600MG	A078926	001	Feb 11, 2011	Jan CTEC	
>D>	AB		800MG	A078926	002	Feb 11, 2011	Jan CTEC	
>A>	AB1		800MG	A078926	002	Feb 11, 2011	Jan CTEC	
GRALISE								
>D>	BX	+!	ALMATICA	300MG	N022544	001	Jan 28, 2011	Jan CTEC
>A>	AB2	+!		300MG	N022544	001	Jan 28, 2011	Jan CTEC
>D>	BX	+!		600MG	N022544	002	Jan 28, 2011	Jan CTEC
>A>	AB2	+		600MG	N022544	002	Jan 28, 2011	Jan CTEC
>D>		+		900MG	N022544	005	Apr 18, 2023	Jan CHRS
>A>		+!		900MG	N022544	005	Apr 18, 2023	Jan CHRS
NEURONTIN								
>D>	AB	+	VIATRIS	600MG	N020882	001	Oct 09, 1998	Jan CTEC
>A>	AB1	+		600MG	N020882	001	Oct 09, 1998	Jan CTEC
>D>	AB	+!		800MG	N020882	002	Oct 09, 1998	Jan CTEC
>A>	AB1	+!		800MG	N020882	002	Oct 09, 1998	Jan CTEC

GRISEOFULVIN, MICROCRYSTALLINE

TABLET;ORAL
FULVICIN-U/F

>D> CHARTWELL RX 250MG A 060569 002 Jan CTEC
>D> 500MG A 060569 001 Jan CTEC

GRISEOFULVIN, MICROSIZE

TABLET;ORAL
FULVICIN-U/F

>A> AB CHARTWELL RX 250MG A 060569 002 Jan CTEC
>A> AB 500MG A 060569 001 Jan CTEC
GRISEOFULVIN
>D> SANDOZ 250MG A 091592 001 Aug 07, 2013 Jan CTEC
>A> AB 250MG A 091592 001 Aug 07, 2013 Jan CTEC

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET;ORAL
FULVICIN P/G

>D> CHARTWELL RX 125MG A 061996 001 Jan CTEC
>D> 250MG A 061996 002 Jan CTEC
>D> FULVICIN P/G 165
>D> CHARTWELL RX 165MG A 061996 003 Apr 06, 1982 Jan CAIN
>D> FULVICIN P/G 330
>D> CHARTWELL RX 330MG A 061996 004 Apr 06, 1982 Jan CAIN

GRISEOFULVIN, ULTRAMICROSIZE

TABLET;ORAL
FULVICIN P/G

>A> AB CHARTWELL RX 125MG A 061996 001 Jan CTEC
>A> AB 250MG A 061996 002 Jan CTEC
>A> FULVICIN P/G 165
>A> CHARTWELL RX 165MG A 061996 003 Apr 06, 1982 Jan CAIN
>A> FULVICIN P/G 330
>A> CHARTWELL RX 330MG A 061996 004 Apr 06, 1982 Jan CAIN

HALCINONIDE

OINTMENT;TOPICAL
HALOG

>D> +! SUN PHARM INDS INC 0.1% N 017824 001 Jan DISC
>A> + @ 0.1% N 017824 001 Jan DISC

SOLUTION;TOPICAL
HALOG

>D> +! SUN PHARM INDS INC 0.1% N 017823 001 Jan DISC
>A> + @ 0.1% N 017823 001 Jan DISC

HALOPERIDOL

TABLET;ORAL
HALOPERIDOL

>A> AB CHARTWELL RX 0.5MG A 071209 002 Nov 17, 1986 Jan CAHN
>A> AB 1MG A 071209 003 Nov 17, 1986 Jan CAHN
>A> @ 2MG A 071209 004 Nov 17, 1986 Jan CAHN
>A> AB 5MG A 071209 001 Nov 17, 1986 Jan CAHN
>A> AB 10MG A 071210 001 Mar 11, 1988 Jan CAHN
>A> AB 20MG A 071211 001 Mar 11, 1988 Jan CAHN
>D> AB SANDOZ 0.5MG A 071209 002 Nov 17, 1986 Jan CAHN
>D> AB 1MG A 071209 003 Nov 17, 1986 Jan CAHN
>D> @ 2MG A 071209 004 Nov 17, 1986 Jan CAHN
>D> AB 5MG A 071209 001 Nov 17, 1986 Jan CAHN
>D> AB 10MG A 071210 001 Mar 11, 1988 Jan CAHN
>D> AB 20MG A 071211 001 Mar 11, 1988 Jan CAHN

HALOPERIDOL DECANOATE

INJECTABLE;INJECTION
HALOPERIDOL DECANOATE

>D> AO TEVA PHARMS USA EQ 50MG BASE/ML A 075393 001 May 11, 1999 Jan DISC
>A> @ EQ 50MG BASE/ML A 075393 001 May 11, 1999 Jan DISC
>D> AO EQ 100MG BASE/ML A 075393 002 May 11, 1999 Jan DISC
>A> @ EQ 100MG BASE/ML A 075393 002 May 11, 1999 Jan DISC

HALOPERIDOL LACTATECONCENTRATE;ORAL
HALOPERIDOL

>A>	AA	RUBICON	EQ 2MG BASE/ML	A218371	001	Jan 31, 2024	Jan NEWA
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HYDRALAZINE HYDROCHLORIDE; ISOSORBIDE DINITRATETABLET;ORAL
ISOSORBIDE DINITRATE AND HYDRALAZINE HYDROCHLORIDE

>A>	AB	I3 PHARMS	37.5MG;20MG	A215988	001	Jan 17, 2024	Jan NEWA
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HYDROMORPHONE HYDROCHLORIDEINJECTABLE;INJECTION
DILAUDID

>A>	+!	FRESENIUS KABI USA	0.5MG/0.5ML	N019034	007	Feb 10, 2017	Jan NEWA
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SOLUTION;ORAL
HYDROMORPHONE HYDROCHLORIDE

>D>	@	ANDA REPOSITORY	5MG/5ML	A207108	001	Apr 22, 2020	Jan CAHN
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>A>	@	GENUS	5MG/5ML	A207108	001	Apr 22, 2020	Jan CAHN
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TABLET;ORAL
HYDROMORPHONE HYDROCHLORIDE

>D>	@	ANDA REPOSITORY	2MG	A077471	002	Dec 09, 2009	Jan CAHN
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>D>	@		4MG	A077471	003	Dec 09, 2009	Jan CAHN
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>D>	@		8MG	A077471	001	Dec 09, 2009	Jan CAHN
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>A>	@	GENUS	2MG	A077471	002	Dec 09, 2009	Jan CAHN
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>A>	@		4MG	A077471	003	Dec 09, 2009	Jan CAHN
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>A>	@		8MG	A077471	001	Dec 09, 2009	Jan CAHN
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HYDROXYCHLOROQUINE SULFATETABLET;ORAL
HYDROXYCHLOROQUINE SULFATE

>A>	@	CREEKWOOD PHARMS	200MG	A040150	001	Jan 27, 1996	Jan CAHN
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>D>	@	INVATECH	200MG	A040150	001	Jan 27, 1996	Jan CAHN
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IBRUTINIBTABLET;ORAL
IMBRUVICA

>D>	+	PHARMACYCLICS LLC	420MG	N210563	003	Feb 16, 2018	Jan CHRS
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>A>	+!		420MG	N210563	003	Feb 16, 2018	Jan CHRS
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INDOMETHACINSUSPENSION;ORAL
INDOCIN

>D>	+!	ZYLA	25MG/5ML	N018332	001	Oct 10, 1985	Jan CTEC
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>A>	AB	+!	25MG/5ML	N018332	001	Oct 10, 1985	Jan CTEC
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INDOMETHACIN

>A>	AB	NOVITIUM PHARMA	25MG/5ML	A217883	001	Jan 12, 2024	Jan NEWA
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ISOSORBIDE MONONITRATETABLET;ORAL
MONOKET

>D>	AB	+	GENUS LIFESCIENCES	10MG	N020215	002	Jun 30, 1993	Jan CAHN
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>D>	AB	+!		20MG	N020215	001	Jun 30, 1993	Jan CAHN
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>A>	AB	+	OMNIVIUM PHARMS	10MG	N020215	002	Jun 30, 1993	Jan CAHN
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>A>	AB	+!		20MG	N020215	001	Jun 30, 1993	Jan CAHN
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ISOTRETINOINCAPSULE;ORAL
ISOTRETINOIN

>A>	AB2	AUROBINDO PHARMA	10MG	A218194	001	Jan 29, 2024	Jan NEWA
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>A>	AB2		20MG	A218194	002	Jan 29, 2024	Jan NEWA
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>A>	AB2		25MG	A218194	003	Jan 29, 2024	Jan NEWA
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>A>	AB2		30MG	A218194	004	Jan 29, 2024	Jan NEWA
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>A>	AB2		35MG	A218194	005	Jan 29, 2024	Jan NEWA
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>A>	AB2		40MG	A218194	006	Jan 29, 2024	Jan NEWA
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LACOSAMIDE

SOLUTION;ORAL
LACOSAMIDE

>A> AA AUROBINDO PHARMA LTD 10MG/ML A209224 001 Jan 24, 2024 Jan NEWA

LAMIVUDINE

TABLET;ORAL
LAMIVUDINE

>D> AB MYLAN LABS LTD 150MG A078545 001 Mar 05, 2019 Jan DISC
>A> @ 150MG A078545 001 Mar 05, 2019 Jan DISC
>D> AB 300MG A078545 002 Mar 05, 2019 Jan DISC
>A> @ 300MG A078545 002 Mar 05, 2019 Jan DISC

LAMIVUDINE; ZIDOVUDINE

TABLET;ORAL
COMBIVIR

>D> AB +! VIIV HLTHCARE 150MG;300MG N020857 001 Sep 26, 1997 Jan DISC
>A> + @ 150MG;300MG N020857 001 Sep 26, 1997 Jan DISC
LAMIVUDINE AND ZIDOVUDINE
>D> AB HETERO LABS LTD III 150MG;300MG A079124 001 Sep 17, 2015 Jan CHRS
>A> AB ! 150MG;300MG A079124 001 Sep 17, 2015 Jan CHRS

LEVOFLOXACIN

INJECTABLE; INJECTION
LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

>A> AP KNACK EQ 250MG/50ML (EQ 5MG/ML) A216164 001 Jan 29, 2024 Jan NEWA
>A> AP EQ 500MG/100ML (EQ 5MG/ML) A216164 002 Jan 29, 2024 Jan NEWA
>A> AP EQ 750MG/150ML (EQ 5MG/ML) A216164 003 Jan 29, 2024 Jan NEWA

LIFITEGRAST

SOLUTION/DROPS;OPHTHALMIC
XIIDRA

>A> AB +! BAUSCH AND LOMB INC 5% N208073 001 Jul 11, 2016 Jan CAHN
>D> AB +! NOVARTIS 5% N208073 001 Jul 11, 2016 Jan CAHN

LIOTHYRONINE SODIUM

TABLET;ORAL
LIOTHYRONINE SODIUM

>A> AB CARNEGIE EQ 0.005MG BASE A218070 001 Feb 06, 2024 Jan NEWA
>A> AB EQ 0.025MG BASE A218070 002 Feb 06, 2024 Jan NEWA
>A> AB EQ 0.05MG BASE A218070 003 Feb 06, 2024 Jan NEWA

LISDEXAMFETAMINE DIMESYLATE

CAPSULE;ORAL
LISDEXAMFETAMINE DIMESYLATE

>A> AB HIKMA 10MG A202827 007 Jan 17, 2024 Jan NEWA
TABLET, CHEWABLE;ORAL
LISDEXAMFETAMINE DIMESYLATE
>A> AB MSN 10MG A218306 001 Feb 02, 2024 Jan NEWA
>A> AB 20MG A218306 002 Feb 02, 2024 Jan NEWA
>A> AB 30MG A218306 003 Feb 02, 2024 Jan NEWA
>A> AB 40MG A218306 004 Feb 02, 2024 Jan NEWA
>A> AB 50MG A218306 005 Feb 02, 2024 Jan NEWA
>A> AB 60MG A218306 006 Feb 02, 2024 Jan NEWA

LOMITAPIDE MESYLATE

CAPSULE;ORAL
JUXTAPID

>D> + AMRYT EQ 5MG BASE N203858 001 Dec 21, 2012 Jan CAHN
>D> + EQ 10MG BASE N203858 002 Dec 21, 2012 Jan CAHN
>D> + EQ 20MG BASE N203858 003 Dec 21, 2012 Jan CAHN
>D> + EQ 30MG BASE N203858 004 Apr 23, 2015 Jan CAHN
>D> + @ EQ 40MG BASE N203858 005 Apr 23, 2015 Jan CAHN
>D> + @ EQ 60MG BASE N203858 006 Apr 23, 2015 Jan CAHN
>A> + CHIESI EQ 5MG BASE N203858 001 Dec 21, 2012 Jan CAHN
>A> + EQ 10MG BASE N203858 002 Dec 21, 2012 Jan CAHN
>A> + EQ 20MG BASE N203858 003 Dec 21, 2012 Jan CAHN
>A> + EQ 30MG BASE N203858 004 Apr 23, 2015 Jan CAHN
>A> + @ EQ 40MG BASE N203858 005 Apr 23, 2015 Jan CAHN
>A> + @ EQ 60MG BASE N203858 006 Apr 23, 2015 Jan CAHN

LOPINAVIR; RITONAVIR

TABLET;ORAL

LOPINAVIR AND RITONAVIR

>A>	AB	MYLAN LABS LTD	100MG;25MG	A 079074	001	Feb 07, 2024	Jan	NEWA
>A>	AB		200MG;50MG	A 079074	002	Feb 07, 2024	Jan	NEWA

LOSARTAN POTASSIUM

TABLET;ORAL

LOSARTAN POTASSIUM

>A>	AB	CHARTWELL RX	25MG	A 077424	001	Oct 06, 2010	Jan	CAHN
>A>	AB		50MG	A 077424	002	Oct 06, 2010	Jan	CAHN
>A>	AB		100MG	A 077424	003	Oct 06, 2010	Jan	CAHN
>D>	AB	SANDOZ	25MG	A 077424	001	Oct 06, 2010	Jan	CAHN
>D>	AB		50MG	A 077424	002	Oct 06, 2010	Jan	CAHN
>D>	AB		100MG	A 077424	003	Oct 06, 2010	Jan	CAHN

MARAVIROC

TABLET;ORAL

SELZENTRY

>D>	+	VIIV HLTHCARE	25MG	N 022128	003	Nov 04, 2016	Jan	DISC
>A>	+	@	25MG	N 022128	003	Nov 04, 2016	Jan	DISC
>D>	+		75MG	N 022128	004	Nov 04, 2016	Jan	DISC
>A>	+	@	75MG	N 022128	004	Nov 04, 2016	Jan	DISC

MEDROXYPROGESTERONE ACETATE

INJECTABLE;INJECTION

MEDROXYPROGESTERONE ACETATE

>A>	AB	HONG KONG	150MG/ML	A 076553	001	Jul 28, 2004	Jan	CAHN
>D>	AB	MEITHEAL	150MG/ML	A 076553	001	Jul 28, 2004	Jan	CAHN

MELOXICAM

TABLET;ORAL

MELOXICAM

>D>	AB	ZYDUS PHARMS USA	15MG	A 077921	002	Jul 19, 2006	Jan	CTEC
>A>	AB	!	15MG	A 077921	002	Jul 19, 2006	Jan	CTEC
>D>		MOBIC						
>D>	AB	+ BOEHRINGER INGELHEIM	7.5MG	N 020938	001	Apr 13, 2000	Jan	DISC
>A>		+ @	7.5MG	N 020938	001	Apr 13, 2000	Jan	DISC
>D>	AB	+!	15MG	N 020938	002	Aug 23, 2000	Jan	DISC
>A>		+ @	15MG	N 020938	002	Aug 23, 2000	Jan	DISC

MEMANTINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

MEMANTINE HYDROCHLORIDE

>A>	AB	XIAMEN LP PHARM CO	21MG	A 213985	004	Feb 06, 2024	Jan	NEWA
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TABLET;ORAL

MEMANTINE HYDROCHLORIDE

>A>	AB	RENATA	5MG	A 209527	001	May 07, 2018	Jan	CAHN
>A>	AB		10MG	A 209527	002	May 07, 2018	Jan	CAHN
>D>	AB	WESTMINSTER PHARMS	5MG	A 209527	001	May 07, 2018	Jan	CAHN
>D>	AB		10MG	A 209527	002	May 07, 2018	Jan	CAHN

MEPERIDINE HYDROCHLORIDE

TABLET;ORAL

MEPERIDINE HYDROCHLORIDE

>D>	@	ANDA REPOSITORY	50MG	A 040893	001	Jun 24, 2009	Jan	CAHN
>D>	@		75MG	A 040893	002	Jun 24, 2009	Jan	CAHN
>D>	@		100MG	A 040893	003	Jun 24, 2009	Jan	CAHN
>D>	@		150MG	A 040893	004	Jun 24, 2009	Jan	CAHN
>A>	@	GENUS	50MG	A 040893	001	Jun 24, 2009	Jan	CAHN
>A>	@		75MG	A 040893	002	Jun 24, 2009	Jan	CAHN
>A>	@		100MG	A 040893	003	Jun 24, 2009	Jan	CAHN
>A>	@		150MG	A 040893	004	Jun 24, 2009	Jan	CAHN

MESALAMINE

TABLET, DELAYED RELEASE;ORAL

MESALAMINE

>A>	AB	ANNORA PHARMA	1.2GM	A 216334	001	Feb 05, 2024	Jan	NEWA
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METAPROTERENOL SULFATE

SYRUP;ORAL

METAPROTERENOL SULFATE

>D>	!	ANDA REPOSITORY	10MG/5ML	A 073632	001	Jul 22, 1992	Jan CAHN
>A>	!	GENUS	10MG/5ML	A 073632	001	Jul 22, 1992	Jan CAHN

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET;ORAL

PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

>A>	@	CHARTWELL RX	500MG;EQ 15MG BASE	A 091273	001	Apr 16, 2013	Jan CAHN
>A>	@		850MG;EQ 15MG BASE	A 091273	002	Apr 16, 2013	Jan CAHN
>D>	@	SANDOZ	500MG;EQ 15MG BASE	A 091273	001	Apr 16, 2013	Jan CAHN
>D>	@		850MG;EQ 15MG BASE	A 091273	002	Apr 16, 2013	Jan CAHN

METHSCOPOLAMINE BROMIDE

TABLET;ORAL

METHSCOPOLAMINE BROMIDE

>A>	AA	AACE PHARMS	2.5MG	A 216786	001	Feb 01, 2024	Jan NEWA
>A>	AA		5MG	A 216786	002	Feb 01, 2024	Jan NEWA

METHYLDOPA

TABLET;ORAL

METHYLDOPA

>D>	@	CHARTWELL RX	250MG	N 018934	001	Jun 29, 1984	Jan CMFD
>A>			250MG	N 018934	001	Jun 29, 1984	Jan CMFD
>D>	@		500MG	N 018934	002	Jun 29, 1984	Jan CMFD
>A>	!		500MG	N 018934	002	Jun 29, 1984	Jan CMFD

METHYLPREDNISOLONE ACETATE

INJECTABLE;INJECTION

METHYLPREDNISOLONE ACETATE

>A>	AB	HONG KONG	40MG/ML	A 040557	001	Feb 23, 2005	Jan CAHN
>A>	AB		80MG/ML	A 040557	002	Feb 23, 2005	Jan CAHN
>D>	AB	MEITHEAL	40MG/ML	A 040557	001	Feb 23, 2005	Jan CAHN
>D>	AB		80MG/ML	A 040557	002	Feb 23, 2005	Jan CAHN
>D>	AB	TEVA PHARMS USA	40MG/ML	A 040620	001	Oct 27, 2006	Jan DISC
>A>	@		40MG/ML	A 040620	001	Oct 27, 2006	Jan DISC
>D>	AB		80MG/ML	A 040620	002	Oct 27, 2006	Jan DISC
>A>	@		80MG/ML	A 040620	002	Oct 27, 2006	Jan DISC

MIDAZOLAM HYDROCHLORIDE

INJECTABLE;INJECTION

MIDAZOLAM HYDROCHLORIDE

>D>		FRESENIUS KABI USA	EQ 5MG BASE/ML	A 208878	001	Mar 28, 2017	Jan DISC
>A>	@		EQ 5MG BASE/ML	A 208878	001	Mar 28, 2017	Jan DISC

MINOCYCLINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

MINOCYCLINE HYDROCHLORIDE

>D>	AB	SUN PHARM INDS LTD	EQ 45MG BASE	A 091118	001	Sep 25, 2014	Jan DISC
>A>	@		EQ 45MG BASE	A 091118	001	Sep 25, 2014	Jan DISC
>D>	AB		EQ 65MG BASE	A 091118	003	Dec 03, 2019	Jan DISC
>A>	@		EQ 65MG BASE	A 091118	003	Dec 03, 2019	Jan DISC
>D>	AB		EQ 80MG BASE	A 091118	004	Sep 25, 2014	Jan DISC
>A>	@		EQ 80MG BASE	A 091118	004	Sep 25, 2014	Jan DISC
>D>	AB		EQ 90MG BASE	A 091118	005	Sep 25, 2014	Jan DISC
>A>	@		EQ 90MG BASE	A 091118	005	Sep 25, 2014	Jan DISC
>D>	AB		EQ 105MG BASE	A 091118	006	Sep 25, 2014	Jan DISC
>A>	@		EQ 105MG BASE	A 091118	006	Sep 25, 2014	Jan DISC
>D>	AB		EQ 115MG BASE	A 091118	007	Dec 03, 2019	Jan DISC
>A>	@		EQ 115MG BASE	A 091118	007	Dec 03, 2019	Jan DISC
>D>	AB		EQ 135MG BASE	A 091118	008	Sep 25, 2014	Jan DISC
>A>	@		EQ 135MG BASE	A 091118	008	Sep 25, 2014	Jan DISC
>D>	AB	ZYDUS PHARMS	EQ 45MG BASE	A 203553	001	Nov 16, 2017	Jan DISC
>A>	@		EQ 45MG BASE	A 203553	001	Nov 16, 2017	Jan DISC
>D>	AB		EQ 55MG BASE	A 203553	002	Jun 16, 2023	Jan DISC
>A>	@		EQ 55MG BASE	A 203553	002	Jun 16, 2023	Jan DISC
>D>	AB		EQ 65MG BASE	A 203553	003	Jun 16, 2023	Jan DISC
>A>	@		EQ 65MG BASE	A 203553	003	Jun 16, 2023	Jan DISC
>D>	AB		EQ 80MG BASE	A 203553	004	Nov 16, 2017	Jan DISC
>A>	@		EQ 80MG BASE	A 203553	004	Nov 16, 2017	Jan DISC
>D>	AB		EQ 90MG BASE	A 203553	005	Nov 16, 2017	Jan DISC

TABLET, EXTENDED RELEASE;ORAL
MINOCYCLINE HYDROCHLORIDE

>A>	@	EQ 90MG BASE	A203553	005	Nov 16, 2017	Jan DISC
>D>	AB	EQ 105MG BASE	A203553	006	Nov 16, 2017	Jan DISC
>A>	@	EQ 105MG BASE	A203553	006	Nov 16, 2017	Jan DISC
>D>	AB	EQ 115MG BASE	A203553	007	Jun 16, 2023	Jan DISC
>A>	@	EQ 115MG BASE	A203553	007	Jun 16, 2023	Jan DISC
>D>	AB	EQ 135MG BASE	A203553	008	Nov 16, 2017	Jan DISC
>A>	@	EQ 135MG BASE	A203553	008	Nov 16, 2017	Jan DISC

MONTELUKAST SODIUM

GRANULE;ORAL
MONTELUKAST SODIUM

>D>	AB	TEVA PHARMS	EQ 4MG BASE/PACKET	A090955	001	Aug 03, 2012	Jan DISC
>A>	@		EQ 4MG BASE/PACKET	A090955	001	Aug 03, 2012	Jan DISC

MORPHINE SULFATE

SOLUTION;ORAL
MORPHINE SULFATE

>D>	@	WINDER LABS LLC	10MG/5ML	A211454	001	Feb 12, 2021	Jan CMFD
>A>	AA		10MG/5ML	A211454	001	Feb 12, 2021	Jan CMFD
>D>	@		20MG/5ML	A211454	002	Feb 12, 2021	Jan CMFD
>A>	AA		20MG/5ML	A211454	002	Feb 12, 2021	Jan CMFD
>D>	@		100MG/5ML	A211454	003	Feb 12, 2021	Jan CMFD
>A>	AA		100MG/5ML	A211454	003	Feb 12, 2021	Jan CMFD

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC
VIGAMOX

>A>	AT1	+! HARROW EYE	EQ 0.5% BASE	N021598	001	Apr 15, 2003	Jan CAHN
>D>	AT1	+! NOVARTIS	EQ 0.5% BASE	N021598	001	Apr 15, 2003	Jan CAHN

NALOXONE HYDROCHLORIDE

INJECTABLE;INJECTION
NALOXONE HYDROCHLORIDE

>D>	@	PAR STERILE PRODUCTS	1MG/ML	A215964	001	Jul 29, 2022	Jan CMFD
>A>	AP		1MG/ML	A215964	001	Jul 29, 2022	Jan CMFD

NALTREXONE

FOR SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR
NALTREXONE

>D>	AP	TEVA PHARMS USA INC	380MG/VIAL	A213195	001	Jul 06, 2023	Jan DISC
>A>	@		380MG/VIAL	A213195	001	Jul 06, 2023	Jan DISC
>D>	AP	+! ALKERMES	380MG/VIAL	N021897	001	Apr 13, 2006	Jan CTEC
>A>	+!		380MG/VIAL	N021897	001	Apr 13, 2006	Jan CTEC

NEOSTIGMINE METHYLSULFATE

SOLUTION;INTRAVENOUS
NEOSTIGMINE METHYLSULFATE

>A>	AP	NIVAGEN PHARMS INC	5MG/10ML (0.5MG/ML)	A212627	001	Nov 03, 2022	Jan CAHN
>A>	AP		10MG/10ML (1MG/ML)	A212627	002	Nov 03, 2022	Jan CAHN
>D>	AP	UMEDICA	5MG/10ML (0.5MG/ML)	A212627	001	Nov 03, 2022	Jan CAHN
>D>	AP		10MG/10ML (1MG/ML)	A212627	002	Nov 03, 2022	Jan CAHN

NOREPINEPHRINE BITARTRATE

SOLUTION;INTRAVENOUS
NOREPINEPHRINE BITARTRATE IN 0.9% SODIUM CHLORIDE

>D>	+ @	LONG GROVE PHARMS	EQ 4MG BASE/250 ML (EQ 16MCG BASE/ML)	N214628	001	Oct 06, 2022	Jan CMFD
>A>	+!		EQ 4MG BASE/250 ML (EQ 16MCG BASE/ML)	N214628	001	Oct 06, 2022	Jan CMFD
>D>	+ @		EQ 8MG BASE/250ML (EQ 32MCG BASE/ML)	N214628	002	Oct 06, 2022	Jan CMFD
>A>	+!		EQ 8MG BASE/250ML (EQ 32MCG BASE/ML)	N214628	002	Oct 06, 2022	Jan CMFD
>D>	+ @		EQ 16MG BASE/250ML (EQ 64MCG BASE/ML)	N214628	003	Oct 06, 2022	Jan CMFD
>A>	+!		EQ 16MG BASE/250ML (EQ 64MCG BASE/ML)	N214628	003	Oct 06, 2022	Jan CMFD

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
OCTREOTIDE ACETATE

>D>	AP	TEVA PHARMS USA INC	EQ 10MG BASE/VIAL	A210317	001	Dec 05, 2023	Jan CTEC
>A>	AB		EQ 10MG BASE/VIAL	A210317	001	Dec 05, 2023	Jan CTEC
>D>	AP		EQ 20MG BASE/VIAL	A210317	002	Dec 05, 2023	Jan CTEC
>A>	AB		EQ 20MG BASE/VIAL	A210317	002	Dec 05, 2023	Jan CTEC
>D>	AP		EQ 30MG BASE/VIAL	A210317	003	Dec 05, 2023	Jan CTEC
>A>	AB		EQ 30MG BASE/VIAL	A210317	003	Dec 05, 2023	Jan CTEC

SANDOSTATIN LAR

>D>	AP	+ NOVARTIS	EQ 10MG BASE/VIAL	N021008	001	Nov 25, 1998	Jan CTEC
>A>	AB	+	EQ 10MG BASE/VIAL	N021008	001	Nov 25, 1998	Jan CTEC
>D>	AP	+	EQ 20MG BASE/VIAL	N021008	002	Nov 25, 1998	Jan CTEC
>A>	AB	+	EQ 20MG BASE/VIAL	N021008	002	Nov 25, 1998	Jan CTEC
>D>	AP	+!	EQ 30MG BASE/VIAL	N021008	003	Nov 25, 1998	Jan CTEC
>A>	AB	+!	EQ 30MG BASE/VIAL	N021008	003	Nov 25, 1998	Jan CTEC

ODEVIXIBAT

CAPSULE; ORAL
BYLVAY

>D>		+ ALBIREO	0.4MG	N215498	002	Jul 20, 2021	Jan CAHN
>D>		+!	1.2MG	N215498	004	Jul 20, 2021	Jan CAHN
>A>		+ IPSEN	0.4MG	N215498	002	Jul 20, 2021	Jan CAHN
>A>		+!	1.2MG	N215498	004	Jul 20, 2021	Jan CAHN

CAPSULE, PELLETS; ORAL
BYLVAY

>D>		+ ALBIREO	0.2MG	N215498	001	Jul 20, 2021	Jan CAHN
>D>		+!	0.6MG	N215498	003	Jul 20, 2021	Jan CAHN
>A>		+ IPSEN	0.2MG	N215498	001	Jul 20, 2021	Jan CAHN
>A>		+!	0.6MG	N215498	003	Jul 20, 2021	Jan CAHN

OLMESARTAN MEDOXOMIL

TABLET; ORAL
OLMESARTAN MEDOXOMIL

>A>	AB	BRECKENRIDGE	5MG	A206227	001	Jan 25, 2024	Jan NEWA
>A>	AB		20MG	A206227	002	Jan 25, 2024	Jan NEWA
>A>	AB		40MG	A206227	003	Jan 25, 2024	Jan NEWA

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL
ONDANSETRON

>D>	AB	SUN PHARM INDS LTD	4MG	A078602	001	Feb 24, 2011	Jan DISC
>A>		@	4MG	A078602	001	Feb 24, 2011	Jan DISC
>D>	AB		8MG	A078602	002	Feb 24, 2011	Jan DISC
>A>		@	8MG	A078602	002	Feb 24, 2011	Jan DISC

OXALIPLATIN

INJECTABLE; INTRAVENOUS
OXALIPLATIN

>A>	AP	KINDOS	50MG/10ML (5MG/ML)	A217348	001	Jan 11, 2024	Jan NEWA
>A>	AP		100MG/20ML (5MG/ML)	A217348	002	Jan 11, 2024	Jan NEWA

OXAPROZIN

TABLET; ORAL
OXAPROZIN

>D>	AB	TEVA	600MG	A075849	001	Jul 03, 2002	Jan DISC
>A>		@	600MG	A075849	001	Jul 03, 2002	Jan DISC

OXCARBAZEPINE

TABLET; ORAL
OXCARBAZEPINE

>D>	AB	ZYDUS	150MG	A211747	001	Jul 03, 2023	Jan DISC
>A>		@	150MG	A211747	001	Jul 03, 2023	Jan DISC
>D>	AB		300MG	A211747	002	Jul 03, 2023	Jan DISC
>A>		@	300MG	A211747	002	Jul 03, 2023	Jan DISC
>D>	AB		600MG	A211747	003	Jul 03, 2023	Jan DISC
>A>		@	600MG	A211747	003	Jul 03, 2023	Jan DISC

OZANIMOD HYDROCHLORIDE

CAPSULE;ORAL
ZEPOSIA

>A>	+	BRISTOL	EQ 0.23MG BASE	N209899	001	Mar 25, 2020	Jan CAHN
>A>	+		EQ 0.46MG BASE	N209899	002	Mar 25, 2020	Jan CAHN
>A>	+		EQ 0.92MG BASE	N209899	003	Mar 25, 2020	Jan CAHN
>D>	+	CELGENE INTL	EQ 0.23MG BASE	N209899	001	Mar 25, 2020	Jan CAHN
>D>	+		EQ 0.46MG BASE	N209899	002	Mar 25, 2020	Jan CAHN
>D>	+		EQ 0.92MG BASE	N209899	003	Mar 25, 2020	Jan CAHN

PACLITAXEL

POWDER;INTRAVENOUS
ABRAXANE

>D>	+	BRISTOL-MYERS	100MG/VIAL	N021660	001	Jan 07, 2005	Jan CTEC
>A>	AB	+	100MG/VIAL	N021660	001	Jan 07, 2005	Jan CTEC

PACLITAXEL

>D>	+	@ TEVA PHARMS INC	100MG/VIAL	N216338	001	May 11, 2023	Jan CMFD
>A>	AB	+	100MG/VIAL	N216338	001	May 11, 2023	Jan CMFD

PALBOCICLIB

TABLET;ORAL
IBRANCE

>D>	AB	+	PFIZER	75MG	N212436	001	Nov 01, 2019	Jan CTEC
>A>		+		75MG	N212436	001	Nov 01, 2019	Jan CTEC
>D>	AB	+		100MG	N212436	002	Nov 01, 2019	Jan CTEC
>A>		+		100MG	N212436	002	Nov 01, 2019	Jan CTEC
>D>	AB	+		125MG	N212436	003	Nov 01, 2019	Jan CTEC
>A>		+		125MG	N212436	003	Nov 01, 2019	Jan CTEC

PENICILLIN V POTASSIUM

TABLET;ORAL
PENICILLIN V POTASSIUM

>D>	AB		AUROBINDO PHARMA	EQ 500MG BASE	A065435	002	Apr 29, 2008	Jan CHRS
>A>	AB	!		EQ 500MG BASE	A065435	002	Apr 29, 2008	Jan CHRS
>D>	AB		SANDOZ	EQ 250MG BASE	A064071	001	Nov 30, 1995	Jan DISC
>A>		@		EQ 250MG BASE	A064071	001	Nov 30, 1995	Jan DISC
>D>	AB	!		EQ 500MG BASE	A064071	002	Nov 30, 1995	Jan DISC
>A>		@		EQ 500MG BASE	A064071	002	Nov 30, 1995	Jan DISC

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE;ORAL
PENTOXIFYLLINE

>D>		@	ANI PHARMS	400MG	A074878	001	Jul 09, 1997	Jan CMFD
>A>	AB			400MG	A074878	001	Jul 09, 1997	Jan CMFD

PERMETHRIN

CREAM;TOPICAL
PERMETHRIN

>D>	AB		DR REDDYS LABS EU	5%	A209732	001	Aug 01, 2023	Jan DISC
>A>		@		5%	A209732	001	Aug 01, 2023	Jan DISC

PHENTOLAMINE MESYLATE

SOLUTION;OPHTHALMIC
RYZUMVI

>A>	+	FAMYGEN LIFE SCI	EQ 0.75% BASE	N217064	001	Sep 25, 2023	Jan CAHN
>D>	+	OCUPHIRE	EQ 0.75% BASE	N217064	001	Sep 25, 2023	Jan CAHN

PIMAVANSERIN TARTRATE

CAPSULE;ORAL
NUPLAZID

>D>	+	ACADIA PHARMS INC	EQ 34MG BASE	N210793	001	Jun 28, 2018	Jan CFTG
>A>	AB	+	EQ 34MG BASE	N210793	001	Jun 28, 2018	Jan CFTG

PIMAVANSERIN

>A>	AB		MSN	EQ 34MG BASE	A214925	001	Jan 16, 2024	Jan NEWA
>A>	AB		ZYDUS	EQ 34MG BASE	A214493	001	Jan 16, 2024	Jan CAHN

TABLET;ORAL
NUPLAZID

>D>	+	ACADIA PHARMS INC	EQ 10MG BASE	N207318	002	Jun 28, 2018	Jan CFTG
>A>	AB	+	EQ 10MG BASE	N207318	002	Jun 28, 2018	Jan CFTG

PIMAVANSERIN

>A>	AB		ZYDUS	EQ 10MG BASE	A214502	001	Jan 16, 2024	Jan CAHN
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POTASSIUM CHLORIDE

SOLUTION;ORAL
POTASSIUM CHLORIDE

>A> AA STRIDES PHARMA 20MEQ/15ML A211665 002 Jan 16, 2024 Jan NEWA

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE;ORAL
POTASSIUM CITRATE

>A> AB TORRENT 5MEQ A213986 001 Feb 06, 2024 Jan NEWA
>A> AB 10MEQ A213986 002 Feb 06, 2024 Jan NEWA
>A> AB 15MEQ A213986 003 Feb 06, 2024 Jan NEWA

PREDNISONE

SOLUTION;ORAL
PREDNISONE INTENSOL

>D> ! HIKMA 5MG/ML A088810 001 Feb 20, 1985 Jan CRLD
>A> +! 5MG/ML A088810 001 Feb 20, 1985 Jan CRLD

PREGABALIN

CAPSULE;ORAL

>D> PREGABALIN
>D> AB CADILA PHARMS LTD 25MG A206452 001 Jul 12, 2023 Jan DISC
>A> @ 25MG A206452 001 Jul 12, 2023 Jan DISC
>D> AB 50MG A206452 002 Jul 12, 2023 Jan DISC
>A> @ 50MG A206452 002 Jul 12, 2023 Jan DISC
>D> AB 75MG A206452 003 Jul 12, 2023 Jan DISC
>A> @ 75MG A206452 003 Jul 12, 2023 Jan DISC
>D> AB 100MG A206452 004 Jul 12, 2023 Jan DISC
>A> @ 100MG A206452 004 Jul 12, 2023 Jan DISC
>D> AB 150MG A206452 005 Jul 12, 2023 Jan DISC
>A> @ 150MG A206452 005 Jul 12, 2023 Jan DISC
>D> AB 200MG A206452 006 Jul 12, 2023 Jan DISC
>A> @ 200MG A206452 006 Jul 12, 2023 Jan DISC
>D> AB 225MG A206452 007 Jul 12, 2023 Jan DISC
>A> @ 225MG A206452 007 Jul 12, 2023 Jan DISC
>D> AB 300MG A206452 008 Jul 12, 2023 Jan DISC
>A> @ 300MG A206452 008 Jul 12, 2023 Jan DISC
>A> AB STRIDES PHARMA 25MG A209883 001 Jan 24, 2024 Jan NEWA
>A> AB 50MG A209883 002 Jan 24, 2024 Jan NEWA
>A> AB 75MG A209883 003 Jan 24, 2024 Jan NEWA
>A> AB 100MG A209883 004 Jan 24, 2024 Jan NEWA
>A> AB 150MG A209883 005 Jan 24, 2024 Jan NEWA
>A> AB 200MG A209883 006 Jan 24, 2024 Jan NEWA
>A> AB 225MG A209883 007 Jan 24, 2024 Jan NEWA
>A> AB 300MG A209883 008 Jan 24, 2024 Jan NEWA
>D> AB SUN PHARM 25MG A091157 001 Nov 29, 2019 Jan DISC
>A> @ 25MG A091157 001 Nov 29, 2019 Jan DISC
>D> AB 50MG A091157 002 Nov 29, 2019 Jan DISC
>A> @ 50MG A091157 002 Nov 29, 2019 Jan DISC
>D> AB 75MG A091157 003 Nov 29, 2019 Jan DISC
>A> @ 75MG A091157 003 Nov 29, 2019 Jan DISC
>D> AB 100MG A091157 004 Nov 29, 2019 Jan DISC
>A> @ 100MG A091157 004 Nov 29, 2019 Jan DISC
>D> AB 150MG A091157 005 Nov 29, 2019 Jan DISC
>A> @ 150MG A091157 005 Nov 29, 2019 Jan DISC
>D> AB 200MG A091157 006 Nov 29, 2019 Jan DISC
>A> @ 200MG A091157 006 Nov 29, 2019 Jan DISC
>D> AB 225MG A091157 007 Nov 29, 2019 Jan DISC
>A> @ 225MG A091157 007 Nov 29, 2019 Jan DISC
>D> AB 300MG A091157 008 Nov 29, 2019 Jan DISC
>A> @ 300MG A091157 008 Nov 29, 2019 Jan DISC

PRIMIDONE

SUSPENSION;ORAL
MYSOLINE

>A> + @ FHTA 250MG/5ML N010401 001 Jan CAHN
>D> + @ NURO PHARMA 250MG/5ML N010401 001 Jan CAHN

TABLET;ORAL
PRIMIDONE

>A> AB CARNEGIE 50MG A218366 001 Jan 23, 2024 Jan NEWA
>A> AB 250MG A218366 002 Jan 23, 2024 Jan NEWA

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL
PROPRANOLOL HYDROCHLORIDE

>A>	AB	LUPIN LTD	60MG	A204349	001	Jan 12, 2024	Jan NEWA
>A>	AB		80MG	A204349	002	Jan 12, 2024	Jan NEWA
>A>	AB		120MG	A204349	003	Jan 12, 2024	Jan NEWA
>A>	AB		160MG	A204349	004	Jan 12, 2024	Jan NEWA

PYRIDOSTIGMINE BROMIDE

TABLET;ORAL
PYRIDOSTIGMINE BROMIDE

>D>		@ ANI PHARMS	60MG	A040512	001	Oct 08, 2003	Jan CMFD
>A>	AB		60MG	A040512	001	Oct 08, 2003	Jan CMFD

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL
RANOLAZINE

>D>	AB	PIRAMAL HLTHCARE UK	500MG	A213085	001	Jul 25, 2023	Jan DISC
>A>		@	500MG	A213085	001	Jul 25, 2023	Jan DISC
>D>	AB		1GM	A213085	002	Jul 25, 2023	Jan DISC
>A>		@	1GM	A213085	002	Jul 25, 2023	Jan DISC

RISPERIDONE

INJECTABLE;INTRAMUSCULAR
RISPERDAL CONSTA

>D>	AP	+ JANSSEN PHARMS	12.5MG/VIAL	N021346	004	Apr 12, 2007	Jan CMS1
>A>	AB	+	12.5MG/VIAL	N021346	004	Apr 12, 2007	Jan CMS1
>D>	AP	+!	25MG/VIAL	N021346	001	Oct 29, 2003	Jan CMS1
>A>	AB	+!	25MG/VIAL	N021346	001	Oct 29, 2003	Jan CMS1
>D>	AP	+	37.5MG/VIAL	N021346	002	Oct 29, 2003	Jan CMS1
>A>	AB	+	37.5MG/VIAL	N021346	002	Oct 29, 2003	Jan CMS1
>D>	AP	+	50MG/VIAL	N021346	003	Oct 29, 2003	Jan CMS1
>A>	AB	+	50MG/VIAL	N021346	003	Oct 29, 2003	Jan CMS1

RISPERIDONE

>D>	AP	TEVA PHARMS USA INC	12.5MG/VIAL	A214068	001	Dec 05, 2023	Jan CMS1
>A>	AB		12.5MG/VIAL	A214068	001	Dec 05, 2023	Jan CMS1
>D>	AP		25MG/VIAL	A214068	002	Dec 05, 2023	Jan CMS1
>A>	AB		25MG/VIAL	A214068	002	Dec 05, 2023	Jan CMS1
>D>	AP		37.5MG/VIAL	A214068	003	Dec 05, 2023	Jan CMS1
>A>	AB		37.5MG/VIAL	A214068	003	Dec 05, 2023	Jan CMS1
>D>	AP		50MG/VIAL	A214068	004	Dec 05, 2023	Jan CMS1
>A>	AB		50MG/VIAL	A214068	004	Dec 05, 2023	Jan CMS1

ROSUVASTATIN CALCIUM

TABLET;ORAL
ROSUVASTATIN CALCIUM

>D>	AB	SANDOZ	EQ 5MG BASE	A079171	001	Jul 19, 2016	Jan DISC
>A>		@	EQ 5MG BASE	A079171	001	Jul 19, 2016	Jan DISC
>D>	AB		EQ 10MG BASE	A079171	002	Jul 19, 2016	Jan DISC
>A>		@	EQ 10MG BASE	A079171	002	Jul 19, 2016	Jan DISC
>D>	AB		EQ 20MG BASE	A079171	003	Jul 19, 2016	Jan DISC
>A>		@	EQ 20MG BASE	A079171	003	Jul 19, 2016	Jan DISC
>D>	AB		EQ 40MG BASE	A079171	004	Jul 19, 2016	Jan DISC
>A>		@	EQ 40MG BASE	A079171	004	Jul 19, 2016	Jan DISC

SILVER SULFADIAZINE

CREAM;TOPICAL
SSD

>D>	AB	DR REDDYS LA	1%	N018578	001	Feb 25, 1982	Jan CRLD
>A>	AB	+!	1%	N018578	001	Feb 25, 1982	Jan CRLD

SODIUM BICARBONATE

INJECTABLE;INJECTION
SODIUM BICARBONATE

>D>	AP	STERISCIENCE	1MEQ/ML	A217594	001	Jun 28, 2023	Jan DISC
>A>		@	1MEQ/ML	A217594	001	Jun 28, 2023	Jan DISC

SODIUM FLUORIDE F-18INJECTABLE;INTRAVENOUS
SODIUM FLUORIDE F-18

>D>	AP	PETNET	10-200mCi/ML	A203890	001	Sep 28, 2015	Jan	CHRS
>A>	AP	!	10-200mCi/ML	A203890	001	Sep 28, 2015	Jan	CHRS
>D>	AP	! SOFIE	10-200mCi/ML	A203544	001	Dec 26, 2012	Jan	DISC
>A>		@	10-200mCi/ML	A203544	001	Dec 26, 2012	Jan	DISC

SUCCINYLCHOLINE CHLORIDEINJECTABLE;INJECTION
SUCCINYLCHOLINE CHLORIDE

>A>	AP	NIVAGEN PHARMS INC	20MG/ML	A211625	001	May 19, 2020	Jan	CAHN
>D>	AP	UMEDICA	20MG/ML	A211625	001	May 19, 2020	Jan	CAHN
SOLUTION;INTRAMUSCULAR, INTRAVENOUS								
SUCCINYLCHOLINE CHLORIDE								
>A>	AP	DR REDDYS	100MG/5ML (20MG/ML)	A218467	001	Jan 17, 2024	Jan	NEWA
>D>		+! HIKMA	100MG/5ML (20MG/ML)	N215143	001	Aug 20, 2021	Jan	CFTG
>A>	AP	+!	100MG/5ML (20MG/ML)	N215143	001	Aug 20, 2021	Jan	CFTG

SUCRALFATESUSPENSION;ORAL
SUCRALFATE

>A>	AB	PD PARTNERS	1GM/10ML	A213549	001	Jan 17, 2024	Jan	NEWA
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SUMATRIPTAN SUCCINATEINJECTABLE;SUBCUTANEOUS
IMITREX

>D>	AP	+! GLAXOSMITHKLINE	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N020080	001	Dec 28, 1992	Jan	DISC
>A>		+ @	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	N020080	001	Dec 28, 1992	Jan	DISC
SUMATRIPTAN SUCCINATE								
>D>	AP	EUGIA PHARMA	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A202758	001	Apr 23, 2013	Jan	CHRS
>A>	AP	!	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A202758	001	Apr 23, 2013	Jan	CHRS

TACROLIMUSCAPSULE, EXTENDED RELEASE;ORAL
ASTAGRAF XL

>D>		+ ASTELLAS	EQ 0.5MG BASE	N204096	001	Jul 19, 2013	Jan	CFTG
>A>	AB	+	EQ 0.5MG BASE	N204096	001	Jul 19, 2013	Jan	CFTG
>D>		+	EQ 1MG BASE	N204096	002	Jul 19, 2013	Jan	CFTG
>A>	AB	+	EQ 1MG BASE	N204096	002	Jul 19, 2013	Jan	CFTG
>D>		+!	EQ 5MG BASE	N204096	003	Jul 19, 2013	Jan	CFTG
>A>	AB	+!	EQ 5MG BASE	N204096	003	Jul 19, 2013	Jan	CFTG
TACROLIMUS								
>A>	AB	CHENGDU	EQ 0.5MG BASE	A215012	001	Jan 25, 2024	Jan	NFTG
>A>	AB		EQ 1MG BASE	A215012	002	Jan 25, 2024	Jan	NFTG
>A>	AB		EQ 5MG BASE	A215012	003	Jan 25, 2024	Jan	NFTG

TEMAZEPAMCAPSULE;ORAL
TEMAZEPAM

>A>	AB	CHARTWELL RX	15MG	A071427	001	Jan 12, 1988	Jan	CAHN
>A>	AB		30MG	A071428	001	Jan 12, 1988	Jan	CAHN
>D>	AB	SANDOZ	15MG	A071427	001	Jan 12, 1988	Jan	CAHN
>D>	AB		30MG	A071428	001	Jan 12, 1988	Jan	CAHN

TERAZOSIN HYDROCHLORIDECAPSULE;ORAL
TERAZOSIN HYDROCHLORIDE

>D>		@ BIONPHARMA	EQ 1MG BASE	A075667	001	Jul 28, 2000	Jan	CMFD
>A>	AB		EQ 1MG BASE	A075667	001	Jul 28, 2000	Jan	CMFD
>D>		@	EQ 2MG BASE	A075667	002	Jul 28, 2000	Jan	CMFD
>A>	AB		EQ 2MG BASE	A075667	002	Jul 28, 2000	Jan	CMFD
>D>		@	EQ 5MG BASE	A075667	003	Jul 28, 2000	Jan	CMFD
>A>	AB		EQ 5MG BASE	A075667	003	Jul 28, 2000	Jan	CMFD
>D>		@	EQ 10MG BASE	A075667	004	Jul 28, 2000	Jan	CMFD
>A>	AB		EQ 10MG BASE	A075667	004	Jul 28, 2000	Jan	CMFD

TESTOSTERONE

GEL, METERED; TRANSDERMAL

>D>		FORTESTA							
>D>	AB	+!	ENDO PHARMS	10MG/0.5GM ACTUATION	N021463	001	Dec 29, 2010	Jan	DISC
>A>		+ @		10MG/0.5GM ACTUATION	N021463	001	Dec 29, 2010	Jan	DISC
			TESTOSTERONE						
>D>	AB		ACTAVIS LABS UT INC	10MG/0.5GM ACTUATION	A204571	001	Aug 05, 2015	Jan	CTEC
>A>		!		10MG/0.5GM ACTUATION	A204571	001	Aug 05, 2015	Jan	CTEC

TESTOSTERONE UNDECANOATE

CAPSULE; ORAL

TLANDO

>D>		+!	ANTARES PHARMA INC	112.5MG	N208088	001	Mar 28, 2022	Jan	CAHN
>A>		+!	VERITY	112.5MG	N208088	001	Mar 28, 2022	Jan	CAHN

TETRACYCLINE HYDROCHLORIDE

TABLET; ORAL

SUMYCIN

>D>		@	STRIDES PHARMA	250MG	A061147	001		Jan	CMFD
>A>				250MG	A061147	001		Jan	CMFD
>D>		@		500MG	A061147	004		Jan	CMFD
>A>		!		500MG	A061147	004		Jan	CMFD

TIOPRONIN

TABLET, DELAYED RELEASE; ORAL

THIOLA EC

>D>		+	MISSION PHARMACAL	100MG	N211843	001	Jun 28, 2019	Jan	CFTG
>A>	AB	+		100MG	N211843	001	Jun 28, 2019	Jan	CFTG
			TIOPRONIN						
>A>	AB		TORRENT	100MG	A216990	001	Jan 30, 2024	Jan	NFTG
>A>	AB			300MG	A216990	002	Jan 30, 2024	Jan	NEWA

TIRZEPATIDE

SOLUTION; SUBCUTANEOUS

>D>			MOUNJARO						
>D>		+!	ELI LILLY AND CO	2.5MG/0.5ML (2.5MG/0.5ML)	N215866	001	May 13, 2022	Jan	CTNA
>A>		+!		2.5MG/0.5ML (2.5MG/0.5ML)	N215866	007	Jul 28, 2023	Jan	NEWA
>D>		+!		5MG/0.5ML (5MG/0.5ML)	N215866	002	May 13, 2022	Jan	CTNA
>A>		+!		5MG/0.5ML (5MG/0.5ML)	N215866	008	Jul 28, 2023	Jan	NEWA
>D>		+!		7.5MG/0.5ML (7.5MG/0.5ML)	N215866	003	May 13, 2022	Jan	CTNA
>A>		+!		7.5MG/0.5ML (7.5MG/0.5ML)	N215866	009	Jul 28, 2023	Jan	NEWA
>D>		+!		10MG/0.5ML (10MG/0.5ML)	N215866	004	May 13, 2022	Jan	CTNA
>A>		+!		10MG/0.5ML (10MG/0.5ML)	N215866	010	Jul 28, 2023	Jan	NEWA
>D>		+!		12.5MG/0.5ML (12.5MG/0.5ML)	N215866	005	May 13, 2022	Jan	CTNA
>A>		+!		12.5MG/0.5ML (12.5MG/0.5ML)	N215866	011	Jul 28, 2023	Jan	NEWA
>D>		+!		15MG/0.5ML (15MG/0.5ML)	N215866	006	May 13, 2022	Jan	CTNA
>A>		+!		15MG/0.5ML (15MG/0.5ML)	N215866	012	Jul 28, 2023	Jan	NEWA
>A>			MOUNJARO (AUTOINJECTOR)						
>A>		+!	ELI LILLY AND CO	2.5MG/0.5ML (2.5MG/0.5ML)	N215866	001	May 13, 2022	Jan	CTNA
>A>		+!		5MG/0.5ML (5MG/0.5ML)	N215866	002	May 13, 2022	Jan	CTNA
>A>		+!		7.5MG/0.5ML (7.5MG/0.5ML)	N215866	003	May 13, 2022	Jan	CTNA
>A>		+!		10MG/0.5ML (10MG/0.5ML)	N215866	004	May 13, 2022	Jan	CTNA
>A>		+!		12.5MG/0.5ML (12.5MG/0.5ML)	N215866	005	May 13, 2022	Jan	CTNA
>A>		+!		15MG/0.5ML (15MG/0.5ML)	N215866	006	May 13, 2022	Jan	CTNA

TOPIRAMATE

TABLET; ORAL

TOPIRAMATE

>D>	AB		SUN PHARM INDS LTD	25MG	A076327	001	Mar 27, 2009	Jan	DISC
>A>		@		25MG	A076327	001	Mar 27, 2009	Jan	DISC
>D>	AB			100MG	A076327	002	Mar 27, 2009	Jan	DISC
>A>		@		100MG	A076327	002	Mar 27, 2009	Jan	DISC
>D>	AB			200MG	A076327	003	Mar 27, 2009	Jan	DISC
>A>		@		200MG	A076327	003	Mar 27, 2009	Jan	DISC

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDE

>A>		@	AUROBINDO PHARMA LTD	0.1%	A211315	001	Mar 18, 2020	Jan	CAHN
>A>		@		0.5%	A211315	002	Mar 18, 2020	Jan	CAHN
>D>		@	STRIDES PHARMA	0.1%	A211315	001	Mar 18, 2020	Jan	CAHN

OINTMENT;TOPICAL

TRIAMCINOLONE ACETONIDE

>D>	@	0.5%	A211315	002	Mar 18, 2020	Jan CAHN
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UMECLIDINIUM BROMIDE

POWDER; INHALATION

INCRUSE ELLIPTA

>A>	+!	GLAXO GRP ENGLAND	EQ 0.0625MG BASE/INH	N205382	001	Apr 30, 2014	Jan CPOT
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>D>	+!		EQ 62.5MCG BASE/INH	N205382	001	Apr 30, 2014	Jan CPOT
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VALPROIC ACID

SYRUP;ORAL

VALPROIC ACID

>A>	AA	QUAGEN	250MG/5ML	A090517	001	May 28, 2010	Jan CAHN
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>D>	AA	SCIEGEN PHARMS INC	250MG/5ML	A090517	001	May 28, 2010	Jan CAHN
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ESOMEPRAZOLE MAGNESIUM

TABLET, DELAYED RELEASE;ORAL
ESOMEPRAZOLE MAGNESIUM

>D>	AUROBINDO PHARMA LTD	EQ 20MG BASE	A214473	001	Jul 12, 2023	Jan DISC
>A>	@	EQ 20MG BASE	A214473	001	Jul 12, 2023	Jan DISC

LOPERAMIDE HYDROCHLORIDE

SOLUTION;ORAL
LOPERAMIDE HYDROCHLORIDE

>D>	@ AKORN	1MG/5ML	A074352	001	Nov 17, 1995	Jan CAHN
>A>	@ SAPTALIS PHARMS	1MG/5ML	A074352	001	Nov 17, 1995	Jan CAHN

NAPROXEN SODIUM

TABLET;ORAL
NAPROXEN SODIUM

>D>	SUN PHARM INDS LTD	220MG	A091183	001	May 20, 2011	Jan DISC
>A>	@	220MG	A091183	001	May 20, 2011	Jan DISC

NICOTINE POLACRILEX

TROCHE/LOZENGE;ORAL
NICORETTE

>D>	+ GLAXOSMITHKLINE	EQ 2MG BASE	N022360	001	May 18, 2009	Jan CAHN
>D>	+!	EQ 4MG BASE	N022360	002	May 18, 2009	Jan CAHN
>A>	+ HALEON US HOLDINGS	EQ 2MG BASE	N022360	001	May 18, 2009	Jan CAHN
>A>	+!	EQ 4MG BASE	N022360	002	May 18, 2009	Jan CAHN

OLOPATADINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC
OLOPATADINE HYDROCHLORIDE

>D>	@ AKORN	EQ 0.2% BASE	A204723	001	Dec 05, 2017	Jan CAHN
>A>	@ SAPTALIS PHARMS	EQ 0.2% BASE	A204723	001	Dec 05, 2017	Jan CAHN

**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND
RESEARCH LIST**

CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY 2024

NO JANUARY 2024 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of Orphan Designations and Approvals is available at:

[https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products.](https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products)

**DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY
ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION**

NO JANUARY 2024 APPROVALS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2024

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ACYCLOVIR - ACYCLOVIR</u>						
A 212361	001				>A> CGT	Jun 12, 2024
<u>APREPITANT - APONVIE</u>						
N 216457	001	>A> 11878074	Sep 18, 2035	U-3787		
<u>AVATROMBOPAG MALEATE - DOPTELET</u>						
N 210238	001	>A> 7638536	Jul 28, 2027	DS DP		
<u>BACLOFEN - LYVISPAH</u>						
N 215422	001	>A> 11850225	Sep 29, 2041	DP U-3488		
		>A> 11850225	Sep 29, 2041	DP U-3489		
<u>BACLOFEN - LYVISPAH</u>						
N 215422	002	>A> 11850225	Sep 29, 2041	DP U-3488		
		>A> 11850225	Sep 29, 2041	DP U-3489		
<u>BACLOFEN - LYVISPAH</u>						
N 215422	003	>A> 11850225	Sep 29, 2041	DP U-3488		
		>A> 11850225	Sep 29, 2041	DP U-3489		
<u>BECLOMETHASONE DIPROPIONATE - OVAR REDIHALER</u>						
N 207921	001	>A> 11865247	Jan 26, 2038	DP		
<u>BECLOMETHASONE DIPROPIONATE - OVAR REDIHALER</u>						
N 207921	002	>A> 11865247	Jan 26, 2038	DP		
<u>BENDAMUSTINE HYDROCHLORIDE - BELRAPZO</u>						
N 205580	001	>A> 11872214	Jan 28, 2031	DP		
<u>BENDAMUSTINE HYDROCHLORIDE - BENDEKA</u>						
N 208194	001	>A> 11872214	Jan 28, 2031	DP		
<u>BENZOYL PEROXIDE - EPSOLAY</u>						
N 214510	001	>A> 11865100	Feb 19, 2040	U-3357		
<u>BERDAZIMER SODIUM - ZELSUVMI</u>						
N 217424	001	>A> 10265334	Jul 03, 2032	DP	>A> NCE	Jan 05, 2029
		>A> 10376538	Aug 20, 2030	DP		
		>A> 11285098	Feb 28, 2034	DP		
		>A> 8282967	May 30, 2026	DS		
		>A> 8956658	May 30, 2026	DS		
		>A> 9526738	Sep 03, 2031	DP		
<u>BIRCH TRITERPENES - FILSUVEZ</u>						
N 215064	001				>A> ODE-460	Dec 18, 2030
<u>BROMFENAC SODIUM - BROMFENAC SODIUM</u>						
A 206027	001				>A> PC	Jul 06, 2024
<u>BUDESONIDE - TARPEYO</u>						
N 215935	001	>A> 8491932	May 07, 2029	DP U-3269		
		>A> 8491932	May 07, 2029	DP U-3781		
<u>BUPIVACAINE - EXPAREL</u>						
N 022496	001				>A> I-929	Nov 09, 2026
<u>BUPIVACAINE - EXPAREL</u>						
N 022496	002				>A> I-929	Nov 09, 2026

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2024

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>CANNABIDIOL - EPIDIOLEX</u>						
N 210365 001	>A> 11865102	Apr 26, 2039	DS DP U-2781			
	>A> 11865102	Apr 26, 2039	DS DP U-3236			
	>A> 11865102	Apr 26, 2039	DS DP U-3277			
<u>CYCLOSPORINE - RESTASIS MULTIDOSE</u>						
N 050790 002	>A> 8629111	Aug 27, 2024	DP		Y	
	>A> 8633162	Aug 27, 2024	U-1479		Y	
	>A> 8642556	Aug 27, 2024	DP		Y	
	>A> 8648048	Aug 27, 2024	U-1483		Y	
	>A> 8685930	Aug 27, 2024	DP		Y	
	>A> 9248191	Aug 27, 2024	U-1479		Y	
<u>DEXMEDETOMIDINE HYDROCHLORIDE - IGALMI</u>						
N 215390 001	>A> 11890272	Jul 17, 2040	U-3756			
<u>DEXMEDETOMIDINE HYDROCHLORIDE - IGALMI</u>						
N 215390 002	>A> 11890272	Jul 17, 2040	U-3756			
<u>EDOXABAN TOSYLATE - SAVAYSA</u>						
N 206316 001					>A> M-14	Oct 18, 2026
<u>EDOXABAN TOSYLATE - SAVAYSA</u>						
N 206316 002					>A> M-14	Oct 18, 2026
<u>EDOXABAN TOSYLATE - SAVAYSA</u>						
N 206316 003					>A> M-14	Oct 18, 2026
<u>ELAGOLIX SODIUM - ORILISSA</u>						
N 210450 001	>A> 7419983	Jul 06, 2029	DS DP U-2360			
<u>ELAGOLIX SODIUM - ORILISSA</u>						
N 210450 002	>A> 7419983	Jul 06, 2029	DS DP U-2360			
<u>ELAGOLIX SODIUM, ESTRADIOL, NORETHINDRONE ACETATE; ELAGOLIX SODIUM - ORIAHNN (COPACKAGED)</u>						
N 213388 001	>A> 7419983	Jul 06, 2029	DS DP			
<u>EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - DESCOVY</u>						
N 208215 002					>A> ODE-457	Jan 07, 2029
<u>EPLONTERSEN SODIUM - WAINUA</u>						
N 217388 001	>A> 10683499	Aug 25, 2034	DS DP U-2378		>A> NCE	Dec 21, 2028
	>A> 8101743	Apr 01, 2025	DS DP		>A> ODE-461	Dec 21, 2030
	>A> 9127276	May 01, 2034	DS			
	>A> 9181549	May 01, 2034	DS			
<u>ESTRADIOL; PROGESTERONE - BIJUVA</u>						
N 210132 001	>A> 11865179	Nov 21, 2032	DS DP			
<u>ESTRADIOL; PROGESTERONE - BIJUVA</u>						
N 210132 002	>A> 11865179	Nov 21, 2032	DS DP			
<u>ETHINYL ESTRADIOL; SEGESTERONE ACETATE - ANNOVERA</u>						
N 209627 001	>A> 11850251	Jun 21, 2039	U-3785			
<u>FERRIC CARBOXYMALTOSE - INJECTAFER</u>						
N 203565 001	>A> 7612109	Feb 05, 2025	DS DP			
<u>FERRIC CARBOXYMALTOSE - INJECTAFER</u>						
N 203565 002	>A> 7612109	Feb 05, 2025	DS DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2024

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>FERRIC CARBOXYMALTOSE - INJECTAFER</u>						
N 203565 003	>A> 7612109	Feb 05, 2025	DS DP			
<u>FERRIC CARBOXYMALTOSE - INJECTAFER</u>						
N 203565 004	>A> 7612109	Feb 05, 2025	DS DP			
<u>FIDAXOMICIN - DIFICID</u>						
N 213138 001	>A> 8586551*PED	Jan 15, 2024				
<u>FLUOROMETHOLONE - FLUOROMETHOLONE</u>						
A 216348 001					>A> CGT	Jul 07, 2024
<u>GLYCEROL PHENYL BUTYRATE - RAVICTI</u>						
N 203284 001	8404215	Mar 09, 2032	U-1383	Y		
<u>HALOBETASOL PROPIONATE - HALOBETASOL PROPIONATE</u>						
A 215266 001					>A> PC	Jun 24, 2024
<u>HEPARIN SODIUM; TAUROLIDINE - DEFENCATH</u>						
N 214520 001					>A> NCE >A> GAIN	Nov 15, 2028 Nov 15, 2033
<u>HEPARIN SODIUM; TAUROLIDINE - DEFENCATH</u>						
N 214520 002					>A> NCE >A> GAIN	Nov 15, 2028 Nov 15, 2033
<u>IBRUTINIB - IMBRUVICA</u>						
N 205552 001	>A> 8754090 >A> 8754090*PED	Jun 03, 2031 Dec 03, 2031	U-1456	Y		
<u>IBRUTINIB - IMBRUVICA</u>						
N 205552 002	>A> 8754090 >A> 8754090*PED	Jun 03, 2031 Dec 03, 2031	U-1456	Y		
<u>IMIQUIMOD - ZYCLARA</u>						
N 022483 001	>A> 11850245 >A> 11850245	Apr 30, 2030 Apr 30, 2030	U-1455 U-172			
<u>INDOMETHACIN - INDOMETHACIN</u>						
A 217883 001					>A> CGT	Jul 10, 2024
<u>IPTACOPAN HYDROCHLORIDE - FABHALTA</u>						
N 218276 001					>A> NCE >A> ODE-456	Dec 05, 2028 Dec 05, 2030
<u>ISAVUCONAZONIUM SULFATE - CRESEMBA</u>						
N 207500 001					>A> NPP >A> ODE-454 >A> ODE-458 >A> PED	Dec 08, 2026 Dec 08, 2030 Dec 08, 2030 Jun 08, 2027
<u>ISAVUCONAZONIUM SULFATE - CRESEMBA</u>						
N 207500 002					>A> NPP >A> ODE-454 >A> ODE-458 >A> PED	Dec 08, 2026 Dec 08, 2030 Dec 08, 2030 Jun 08, 2027
<u>ISAVUCONAZONIUM SULFATE - CRESEMBA</u>						
N 207501 001					>A> NPP >A> ODE-453 >A> ODE-459 >A> PED >A> PED	Dec 08, 2026 Dec 08, 2030 Dec 08, 2030 Jun 08, 2027 Jun 08, 2031

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2024

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ISAVUCONAZONIUM SULFATE - CRESEMBA</u>						
N 207501	001				>A> NPP >A> ODE-453 >A> ODE-459 >A> PED >A> PED	Dec 08, 2026 Dec 08, 2030 Dec 08, 2030 Jun 08, 2027 Jun 08, 2031
<u>LOTEPREDNOL ETABONATE - INVELTYS</u>						
N 210565	001	>A> 11872318	May 03, 2033	DP		
<u>LOTEPREDNOL ETABONATE - EYSUVIS</u>						
N 210933	001	>A> 11872318	May 03, 2033	DP		
<u>LUMATEPERONE TOSYLATE - CAPLYTA</u>						
N 209500	001	>A> 8598119	Dec 28, 2029	U-543	Y	
<u>MIFEPRISTONE - MIFEPRISTONE</u>						
A 211436	001				>A> PC	Jul 17, 2024
<u>MITAPIVAT SULFATE - PYRUKYND</u>						
N 216196	001	>A> 11878049	Jul 31, 2041	U-3782		
<u>MITAPIVAT SULFATE - PYRUKYND</u>						
N 216196	002	>A> 11878049	Jul 31, 2041	U-3782		
<u>MITAPIVAT SULFATE - PYRUKYND</u>						
N 216196	003	>A> 11878049	Jul 31, 2041	U-3782		
<u>NALOXONE HYDROCHLORIDE - RIVIVE</u>						
N 217722	001	>A> 11806428	May 11, 2032	DP		
<u>NIROGACESTAT HYDROBROMIDE - OGSIVEO</u>						
N 217677	001	>A> 11872211	May 19, 2043	U-3754	>A> NCE	Nov 27, 2028
		>A> 11884634	Aug 09, 2039	DP	>A> ODE-452	Nov 27, 2030
		>A> 11884635	Aug 09, 2039	DP		
<u>OCTREOTIDE ACETATE - MYCAPSSA</u>						
N 208232	001	>A> 11857595	Feb 03, 2036	U-3784		
<u>OXYCODONE HYDROCHLORIDE - OXYCODONE HYDROCHLORIDE</u>						
N 200534	001				>A> M-14	Jul 21, 2024
<u>OXYCODONE HYDROCHLORIDE - OXYCODONE HYDROCHLORIDE</u>						
N 200535	001				>A> M-14	Jul 21, 2024
<u>OXYCODONE HYDROCHLORIDE - OXYCODONE HYDROCHLORIDE</u>						
N 200535	002				>A> M-14	Jul 21, 2024
<u>OXYCODONE HYDROCHLORIDE - OXYCODONE HYDROCHLORIDE</u>						
N 201194	001				>A> M-14	Jul 21, 2024
<u>PEGCETACOPLAN - EMPAVELI</u>						
N 215014	001	>A> 11844841	Dec 09, 2038	DP U-3172		
		>A> 11844841	Dec 09, 2038	DP U-3173		
		>A> 11844841	Dec 09, 2038	DP U-3174		
<u>PERFLUTREN - DEFINITY</u>						
N 021064	001	>A> 11857646	Mar 16, 2037	U-665		
<u>PERFLUTREN - DEFINITY RT</u>						
N 021064	002	>A> 11857646	Mar 16, 2037	U-665		

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2024

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>PHENTOLAMINE MESYLATE - RYZUMVI</u>						
N 217064 001	>A> 10278918	Jan 31, 2034	DP			
	>A> 10772829	Jan 31, 2034	DP			
	>A> 11090261	Jan 31, 2034	DP			
	>A> 11844858	Jan 31, 2034	DP			
	>A> 9795560	Jan 31, 2034	DP			
<u>PHENYLEPHRINE HYDROCHLORIDE; TROPICAMIDE - MYDCOMBI</u>						
N 215352 001	>A> 11839487	Jul 15, 2031		U-3685		
<u>PIFLUFOLASTAT F-18 - PYLARIFY</u>						
N 214793 001	>A> 11851407	Jun 09, 2037	DS DP	U-3130		
<u>PIRTOBRUTINIB - JAYPIRCA</u>						
N 216059 001					>A> ODE-451	Dec 01, 2030
<u>PIRTOBRUTINIB - JAYPIRCA</u>						
N 216059 002					>A> ODE-451	Dec 01, 2030
<u>PRALSETINIB - GAVRETO</u>						
N 213721 001	>A> 11872192	Apr 03, 2039		U-2952		
<u>REMEDESIVIR - VEKLURY</u>						
N 214787 001	>A> 10065958	Sep 16, 2031	DS		>A> D-183	Jan 21, 2025
	>A> 10065958*PED	Mar 16, 2032			>A> M-301	Jul 13, 2026
	>A> 10675296	Jul 10, 2038	DP		>A> NCE	Oct 22, 2025
	>A> 10675296*PED	Jan 10, 2039			>A> NPP	Apr 25, 2025
	>A> 10695361	Sep 16, 2036		U-2984	>A> PED	Jul 21, 2025
	>A> 10695361	Sep 16, 2036		U-3249	>A> PED	Oct 25, 2025
	>A> 10695361	Sep 16, 2036		U-3367	>A> PED	Apr 22, 2026
	>A> 10695361	Sep 16, 2036		U-3368	>A> PED	Jan 13, 2027
	>A> 10695361*PED	Mar 16, 2037				
	>A> 11007208	Sep 16, 2036		U-2984		
	>A> 11007208	Sep 16, 2036		U-3249		
	>A> 11007208	Sep 16, 2036		U-3367		
	>A> 11007208	Sep 16, 2036		U-3368		
	>A> 11007208*PED	Mar 16, 2037				
	>A> 11266681	Jul 10, 2038		U-2984		
	>A> 11266681	Jul 10, 2038		U-3249		
	>A> 11266681	Jul 10, 2038		U-3367		
	>A> 11266681	Jul 10, 2038		U-3368		
	>A> 11266681*PED	Jan 10, 2039				
	>A> 11382926	Sep 16, 2036		U-3367		
	>A> 11382926	Sep 16, 2036		U-3368		
	>A> 11382926*PED	Mar 16, 2037				
	>A> 11491169	May 28, 2041		U-3484		
	>A> 11491169	May 28, 2041		U-3485		
	>A> 11491169*PED	Nov 28, 2041				
	>A> 11492353	Dec 08, 2031	DS			
	>A> 11492353*PED	Jun 08, 2032				
	>A> 8008264	Sep 06, 2029	DS DP			
	>A> 8008264*PED	Mar 06, 2030				
	>A> 8318682	Apr 22, 2029	DS DP			
	>A> 8318682*PED	Oct 22, 2029				
	>A> 9724360	Oct 29, 2035	DS DP			
	>A> 9724360*PED	Apr 29, 2036				
	>A> 9949994	Oct 29, 2035	DS			
	>A> 9949994*PED	Apr 29, 2036				
	>A> RE46762	Apr 22, 2029	DS DP			
	>A> RE46762*PED	Oct 22, 2029				
<u>REMEDESIVIR - VEKLURY</u>						
N 214787 002	>A> 10065958	Sep 16, 2031	DS		>A> D-183	Jan 21, 2025
	>A> 10065958*PED	Mar 16, 2032			>A> M-301	Jul 13, 2026
	>A> 10675296	Jul 10, 2038	DP		>A> NCE	Oct 22, 2025
	>A> 10675296*PED	Jan 10, 2039			>A> NPP	Apr 25, 2025
	>A> 10695361	Sep 16, 2036		U-2984	>A> PED	Jul 21, 2025

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2024

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>REMDESIVIR - VEKLURY</u>						
N 214787 002	>A> 10695361	Sep 16, 2036	U-3249		>A> PED	Oct 25, 2025
	>A> 10695361	Sep 16, 2036	U-3367		>A> PED	Apr 22, 2026
	>A> 10695361	Sep 16, 2036	U-3368		>A> PED	Jan 13, 2027
	>A> 10695361*PED	Mar 16, 2037				
	>A> 11007208	Sep 16, 2036	U-2984			
	>A> 11007208	Sep 16, 2036	U-3249			
	>A> 11007208	Sep 16, 2036	U-3367			
	>A> 11007208	Sep 16, 2036	U-3368			
	>A> 11007208*PED	Mar 16, 2037				
	>A> 11266681	Jul 10, 2038	U-2984			
	>A> 11266681	Jul 10, 2038	U-3249			
	>A> 11266681	Jul 10, 2038	U-3367			
	>A> 11266681	Jul 10, 2038	U-3368			
	>A> 11266681*PED	Jan 10, 2039				
	>A> 11382926	Sep 16, 2036	U-3367			
	>A> 11382926	Sep 16, 2036	U-3368			
	>A> 11382926*PED	Mar 16, 2037				
	>A> 11491169	May 28, 2041	U-3484			
	>A> 11491169	May 28, 2041	U-3485			
	>A> 11491169*PED	Nov 28, 2041				
	>A> 11492353	Dec 08, 2031	DS			
	>A> 11492353*PED	Jun 08, 2032				
	>A> 8008264	Sep 06, 2029	DS DP			
	>A> 8008264*PED	Mar 06, 2030				
	>A> 8318682	Apr 22, 2029	DS DP			
	>A> 8318682*PED	Oct 22, 2029				
	>A> 9724360	Oct 29, 2035	DS DP			
	>A> 9724360*PED	Apr 29, 2036				
	>A> 9949994	Oct 29, 2035	DS			
	>A> 9949994*PED	Apr 29, 2036				
	>A> RE46762	Apr 22, 2029	DS DP			
	>A> RE46762*PED	Oct 22, 2029				
<u>REPOTRECTINIB - AUGTYRO</u>						
N 218213 001					>A> ODE-455	Nov 15, 2030
<u>RILPIVIRINE HYDROCHLORIDE - EDURANT</u>						
N 202022 001	>A> 7125879	Apr 21, 2025	DS DP U-1153			
	>A> 7125879	Apr 21, 2025	DS DP U-1307			
	>A> 7125879	Apr 21, 2025	DS DP U-1740			
	>A> 7125879	Apr 21, 2025	DS DP U-3353			
	>A> 7125879*PED	Oct 21, 2025				
<u>ROFLUMILAST - ZORYVE</u>						
N 217242 001					>A> NP	Dec 15, 2026
<u>SELUMETINIB SULFATE - KOSELUGO</u>						
N 213756 001	>A> 7425637	Mar 13, 2025	DS			
	>A> 8178693	Mar 13, 2025	DS DP			
<u>SELUMETINIB SULFATE - KOSELUGO</u>						
N 213756 002	>A> 7425637	Mar 13, 2025	DS			
	>A> 8178693	Mar 13, 2025	DS DP			
<u>SOLRIAMFETOL HYDROCHLORIDE - SUNOSI</u>						
N 211230 001	>A> 11857528	Mar 19, 2040	U-3521			
	>A> 11872203	Dec 30, 2042	U-3693			
	>A> 11872204	Dec 30, 2042	U-3693			
<u>SOLRIAMFETOL HYDROCHLORIDE - SUNOSI</u>						
N 211230 002	>A> 11857528	Mar 19, 2040	U-3521			
	>A> 11872203	Dec 30, 2042	U-3693			
	>A> 11872204	Dec 30, 2042	U-3693			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2024

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>TAZEMETOSTAT HYDROBROMIDE - TAZVERIK</u>						
N 211723 001	>A> 10155002	Sep 12, 2031				U-2736
	>A> 10420775	Sep 12, 2031				U-2736
	>A> 10420775	Sep 12, 2031				U-2852
	>A> 10420775	Sep 12, 2031				U-2853
	>A> 11052093	Apr 13, 2032	DS DP			U-2736
	>A> 11052093	Apr 13, 2032	DS DP			U-2852
	>A> 11052093	Apr 13, 2032	DS DP			U-2853
	>A> 11491163	Apr 11, 2033				U-2736
	>A> 11491163	Apr 11, 2033				U-2852
	>A> 11491163	Apr 11, 2033				U-2853
	>A> 8765732	Sep 12, 2031				U-2852
	>A> 8765732	Sep 12, 2031				U-2853
	>A> 9090562	Sep 12, 2031	DS DP			
	>A> 9549931	Sep 12, 2031				U-2736
	>A> 9549931	Sep 12, 2031				U-2852
	>A> 9549931	Sep 12, 2031				U-2853
	>A> 9855275	Sep 12, 2031				U-2736
<u>TESTOSTERONE ENANTHATE - XYOSTED (AUTOINJECTOR)</u>						
N 209863 001	>A> 11844804	Jun 04, 2033				U-2418
<u>TESTOSTERONE ENANTHATE - XYOSTED (AUTOINJECTOR)</u>						
N 209863 002	>A> 11844804	Jun 04, 2033				U-2418
<u>TESTOSTERONE ENANTHATE - XYOSTED (AUTOINJECTOR)</u>						
N 209863 003	>A> 11844804	Jun 04, 2033				U-2418
<u>TIVOZANIB HYDROCHLORIDE - FOTIVDA</u>						
N 212904 001	>A> 7166722	Nov 16, 2024	DS DP			
<u>TIVOZANIB HYDROCHLORIDE - FOTIVDA</u>						
N 212904 002	>A> 7166722	Nov 16, 2024	DS DP			
<u>TRAVOPROST - IDOSE TR</u>						
N 218010 001					>A> NP	Dec 13, 2026
<u>TUCATINIB - TUKYSA</u>						
N 213411 001	>A> 11207324	Apr 27, 2038				U-3783
	>A> 11666572	Apr 27, 2038				U-3783
<u>TUCATINIB - TUKYSA</u>						
N 213411 002	>A> 11207324	Apr 27, 2038				U-3783
	>A> 11666572	Apr 27, 2038				U-3783
<u>UBROGEPANT - UBRELVY</u>						
N 211765 001	>A> 11857542	Dec 22, 2041				U-3786
<u>VAMOROLONE - AGAMREE</u>						
N 215239 001	>A> 11690853	Mar 07, 2033				U-3747
<u>ZANUBRUTINIB - BRUKINSA</u>						
N 213217 001	>A> 11851437	Aug 15, 2037	DS DP			

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 44TH Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of patent terms is available at http://www.accessdata.fda.gov/scripts/cder/ob/results_patent.cfm

The current complete list of exclusivity terms is available at http://www.accessdata.fda.gov/scripts/cder/ob/results_exclusivity.cfm