Overview of FDA Resources

Heena Patel, PharmD
Center for Drug Evaluation and Research | Food and Drug Administration
Division of Drug Information | Office of Communications
Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be construed to represent FDA’s view or policies.
Objectives

1. Identify FDA resources that contain information on drug safety issues

2. Locate adverse event reporting information on FDA’s website

3. Utilize drug information resources to stay informed on FDA actions, decisions and initiatives
FDA: What We Do

• Mission: Promote and protect public health

• FDA’s primary responsibility is to protect the American people from unsafe or mislabeled food, drugs, and other medical products and to make sure consumers have access to accurate, science-based information about the products they need and rely on every day

• FDA/CDER (Center for Drug Evaluation and Research) ensures that safe, effective and high quality drugs are available for U.S. consumers
Division of Drug Information (DDI)

- DDI is CDER’s focal point for public inquiries regarding human drug products

- The mission of DDI is to optimize CDER's educational and communication efforts to our global community

- We support the FDA’s mission to promote and protect public health
Objectives

1. Identify FDA resources that contain information on drug safety issues

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FDA Databases/Resources

- Drugs@FDA
- National Drug Code (NDC) Directory
- Orange Book
- Purple Book
- Drug Safety Labeling Changes (SLC) Database
- Drug Shortages
- Approved Risk Evaluation and Mitigation Strategies (REMS)
- Drug Safety Communications
- MedWatch
CDER Small Business and Industry Assistance (SBIA)

CDER SBIA REDI Conference
PRESCRIPTION DRUG LABELING CONFERENCE 2017
NOVEMBER 1 & 2
TOMMY DOUGLAS CONFERENCE CENTER
10000 New Hampshire Ave
Silver Spring, MD 20903

Join us for our REDI Prescription Drug Labeling Conference 2017
FDA and Industry labeling specialists present their unique perspectives

Navigate the Drugs Section

Spotlight
- Find Information about a Drug
- Search Drugs@FDA
- Orange Book Search
- National Drug Code Directory
- Drug Shortages

Recalls & Alerts
- Drug Recalls
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Recalls, Market Withdrawals, & Safety Alerts
Drugs@FDA
## Search Results for "LAMOTRIGINE"

Products listed on this page may not be equivalent to one another.

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# Drugs@FDA: FDA Approved Drug Products

## New Drug Application (NDA): 020241
Company: GLAXOSMITHKLINE LLC

- Medication Guide

## Products on NDA 020241

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Showing 1 to 8 of 8 entries

## Approval Date(s) and History, Letters, Labels, Reviews for NDA 020241

## Labels for NDA 020241

- Therapeutic Equivalents for NDA 020241
### Approval Date(s) and History, Letters, Labels, Reviews for NDA 020241

#### Original Approvals or Tentative Approvals

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#### Supplements

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### Medication Guide

**Products on NDA 020241**

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Drug Approval Package

Lamictal Chewable Dispersible Tablets (Lamotrigine)
Company: Glaxo Wellcome, Inc.
Application No.: 020-764 & 020-241/S002
Approval Date: 8/24/1998

- Approval Letter & Printed Labeling (PDF) (3.6 MB)
- Medical Review(s) (PDF)
  Part 1 (2 MB)
  Part 2 (2 MB)
  Part 3 (2.8 MB)
  Part 4 (2.8 MB)
- Chemistry Review(s) (PDF) (762 KB)
- Pharmacology Review(s) & Statistical Review(s) (PDF) (2.3 MB)
- Clinical Pharmacology Biopharmaceutics Review(s) (PDF)
  Part 1 (3 MB)
  Part 2 (2.2 MB)
  Part 3 (2 MB)
  Part 4 (1 MB)
- Administrative Document(s)/Correspondence (PDF)
  Part 1 (3 MB)
  Part 2 (2.2 MB)
  Part 3 (2 MB)
  Part 4 (1 MB)

Date created: March 30, 2001; last updated: July 1, 2005
Back to Top Drugs@FDA
National Drug Code (NDC) Directory
National Drug Code Directory

The National Drug Code (NDC) Directory is updated daily.
Current through: September 17, 2017

*Required Field

Search the database

Choose a Search Type*: Nonproprietary Name

Search by Non Proprietary Name*: lamotrigine

(Type in part or all of Non Proprietary Name)

SEARCH  CLEAR

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files
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The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

The information submitted as part of the listing process, the NDC number, and the NDC Directory are used in the implementation and enforcement of the Act.

Download the New NDC Express Mobile Application!

Searching the NDC Directory is now faster and easier with our new mobile app!

Download NDC Express
Orange Book
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Additional information and resources for the Orange Book

Mobile App Users: Please replace Orange Book Express with Orange Book Express 2.0

Find Approved Drugs

- Search by Proprietary Name, Active Ingredient or Application Number
  - Entecavir
  - Search
- Search by Applicant (Company)
- Search by Dosage Form (for example: TABLET)
- Search by Route of Administration (for example: ORAL)

Find Patent Information

- Search by Patent Number
- View Newly Added Patents or Delisted Patents
### Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

#### Search Results for Proprietary Name, Active Ingredient or Application Number: Entecavir

21 records returned

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Additional information and resources for the Orange Book

Mobile App Users: Please replace Orange Book Express with Orange Book Express 2.0

Find Approved Drugs

- Search by Proprietary Name, Active Ingredient or Application Number
  - Xidra
  - Search

- Search by Applicant (Company)
- Search by Dosage Form (for example: TABLET)
- Search by Route of Administration (for example: ORAL)

Find Patent Information

- Search by Patent Number
- View Newly Added Patents or Dropped Patents
Search Results for Proprietary Name, Active Ingredient or Application Number: Xiidra

1 record returned

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| Dosage Form; Route of Administration: SOLUTION/DROPS, OPHTHALMIC  
| Strength: 5%  
| Reference Listed Drug: Yes  
| Reference Standard: Yes  
| TE Code:  
| Application Number: N208073  
| Product Number: 001  
| Approval Date: Jul 11, 2016  
| Applicant Holder Full Name: SHIRE DEVELOPMENT LLC  
| Marketing Status: Prescription  

**Patent and Exclusivity Information**
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<td>U-1880</td>
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<td>001</td>
<td>8367701</td>
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<td>Apr 15, 2029</td>
<td>DP</td>
<td></td>
<td>U-1900</td>
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</table>

### Exclusivity Data

<table>
<thead>
<tr>
<th>Product No</th>
<th>Exclusivity Code</th>
<th>Exclusivity Expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>NCE</td>
<td>Jul 11, 2021</td>
</tr>
</tbody>
</table>
The Purple Book includes:

- A list of biological products, including any biosimilar and interchangeable biological products
- The date a biological product was licensed and whether FDA evaluated the biological product for reference product exclusivity
- Indicates whether a biological product has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product
- Biosimilar and interchangeable biological products licensed will be listed under the reference product to which biosimilarity or interchangeability was demonstrated
- Separate lists for those biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER)
## Center for Drug Evaluation and Research

List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

<table>
<thead>
<tr>
<th>BLASTN</th>
<th>PRODUCT (PROPER) NAME</th>
<th>PROPRIETARY NAME</th>
<th>DATE OF LICENSURE (mo/day/yr)</th>
<th>DATE OF FIRST LICENSE (mo/day/yr)</th>
<th>REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)</th>
<th>INTERCHANGEABLE (I)/BIOSIMILAR (B)</th>
<th>WITHDRAWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>125118</td>
<td>abatacept</td>
<td>Orencia</td>
<td>12/23/05</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>103575</td>
<td>abciximab</td>
<td>ResPro</td>
<td>12/22/94</td>
<td>NA</td>
<td>NA</td>
<td></td>
<td></td>
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<tr>
<td>123274</td>
<td>abobotulinumtoxinA</td>
<td>Dysport</td>
<td>04/29/98</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>125057</td>
<td>adalimumab</td>
<td>Humira</td>
<td>12/31/02</td>
<td>NA</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>751058</td>
<td>adalimumab-adbm</td>
<td>Cytezo</td>
<td>08/25/17</td>
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<td></td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>751024</td>
<td>adalimumab-atto</td>
<td>Amjevita</td>
<td>09/23/16</td>
<td></td>
<td></td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>125427</td>
<td>ado-trastuzumab emtansine</td>
<td>Kadcyla</td>
<td>02/22/13</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Drug Shortages
Upgraded Drug Shortages app for Android devices adds alert feature

The Food and Drug Administration released Drug Shortages 2 mobile application for Android devices. Android device users are able to receive notifications when there is new or updated information about a shortage of a drug product or about a drug within selected therapeutic categories.

Designed for Android devices, Drug Shortages 2 sends alerts when the Agency adds or updates shortage information about a drug product or about a drug within selected therapeutic categories. We are currently working on notifications for the iOS version of the Drug Shortage mobile app, which will be available soon.

Download the Drug Shortages 2 app for Android devices

Download the Drug Shortages Mobile Application
A drug receives Resolved status when the Drug Shortages Staff (DSS) determines that the market is covered, based on information from all manufacturers. The market is considered covered when supply is available from at least one manufacturer to cover total market demand. However, some manufacturers may not have all presentations available. DSS monitors the supply of products with Resolved status. For the most current supply information, contact the manufacturers.

<table>
<thead>
<tr>
<th>Generic Name or Active Ingredient</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetohydroxamic Acid (Lithostat) Tablets</td>
<td>Resolved</td>
</tr>
<tr>
<td>Albuterol Sulfate Inhalation Solution (0.5%)</td>
<td>Resolved</td>
</tr>
<tr>
<td>Alitretinoin (Panretin) Gel</td>
<td>Resolved</td>
</tr>
<tr>
<td>Asparaginase Erwinia Chrysanthemi (Erwinaze)</td>
<td>Currently in Shortage</td>
</tr>
<tr>
<td>Atenolol Tablets</td>
<td>Currently in Shortage</td>
</tr>
</tbody>
</table>
Drug Shortages Mobile App
Drug Shortage Data

Drug Shortages: New vs. Prevented

Number of Drug Shortages

FY 2010: 178
FY 2011: 251
FY 2012: 282
FY 2013: 26
FY 2014: 23
FY 2015: 142
FY 2016: 115
Responding to Drug Shortages

• Regulatory Discretion
  • Allows for manufacture of medically necessary products to continue
  • May require additional safety controls
    • Filters with product; extra testing at plant; 3rd party oversight of production; special instructions for safe use

• Request other firms to raise production

• Expedite reviews
  • New manufacturing sites, longer expiry date, new raw material source, changes in specifications, etc.

• In rare cases, temporary importation from unapproved sources
**Extended Use Dates Provided by Pfizer to Assist with Emergency Syringe Shortages**

**UPDATE [8/17/17]** Due to the ongoing critical shortages of injectable drugs used in critical care, please see additional products with extended use dates and corresponding lot numbers in the tables below. To help ensure patient safety, these products should have been — and should continue to be — stored as per labeled conditions. As data become available, this list can continue to expand.

For more information, see the [CDER Statement](#). Please contact CDER Drug Shortage Staff at [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov) with questions regarding these tables.

Product and lot numbers of Sodium Bicarbonate products in glass flip-top vials eligible for use beyond the manufacturer’s labeled expiration date (as of August 17, 2017).

- Sodium Bicarbonate Injection, USP 8.4% (1 mEq/mL); 50 mEq/50 mL Single Dose Glass Flip-top Vial (NDC 0409-6625-25) LABELLED AS NOVAPLUS

<table>
<thead>
<tr>
<th>Product/Lot Number</th>
<th>Manufacturer’s Original Expiry Date</th>
<th>New Use Date (beyond manufacturer’s original expiry date)</th>
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<tbody>
<tr>
<td>57254EV00</td>
<td>9/1/2017</td>
<td>2/1/2018</td>
</tr>
<tr>
<td>57496EV00</td>
<td>9/1/2017</td>
<td>2/1/2018</td>
</tr>
<tr>
<td>60043EV00</td>
<td>12/1/2017</td>
<td>5/1/2018</td>
</tr>
<tr>
<td>60122EV00</td>
<td>12/1/2017</td>
<td>5/1/2018</td>
</tr>
</tbody>
</table>
Drug Recalls
Recalls, Market Withdrawals, & Safety Alerts

The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See Additional information about recalls for a more complete listing.

For recall notices older than 60 days, see the Recall and Safety Alerts Archive.

Sign up to receive Recalls, Market Withdrawals and Safety Alerts.

Filter by Keyword(s):
Filter by Recall Type:

<table>
<thead>
<tr>
<th>Date</th>
<th>Brand Name</th>
<th>Product Description</th>
<th>Reason/ Problem</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/09/2016</td>
<td>Granna's</td>
<td>French Toast with diced potatoes and mandarin oranges</td>
<td>Undeclared Milk</td>
<td>Granna's LLC</td>
</tr>
</tbody>
</table>
Enforcement Reports

All recalls monitored by FDA are included in the Enforcement Report once they are classified. Information about how to navigate the report and for definitions of the report labels are found on the Enforcement Report Navigation and Definitions page.

For information gathered from press releases and other public notices about certain recalls of FDA-regulated products you can visit Recalls, Market Withdrawals, & Safety Alerts.

FDA is conducting two pilot programs to expedite notifications of Non-Blood (HCT/P, Vaccine, Derivative, etc.) and human drug product recalls to the public which can be found in the below links:

- Human Drug Product Recalls Pending Classification (also available by selecting “Pending Recalls”)
- Non-Blood Product On-Going Recalls

To subscribe to the enforcement report mailing list please follow this link: Enforcement Report email subscription.

Please e-mail enforcementreports@fda.hhs.gov with any comments.
Enforcement Reports

- All recalls go into FDA's Enforcement Report once they are classified according to the level of hazard involved.
Compounding Risk Alerts

The information provided on this webpage is intended to alert health care professionals of adverse event reports related to compounded drugs. Providing this information to health care professionals should further FDA’s goal of protecting patients from unsafe, ineffective, and poor quality compounded drugs.

Please contact compounding@fda.hhs.gov if you have any questions regarding the information provided in a compounding risk alert below:

- A Case of Hemorrhagic Occlusive Retinal Vasculitis (HORV) Following Intraocular Injections of a Compounded Triamcinolone, Moxifloxacin, and Vancomycin Formulation
- FDA alerts health care professionals of adverse events associated with Guardian’s compounded triamcinolone and moxifloxacin product for intravitreal injection
- FDA investigates two serious adverse events associated with ImprimisRx’s compounded curcumin emulsion product for injection

FDA encourages health care professionals to report adverse events and product quality defects associated with compounded drugs to FDA’s MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.
Objectives

1. Identify FDA resources that contain information on drug safety issues

2. Locate adverse event reporting information on FDA’s website

3. Utilize drug information resources to stay informed on FDA actions, decisions and initiatives
MedWatch

Report:
- Adverse events
- Product problems
- Product use errors

Forms:
Voluntary
- Form FDA 3500
- Form FDA 3500B

Mandatory
- Form FDA 3500A
MedWatch: The FDA Safety Information and Adverse Event Reporting Program

Your FDA gateway for clinically important safety information and reporting serious problems with human medical products.

Report a Problem

What's New

- Baby Organic Liquid Formula by Garden of Life: Recall - Directions For Use May Be Misinterpreted If not administered precisely following the labeled instructions, the product may present difficulties in swallowing and potentially pose a choking hazard due to the thickness of the liquid. Posted 09/08/2017
MedWatch Online Voluntary Reporting Form

Welcome

Begin report as a:

Health Professional
(FDA Form 3500)

Consumer/Patient
(FDA Form 3500B)
Drug Safety Communications (DSC)

CDER’s primary tool for communicating important new and emerging safety information to the public

- New drug warnings
- Drug label changes
- Other safety information
Drug Safety Communications

**September 2017:** FDA warns about serious liver injury with Ocaliva (obeticholic acid) for rare chronic liver disease

**September 2017:** FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks

**September 2017:** FDA recommends separating dosing of potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) from all other oral drugs

**May 2017:** FDA identifies no harmful effects to date with brain retention of gadolinium-based contrast agents for MRIs; review to continue
Medication Errors

Division of Medication Error Prevention and Analysis (DMEPA) reviews:

- Medication error reports on marketed human drugs including prescription drugs, generic drugs, and OTC drugs
- MedWatch Reports
- Proprietary names, labeling, packaging, and product design prior to drug approval to help prevent medication errors
Medication Errors Related to Drugs

Within the Center for Drug Evaluation and Research (CDER), the Division of Medication Error Prevention and Analysis (DMEPA) reviews medication error reports on marketed human drugs including prescription drugs, generic drugs, and over-the-counter drugs. DMEPA uses the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) definition of a medication error. Specifically, a medication error is "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

DMEPA includes a medication error prevention program staffed with healthcare professionals. Among their many duties, program staff review medication error reports sent to MedWatch, evaluate causality, and analyze the data to provide solutions to reduce the risk of medication errors to industry and others at FDA.

Additionally, DMEPA prospectively reviews proprietary names, labeling, packaging, and product design prior to drug approval to help prevent medication errors.

Although DMEPA encourages manufacturers to perform their due diligence when naming their drug products and we strive to avoid approving confusing proprietary names for drug products, there are cases of adverse
Objectives

1. Identify FDA resources that contain information on drug safety issues

2. Locate adverse event reporting information on FDA’s website

3. Utilize drug information resources to stay informed on FDA actions, decisions and initiatives
Labeling Initiatives
Approved Risk Evaluation and Mitigation Strategies (REMS)

<table>
<thead>
<tr>
<th>REMS Name</th>
<th>Date Added</th>
<th>Medication Source</th>
<th>Communication Strategy</th>
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<tr>
<td>Approved REMS</td>
<td>12/24/2015</td>
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<tr>
<td>Approved REMS</td>
<td>08/25/2015</td>
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<tr>
<td>Approved REMS</td>
<td>06/07/2016</td>
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<td>Approved REMS</td>
<td>05/12/2015</td>
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<tr>
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<td>12/24/2015</td>
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<tr>
<td>Approved REMS</td>
<td>12/24/2015</td>
<td></td>
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<td>Approved REMS</td>
<td>07/25/2014</td>
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<td>06/22/2014</td>
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<td>07/10/2013</td>
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<td>Approved REMS</td>
<td>03/29/2014</td>
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<td>01/03/2014</td>
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<td>Approved REMS</td>
<td>01/06/2014</td>
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<tr>
<td>Approved REMS</td>
<td>01/06/2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approved REMS</td>
<td>01/06/2014</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The FDA and Drug Administration Amendments Act of 2007 give FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of a drug or biological product outweigh its risks.
Get email alerts when the site changes

Download historic REMS data in CSV format

Search by REMS, drug name, and element

Sort to find the most recently updated REMS

Click for more detailed info on each REMS

---

<table>
<thead>
<tr>
<th>Name</th>
<th>Last Updated</th>
<th>Medication Guide</th>
<th>Communication Plan</th>
<th>ETASU</th>
<th>Implementation System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actemra (tocilizumab), injection, solution; injection, solution, concentrate</td>
<td>10/21/2013</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>BLA #125276</td>
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<td>BLA #125472</td>
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<tr>
<td>Adasuve (loxapine), aerosol, powder</td>
<td>12/09/2013</td>
<td></td>
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<tr>
<td>NDA #22549</td>
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<tr>
<td>Addyi (flibanserin), tablet</td>
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<tr>
<td>NDA #022526</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
REMS: Information for Participants

What do participants need to know?

Below is a general overview of the REMS for all REMS participants (e.g., patients, pharmacies, and healthcare providers). See the product-specific REMS website or the approved REMS materials for more information.

Go to application holder’s REMS website

View application holder(s) REMS Website

- Healthcare Providers who prescribe isotretinoin products must
- Patients who are prescribed isotretinoin products
- Pharmacies that dispense isotretinoin products must

View requirements for each participant
# REMS: Information for HCPs

**Healthcare Providers who prescribe isotretinoin products must**

- Designate an authorized representative to carry out the certification process on behalf of the pharmacy.
- Have the authorized representative enroll in the REMS by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.

**Before dispensing**

- Provide the patient with the Medication Guide.
- Obtain authorization to dispense by contacting the iPLEDGE Program via web or voice-based system. Document the Risk Management Authorization (RMA) number on the prescription.
- Dispense prior to the “do not dispense to a patient after” date provided by the iPLEDGE Program.
- Dispense no more than a 30 days’ supply.
- Do not dispense refills.

**Every year**

- Re-enroll in the iPLEDGE Program.

**At all times**

- Return unused product to the manufacturer.
- Do not distribute, transfer, loan, or sell product.
Medication Guides

- Prevent serious adverse effects
- Assist with informed patient decision making
- Information for patient adherence to directions for use of a product
Drug Safety Labeling Changes (SLC)

The Drug Safety Labeling Changes (SLC) database provides approved safety labeling changes from January 2016 forward. Data prior to January 2016 will continue to be available on the MedWatch website.

Additional information and resources for drug safety labeling.

There are two ways to search: a Drug Name Search and a Date Search.

Drug Name Search

Drug Name or Active Ingredient: Enter at least 3 characters
    Search  Reset

OR

Date Search

For Safety Labeling Changes before January 1, 2016 see the MedWatch Safety Labeling Page

Date Range: 01/01/2016 - 09/02/2016

Labeling Section:

- Boxed Warning
- Contraindications
- Adverse Reactions
- Warnings and Precautions
- Drug Interactions
- Use in Specific Populations
- PCI/PI/IMG (Patient Counseling Information/Patient Information/Medication Guide)

Search  Reset
SLC Database Search

How to Search Within Results / Choose Result
Search within multiple results, filter results, sort by column, or select drug name.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Active Ingredient</th>
<th>Application Number</th>
<th>Supplement Date</th>
<th>Database Updated</th>
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</thead>
<tbody>
<tr>
<td>DRUG PRODUCT</td>
<td>DRUG PRODUCT</td>
<td>060000</td>
<td>01/15/2016</td>
<td>08/22/2018</td>
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<td>060009</td>
<td>01/15/2016</td>
<td>08/06/2016</td>
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<td>05/06/2016</td>
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<td>DRUG PRODUCT</td>
<td>060000</td>
<td>01/15/2016</td>
<td>09/17/2015</td>
</tr>
</tbody>
</table>

How to Download Data Files
Search results can be downloaded and saved in CSV format.

Drug Safety Labeling Changes (SLC)

Click here to download the approved drug labeling.

Approved Drug Label (PDF)

Boxed Warnings

WARNINGS: DRUG PRODUCT CAN INCREASE THE RISK OF CARDIOVASCULAR EVENTS

Contraindications
Concurrent use of DRUG PRODUCT with other nephrotoxic drugs should be avoided

Warnings and Precautions
Hepatic impairment can potentiate the response to DRUG PRODUCT and decrease its metabolism. Use DRUG PRODUCT with caution in these patients

Adverse Reactions
DRUG PRODUCT can cause nausea, vomiting and/or gastrointestinal distress

Click here to download data in a CSV file.
Stay Informed

Social Media
- Facebook
- Twitter
- LinkedIn
- Podcasts
- Webinars
- Mobile Apps
- YouTube
- iTunes

FDA.gov
- Drug Safety Communications
- FDA Listserves
- MedWatch Alerts
- Safety Labeling Changes (SLCs)

External Outreach
- Mass Media
- Stakeholder Briefings
- Consumer, Trade, Professional Groups
- Medical Journals

“Webinars”

“MedGuides”
Stay Informed

• Links to social media, webinars, and much more!  
  www.fda.gov/AboutDDI

• Sign up for email updates:  
  www.fda.gov/aboutfda/contactfda/stayinformed/getemailupdates/default.htm

• Pharmacy Student Experiential Program:  
  www.fda.gov/PharmStudentProgram

• Regulatory Pharmacist Fellowship Program:  
  www.fda.gov/RegPharmFellowship

• Global Alliance of Drug Information Specialists (GADIS)  
  www.fda.gov/GADIS
Thank you
QUESTIONS?

Contact DDI:
Phone: 855-543-3784 or 301-796-3400
Email: druginfo@fda.hhs.gov