# APPROVED DRUG PRODUCTS
## With Therapeutic Equivalence Evaluations

## The "Orange Book"

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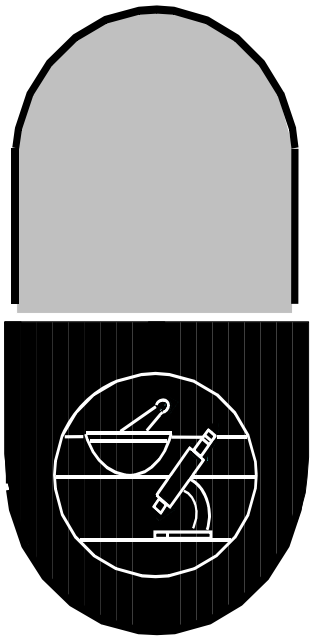
**CUMULATIVE SUPPLEMENT 5**
**May 2011**



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

## 31st EDITION

**Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Generic Drugs**

**2011**

Prepared By
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

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# with
# THERAPEUTIC EQUIVALENCE EVALUATIONS

## 31st EDITION

## Cumulative Supplement 5

## May 2011

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# APPROVED DRUG PRODUCTS
# with
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## 31st EDITION

## CUMULATIVE SUPPLEMENT 5
## May 2011

## 1.0 INTRODUCTION

### 1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 30th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, 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, or have been discontinued from marketing 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 the 30th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 31st Edition. The current Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

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.
  - o Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - o Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

- New Drug Application (NDA) approvals (20,000 and 50,000 series) 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 current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@fda.hhs.gov. Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
7620 Standish Place
Rockville, MD 20855-2773

## 1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every 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.

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|

## 1.4 LEVOTHYROXINE SODIUM

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

Levothyroxine Sodium (Mylan ANDA 76187) and Levo-T (Alara NDA 21342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Merck KGAA ANDA 76752)tablets have been determined to be therapeutically

equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

Levo-T (Alara NDA 021342), Unithroid (Jerome Stevens NDA 021210), Levothyroxine Sodium (Mylan ANDA 076187), and Levothyroxine Sodium (Merck KGAA ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levothroid (Lloyd NDA 021116) tablets.

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

| Trade Name | Applicant | Potency | TE Code | Appl No | Product No |
|---|---|---|---|---|---|
| UNITHROID | STEVENS J | 0.025MG | AB1 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB1 | 76187 | 001 |
| LEVOXYL | KING PHARMS | 0.025MG | AB1 | 21301 | 001 |
| SYNTHROID | ABBOTT | 0.025MG | AB1 | 21402 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB1 | 21342 | 001 |
| | | | | | |
| SYNTHROID | ABBOTT | 0.025MG | AB2 | 21402 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB2 | 76187 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB2 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB2 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MERCK KGAA | 0.025MG | AB2 | 76752 | 001 |
| | | | | | |
| LEVOXYL | KUNG PHARMS | 0.025MG | AB3 | 21301 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB3 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB3 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB3 | 76187 | 001 |
| LEVOTHYROXINE SODIUM | MERCK KGAA | 0.025MG | AB3 | 76752 | 001 |
| | | | | | |
| LEVOTHROID | LLOYD | 0.025MG | AB4 | 21116 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB4 | 76187 | 001 |
| | | | | | |

## 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.

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, http://www.fda.gov/opacom/morechoices/fdaforms/default.html.

The current listing of the Orphan Product Designations and Approvals is available at http://www.fda.gov/orphan/designat/list.htm.

## 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 (Dec 2008) 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

| CATEGORIES COUNTED | DEC 2010 | MAR 2011 | JUN 2011 | SEPT 2011 | DEC 2011 |
|---|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 13838 | 14029 | | | |
| SINGLE SOURCE | 2482 (17.9%) | 2477 (17.7%) | | | |
| MULTISOURCE | 11267 (81.4%) | 11463 (81.7%) | | | |
| THERAPEUTICALLY EQUIVALENT | 11107 (80.3%) | 11301 (80.6%) | | | |
| NOT THERAPEUTICALLY EQUIVALENT | 160 (1.2%) | 162 (1.2%) | | | |
| EXCEPTIONS[1] | 89 (0.6%) | 89 (0.6%) | | | |
| NEW MOLECULAR ENTITIES APPROVED | 8 | 6 | | | |
| NUMBER OF APPLICANTS | 752 | 768 | | | |

[1]Amino acid-containing products of varying composition (see Introduction, page xx of the List).

## 1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug 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; route(s), 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 proceeded 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 usually in the supplement month. |
| CAHN | Applicant holder firm name has changed. |
| 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 first time generic for the innovator product. A TE Code is added. |
| CMFD | Change. The product is moved from the Discontinued Section due to a change in marketing status. |
| CMS1 | Change. Miscellaneous addition to list. |

| | |
|---|---|
| CMS2 | Change. Miscellaneous deletion from list. |
| CPOT | Change. Potency amount/unit. |
| CRLD | Change. Reference Listed Drug. |
| CTEC | Change. Therapeutic Equivalence Code. |
| CTNA | Change. Trade Name. |
| DISC | Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition. |

ABIRATERONE ACETATE

TABLET; ORAL

ZYTIGA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | CENTOCOR ORTHO | 250MG | N202379 | 001 | Apr 28, 2011 | Apr | NEWA |

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | MIRROR PHARMS | 325MG;50MG;40MG | A040864 | 001 | Dec 01, 2008 | Mar | CAHN |
| AA | | 500MG;50MG;40MG | A040883 | 001 | Dec 23, 2008 | Mar | CAHN |

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | WRASER PHARMS LLC | 356.4MG;30MG;16MG | A040688 | 001 | Apr 03, 2007 | Jan | CAHN |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | BOCA PHARMA | 300MG;5MG | A090415 | 001 | Jan 24, 2011 | Feb | CTEC |
| AB | | 300MG;5MG | A090415 | 001 | Jan 24, 2011 | Jan | NEWA |
| AA | | 300MG;7.5MG | A090415 | 002 | Jan 24, 2011 | Feb | CTEC |
| AB | | 300MG;7.5MG | A090415 | 002 | Jan 24, 2011 | Jan | NEWA |
| AA | | 300MG;10MG | A090415 | 003 | Jan 24, 2011 | Feb | CTEC |
| AB | | 300MG;10MG | A090415 | 003 | Jan 24, 2011 | Jan | NEWA |
| AA | + MIKART | 300MG;5MG | A040658 | 001 | Jan 19, 2006 | Mar | CRLD |
| AA | | 300MG;5MG | A040658 | 001 | Jan 19, 2006 | Feb | CTEC |
| AA | + | 300MG;7.5MG | A040556 | 002 | Mar 24, 2006 | Feb | CTEC |
| AA | + | 300MG;10MG | A040556 | 001 | Jun 23, 2004 | Feb | CTEC |
| >D> AA | RANBAXY | 325MG;10MG | A040826 | 001 | Aug 16, 2007 | May | DISC |
| >D> AA | | 500MG;5MG | A040825 | 001 | Aug 16, 2007 | May | DISC |
| >A> | @ | 500MG;5MG | A040825 | 001 | Aug 16, 2007 | May | DISC |
| >D> AA | | 500MG;10MG | A040824 | 001 | Aug 16, 2007 | May | DISC |
| >A> | @ | 500MG;10MG | A040824 | 001 | Aug 16, 2007 | May | DISC |
| >D> AA | | 750MG;7.5MG | A040822 | 001 | Aug 16, 2007 | May | DISC |
| >A> | @ RANBAXY LABS LTD | 325MG;10MG | A040826 | 001 | Aug 16, 2007 | May | DISC |
| >A> | @ | 750MG;7.5MG | A040822 | 001 | Aug 16, 2007 | May | DISC |

LORTAB

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | UCB INC | 500MG;5MG | A087722 | 001 | Jul 09, 1982 | Jan | CAHN |

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL

PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | VINTAGE PHARMS | 650MG;65MG | A040507 | 001 | Jul 30, 2003 | Mar | DISC |

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

DARVOCET-N 100

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | XANODYNE PHARM | 650MG;100MG | N017122 | 002 | | Jan | DISC |

DARVOCET-N 50

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | XANODYNE PHARM | 325MG;50MG | N017122 | 001 | | Jan | DISC |

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | CORNERSTONE | 325MG;100MG | A076743 | 001 | May 07, 2004 | Mar | DISC |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | TABLET; ORAL | | | | | | | |
| | | PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN | | | | | | | |
| | | @ CORNERSTONE | 500MG;100MG | A076750 | 001 | Jun 28, 2004 | Mar | DISC | |
| | | @ MIRROR PHARMS | 650MG;100MG | A077821 | 001 | Feb 11, 2008 | Apr | DISC | |
| | AB | | 650MG;100MG | A077821 | 001 | Feb 11, 2008 | Mar | CAHN | |
| | | @ TEVA | 650MG;100MG | A074119 | 001 | Dec 19, 1994 | Mar | DISC | |
| | | @ VINTAGE PHARMS | 325MG;50MG | A074843 | 002 | Feb 15, 2001 | Mar | DISC | |
| | | @ | 650MG;100MG | A074843 | 001 | Feb 12, 1997 | Mar | DISC | |
| | | ACYCLOVIR | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | ACYCLOVIR | | | | | | | |
| | AB | MYLAN | 200MG | A074977 | 001 | Apr 13, 1998 | Feb | CAHN | |
| | | TABLET; ORAL | | | | | | | |
| | | ACYCLOVIR | | | | | | | |
| | AB | MYLAN | 400MG | A074976 | 001 | Apr 13, 1998 | Feb | CAHN | |
| | AB | | 800MG | A074976 | 002 | Apr 13, 1998 | Feb | CAHN | |
| | | ACYCLOVIR SODIUM | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | ACYCLOVIR SODIUM | | | | | | | |
| | | @ HOSPIRA | EQ 50MG BASE/ML | A075065 | 001 | Feb 25, 1999 | Feb | DISC | |
| | | ACYCLOVIR; HYDROCORTISONE | | | | | | | |
| | | CREAM; TOPICAL | | | | | | | |
| >D> | | ACYCLOVIR AND HYDROCORTISONE | | | | | | | |
| >D> | + | MEDA PHARMS | 5%;1% | N022436 | 001 | Jul 31, 2009 | May | CTNA | |
| >A> | | XERESE | | | | | | | |
| >A> | + | MEDA PHARMS | 5%;1% | N022436 | 001 | Jul 31, 2009 | May | CTNA | |
| | | ALCLOMETASONE DIPROPIONATE | | | | | | | |
| | | OINTMENT; TOPICAL | | | | | | | |
| | | ACLOVATE | | | | | | | |
| | AB + | NYCOMED US | 0.05% | N018702 | 001 | Dec 14, 1982 | Mar | CAHN | |
| | | ALENDRONATE SODIUM | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | ALENDRONATE SODIUM | | | | | | | |
| | AB | MYLAN | EQ 35MG BASE | A078638 | 001 | Aug 04, 2008 | Feb | CAHN | |
| | AB | | EQ 70MG BASE | A078638 | 002 | Aug 04, 2008 | Feb | CAHN | |
| | | @ SANDOZ | EQ 5MG BASE | A075871 | 001 | Apr 22, 2009 | Mar | DISC | |
| | | @ | EQ 10MG BASE | A075871 | 002 | Apr 22, 2009 | Mar | DISC | |
| | | @ | EQ 35MG BASE | A075871 | 004 | Apr 22, 2009 | Mar | DISC | |
| | | @ | EQ 40MG BASE | A075871 | 003 | Apr 22, 2009 | Mar | DISC | |
| | | @ | EQ 70MG BASE | A075871 | 005 | Apr 22, 2009 | Mar | DISC | |
| | | ALLOPURINOL | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | ALLOPURINOL | | | | | | | |
| | AB | IPCA LABS LTD | 100MG | A090637 | 001 | Mar 16, 2011 | Feb | NEWA | |
| | AB | | 300MG | A090637 | 002 | Mar 16, 2011 | Feb | NEWA | |
| | | ALPRAZOLAM | | | | | | | |
| | | TABLET, EXTENDED RELEASE; ORAL | | | | | | | |
| | | ALPRAZOLAM | | | | | | | |
| >A> | AB | AUROBINDO PHARMA USA | 0.5MG | A090871 | 001 | Jun 07, 2011 | May | NEWA | |

TABLET, EXTENDED RELEASE; ORAL
ALPRAZOLAM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | AUROBINDO PHARMA USA | 1MG | A090871 | 002 | Jun 07, 2011 | May | NEWA |
| >A> | AB | | 2MG | A090871 | 003 | Jun 07, 2011 | May | NEWA |
| >A> | AB | | 3MG | A090871 | 004 | Jun 07, 2011 | May | NEWA |

ALPROSTADIL

SUPPOSITORY; URETHRAL
MUSE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | MEDA PHARMS | 0.125MG | N020700 | 001 | Nov 19, 1996 | May | CAHN |
| >A> | | | 0.25MG | N020700 | 002 | Nov 19, 1996 | May | CAHN |
| >A> | | | 0.5MG | N020700 | 003 | Nov 19, 1996 | May | CAHN |
| >A> | + | | 1MG | N020700 | 004 | Nov 19, 1996 | May | CAHN |
| >D> | | VIVUS | 0.125MG | N020700 | 001 | Nov 19, 1996 | May | CAHN |
| >D> | | | 0.25MG | N020700 | 002 | Nov 19, 1996 | May | CAHN |
| >D> | | | 0.5MG | N020700 | 003 | Nov 19, 1996 | May | CAHN |
| >D> | + | | 1MG | N020700 | 004 | Nov 19, 1996 | May | CAHN |

AMLODIPINE BESYLATE

TABLET; ORAL
AMLODIPINE BESYLATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | ACTAVIS TOTOWA | EQ 2.5MG BASE | A078131 | 001 | Sep 04, 2007 | May | CAHN |
| >D> | AB | | EQ 5MG BASE | A078131 | 002 | Sep 04, 2007 | May | CAHN |
| >D> | AB | | EQ 10MG BASE | A078131 | 003 | Sep 04, 2007 | May | CAHN |
| | AB | EPIC PHARMA LLC | EQ 2.5MG BASE | A078552 | 001 | Apr 08, 2009 | Apr | CAHN |
| | AB | | EQ 5MG BASE | A078552 | 002 | Apr 08, 2009 | Apr | CAHN |
| | AB | | EQ 10MG BASE | A078552 | 003 | Apr 08, 2009 | Apr | CAHN |
| | AB | HIKMA PHARMS | EQ 2.5MG BASE | A077771 | 001 | Apr 12, 2011 | Mar | NEWA |
| | AB | | EQ 5MG BASE | A077771 | 002 | Apr 12, 2011 | Mar | NEWA |
| | AB | | EQ 10MG BASE | A077771 | 003 | Apr 12, 2011 | Mar | NEWA |
| >A> | AB | PURACAP PHARM | EQ 2.5MG BASE | A078131 | 001 | Sep 04, 2007 | May | CAHN |
| >A> | AB | | EQ 5MG BASE | A078131 | 002 | Sep 04, 2007 | May | CAHN |
| >A> | AB | | EQ 10MG BASE | A078131 | 003 | Sep 04, 2007 | May | CAHN |
| | AB | SECAN PHARMS | EQ 5MG BASE | A090752 | 001 | Apr 15, 2011 | Apr | NEWA |
| | AB | | EQ 10MG BASE | A090752 | 002 | Apr 15, 2011 | Apr | NEWA |

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL
LOTREL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | NOVARTIS | EQ 5MG BASE;40MG | N020364 | 007 | Apr 11, 2006 | Jan | CFTG |
| | AB | + | EQ 10MG BASE;40MG | N020364 | 006 | Apr 11, 2006 | Jan | CFTG |

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | AM ANTIBIOTICS | 250MG | A062058 | 001 | | Feb | CDFR |
| | AB | | 500MG | A062058 | 002 | | Feb | CDFR |

AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE

CAPSULE, TABLET, CAPSULE, DELAYED RELEASE; ORAL
OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | + | DAVA PHARMS INC | 500MG,N/A,N/A;N/A,500MG,N/A;N/A,N/A,20MG | N050824 | 001 | Feb 08, 2011 | Feb | NEWA |

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION

AMPICILLIN AND SULBACTAM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | AUROBINDO PHARMA | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | A090349 | 001 | Sep 20, 2010 | Apr | CAIN |
| AP | | | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | A090340 | 001 | Sep 20, 2010 | Apr | CAIN |
| AP | | | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | A090340 | 002 | Sep 20, 2010 | Apr | CAIN |
| AP | | | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | A090349 | 002 | Sep 20, 2010 | Apr | CAIN |
| AP | | | EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL | A090339 | 001 | Sep 20, 2010 | Apr | CAIN |

ANASTROZOLE

TABLET; ORAL

ANASTROZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | SANTOS BIOTECH | 1MG | A078944 | 001 | Jun 28, 2010 | Feb | CAHN |

ARGATROBAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | INJECTABLE; IV (INFUSION) | | | | | | |
| >A> | | ARGATROBAN IN SODIUM CHLORIDE | | | | | | |
| >A> | + | SANDOZ | 125MG/125ML (1MG/ML) | N022485 | 001 | May 09, 2011 | May | NEWA |
| >D> | | SOLUTION; IV (INFUSION) | | | | | | |
| >D> | | ARGATROBAN IN DEXTROSE | | | | | | |
| >A> | | @ SANDOZ | 125MG/125ML (1MG/ML) | N201743 | 001 | May 09, 2011 | May | DISC |

ASPIRIN; CARISOPRODOL

TABLET; ORAL

CARISOPRODOL AND ASPIRIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MIRROR PHARMS | 325MG;200MG | A040832 | 001 | Jan 07, 2010 | Mar | CAHN |
| AB | | PROSAM LABS | 325MG;200MG | A040252 | 001 | Dec 10, 1997 | Feb | CAHN |

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL

CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MIRROR PHARMS | 325MG;200MG;16MG | A040860 | 001 | Jan 07, 2010 | Mar | CAHN |
| AB | | PROSAM LABS | 325MG;200MG;16MG | A040283 | 001 | Dec 29, 1998 | Feb | CAHN |

ASPIRIN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE AND ASPIRIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | | COASTAL PHARMS | 325MG;4.8355MG | A091670 | 001 | Mar 16, 2011 | Feb | NEWA |
| AA | | WATSON LABS | 325MG;4.8355MG | A090084 | 001 | Mar 22, 2011 | Mar | NEWA |

PERCODAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | + | ENDO PHARMS | 325MG;4.8355MG | N007337 | 007 | Aug 05, 2005 | Feb | CFTG |

ATENOLOL

TABLET; ORAL

ATENOLOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | 25MG | A074126 | 003 | Aug 26, 1998 | Feb | CAHN |
| AB | | | 50MG | A074126 | 001 | Mar 23, 1994 | Feb | CAHN |
| AB | | | 100MG | A074126 | 002 | Mar 23, 1994 | Feb | CAHN |

ATOVAQUONE; PROGUANIL HYDROCHLORIDE

TABLET; ORAL

ATOVAQUONE AND PROGUANIL HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | GLENMARK GENERICS | 250MG;100MG | A091211 | 001 | Jan 12, 2011 | Jan | NEWA |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | TABLET; ORAL | | | | | | |
| | | MALARONE | | | | | | |
| AB | + | GLAXOSMITHKLINE | 250MG;100MG | N021078 | 001 | Jul 14, 2000 | Jan | CFTG |
| | | AZILSARTAN MEDOXOMIL | | | | | | |
| | | TABLET; ORAL | | | | | | |
| | | EDARBI | | | | | | |
| | | TAKEDA PHARMS | 40MG | N200796 | 001 | Feb 25, 2011 | Feb | NEWA |
| | + | | 80MG | N200796 | 002 | Feb 25, 2011 | Feb | NEWA |
| | | AZTREONAM | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | |
| | | AZTREONAM | | | | | | |
| AP | | BEDFORD | 1GM/VIAL | A065286 | 001 | Mar 23, 2011 | Mar | NEWA |
| AP | | | 2GM/VIAL | A065286 | 002 | Mar 23, 2011 | Mar | NEWA |
| | | BACITRACIN | | | | | | |
| | | OINTMENT; OPHTHALMIC | | | | | | |
| | | BACITRACIN | | | | | | |
| | + | FERA PHARMS | 500 UNITS/GM | A061212 | 001 | | Feb | CAHN |
| | + | NYCOMED US | 500 UNITS/GM | A061212 | 001 | | Jan | CAHN |
| | | BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE | | | | | | |
| | | OINTMENT; OPHTHALMIC | | | | | | |
| | | NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC | | | | | | |
| AT | | FERA PHARMS | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A060764 | 002 | | Feb | CAHN |
| AT | | NYCOMED US | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A060764 | 002 | | Jan | CAHN |
| | | BACITRACIN ZINC; POLYMYXIN B SULFATE | | | | | | |
| | | OINTMENT; OPHTHALMIC | | | | | | |
| | | BACITRACIN ZINC AND POLYMYXIN B SULFATE | | | | | | |
| AT | | FERA PHARMS | 500 UNITS/GM;10,000 UNITS/GM | A065022 | 001 | Feb 27, 2002 | Feb | CAHN |
| AT | | NYCOMED US | 500 UNITS/GM;10,000 UNITS/GM | A065022 | 001 | Feb 27, 2002 | Jan | CAHN |
| | | BACITRACIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE | | | | | | |
| | | OINTMENT; OPHTHALMIC | | | | | | |
| | | BACITRACIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE | | | | | | |
| | + | FERA PHARMS | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A062166 | 002 | | Feb | CAHN |
| | + | NYCOMED US | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A062166 | 002 | | Jan | CAHN |
| | | BACLOFEN | | | | | | |
| | | INJECTABLE; INTRATHECAL | | | | | | |
| | | GABLOFEN | | | | | | |
| AP | | CNS THERAPS INC | 0.05MG/ML | N022462 | 001 | Nov 19, 2010 | Feb | CTEC |
| AP | | | 0.5MG/ML | N022462 | 002 | Nov 19, 2010 | Feb | CTEC |
| AP | | | 2MG/ML | N022462 | 003 | Nov 19, 2010 | Feb | CTEC |
| | | LIORESAL | | | | | | |
| AP | + | MEDTRONIC | 0.05MG/ML | N020075 | 003 | Nov 07, 1996 | Feb | CTEC |
| AP | + | | 0.5MG/ML | N020075 | 001 | Jun 17, 1992 | Feb | CTEC |
| AP | + | | 2MG/ML | N020075 | 002 | Jun 17, 1992 | Feb | CTEC |
| | | TABLET; ORAL | | | | | | |
| | | BACLOFEN | | | | | | |
| AB | | PROSAM LABS | 10MG | A077089 | 001 | Oct 31, 2007 | Feb | CAHN |

TABLET; ORAL
BACLOFEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | PROSAM LABS | 20MG | A077088 | 001 | Oct 31, 2007 | Feb | CAHN |

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL
BENAZEPRIL HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | HUAHAI US INC | 5MG | A076118 | 001 | Feb 11, 2004 | May | CAHN |
| >D> | AB | | 10MG | A076118 | 002 | Feb 11, 2004 | May | CAHN |
| >D> | AB | | 20MG | A076118 | 003 | Feb 11, 2004 | May | CAHN |
| >D> | AB | | 40MG | A076118 | 004 | Feb 11, 2004 | May | CAHN |
| >A> | AB | PRINSTON PHARM LLC | 5MG | A076118 | 001 | Feb 11, 2004 | May | CAHN |
| >A> | AB | | 10MG | A076118 | 002 | Feb 11, 2004 | May | CAHN |
| >A> | AB | | 20MG | A076118 | 003 | Feb 11, 2004 | May | CAHN |
| >A> | AB | | 40MG | A076118 | 004 | Feb 11, 2004 | May | CAHN |

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
BENAZEPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | MYLAN | 5MG;6.25MG | A076612 | 001 | Feb 11, 2004 | Feb | CAHN |
| | AB | | 10MG;12.5MG | A076612 | 002 | Feb 11, 2004 | Feb | CAHN |
| | AB | | 20MG;12.5MG | A076612 | 003 | Feb 11, 2004 | Feb | CAHN |
| | AB | | 20MG;25MG | A076612 | 004 | Feb 11, 2004 | Feb | CAHN |

BENZTROPINE MESYLATE

INJECTABLE; INJECTION
BENZTROPINE MESYLATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP | LUITPOLD | 1MG/ML | A091152 | 001 | Mar 29, 2010 | Feb | CAHN |

BETAMETHASONE VALERATE

LOTION; TOPICAL
BETAMETHASONE VALERATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | STI PHARMA LLC | EQ 0.1% BASE | A070052 | 001 | Jul 31, 1985 | Apr | CAHN |

BICALUTAMIDE

TABLET; ORAL
BICALUTAMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | ROXANE | 50MG | A078285 | 001 | Mar 24, 2011 | Mar | NEWA |

>A> BOCEPREVIR

>A> CAPSULE; ORAL
>A> VICTRELIS

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | SCHERING | 200MG | N202258 | 001 | May 13, 2011 | May | NEWA |

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
BROMDAY

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | ISTA PHARMS INC | 0.09% | N021664 | 002 | Oct 16, 2010 | Mar | CRLD |

BROMFENAC SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | COASTAL PHARMS | 0.09% | A201211 | 001 | May 11, 2011 | Apr | NEWA |

XIBROM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | ISTA PHARMS INC | 0.09% | N021664 | 001 | Mar 24, 2005 | Mar | DISC |

BUDESONIDE

CAPSULE; ORAL

BUDESONIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | MYLAN | 3MG | A090410 | 001 | May 16, 2011 | May | NEWA |

ENTOCORT EC

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | + | ASTRAZENECA | 3MG | N021324 | 001 | Oct 02, 2001 | May | CFTG |
| >A> | AB | + | | 3MG | N021324 | 001 | Oct 02, 2001 | May | CFTG |

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB1 | | ANCHEN PHARMS | 100MG | A091459 | 001 | Jun 09, 2011 | May | NEWA |
| >A> | AB1 | | | 150MG | A091459 | 002 | Jun 09, 2011 | May | NEWA |
| >A> | AB2 | | | 150MG | A091520 | 001 | Jun 09, 2011 | May | NEWA |
| >A> | AB1 | | | 200MG | A091459 | 003 | Jun 09, 2011 | May | NEWA |
| >D> | AB1 | | WATSON LABS | 100MG | A079095 | 001 | Mar 24, 2009 | May | CAHN |
| >D> | AB1 | | | 150MG | A079095 | 002 | Mar 24, 2009 | May | CAHN |
| >D> | AB2 | | | 150MG | A079094 | 001 | Mar 24, 2009 | May | CAHN |
| >D> | AB1 | | | 200MG | A079095 | 003 | Mar 24, 2009 | May | CAHN |
| >A> | AB1 | | WATSON LABS FLORIDA | 100MG | A079095 | 001 | Mar 24, 2009 | May | CAHN |
| >A> | AB2 | | | 150MG | A079094 | 001 | Mar 24, 2009 | May | CAHN |
| >A> | AB1 | | | 150MG | A079095 | 002 | Mar 24, 2009 | May | CAHN |
| >A> | AB1 | | | 200MG | A079095 | 003 | Mar 24, 2009 | May | CAHN |

CALCIPOTRIENE

SOLUTION; TOPICAL

CALCIPOTRIENE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AT | | G AND W LABS INC | 0.005% | A078468 | 001 | Mar 24, 2011 | Mar | NEWA |

CALCIUM ACETATE

SOLUTION; ORAL

PHOSLYRA

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | + | FRESENIUS MEDCL | EQ 169MG CALCIUM/5ML | N022581 | 001 | Apr 18, 2011 | Apr | NEWA |

TABLET; ORAL

CALCIUM ACETATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | PADDOCK LABS | EQ 169MG CALCIUM | A091561 | 001 | Apr 13, 2011 | Mar | NEWA |

ELIPHOS

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | + | CYPRESS PHARM | EQ 169MG CALCIUM | A078502 | 001 | Nov 25, 2008 | Mar | CTEC |

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | AB | | HUAHAI US INC | 12.5MG | A074477 | 001 | Feb 13, 1996 | May | CAHN |
| >D> | AB | | | 25MG | A074477 | 002 | Feb 13, 1996 | May | CAHN |
| >D> | AB | | | 50MG | A074477 | 003 | Feb 13, 1996 | May | CAHN |
| >D> | AB | | | 100MG | A074477 | 004 | Feb 13, 1996 | May | CAHN |
| >A> | AB | | PRINSTON PHARM LLC | 12.5MG | A074477 | 001 | Feb 13, 1996 | May | CAHN |
| >A> | AB | | | 25MG | A074477 | 002 | Feb 13, 1996 | May | CAHN |
| >A> | AB | | | 50MG | A074477 | 003 | Feb 13, 1996 | May | CAHN |
| >A> | AB | | | 100MG | A074477 | 004 | Feb 13, 1996 | May | CAHN |

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL

CARBAMAZEPINE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | NOSTRUM | 100MG | A076697 | 001 | May 20, 2011 | May | NEWA |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | CAPSULE, EXTENDED RELEASE; ORAL | | | | | | | |
| >A> | | CARBAMAZEPINE | | | | | | | |
| >A> | AB | NOSTRUM | 200MG | | A076697 | 002 | May 20, 2011 | May | NEWA |
| >A> | AB | | 300MG | | A076697 | 003 | May 20, 2011 | May | NEWA |
| | | CARBATROL | | | | | | | |
| >D> | | SHIRE | 100MG | | N020712 | 003 | Sep 30, 1997 | May | CFTG |
| >A> | AB | | 100MG | | N020712 | 003 | Sep 30, 1997 | May | CFTG |
| >D> | | | 200MG | | N020712 | 001 | Sep 30, 1997 | May | CFTG |
| >A> | AB | | 200MG | | N020712 | 001 | Sep 30, 1997 | May | CFTG |
| >D> | + | | 300MG | | N020712 | 002 | Sep 30, 1997 | May | CFTG |
| >A> | AB + | | 300MG | | N020712 | 002 | Sep 30, 1997 | May | CFTG |
| | | TABLET, CHEWABLE; ORAL | | | | | | | |
| | | CARBAMAZEPINE | | | | | | | |
| | | @ JUBILANT CADISTA | 100MG | | A071940 | 001 | Feb 01, 1988 | Jan | CAHN |
| | | CARBIDOPA; LEVODOPA | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | SINEMET | | | | | | | |
| | AB | MERCK SHARP DOHME | 10MG;100MG | | N017555 | 001 | | Jan | CAHN |
| | AB | | 25MG;100MG | | N017555 | 003 | | Jan | CAHN |
| | AB + | | 25MG;250MG | | N017555 | 002 | | Jan | CAHN |
| | | TABLET, EXTENDED RELEASE; ORAL | | | | | | | |
| | | SINEMET CR | | | | | | | |
| | AB | MERCK SHARP DOHME | 25MG;100MG | | N019856 | 002 | Dec 24, 1992 | Jan | CAHN |
| | AB + | | 50MG;200MG | | N019856 | 001 | May 30, 1991 | Jan | CAHN |
| | | CARBINOXAMINE MALEATE | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | CARBINOXAMINE MALEATE | | | | | | | |
| >A> | AA | RIVERS EDGE PHARMS | 4MG | | A090756 | 001 | May 27, 2011 | May | NEWA |
| | | CARISOPRODOL | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | CARISOPRODOL | | | | | | | |
| | AA | MIRROR PHARMS | 350MG | | A040823 | 001 | Oct 22, 2008 | Mar | CAHN |
| | AA | PROSAM LABS | 350MG | | A040188 | 001 | Mar 07, 1997 | Feb | CAHN |
| | | CEFAZOLIN SODIUM | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | CEFAZOLIN SODIUM | | | | | | | |
| | AP | HOSPIRA INC | EQ 500MG BASE/VIAL | | A065226 | 001 | Apr 21, 2005 | Jan | CAHN |
| | AP | | EQ 1GM BASE/VIAL | | A065244 | 001 | Aug 12, 2005 | Jan | CAHN |
| | AP | | EQ 1GM BASE/VIAL | | A065226 | 002 | Apr 21, 2005 | Jan | CAHN |
| | AP | | EQ 10GM BASE/VIAL | | A065247 | 001 | Aug 12, 2005 | Jan | CAHN |
| | | CEFEPIME HYDROCHLORIDE | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | CEFEPIME HYDROCHLORIDE | | | | | | | |
| | AP | HOSPIRA INC | EQ 500MG BASE/VIAL | | A065369 | 001 | Jun 18, 2007 | Jan | CAHN |
| | AP | | EQ 1GM BASE/VIAL | | A065369 | 002 | Jun 18, 2007 | Jan | CAHN |
| | AP | | EQ 2GM BASE/VIAL | | A065369 | 003 | Jun 18, 2007 | Jan | CAHN |
| | | CEFOTAXIME SODIUM | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | CEFOTAXIME SODIUM | | | | | | | |
| | AP | HOSPIRA INC | EQ 500MG BASE/VIAL | | A065290 | 001 | Aug 11, 2006 | Jan | CAHN |

INJECTABLE; INJECTION
CEFOTAXIME SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | HOSPIRA INC | EQ 1GM BASE/VIAL | A065290 | 002 | Aug 11, 2006 | Jan | CAHN |
| AP | | | EQ 1GM BASE/VIAL | A065293 | 001 | Aug 10, 2006 | Jan | CAHN |
| AP | | | EQ 2GM BASE/VIAL | A065290 | 003 | Aug 11, 2006 | Jan | CAHN |
| AP | | | EQ 2GM BASE/VIAL | A065293 | 002 | Aug 10, 2006 | Jan | CAHN |
| AP | | | EQ 10GM BASE/VIAL | A065292 | 001 | Aug 10, 2006 | Jan | CAHN |

CEFOXITIN SODIUM

INJECTABLE; INJECTION
CEFOXITIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | HOSPIRA INC | EQ 1GM BASE/VIAL | A065313 | 001 | Jan 23, 2006 | Jan | CAHN |
| AP | | | EQ 2GM BASE/VIAL | A065313 | 002 | Jan 23, 2006 | Jan | CAHN |
| AP | | | EQ 10GM BASE/VIAL | A065312 | 001 | Feb 13, 2006 | Jan | CAHN |

CEFPODOXIME PROXETIL

TABLET; ORAL
CEFPODOXIME PROXETIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | SANDOZ | EQ 200MG BASE | A065462 | 002 | May 28, 2008 | Jan | CRLD |

VANTIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | PHARMACIA AND UPJOHN | EQ 100MG BASE | N050674 | 001 | Aug 07, 1992 | Jan | DISC |
| | @ | | EQ 200MG BASE | N050674 | 002 | Aug 07, 1992 | Jan | DISC |

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV
CEFTRIAXONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | HOSPIRA INC | EQ 250MG BASE/VIAL | A065230 | 001 | Aug 02, 2005 | Jan | CAHN |
| AP | | | EQ 500MG BASE/VIAL | A065230 | 002 | Aug 02, 2005 | Jan | CAHN |
| AP | | | EQ 1GM BASE/VIAL | A065230 | 003 | Aug 02, 2005 | Jan | CAHN |
| AP | | | EQ 2GM BASE/VIAL | A065230 | 004 | Aug 02, 2005 | Jan | CAHN |

INJECTABLE; INJECTION
CEFTRIAXONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | HOSPIRA INC | EQ 1GM BASE/VIAL | A065231 | 001 | Aug 02, 2005 | Jan | CAHN |
| AP | | | EQ 2GM BASE/VIAL | A065231 | 002 | Aug 02, 2005 | Jan | CAHN |
| AP | | | EQ 10GM BASE/VIAL | A065232 | 001 | Aug 02, 2005 | Jan | CAHN |
| AP | + | SANDOZ | EQ 10GM BASE/VIAL | A065168 | 001 | May 17, 2005 | Jan | CRLD |

CEFUROXIME AXETIL

TABLET; ORAL
CEFUROXIME AXETIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | ALKEM | EQ 250MG BASE | A065496 | 001 | Jun 07, 2010 | May | CAHN |
| >D> | AB | | EQ 500MG BASE | A065496 | 002 | Jun 07, 2010 | May | CAHN |
| >A> | AB | ALKEM LABS LTD | EQ 250MG BASE | A065496 | 001 | Jun 07, 2010 | May | CAHN |
| >A> | AB | | EQ 500MG BASE | A065496 | 002 | Jun 07, 2010 | May | CAHN |

CEFUROXIME SODIUM

INJECTABLE; IM-IV
CEFUROXIME SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | HIKMA FARMACEUTICA | EQ 750MG BASE/VIAL | A065048 | 001 | Jan 09, 2004 | Mar | CTEC |
| AP | | HOSPIRA INC | EQ 750MG BASE/VIAL | A065483 | 001 | Oct 15, 2008 | Jan | CAHN |

INJECTABLE; INJECTION
CEFUROXIME SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | HOSPIRA INC | EQ 1.5GM BASE/VIAL | A065483 | 002 | Oct 15, 2008 | Jan | CAHN |
| AP | | | EQ 1.5GM BASE/VIAL | A065503 | 001 | Oct 15, 2008 | Jan | CAHN |
| AP | | | EQ 7.5GM BASE/VIAL | A065484 | 001 | Oct 15, 2008 | Jan | CAHN |

CEPHALEXIN

FOR SUSPENSION; ORAL

CEPHALEXIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ ACS DOBFAR | EQ 100MG BASE/ML | A062117 | 001 | | Jan | CAHN |
| AB | | | EQ 125MG BASE/5ML | A062117 | 002 | | Jan | CAHN |
| AB | + | | EQ 250MG BASE/5ML | A062117 | 003 | | Jan | CAHN |

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

CHLORHEXIDINE GLUCONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AT | | LYNE | 0.12% | A074291 | 001 | Dec 28, 1995 | Feb | CAHN |

CHLOROQUINE PHOSPHATE

TABLET; ORAL

CHLOROQUINE PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | | NATCO PHARMA LTD | EQ 150MG BASE | A091621 | 001 | Jan 21, 2011 | Jan | NEWA |
| AA | | | EQ 300MG BASE | A090612 | 001 | Jan 21, 2011 | Jan | NEWA |

CHOLESTYRAMINE

POWDER; ORAL

CHOLESTYRAMINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | SANDOZ | EQ 4GM RESIN/PACKET | A074557 | 001 | Aug 15, 1996 | Apr | CRLD |

CHOLESTYRAMINE LIGHT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | SANDOZ | EQ 4GM RESIN/PACKET | A074558 | 001 | Aug 15, 1996 | Apr | CRLD |

QUESTRAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ BRISTOL MYERS | EQ 4GM RESIN/PACKET | N016640 | 001 | | Apr | DISC |
| | | @ | EQ 4GM RESIN/SCOOPFUL | N016640 | 003 | | Apr | DISC |

QUESTRAN LIGHT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ BRISTOL MYERS | EQ 4GM RESIN/PACKET | N019669 | 001 | Dec 05, 1988 | Apr | DISC |
| | | @ | EQ 4GM RESIN/SCOOPFUL | N019669 | 003 | Dec 05, 1988 | Apr | DISC |
| AB | + | | EQ 4GM RESIN/PACKET | N019669 | 001 | Dec 05, 1988 | Mar | CRLD |

CICLOPIROX

SHAMPOO; TOPICAL

CICLOPIROX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AT | | TARO | 1% | A090269 | 001 | Feb 23, 2011 | Feb | NEWA |

CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PROQUIN XR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | | | | | | | |
| >D> | + | DEPOMED INC | EQ 500MG BASE | N021744 | 001 | May 19, 2005 | May | DISC |
| >A> | | @ | EQ 500MG BASE | N021744 | 001 | May 19, 2005 | May | DISC |

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | EQ 10MG BASE | A077042 | 001 | Nov 05, 2004 | Apr | CAHN |
| AB | | | EQ 20MG BASE | A077042 | 002 | Nov 05, 2004 | Apr | CAHN |
| AB | | | EQ 40MG BASE | A077042 | 003 | Nov 05, 2004 | Apr | CAHN |

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | MATRIX LABS LTD | EQ 75MG BASE | A091225 | 001 | May 31, 2011 | May | NEWA |
| >A> | AB | | EQ 150MG BASE | A091225 | 002 | May 31, 2011 | May | NEWA |

CAPSULE; ORAL
CLINDAMYCIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | MATRIX LABS LTD | EQ 300MG BASE | A091225 | 003 | May 31, 2011 | May | NEWA |

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
CLINDAGEL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BT | + GALDERMA LABS LP | EQ 1% BASE | N050782 | 001 | Nov 27, 2000 | Mar | CRLD |

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ COREPHARMA | EQ 1% BASE | A064108 | 001 | Sep 27, 1996 | Apr | CAHN |

CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL
OLUX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | + CONNETICS | 0.05% | N021142 | 001 | May 26, 2000 | May | CAHN |
| >A> | AB | + STIEFEL LABS INC | 0.05% | N021142 | 001 | May 26, 2000 | May | CAHN |

CREAM; TOPICAL
CLOBETASOL PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ COREPHARMA | 0.05% | A075338 | 001 | Feb 09, 2001 | Apr | CAHN |

CLOBETASOL PROPIONATE (EMOLLIENT)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ COREPHARMA | 0.05% | A075733 | 001 | Aug 22, 2001 | Apr | CAHN |

OINTMENT; TOPICAL
CLOBETASOL PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ COREPHARMA | 0.05% | A075057 | 001 | Aug 12, 1998 | Apr | CAHN |

SHAMPOO; TOPICAL
>A> CLOBETASOL PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | ACTAVIS MID ATLANTIC | 0.05% | A078854 | 001 | Jun 07, 2011 | May | NEWA |

CLOBEX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + GALDERMA LABS | 0.05% | N021644 | 001 | Feb 05, 2004 | May | CFTG |
| >A> | AB | + | 0.05% | N021644 | 001 | Feb 05, 2004 | May | CFTG |

SOLUTION; TOPICAL
CLOBETASOL PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AT | NYCOMED US | 0.05% | A075391 | 001 | Feb 08, 1999 | Apr | CAHN |

SPRAY; TOPICAL
>A> CLOBETASOL PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | PADDOCK LABS | 0.05% | A090898 | 001 | Jun 16, 2011 | May | NEWA |

CLOBEX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | + GALDERMA LABS LP | 0.05% | N021835 | 001 | Oct 27, 2005 | May | CFTG |
| >A> | | + | 0.05% | N021835 | 001 | Oct 27, 2005 | May | CFTG |

CLONIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CLONIDINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP | WEST WARD | 1MG/10ML (0.1MG/ML) | A200300 | 001 | Jan 26, 2011 | Jan | NEWA |
| | AP | | 5MG/10ML (0.5MG/ML) | A200300 | 002 | Jan 26, 2011 | Jan | NEWA |

COLCHICINE; PROBENECID

TABLET; ORAL
PROBENECID AND COLCHICINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | MIRROR PHARMS | 0.5MG;500MG | A040618 | 001 | May 13, 2008 | Mar | CAHN |

CYCLOBENZAPRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
AMRIX

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | ANESTA AG | 15MG | N021777 | 001 | Feb 01, 2007 | Apr | CFTG |

CAPSULE, EXTENDED RELEASE; ORAL
AMRIX
AB + ANESTA AG 30MG N021777 002 Feb 01, 2007 Apr CFTG
CYCLOBENZAPRINE HYDROCHLORIDE
AB MYLAN 15MG A090738 001 Apr 18, 2011 Apr NEWA
AB 30MG A090738 002 Apr 18, 2011 Apr NEWA
TABLET; ORAL
CYCLOBENZAPRINE HYDROCHLORIDE
AB JUBILANT CADISTA 5MG A077563 001 Apr 19, 2006 Jan CAHN
AB 10MG A077563 002 Apr 19, 2006 Jan CAHN
AB KVK TECH 5MG A078048 001 Feb 28, 2011 Feb NEWA
AB 10MG A078048 002 Feb 28, 2011 Feb NEWA
AB PROSAM LABS 5MG A077291 001 Feb 03, 2006 Feb CAHN
AB 10MG A077209 001 Oct 04, 2005 Feb CAHN

DARIFENACIN HYDROBROMIDE

TABLET, EXTENDED RELEASE; ORAL
ENABLEX
>D> NOVARTIS EQ 7.5MG BASE N021513 001 Dec 22, 2004 May CAHN
>D> + EQ 15MG BASE N021513 002 Dec 22, 2004 May CAHN
>A> WARNER CHILCOTT LLC EQ 7.5MG BASE N021513 001 Dec 22, 2004 May CAHN
>A> + EQ 15MG BASE N021513 002 Dec 22, 2004 May CAHN

DARUNAVIR ETHANOLATE

TABLET; ORAL
PREZISTA
>D> TIBOTEC EQ 300MG BASE N021976 001 Jun 23, 2006 May DISC
>A> @ EQ 300MG BASE N021976 001 Jun 23, 2006 May DISC

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL
DECLOMYCIN
>A> @ COREPHARMA 75MG N050261 001 May CAHN
>A> AB 150MG N050261 002 May CAHN
>A> AB + 300MG N050261 003 May CAHN
>D> @ STIEFEL 75MG N050261 001 May CAHN
>D> AB 150MG N050261 002 May CAHN
>D> AB + 300MG N050261 003 May CAHN
DEMECLOCYCLINE HYDROCHLORIDE
>D> AB COVENANT PHARMA INC 150MG A065389 001 Dec 01, 2008 May CAHN
>D> AB 300MG A065389 002 Dec 01, 2008 May CAHN
>A> AB VERSAPHARM 150MG A065389 001 Dec 01, 2008 May CAHN
>A> AB 300MG A065389 002 Dec 01, 2008 May CAHN

DESLORATADINE

TABLET; ORAL
DESLORATADINE
AB DR REDDYS LABS LTD 5MG A078365 001 Mar 08, 2011 Feb NEWA

DESLORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
CLARINEX D 24 HOUR
AB + SCHERING 5MG;240MG N021605 001 Mar 03, 2005 Apr CFTG
DESLORATADINE AND PSEUDOEPHEDRINE SULFATE 24 HOUR
AB DR REDDYS LABS LTD 5MG;240MG A078366 001 Apr 26, 2011 Apr NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | STIMATE | | | | | | |
| >D> | + | CSL BEHRING | 0.15MG/SPRAY | N020355 | 001 | Mar 07, 1994 | May | DISC |
| >A> | | @ | 0.15MG/SPRAY | N020355 | 001 | Mar 07, 1994 | May | DISC |

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | EMOQUETTE | | | | | | |
| | AB | VINTAGE | 0.15MG;0.03MG | A076675 | 001 | Feb 25, 2011 | Feb | NEWA |

DESOXIMETASONE

GEL; TOPICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | DESOXIMETASONE | | | | | | |
| | AB | VERSAPHARM | 0.05% | A090727 | 001 | Mar 10, 2011 | Feb | NEWA |

OINTMENT; TOPICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | TOPICORT | | | | | | |
| >D> | | @ TARO PHARMS NORTH | 0.05% | N018594 | 001 | Jan 17, 1985 | May | CMFD |
| >A> | | + | 0.05% | N018594 | 001 | Jan 17, 1985 | May | CMFD |

DEXAMETHASONE

ELIXIR; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | DEXAMETHASONE | | | | | | |
| | AA | VINTAGE PHARMS | 0.5MG/5ML | A091188 | 001 | May 11, 2011 | Apr | NEWA |

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | DEXAMETHASONE SODIUM PHOSPHATE | | | | | | |
| >D> | AP | AKORN STRIDES | EQ 4MG PHOSPHATE/ML | A040803 | 001 | Aug 29, 2008 | May | CAHN |
| >D> | AP | | EQ 10MG PHOSPHATE/ML | A040802 | 001 | Aug 29, 2008 | May | CAHN |
| >A> | AP | PFIZER | EQ 4MG PHOSPHATE/ML | A040803 | 001 | Aug 29, 2008 | May | CAHN |
| >A> | AP | | EQ 10MG PHOSPHATE/ML | A040802 | 001 | Aug 29, 2008 | May | CAHN |

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE | | | | | | |
| | AT | FERA PHARMS | 0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A062938 | 001 | Jul 31, 1989 | Feb | CAHN |
| | AT | NYCOMED US | 0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM | A062938 | 001 | Jul 31, 1989 | Jan | CAHN |

DEXMETHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | FOCALIN XR | | | | | | |
| >A> | | NOVARTIS | 25MG | N021802 | 008 | Apr 21, 2011 | May | NEWA |
| >A> | | | 35MG | N021802 | 007 | Apr 21, 2011 | May | NEWA |

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE | | | | | | |
| | AA | AMNEAL PHARMS | 15MG/5ML;6.25MG/5ML | A090575 | 001 | Feb 08, 2011 | Jan | NEWA |

DICLOFENAC SODIUM

TABLET, EXTENDED RELEASE; ORAL
DICLOFENAC SODIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | VALEANT INTL | 100MG | | A075492 | 001 | Feb 11, 2000 | Apr | CAHN |

DIFLUPREDNATE

EMULSION; OPHTHALMIC
DUREZOL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | + | ALCON PHARMS LTD | 0.05% | | N022212 | 001 | Jun 23, 2008 | May | CAHN |
| >D> | + | ALCON RES | 0.05% | | N022212 | 001 | Jun 23, 2008 | May | CAHN |

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB3 | | VALEANT INTL | 120MG | | A075116 | 001 | Dec 23, 1999 | Apr | CAHN |
| AB3 | | | 180MG | | A075116 | 002 | Dec 23, 1999 | Apr | CAHN |
| AB3 | | | 240MG | | A075116 | 003 | Dec 23, 1999 | Apr | CAHN |
| AB3 | | | 300MG | | A075116 | 004 | Dec 23, 1999 | Apr | CAHN |

DIPYRIDAMOLE

TABLET; ORAL
DIPYRIDAMOLE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | PROSAM LABS | 25MG | | A040542 | 001 | Apr 21, 2006 | Feb | CAHN |
| AB | | | 50MG | | A040542 | 002 | Apr 21, 2006 | Feb | CAHN |
| AB | | | 75MG | | A040542 | 003 | Apr 21, 2006 | Feb | CAHN |

DISULFIRAM

TABLET; ORAL
ANTABUSE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | ODYSSEY PHARMS | 250MG | | A088482 | 001 | Dec 08, 1983 | Mar | CTEC |
| AB | + | | 500MG | | A088483 | 001 | Dec 08, 1983 | Mar | CTEC |

DISULFIRAM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | SIGMAPHARM LABS LLC | 250MG | | A091619 | 001 | Mar 28, 2011 | Mar | NEWA |
| AB | | | 500MG | | A091619 | 002 | Mar 28, 2011 | Mar | NEWA |

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL
DIVALPROEX SODIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | EQ 125MG VALPROIC ACID | | A090407 | 001 | Mar 28, 2011 | Mar | NEWA |

TABLET, DELAYED RELEASE; ORAL
DIVALPROEX SODIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | AUROBINDO PHARMA LTD | EQ 125MG VALPROIC ACID | | A090554 | 001 | Apr 21, 2011 | Apr | NEWA |
| AB | | | EQ 250MG VALPROIC ACID | | A090554 | 002 | Apr 21, 2011 | Apr | NEWA |
| AB | | | EQ 500MG VALPROIC ACID | | A090554 | 003 | Apr 21, 2011 | Apr | NEWA |
| AB | | UNICHEM LABS LTD | EQ 125MG VALPROIC ACID | | A079163 | 001 | Apr 05, 2011 | Mar | NEWA |
| AB | | | EQ 250MG VALPROIC ACID | | A079163 | 002 | Apr 05, 2011 | Mar | NEWA |
| AB | | | EQ 500MG VALPROIC ACID | | A079163 | 003 | Apr 05, 2011 | Mar | NEWA |
| AB | | WATSON LABS FLORIDA | EQ 500MG VALPROIC ACID | | A079080 | 001 | Feb 25, 2011 | Feb | NEWA |

DOCETAXEL

INJECTABLE; INJECTION
DOCEFREZ

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | + | SUN PHARMA GLOBAL | 20MG/VIAL | | N022534 | 001 | May 03, 2011 | May | NEWA |
| >A> | + | | 80MG/VIAL | | N022534 | 002 | May 03, 2011 | May | NEWA |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | INJECTABLE; INJECTION | | | | | | | |
| | | DOCETAXEL | | | | | | | |
| | + | HOSPIRA INC | 20MG/2ML (10MG/ML) | N022234 | 001 | Mar 08, 2011 | Mar | NEWA | |
| | + | | 80MG/8ML (10MG/ML) | N022234 | 002 | Mar 08, 2011 | Mar | NEWA | |
| | + | | 160MG/16ML (10MG/ML) | N022234 | 003 | Mar 08, 2011 | Mar | NEWA | |
| | | TAXOTERE | | | | | | | |
| | @ | SANOFI AVENTIS US | 40MG/ML | N020449 | 001 | May 14, 1996 | Mar | DISC | |
| | | DONEPEZIL HYDROCHLORIDE | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | DONEPEZIL HYDROCHLORIDE | | | | | | | |
| >A> | AB | ACTAVIS PHARMA | 5MG | A090551 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090551 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | APOTEX | 5MG | A078841 | 001 | Jun 02, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A078841 | 002 | Jun 02, 2011 | May | NEWA | |
| >A> | AB | AUROBINDO | 5MG | A090056 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090056 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | CIPLA LTD | 5MG | A077518 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A077518 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | DR REDDYS LABS LTD | 5MG | A201001 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A201001 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | HIKMA PHARMS | 5MG | A090247 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090247 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | HUAHAI US INC | 5MG | A200292 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A200292 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | JUBILANT LIFE | 5MG | A090768 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090768 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | MATRIX LABS LTD | 5MG | A090521 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090521 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | PLIVA HRVATSKA DOO | 5MG | A090425 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090425 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | ROXANE | 5MG | A078662 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A078662 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | SANDOZ | 5MG | A090290 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090290 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | SUN PHARM INDS | 5MG | A090493 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090493 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | TEVA | 5MG | A077344 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A077344 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | TORRENT PHARMS | 5MG | A090686 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A090686 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AB | WOCKHARDT | 5MG | A091267 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AB | | 10MG | A091267 | 002 | May 31, 2011 | May | NEWA | |
| | | TABLET, ORALLY DISINTEGRATING; ORAL | | | | | | | |
| | | DONEPEZIL HYDROCHLORIDE | | | | | | | |
| | AB | SANDOZ | 5MG | A091198 | 001 | May 10, 2011 | Apr | NEWA | |
| | AB | | 10MG | A091198 | 002 | May 10, 2011 | Apr | NEWA | |
| | AB | ZYDUS PHARMS USA INC | 5MG | A090175 | 001 | May 10, 2011 | Apr | NEWA | |
| | AB | | 10MG | A090175 | 002 | May 10, 2011 | Apr | NEWA | |
| | | DOXYCYCLINE | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | DOXYCYCLINE | | | | | | | |
| | AB | IMPAX LABS INC | EQ 150MG BASE | A200065 | 001 | Feb 17, 2011 | Jan | NEWA | |
| | AB | MYLAN | 40MG | A090855 | 001 | Jul 01, 2010 | Jan | CDFR | |
| | AB | + PAR PHARM | EQ 150MG BASE | A065055 | 003 | Jul 15, 2005 | Feb | CTEC | |

CAPSULE; ORAL
DOXYCYCLINE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | + | PAR PHARM | EQ 150MG BASE | A065055 | 003 | Jul 15, 2005 | Jan | CTEC |

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> AB | | WATSON LABS | EQ 50MG BASE | A062031 | 002 | Oct 13, 1982 | May | CAHN |
| >D> AB | | | EQ 100MG BASE | A062031 | 001 | | May | CAHN |
| >A> AB | | WATSON LABS FLORIDA | EQ 50MG BASE | A062031 | 002 | Oct 13, 1982 | May | CAHN |
| >A> AB | | | EQ 100MG BASE | A062031 | 001 | | May | CAHN |

DROSPIRENONE; ETHINYL ESTRADIOL

TABLET; ORAL
LORYNA

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | SANDOZ | 3MG;0.02MG | A079221 | 001 | Mar 28, 2011 | Mar | NEWA |

TABLET; ORAL-28
SYEDA

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | SANDOZ | 3MG;0.03MG | A090114 | 001 | Mar 28, 2011 | Mar | NEWA |

ENOXAPARIN SODIUM

INJECTABLE; INTRAVENOUS, SUBCUTANEOUS
LOVENOX

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | SANOFI AVENTIS US | 300MG/3ML (100MG/ML) | N020164 | 009 | Jan 23, 2003 | Feb | CDFR |

EPINASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
ELESTAT

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AT | + | ALLERGAN | 0.05% | N021565 | 001 | Oct 16, 2003 | Feb | CFTG |

EPINASTINE HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AT | | CYPRESS PHARM | 0.05% | A090870 | 001 | Mar 14, 2011 | Feb | NEWA |

EPIRUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
EPIRUBICIN HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AP | | MUSTAFA NEVSAT | 50MG/25ML (2MG/ML) | A090266 | 001 | Apr 15, 2011 | Apr | NEWA |
| AP | | | 200MG/100ML (2MG/ML) | A090266 | 002 | Apr 15, 2011 | Apr | NEWA |

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL
ERYTHROMYCIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AB | | ARBOR PHARMS INC | 250MG | A062746 | 001 | Dec 22, 1986 | Jan | CAHN |

GEL; TOPICAL
E-GLADES

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AT | | COREPHARMA | 2% | A065009 | 001 | Mar 18, 2002 | Apr | CAHN |

OINTMENT; OPHTHALMIC
ERYTHROMYCIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AT | + | FERA PHARMS | 0.5% | A062447 | 001 | Sep 26, 1983 | Feb | CAHN |
| AT | + | NYCOMED US | 0.5% | A062447 | 001 | Sep 26, 1983 | Jan | CAHN |

SOLUTION; TOPICAL
ERYDERM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | @ ARBOR PHARMS INC | 2% | A062290 | 001 | | Jan | CAHN |

ERYTHROMYCIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | @ COREPHARMA | 2% | A064127 | 001 | Feb 14, 1997 | Apr | CAHN |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | SWAB; TOPICAL | | | | | | | |
| | ERYTHROMYCIN | | | | | | | |
| | @ COREPHARMA | 2% | A064128 | 001 | Jul 03, 1996 | Apr | CAHN | |
| | TABLET; ORAL | | | | | | | |
| | ERYTHROMYCIN | | | | | | | |
| | ARBOR PHARMS INC | 250MG | A061621 | 001 | | Jan | CAHN | |
| + | | 500MG | A061621 | 002 | | Jan | CAHN | |
| | TABLET, COATED PARTICLES; ORAL | | | | | | | |
| | PCE | | | | | | | |
| | ARBOR PHARMS INC | 333MG | N050611 | 001 | Sep 09, 1986 | Jan | CAHN | |
| + | | 500MG | N050611 | 002 | Aug 22, 1990 | Jan | CAHN | |
| | TABLET, DELAYED RELEASE; ORAL | | | | | | | |
| | E-MYCIN | | | | | | | |
| | @ ARBOR PHARMS INC | 250MG | A060272 | 001 | | Jan | CAHN | |
| | @ | 333MG | A060272 | 002 | | Jan | CAHN | |
| | ERY-TAB | | | | | | | |
| + | ARBOR PHARMS INC | 250MG | A062298 | 001 | | Jan | CAHN | |
| + | | 333MG | A062298 | 003 | Mar 29, 1982 | Jan | CAHN | |
| + | | 500MG | A062298 | 002 | | Jan | CAHN | |
| | ERYTHROMYCIN ETHYLSUCCINATE | | | | | | | |
| | GRANULE; ORAL | | | | | | | |
| | E.E.S. | | | | | | | |
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | N050207 | 001 | | Jan | CAHN | |
| | ERYPED | | | | | | | |
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | N050207 | 003 | Mar 30, 1987 | Jan | CAHN | |
| + | | EQ 400MG BASE/5ML | N050207 | 002 | | Jan | CAHN | |
| | SUSPENSION; ORAL | | | | | | | |
| | E.E.S. 200 | | | | | | | |
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | A061639 | 001 | | Jan | CAHN | |
| | E.E.S. 400 | | | | | | | |
| AB + | ARBOR PHARMS INC | EQ 400MG BASE/5ML | A061639 | 002 | | Jan | CAHN | |
| | PEDIAMYCIN | | | | | | | |
| AB | ARBOR PHARMS INC | EQ 200MG BASE/5ML | A062304 | 001 | | Jan | CAHN | |
| | PEDIAMYCIN 400 | | | | | | | |
| AB | ARBOR PHARMS INC | EQ 400MG BASE/5ML | A062304 | 002 | | Jan | CAHN | |
| | TABLET; ORAL | | | | | | | |
| | E.E.S. 400 | | | | | | | |
| | @ ARBOR PHARMS INC | EQ 400MG BASE | A061905 | 001 | | Jan | CAHN | |
| BX + | | EQ 400MG BASE | A061905 | 002 | Aug 12, 1982 | Jan | CAHN | |
| | ERYTHROMYCIN ETHYLSUCCINATE | | | | | | | |
| BX + | ARBOR PHARMS INC | EQ 400MG BASE | A061904 | 001 | | Jan | CAHN | |
| | TABLET, CHEWABLE; ORAL | | | | | | | |
| | E.E.S. | | | | | | | |
| | @ ARBOR PHARMS INC | EQ 200MG BASE | N050297 | 002 | | Jan | CAHN | |
| | ERYPED | | | | | | | |
| | @ ARBOR PHARMS INC | EQ 200MG BASE | N050297 | 003 | Jul 05, 1988 | Jan | CAHN | |
| | ERYTHROMYCIN STEARATE | | | | | | | |
| | TABLET; ORAL | | | | | | | |
| | ERYTHROCIN STEARATE | | | | | | | |
| | @ ARBOR PHARMS INC | EQ 125MG BASE | A060359 | 002 | | Jan | CAHN | |
| | | EQ 250MG BASE | A060359 | 001 | | Jan | CAHN | |
| + | | EQ 500MG BASE | A060359 | 003 | | Jan | CAHN | |

ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

ACTIVELLA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | NOVO NORDISK INC | 0.5MG;0.1MG | N020907 | 002 | Dec 28, 2006 | Mar | CTEC |

ESTRADIOL AND NORETHINDRONE ACETATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> AB | BRECKENRIDGE PHARM | 0.5MG;0.1MG | A078324 | 002 | Jun 09, 2011 | May | NEWA |

ESTROPIPATE

CREAM; VAGINAL

OGEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | PHARMACIA AND UPJOHN | 1.5MG/GM | A084710 | 001 | | Apr | DISC |

ESZOPICLONE

TABLET; ORAL

ESZOPICLONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> AB | TEVA | 1MG | A091169 | 001 | May 23, 2011 | May | NEWA |
| >A> AB | | 2MG | A091169 | 002 | May 23, 2011 | May | NEWA |
| >A> AB | | 3MG | A091169 | 003 | May 23, 2011 | May | NEWA |

LUNESTA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | SEPRACOR | 1MG | N021476 | 001 | Dec 15, 2004 | May | CFTG |
| >D> | | 2MG | N021476 | 002 | Dec 15, 2004 | May | CFTG |
| >D> + | | 3MG | N021476 | 003 | Dec 15, 2004 | May | CFTG |
| >A> AB | SUNOVION PHARMS INC | 1MG | N021476 | 001 | Dec 15, 2004 | May | CFTG |
| >A> AB | | 2MG | N021476 | 002 | Dec 15, 2004 | May | CFTG |
| >A> AB + | | 3MG | N021476 | 003 | Dec 15, 2004 | May | CFTG |

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL

LEVONORGESTREL AND ETHINYL ESTRADIOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> AB | WATSON LABS | 0.02MG;0.09MG | A079218 | 001 | Jun 06, 2011 | May | NEWA |

LEVONORGESTREL AND ETHINYL ESTRADIOL AND ETHINYL ESTRADIOL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> AB | WATSON LABS | 0.03MG,0.01MG;0.15MG,N/A | A078834 | 001 | May 31, 2011 | May | NEWA |

LYBREL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> + | WYETH PHARMS INC | 0.02MG;0.09MG | N021864 | 001 | May 22, 2007 | May | CFTG |
| >A> AB + | | 0.02MG;0.09MG | N021864 | 001 | May 22, 2007 | May | CFTG |

SEASONIQUE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> + | DURAMED RES | 0.03MG,0.01MG;0.15MG,N/A | N021840 | 001 | May 25, 2006 | May | CFTG |
| >A> AB + | TEVA WOMENS | 0.03MG,0.01MG;0.15MG,N/A | N021840 | 001 | May 25, 2006 | May | CFTG |

TABLET; ORAL-28

ORSYTHIA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB1 | VINTAGE PHARMS | 0.02MG;0.1MG | A077099 | 001 | May 11, 2011 | Apr | NEWA |

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

BRIELLYN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | GLENMARK GENERICS | 0.035MG;0.4MG | A090538 | 001 | Mar 22, 2011 | Mar | NEWA |

TABLET, CHEWABLE; ORAL

NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | WARNER CHILCOTT | 0.025MG;0.8MG | N022573 | 001 | Dec 22, 2010 | Jan | CRLD |

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

LO LOESTRIN FE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | WARNER CHILCOTT CO | 0.01MG,0.01MG;1MG,N/A | N022501 | 001 | Oct 21, 2010 | May | CRLD |
| >A> + | | 0.01MG,0.01MG;1MG,N/A | N022501 | 001 | Oct 21, 2010 | May | CRLD |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | TABLET; ORAL-28 | | | | | | | |
| | | GILDESS FE 1.5/30 | | | | | | | |
| | AB | VINTAGE | 0.03MG;1.5MG | A077075 | 001 | Apr 28, 2005 | Jan | CTNA | |
| | | GILDESS FE 1/20 | | | | | | | |
| | AB | VINTAGE | 0.02MG;1MG | A077077 | 001 | May 20, 2005 | Jan | CTNA | |
| | | ETHINYL ESTRADIOL; NORGESTIMATE | | | | | | | |
| | | TABLET; ORAL-28 | | | | | | | |
| | | NORGESTIMATE AND ETHINYL ESTRADIOL | | | | | | | |
| | AB | WATSON LABS | 0.025MG,0.025MG,0.025MG;0.18MG,0.215MG,0.25MG | A090479 | 001 | Mar 09, 2011 | Feb | NEWA | |
| | | ETHOSUXIMIDE | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | ETHOSUXIMIDE | | | | | | | |
| >D> | AB | COVENANT PHARMA INC | 250MG | A040686 | 001 | May 28, 2008 | May | CAHN | |
| >A> | AB | VERSAPHARM | 250MG | A040686 | 001 | May 28, 2008 | May | CAHN | |
| | | ETODOLAC | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | ETODOLAC | | | | | | | |
| | | @ MYLAN | 200MG | A075071 | 001 | Sep 30, 1998 | Feb | CAHN | |
| | | @ | 300MG | A075071 | 002 | Sep 30, 1998 | Feb | CAHN | |
| | | TABLET; ORAL | | | | | | | |
| | | ETODOLAC | | | | | | | |
| | | @ MYLAN | 400MG | A075012 | 001 | Sep 30, 1998 | Feb | CAHN | |
| | | @ | 500MG | A075012 | 002 | Sep 30, 1998 | Feb | CAHN | |
| | | ETONOGESTREL | | | | | | | |
| | | IMPLANT; IMPLANTATION | | | | | | | |
| >A> | | NEXPLANON | | | | | | | |
| >A> | + | ORGANON USA INC | 68MG/IMPLANT | N021529 | 002 | May 31, 2011 | May | NEWA | |
| | | ETRAVIRINE | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | INTELENCE | | | | | | | |
| | | TIBOTEC | 100MG | N022187 | 001 | Jan 18, 2008 | Jan | CRLD | |
| | + | | 200MG | N022187 | 002 | Dec 22, 2010 | Jan | NEWA | |
| | | EXEMESTANE | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | AROMASIN | | | | | | | |
| | AB + | PHARMACIA AND UPJOHN | 25MG | N020753 | 001 | Oct 21, 1999 | Mar | CFTG | |
| | | EXEMESTANE | | | | | | | |
| | AB | ROXANE | 25MG | A077431 | 001 | Apr 01, 2011 | Mar | NEWA | |
| | | FAMCICLOVIR | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | FAMCICLOVIR | | | | | | | |
| | AB | AUROBINDO PHARMA LTD | 125MG | A091114 | 001 | Mar 21, 2011 | Mar | NEWA | |
| | AB | | 250MG | A091114 | 002 | Mar 21, 2011 | Mar | NEWA | |
| | AB | | 500MG | A091114 | 003 | Mar 21, 2011 | Mar | NEWA | |
| | AB | MYLAN | 125MG | A201333 | 001 | Mar 24, 2011 | Mar | NEWA | |
| | AB | | 250MG | A201333 | 002 | Mar 24, 2011 | Mar | NEWA | |
| | AB | | 500MG | A201333 | 003 | Mar 24, 2011 | Mar | NEWA | |
| | AB | ROXANE | 125MG | A090128 | 001 | Mar 21, 2011 | Mar | NEWA | |

TABLET; ORAL
FAMCICLOVIR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | ROXANE | 250MG | A090128 | 002 | Mar 21, 2011 | Mar | NEWA |
| AB | | 500MG | A090128 | 003 | Mar 21, 2011 | Mar | NEWA |
| AB | WATSON LABS | 125MG | A078278 | 001 | Mar 21, 2011 | Mar | NEWA |
| AB | | 250MG | A078278 | 002 | Mar 21, 2011 | Mar | NEWA |
| AB | | 500MG | A078278 | 003 | Mar 21, 2011 | Mar | NEWA |

FAMOTIDINE

INJECTABLE; INJECTION
FAMOTIDINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | AKORN STRIDES | 10MG/ML | A078641 | 001 | Jun 25, 2008 | May | CAHN |
| >A> | AP | PFIZER | 10MG/ML | A078641 | 001 | Jun 25, 2008 | May | CAHN |

FAMOTIDINE PRESERVATIVE FREE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | AKORN STRIDES | 10MG/ML | A078642 | 001 | Jun 25, 2008 | May | CAHN |
| >A> | AP | PFIZER | 10MG/ML | A078642 | 001 | Jun 25, 2008 | May | CAHN |

PEPCID

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ MERCK | 10MG/ML | N019510 | 001 | Nov 04, 1986 | Jan | DISC |

PEPCID PRESERVATIVE FREE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ MERCK | 10MG/ML | N019510 | 004 | Nov 04, 1986 | Jan | DISC |

PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ MERCK | 0.4MG/ML | N020249 | 001 | Feb 18, 1994 | Jan | DISC |

TABLET; ORAL
FAMOTIDINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MYLAN | 20MG | A075457 | 001 | Apr 18, 2001 | Feb | CAHN |
| AB | | 40MG | A075457 | 002 | Apr 18, 2001 | Feb | CAHN |

FAMOTIDINE; IBUPROFEN

TABLET; ORAL
DUEXIS

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | HORIZON PHARMA | 26.6MG;800MG | N022519 | 001 | Apr 23, 2011 | Apr | NEWA |

FENOFIBRATE

TABLET; ORAL
FENOGLIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | SHORE THERAP | 40MG | N022118 | 001 | Aug 10, 2007 | Feb | CAHN |
| + | | 120MG | N022118 | 002 | Aug 10, 2007 | Feb | CAHN |

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL
FENTANYL-100

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MALLINCKRODT INC | 100MCG/HR | A077154 | 004 | Feb 09, 2011 | Jan | NEWA |

FENTANYL-25

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MALLINCKRODT INC | 25MCG/HR | A077154 | 001 | Feb 09, 2011 | Jan | NEWA |

FENTANYL-50

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MALLINCKRODT INC | 50MCG/HR | A077154 | 002 | Feb 09, 2011 | Jan | NEWA |

FENTANYL-75

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MALLINCKRODT INC | 75MCG/HR | A077154 | 003 | Feb 09, 2011 | Jan | NEWA |

FENTANYL CITRATE

TABLET; SUBLINGUAL
ABSTRAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PROSTRAKAN INC | EQ 0.1MG BASE | N022510 | 001 | Jan 07, 2011 | Jan | NEWA |
| | | EQ 0.2MG BASE | N022510 | 002 | Jan 07, 2011 | Jan | NEWA |
| | | EQ 0.3MG BASE | N022510 | 003 | Jan 07, 2011 | Jan | NEWA |
| + | | EQ 0.4MG BASE | N022510 | 004 | Jan 07, 2011 | Jan | NEWA |

TABLET; SUBLINGUAL
ABSTRAL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | PROSTRAKAN INC | EQ 0.6MG BASE | N022510 | 005 | Jan 07, 2011 | Jan | NEWA |
| | | EQ 0.8MG BASE | N022510 | 006 | Jan 07, 2011 | Jan | NEWA |

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | DR REDDYS LABS LTD | 180MG;240MG | A079043 | 001 | Mar 17, 2010 | Jan | CTEC |

FIDAXOMICIN

TABLET; ORAL
DIFICID

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | OPTIMER PHARMS | 200MG | N201699 | 001 | May 27, 2011 | May | NEWA |

FLUCONAZOLE

TABLET; ORAL
FLUCONAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | AMNEAL PHARM | 50MG | A078423 | 001 | Mar 07, 2011 | Feb | NEWA |
| AB | | | 100MG | A078423 | 002 | Mar 07, 2011 | Feb | NEWA |
| AB | | | 150MG | A078423 | 003 | Mar 07, 2011 | Feb | NEWA |
| AB | | | 200MG | A078423 | 004 | Mar 07, 2011 | Feb | NEWA |
| AB | | MYLAN | 50MG | A076042 | 001 | Jul 29, 2004 | Feb | CAHN |
| AB | | | 100MG | A076042 | 002 | Jul 29, 2004 | Feb | CAHN |
| AB | | | 150MG | A076042 | 003 | Jul 29, 2004 | Feb | CAHN |
| AB | | | 200MG | A076042 | 004 | Jul 29, 2004 | Feb | CAHN |

FLUDARABINE PHOSPHATE

TABLET; ORAL
OFORTA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | SANOFI AVENTIS US | 10MG | N022273 | 001 | Dec 18, 2008 | Apr | CMFD |
| | @ | | 10MG | N022273 | 001 | Dec 18, 2008 | Jan | DISC |

FLUDEOXYGLUCOSE F-18

INJECTABLE; INTRAVENOUS
FLUDEOXYGLUCOSE F18

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | + | FEINSTEIN | 20-200mCi/ML | N021870 | 001 | Aug 19, 2005 | Feb | CTEC |
| AP | | PETNET | 20-200mCi/ML | A079086 | 001 | Feb 25, 2011 | Feb | NEWA |

FLUMAZENIL

INJECTABLE; INJECTION
FLUMAZENIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> AP | | AKORN STRIDES | 0.5MG/5ML (0.1MG/ML) | A078595 | 001 | May 13, 2008 | May | CAHN |
| >D> AP | | | 1MG/10ML (0.1MG/ML) | A078595 | 002 | May 13, 2008 | May | CAHN |
| >A> AP | | PFIZER | 0.5MG/5ML (0.1MG/ML) | A078595 | 001 | May 13, 2008 | May | CAHN |
| >A> AP | | | 1MG/10ML (0.1MG/ML) | A078595 | 002 | May 13, 2008 | May | CAHN |

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | SANDOZ | 5GM/100ML (50MG/ML) | A091299 | 002 | May 02, 2011 | Apr | NEWA |
| AP | | | 2.5GM/50ML (50MG/ML) | A091299 | 001 | May 02, 2011 | Apr | NEWA |
| | @ | VALEANT | 500MG/10ML (50MG/ML) | N012209 | 001 | | Mar | DISC |

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
FLUOXETINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB1 | | ALEMBIC PHARMS LTD | EQ 10MG BASE | A090223 | 001 | Mar 19, 2009 | Apr | CAHN |
| AB1 | | | EQ 20MG BASE | A090223 | 002 | Mar 19, 2009 | Apr | CAHN |
| AB | | | EQ 40MG BASE | A090223 | 003 | Mar 19, 2009 | Apr | CAHN |

FLUTAMIDE

CAPSULE; ORAL
FLUTAMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | 125MG | A076224 | 001 | May 09, 2003 | Feb | CAHN |

FLUTICASONE PROPIONATE

LOTION; TOPICAL
CUTIVATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | NYCOMED US | 0.05% | N021152 | 001 | Mar 31, 2005 | Apr | CFTG |

FLUTICASONE PROPIONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | GLENMARK GENERICS | 0.05% | A090759 | 001 | May 02, 2011 | Apr | NEWA |

FLUVOXAMINE MALEATE

TABLET; ORAL
FLUVOXAMINE MALEATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | MYLAN | 50MG | A075950 | 001 | Oct 15, 2001 | Feb | CAHN |
| | @ | | 100MG | A075950 | 002 | Oct 15, 2001 | Feb | CAHN |

FOLIC ACID

TABLET; ORAL
FOLIC ACID

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AA | + | AMNEAL PHARM | 1MG | A040625 | 001 | Jul 21, 2005 | Apr | CAHN |
| AA | | JUBILANT CADISTA | 1MG | A040514 | 001 | Jun 14, 2005 | Jan | CAHN |

FOSINOPRIL SODIUM

TABLET; ORAL
FOSINOPRIL SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | AUROBINDO PHARMA LTD | 10MG | A091163 | 001 | Mar 30, 2011 | Mar | NEWA |
| AB | | | 20MG | A091163 | 002 | Mar 30, 2011 | Mar | NEWA |
| AB | | | 40MG | A091163 | 003 | Mar 30, 2011 | Mar | NEWA |

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION
FOSPHENYTOIN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | | AKORN STRIDES | EQ 50MG PNENYTOIN NA/ML | A078476 | 001 | Mar 18, 2008 | May | CAHN |
| | AP | + | APP PHARMS | EQ 50MG PHENYTOIN NA/ML | A078052 | 001 | Aug 06, 2007 | Apr | CRLD |
| >A> | AP | | PFIZER | EQ 50MG PNENYTOIN NA/ML | A078476 | 001 | Mar 18, 2008 | May | CAHN |

GABAPENTIN

CAPSULE; ORAL
GABAPENTIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | | MATRIX LABS LTD | 100MG | A090158 | 001 | Feb 14, 2011 | May | CAHN |
| | AB | | | 100MG | A090158 | 001 | Feb 14, 2011 | Jan | NEWA |
| >D> | AB | | | 300MG | A090158 | 002 | Feb 14, 2011 | May | CAHN |
| | AB | | | 300MG | A090158 | 002 | Feb 14, 2011 | Jan | NEWA |
| >D> | AB | | | 400MG | A090158 | 003 | Feb 14, 2011 | May | CAHN |
| | AB | | | 400MG | A090158 | 003 | Feb 14, 2011 | Jan | NEWA |
| >A> | AB | | MYLAN | 100MG | A090158 | 001 | Feb 14, 2011 | May | CAHN |

CAPSULE; ORAL
GABAPENTIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | MYLAN | 300MG | A090158 | 002 | Feb 14, 2011 | May | CAHN |
| >A> | AB | | | 400MG | A090158 | 003 | Feb 14, 2011 | May | CAHN |

SOLUTION; ORAL
GABAPENTIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AA | | HI TECH PHARMA | 250MG/5ML | A078974 | 001 | Feb 18, 2011 | Feb | NEWA |

NEURONTIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AA | + | PARKE DAVIS | 250MG/5ML | N021129 | 001 | Mar 02, 2000 | Feb | CFTG |

TABLET; ORAL
GABAPENTIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | ZYDUS PHARMS USA INC | 600MG | A078926 | 001 | Feb 11, 2011 | Jan | NEWA |
| | AB | | | 800MG | A078926 | 002 | Feb 11, 2011 | Jan | NEWA |

GRALISE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | BX | + | ABBOTT PRODS | 300MG | N022544 | 001 | Jan 28, 2011 | Jan | NEWA |
| | BX | + | | 600MG | N022544 | 002 | Jan 28, 2011 | Jan | NEWA |

GABAPENTIN ENACARBIL

TABLET, EXTENDED RELEASE; ORAL
HORIZANT

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | + | GLAXO GRP LTD | 600MG | N022399 | 001 | Apr 06, 2011 | Apr | NEWA |

GADOBUTROL

SOLUTION; INTRAVENOUS
GADAVIST

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | + | BAYER HLTHCARE | 4.5354GM/7.5ML (604.72MG/ML) | N201277 | 001 | Mar 14, 2011 | Mar | NEWA |
| | | + | | 6.0472GM/10ML (604.72MG/ML) | N201277 | 002 | Mar 14, 2011 | Mar | NEWA |
| | | + | | 9.0708GM/15ML (604.72MG/ML) | N201277 | 003 | Mar 14, 2011 | Mar | NEWA |
| | | + | | 18.1416GM/30ML (604.72MG/ML) | N201277 | 004 | Mar 14, 2011 | Mar | NEWA |
| | | + | | 39.3068GM/65ML (604.72MG/ML) | N201277 | 005 | Mar 14, 2011 | Mar | NEWA |

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL
GALANTAMINE HYDROBROMIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | MYLAN | EQ 8MG BASE | A090900 | 001 | Jan 24, 2011 | Jan | NEWA |
| | AB | | | EQ 16MG BASE | A090900 | 002 | Jan 24, 2011 | Jan | NEWA |
| | AB | | | EQ 24MG BASE | A090900 | 003 | Jan 24, 2011 | Jan | NEWA |
| | AB | | SUN PHARMA GLOBAL | EQ 8MG BASE | A090178 | 001 | Feb 02, 2011 | Jan | NEWA |
| | AB | | | EQ 16MG BASE | A090178 | 002 | Feb 02, 2011 | Jan | NEWA |
| | AB | | | EQ 24MG BASE | A090178 | 003 | Feb 02, 2011 | Jan | NEWA |

TABLET; ORAL
GALANTAMINE HYDROBROMIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | AUROBINDO PHARMA LTD | EQ 4MG BASE | A090957 | 001 | Mar 29, 2011 | Mar | NEWA |
| | AB | | | EQ 8MG BASE | A090957 | 002 | Mar 29, 2011 | Mar | NEWA |
| | AB | | | EQ 12MG BASE | A090957 | 003 | Mar 29, 2011 | Mar | NEWA |
| | AB | | ZYDUS PHARMS USA INC | EQ 4MG BASE | A078898 | 001 | Feb 17, 2011 | Jan | NEWA |
| | AB | | | EQ 8MG BASE | A078898 | 002 | Feb 17, 2011 | Jan | NEWA |
| | AB | | | EQ 12MG BASE | A078898 | 003 | Feb 17, 2011 | Jan | NEWA |

GEMCITABINE HYDROCHLORIDE

INJECTABLE; INJECTION
GEMCITABINE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | | | | | | | |
| >D> | | + | HOSPIRA INC | EQ 2GM BASE/VIAL | A079183 | 001 | Nov 15, 2010 | May | CTNA |
| | | + | | EQ 2GM BASE/VIAL | A079183 | 001 | Nov 15, 2010 | Feb | CRLD |

GEMCITABINE HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AP | | APP PHARMS | EQ 2GM BASE/VIAL | A090242 | 003 | May 16, 2011 | May | NEWA |

INJECTABLE; INJECTION

GEMCITABINE HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AP | | FRESENIUS KABI ONCOL | EQ 2GM BASE/VIAL | A090799 | 003 | May 16, 2011 | May | NEWA |
| >A> | | + | HOSPIRA INC | EQ 2GM BASE/VIAL | A079183 | 001 | Nov 15, 2010 | May | CTNA |
| | AP | | TEVA PARENTERAL | EQ 200MG BASE/VIAL | A077983 | 002 | Jan 25, 2011 | Jan | NEWA |
| | AP | | | EQ 1GM BASE/VIAL | A077983 | 001 | Jan 25, 2011 | Jan | NEWA |

GEMZAR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AP | + | LILLY | EQ 200MG BASE/VIAL | N020509 | 001 | May 15, 1996 | Jan | CFTG |
| | AP | + | | EQ 1GM BASE/VIAL | N020509 | 002 | May 15, 1996 | Jan | CFTG |

GEMFIBROZIL

TABLET; ORAL

GEMFIBROZIL

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | BLU CARIBE | 600MG | A078012 | 001 | Mar 26, 2007 | Feb | CAHN |

GENTAMICIN SULFATE

OINTMENT; OPHTHALMIC

GENTAMICIN SULFATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AT | | FERA PHARMS | EQ 0.3% BASE | A065024 | 001 | Jul 30, 2004 | Feb | CAHN |
| | AT | | NYCOMED US | EQ 0.3% BASE | A065024 | 001 | Jul 30, 2004 | Jan | CAHN |

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AT | | FERA PHARMS | EQ 0.3% BASE | A065121 | 001 | Jan 30, 2004 | Feb | CAHN |

GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | MYLAN | 1MG | A077486 | 001 | Feb 10, 2006 | Feb | CAHN |
| | AB | | | 2MG | A077486 | 002 | Feb 10, 2006 | Feb | CAHN |
| | AB | | | 4MG | A077486 | 003 | Feb 10, 2006 | Feb | CAHN |

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLIPIZIDE AND METFORMIN HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | ZYDUS PHARMS USA INC | 2.5MG;250MG | A078905 | 001 | Jan 31, 2011 | Jan | NEWA |
| | AB | | | 2.5MG;500MG | A078905 | 002 | Jan 31, 2011 | Jan | NEWA |
| | AB | | | 5MG;500MG | A078905 | 003 | Jan 31, 2011 | Jan | NEWA |

GLUTAMINE

FOR SOLUTION; ORAL

NUTRESTORE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | + | EMMAUS MEDCL | 5GM/PACKET | N021667 | 001 | Jun 10, 2004 | May | CAHN |
| >D> | | + | NUTRITIONAL RESTART | 5GM/PACKET | N021667 | 001 | Jun 10, 2004 | May | CAHN |

GLYBURIDE

TABLET; ORAL

GLYBURIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | HERITAGE PHARMS INC | 1.25MG | A090937 | 001 | Feb 28, 2011 | May | CAHN |
| >A> | AB | | | 2.5MG | A090937 | 002 | Feb 28, 2011 | May | CAHN |
| >A> | AB | | | 5MG | A090937 | 003 | Feb 28, 2011 | May | CAHN |
| >D> | AB | | INDICUS PHARMA | 1.25MG | A090937 | 001 | Feb 28, 2011 | May | CAHN |
| | AB | | | 1.25MG | A090937 | 001 | Feb 28, 2011 | Feb | NEWA |
| >D> | AB | | | 2.5MG | A090937 | 002 | Feb 28, 2011 | May | CAHN |
| | AB | | | 2.5MG | A090937 | 002 | Feb 28, 2011 | Feb | NEWA |
| >D> | AB | | | 5MG | A090937 | 003 | Feb 28, 2011 | May | CAHN |
| | AB | | | 5MG | A090937 | 003 | Feb 28, 2011 | Feb | NEWA |

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | FULVICIN P/G | | | | | | |
| | | @ ELORAC | 125MG | A061996 | 001 | | Jan | CAHN |
| | | @ | 250MG | A061996 | 002 | | Jan | CAHN |
| | | FULVICIN P/G 165 | | | | | | |
| | | @ ELORAC | 165MG | A061996 | 003 | Apr 06, 1982 | Jan | CAHN |
| | | FULVICIN P/G 330 | | | | | | |
| | | @ ELORAC | 330MG | A061996 | 004 | Apr 06, 1982 | Jan | CAHN |

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | HALOPERIDOL | | | | | | |
| >D> | AP | AKORN STRIDES | EQ 5MG BASE/ML | A078347 | 001 | Sep 14, 2009 | May | CAHN |
| >A> | AP | PFIZER | EQ 5MG BASE/ML | A078347 | 001 | Sep 14, 2009 | May | CAHN |

HEPARIN SODIUM

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | HEPARIN SODIUM | | | | | | |
| >A> | AP | SANDOZ | 1,000 UNITS/ML | A091682 | 001 | Jun 08, 2011 | May | NEWA |
| >A> | AP | | 5,000 UNITS/ML | A091682 | 002 | Jun 08, 2011 | May | NEWA |
| >A> | AP | | 5,000 UNITS/ML | A091659 | 001 | Jun 08, 2011 | May | NEWA |
| >A> | AP | | 10,000 UNITS/ML | A201002 | 001 | Jun 08, 2011 | May | NEWA |

HEXAMINOLEVULINATE HYDROCHLORIDE

FOR SOLUTION; INTRAVESICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | CYSVIEW KIT | | | | | | |
| >A> | + | GE HEALTHCARE | 100MG/VIAL | N022555 | 001 | May 28, 2010 | May | CAHN |
| >D> | + | PHOTOCURE ASA | 100MG/VIAL | N022555 | 001 | May 28, 2010 | May | CAHN |

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE | | | | | | |
| | AB | NOVEL LABS INC | 1.5MG;5MG | A091528 | 001 | Apr 20, 2011 | Apr | NEWA |
| | | TUSSIGON | | | | | | |
| | AB | + KING PHARMS | 1.5MG;5MG | A088508 | 001 | Jul 30, 1985 | Apr | CTEC |

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | HYDROCHLOROTHIAZIDE | | | | | | |
| | AB | ALEMBIC PHARMS LTD | 12.5MG | A200645 | 001 | Nov 30, 2010 | Apr | CAHN |
| | AB | JUBILANT CADISTA | 12.5MG | A078391 | 001 | Feb 11, 2008 | Jan | CAHN |

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | HYDROCHLOROTHIAZIDE | | | | | | |
| | AB | JUBILANT CADISTA | 25MG | A040809 | 001 | Sep 04, 2007 | Jan | CAHN |
| | AB | | 50MG | A040809 | 002 | Sep 04, 2007 | Jan | CAHN |

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | LISINOPRIL AND HYDROCHLOROTHIAZIDE | | | | | | |
| >D> | AB | HUAHAI US INC | 12.5MG;10MG | A076230 | 001 | Jul 01, 2002 | May | CAHN |
| >D> | AB | | 12.5MG;20MG | A076230 | 002 | Jul 01, 2002 | May | CAHN |
| >D> | AB | | 25MG;20MG | A076230 | 003 | Jul 01, 2002 | May | CAHN |
| >A> | AB | PRINSTON PHARM LLC | 12.5MG;10MG | A076230 | 001 | Jul 01, 2002 | May | CAHN |
| >A> | AB | | 12.5MG;20MG | A076230 | 002 | Jul 01, 2002 | May | CAHN |

TABLET; ORAL
LISINOPRIL AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | PRINSTON PHARM LLC | 25MG;20MG | A076230 | 003 | Jul 01, 2002 | May | CAHN |

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL
LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | WATSON LABS | 12.5MG;50MG | A200180 | 001 | Jan 12, 2011 | Jan | NEWA |
| | AB | | 12.5MG;100MG | A200180 | 002 | Jan 12, 2011 | Jan | NEWA |
| | AB | | 25MG;100MG | A200180 | 003 | Jan 12, 2011 | Jan | NEWA |

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL
QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | INVAGEN PHARMS | 12.5MG;10MG | A201356 | 001 | Apr 20, 2011 | Apr | NEWA |
| | AB | | 12.5MG;20MG | A201356 | 002 | Apr 20, 2011 | Apr | NEWA |
| | AB | | 25MG;20MG | A201356 | 003 | Apr 20, 2011 | Apr | NEWA |

HYDROCORTISONE

SOLUTION; TOPICAL
TEXACORT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | JSJ PHARMS | 2.5% | A081271 | 001 | Apr 17, 1992 | May | CAHN |
| >A> | + | TIBER LABS | 2.5% | A081271 | 001 | Apr 17, 1992 | May | CAHN |

TABLET; ORAL
HYDROCORTISONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | COREPHARMA | 5MG | A040646 | 001 | Mar 30, 2007 | Apr | CAHN |
| | AB | | 10MG | A040646 | 002 | Mar 30, 2007 | Apr | CAHN |
| | AB | | 20MG | A040646 | 003 | Mar 30, 2007 | Apr | CAHN |

HYDROCORTISONE ACETATE

OINTMENT; OPHTHALMIC
HYDROCORTISONE ACETATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ FERA PHARMS | 0.5% | A080828 | 001 | | Mar | CAHN |

HYDROFLUMETHIAZIDE

TABLET; ORAL
HYDROFLUMETHIAZIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | PAR PHARM | 50MG | A088850 | 001 | May 31, 1985 | May | DISC |
| >A> | | @ | 50MG | A088850 | 001 | May 31, 1985 | May | DISC |

HYDROMORPHONE HYDROCHLORIDE

TABLET; ORAL
HYDROMORPHONE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | ELITE LABS | 8MG | A076723 | 001 | Oct 18, 2005 | Feb | CAHN |

HYDROXOCOBALAMIN

INJECTABLE; INJECTION
CYANOKIT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ MERCK SANTE SAS | 5GM/VIAL (5GM/KIT) | N022041 | 001 | Apr 08, 2011 | Apr | DISC |

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREDRINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ PHARMICS | 1% | N000004 | 004 | | Jan | CAHN |

HYDROXYPROGESTERONE CAPROATE

SOLUTION; INTRAMUSCULAR
MAKENA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | KV PHARM | 1250MG/5ML (250MG/ML) | N021945 | 001 | Feb 03, 2011 | Feb | NEWA |

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
IDARUBICIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | SANDOZ | 1MG/ML | A091293 | 001 | Mar 29, 2011 | Mar | NEWA |

ILOPERIDONE

TABLET; ORAL
FANAPT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | NOVARTIS | 2MG | N022192 | 002 | May 06, 2009 | Jan | CAHN |
| | | 4MG | N022192 | 003 | May 06, 2009 | Jan | CAHN |
| | | 6MG | N022192 | 004 | May 06, 2009 | Jan | CAHN |
| | | 8MG | N022192 | 005 | May 06, 2009 | Jan | CAHN |
| | | 10MG | N022192 | 006 | May 06, 2009 | Jan | CAHN |

IMIQUIMOD

CREAM; TOPICAL
IMIQUIMOD

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | TARO | 5% | A200173 | 001 | Apr 15, 2011 | Apr | NEWA |
| AB | TEVA PHARMS USA | 5% | A200481 | 001 | Apr 18, 2011 | Apr | NEWA |
| AB | TOLMAR | 5% | A091044 | 001 | Feb 28, 2011 | Feb | NEWA |

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | HETERO DRUGS LTD | 25MG | A091240 | 001 | Apr 12, 2011 | Mar | NEWA |
| AB | | 50MG | A091240 | 002 | Apr 12, 2011 | Mar | NEWA |

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + SANDOZ | 75MG | A074464 | 001 | May 28, 1998 | Jan | CTNA |

IOFLUPANE I-123

SOLUTION; INTRAVENOUS
DATSCAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | GE HLTHCARE INC | 5MCI/2.5ML (2MCI/ML) | N022454 | 001 | Jan 14, 2011 | Jan | NEWA |

IOPAMIDOL

INJECTABLE; INJECTION
IOPAMIDOL-200

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ HOSPIRA | 41% | A074898 | 001 | Dec 30, 1997 | Feb | DISC |

IOPAMIDOL-200 IN PLASTIC CONTAINER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ HOSPIRA | 41% | A074636 | 001 | Dec 30, 1997 | Feb | DISC |

IOPAMIDOL-250

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ HOSPIRA | 51% | A074898 | 002 | Dec 30, 1997 | Feb | DISC |

IOPAMIDOL-250 IN PLASTIC CONTAINER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ HOSPIRA | 51% | A074636 | 002 | Dec 30, 1997 | Feb | DISC |

IOPAMIDOL-300

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ HOSPIRA | 61% | A074898 | 003 | Dec 30, 1997 | Feb | DISC |

IOPAMIDOL-300 IN PLASTIC CONTAINER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ HOSPIRA | 61% | A074636 | 003 | Dec 30, 1997 | Feb | DISC |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | INJECTABLE; INJECTION | | | | | | | |
| | | IOPAMIDOL-370 | | | | | | | |
| | | @ HOSPIRA | 76% | A074898 | 004 | Dec 30, 1997 | Feb | DISC | |
| | | IOPAMIDOL-370 IN PLASTIC CONTAINER | | | | | | | |
| | | @ HOSPIRA | 76% | A074636 | 004 | Dec 30, 1997 | Feb | DISC | |
| | | IRINOTECAN HYDROCHLORIDE | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | IRINOTECAN HYDROCHLORIDE | | | | | | | |
| >A> | AP | BIONICHE PHARMA | 40MG/2ML (20MG/ML) | A090393 | 002 | May 13, 2011 | May | NEWA | |
| >A> | AP | | 100MG/5ML (20MG/ML) | A090393 | 003 | May 13, 2011 | May | NEWA | |
| | | IRON SUCROSE | | | | | | | |
| | | INJECTABLE; INTRAVENOUS | | | | | | | |
| | | VENOFER | | | | | | | |
| | | LUITPOLD | EQ 50MG BASE/2.5ML (EQ 20MG BASE/ML) | N021135 | 002 | Mar 20, 2005 | Apr | CMFD | |
| | | ISOSORBIDE MONONITRATE | | | | | | | |
| | | TABLET, EXTENDED RELEASE; ORAL | | | | | | | |
| | | ISOSORBIDE MONONITRATE | | | | | | | |
| >A> | AB | TORRENT PHARMS | 30MG | A200270 | 001 | Jun 03, 2011 | May | NEWA | |
| >A> | AB | | 60MG | A200495 | 001 | Jun 03, 2011 | May | NEWA | |
| >A> | AB | | 120MG | A200495 | 002 | Jun 03, 2011 | May | NEWA | |
| | | ISRADIPINE | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | ISRADIPINE | | | | | | | |
| | AB | MIKAH PHARMA | 2.5MG | A077169 | 001 | Apr 24, 2006 | Feb | CAHN | |
| | AB | | 5MG | A077169 | 002 | Apr 24, 2006 | Feb | CAHN | |
| | | ITRACONAZOLE | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | SPORANOX | | | | | | | |
| >D> | | + ORTHO MCNEIL JANSSEN | 10MG/ML | N020966 | 001 | Mar 30, 1999 | May | DISC | |
| >A> | | @ | 10MG/ML | N020966 | 001 | Mar 30, 1999 | May | DISC | |
| | | TABLET; ORAL | | | | | | | |
| >D> | | ITRACONAZOLE | | | | | | | |
| >D> | | + STIEFEL LABS INC | 200MG | N022484 | 001 | Apr 29, 2010 | May | CTNA | |
| >A> | | ONMEL | | | | | | | |
| >A> | | + STIEFEL LABS INC | 200MG | N022484 | 001 | Apr 29, 2010 | May | CTNA | |
| | | KETOCONAZOLE | | | | | | | |
| | | GEL; TOPICAL | | | | | | | |
| | | XOLEGEL | | | | | | | |
| >A> | | + AQUA PHARMS | 2% | N021946 | 001 | Jul 28, 2006 | May | CAHN | |
| >D> | | + STIEFEL LABS INC | 2% | N021946 | 001 | Jul 28, 2006 | May | CAHN | |
| | | KETOROLAC TROMETHAMINE | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | KETOROLAC TROMETHAMINE | | | | | | | |
| >D> | AP | AKORN STRIDES | 15MG/ML | A078299 | 001 | Jul 16, 2007 | May | CAHN | |
| >D> | AP | | 30MG/ML | A078299 | 002 | Jul 16, 2007 | May | CAHN | |
| >A> | AP | PFIZER | 15MG/ML | A078299 | 001 | Jul 16, 2007 | May | CAHN | |
| >A> | AP | | 30MG/ML | A078299 | 002 | Jul 16, 2007 | May | CAHN | |

SPRAY, METERED; NASAL
SPRIX
>A> + LUITPOLD 15.75MG/SPRAY N022382 001 May 14, 2010 May CAHN
>D> + ROXRO PHARMA INC 15.75MG/SPRAY N022382 001 May 14, 2010 May CAHN

LAMIVUDINE; ZIDOVUDINE

TABLET; ORAL
COMBIVIR
>D> + VIIV HLTHCARE 150MG;300MG N020857 001 Sep 26, 1997 May CFTG
>A> AB + 150MG;300MG N020857 001 Sep 26, 1997 May CFTG
>A> LAMIVUDINE AND ZIDOVUDINE
>A> AB TEVA PHARMS 150MG;300MG A079081 001 May 25, 2011 May NEWA

LAMOTRIGINE

TABLET; ORAL
LAMOTRIGINE
AB ACTAVIS TOTOWA 25MG A078669 001 Apr 08, 2011 Mar NEWA
AB 100MG A078669 002 Apr 08, 2011 Mar NEWA
AB 150MG A078669 003 Apr 08, 2011 Mar NEWA
AB 200MG A078669 004 Apr 08, 2011 Mar NEWA
AB ALEMBIC LTD 25MG A090607 001 Jan 13, 2011 Jan NEWA
AB 100MG A090607 002 Jan 13, 2011 Jan NEWA
AB 150MG A090607 003 Jan 13, 2011 Jan NEWA
AB 200MG A090607 004 Jan 13, 2011 Jan NEWA
AB ALEMBIC PHARMS LTD 25MG A090607 001 Jan 13, 2011 Apr CAHN
AB 100MG A090607 002 Jan 13, 2011 Apr CAHN
AB 150MG A090607 003 Jan 13, 2011 Apr CAHN
AB 200MG A090607 004 Jan 13, 2011 Apr CAHN
AB HIKMA PHARMS 25MG A078134 001 Apr 19, 2011 Apr NEWA
AB 100MG A078134 002 Apr 19, 2011 Apr NEWA
AB 150MG A078134 003 Apr 19, 2011 Apr NEWA
AB 200MG A078134 004 Apr 19, 2011 Apr NEWA

TABLET, CHEWABLE; ORAL
LAMOTRIGINE
AB JUBILANT LIFE 5MG A200220 001 Feb 28, 2011 Feb NEWA
AB 25MG A200220 002 Feb 28, 2011 Feb NEWA

LATANOPROST

SOLUTION/DROPS; OPHTHALMIC
LATANOPROST
AT ALCON RES 0.005% A091449 001 Mar 22, 2011 Mar NEWA
AT APOTEX 0.005% A077697 001 Mar 22, 2011 Mar NEWA
AT BAUSCH AND LOMB 0.005% A201006 001 Mar 22, 2011 Mar NEWA
>A> AT LUITPOLD 0.005% A200925 001 Mar 22, 2011 May CAHN
AT MYLAN 0.005% A201786 001 Mar 22, 2011 Mar NEWA
>D> AT PHARMAFORCE 0.005% A200925 001 Mar 22, 2011 May CAHN
AT 0.005% A200925 001 Mar 22, 2011 Mar NEWA
XALATAN
AT + PHARMACIA AND UPJOHN 0.005% N020597 001 Jun 05, 1996 Mar CFTG

LETROZOLE

TABLET; ORAL
LETROZOLE
>A> AB ACCORD HLTHCARE 2.5MG A090934 001 Jun 03, 2011 May NEWA
>A> AB DR REDDYS LABS LTD 2.5MG A091191 001 Jun 03, 2011 May NEWA
>A> AB ENDO PHARMS 2.5MG A090789 001 Jun 03, 2011 May NEWA

TABLET; ORAL
LETROZOLE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | FRESENIUS KABI ONCOL | 2.5MG | A090491 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | IMPAX LABS | 2.5MG | A091638 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | INDICUS PHARMA | 2.5MG | A201804 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | KUDCO IRELAND | 2.5MG | A091098 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | NATCO PHARMA LTD | 2.5MG | A200161 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | ROXANE | 2.5MG | A090838 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | SUN PHARM INDS LTD | 2.5MG | A091466 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | SYNTHON PHARMS | 2.5MG | A090196 | 001 | Jun 03, 2011 | May | NEWA |
| >A> | AB | TEVA PHARMS | 2.5MG | A090289 | 001 | Jun 03, 2011 | May | NEWA |

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LEUPROLIDE ACETATE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | @ GENZYME | 1MG/0.2ML | A075721 | 001 | Nov 29, 2001 | Apr | DISC |

LEVETIRACETAM

TABLET; ORAL
LEVETIRACETAM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | ACCORD HLTHCARE | 250MG | A090843 | 001 | Feb 14, 2011 | Jan | NEWA |
| | AB | | 500MG | A090843 | 002 | Feb 14, 2011 | Jan | NEWA |
| | AB | | 750MG | A090843 | 003 | Feb 14, 2011 | Jan | NEWA |
| | AB | | 1GM | A090843 | 004 | Feb 14, 2011 | Jan | NEWA |
| >A> | AB | AJANTA PHARMA | 250MG | A201293 | 001 | Jun 14, 2011 | May | NEWA |
| >A> | AB | | 500MG | A201293 | 002 | Jun 14, 2011 | May | NEWA |
| >A> | AB | | 750MG | A201293 | 003 | Jun 14, 2011 | May | NEWA |
| >A> | AB | | 1GM | A201293 | 004 | Jun 14, 2011 | May | NEWA |

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL
LEVOCETIRIZINE DIHYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | DR REDDYS LABS LTD | 5MG | A090392 | 001 | Feb 24, 2011 | Feb | NEWA |
| | AB | GLENMARK GENERICS | 5MG | A090385 | 001 | Feb 24, 2011 | Feb | NEWA |

LEVOFLOXACIN

SOLUTION/DROPS; OPHTHALMIC
LEVOFLOXACIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AT | HI TECH PHARMA | 0.5% | A076826 | 001 | Feb 10, 2011 | Jan | NEWA |

LEVOLEUCOVORIN CALCIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | POWDER; IV (INFUSION) | | | | | | | |
| >D> | | FUSILEV | | | | | | | |
| >D> | + | SPECTRUM PHARMS | EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) | N020140 | 002 | Apr 20, 2011 | May | CDFR |
| | + | | EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) | N020140 | 002 | Apr 20, 2011 | Apr | NEWA |
| >D> | + | | EQ 250MG BASE/25ML (EQ 10MG BASE/ML) | N020140 | 003 | Apr 20, 2011 | May | CDFR |
| | + | | EQ 250MG BASE/25ML (EQ 10MG BASE/ML) | N020140 | 003 | Apr 20, 2011 | Apr | NEWA |
| >A> | | SOLUTION; IV (INFUSION) | | | | | | | |
| >A> | | FUSILEV | | | | | | | |
| >A> | + | SPECTRUM PHARMS | EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) | N020140 | 002 | Apr 20, 2011 | May | CDFR |
| >A> | + | | EQ 250MG BASE/25ML (EQ 10MG BASE/ML) | N020140 | 003 | Apr 20, 2011 | May | CDFR |

LEVONORGESTREL

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PLAN B | | | | | | | |
| | @ TEVA WOMENS | 0.75MG | N021045 | 001 | Jul 28, 1999 | Feb | CAHN |
| AB | + | 0.75MG | N021045 | 002 | Aug 24, 2006 | Feb | CAHN |

LEVORPHANOL TARTRATE

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | LEVO-DROMORAN | | | | | | | |
| | @ VALEANT PHARM INTL | 2MG | N008720 | 001 | Dec 19, 1991 | Mar | DISC |
| | LEVORPHANOL TARTRATE | | | | | | | |
| | ROXANE | 2MG | A074278 | 001 | Mar 31, 2000 | Mar | CTEC |

LEVOTHYROXINE SODIUM**

**Refer to Annual Edition Preface Section 1.8 Levothyroxine Sodium for amplifying information

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | LEVO-T | | | | | | | |
| AB1, AB2, AB3 | ALARA PHARM | 0.025MG | N021342 | 001 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.05MG | N021342 | 002 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.075MG | N021342 | 003 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.088MG | N021342 | 004 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.1MG | N021342 | 005 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.112MG | N021342 | 006 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.125MG | N021342 | 007 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.137MG | N021342 | 012 | Dec 08, 2003 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.15MG | N021342 | 008 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.175MG | N021342 | 009 | Mar 01, 2002 | Feb | CTEC |
| AB1, AB2, AB3 | | 0.2MG | N021342 | 010 | Mar 01, 2002 | Feb | CTEC |
| AB1, + AB2, AB3 | | 0.3MG | N021342 | 011 | Mar 01, 2002 | Feb | CTEC |

LIDOCAINE

OINTMENT; TOPICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | LIDOCAINE | | | | | | | |
| >A> AT | NOVOCOL INC | 5% | A040911 | 001 | May 23, 2011 | May | NEWA |

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | LIDOCAINE HYDROCHLORIDE | | | | | | | |
| AT | HI TECH PHARMA | 2% | A040837 | 001 | Mar 23, 2011 | Mar | NEWA |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | | LINAGLIPTIN | | | | | | | |
| >A> | | TABLET; ORAL | | | | | | | |
| >A> | | TRADJENTA | | | | | | | |
| >A> | + | BOEHRINGER INGELHEIM | 5MG | N201280 | 001 | May 02, 2011 | May | NEWA | |
| | | LISINOPRIL | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | LISINOPRIL | | | | | | | |
| >D> | AB | HUAHAI US INC | 2.5MG | A076180 | 001 | Jul 01, 2002 | May | CAHN | |
| >D> | AB | | 5MG | A076180 | 002 | Jul 01, 2002 | May | CAHN | |
| >D> | AB | | 10MG | A076180 | 003 | Jul 01, 2002 | May | CAHN | |
| >D> | AB | | 20MG | A076164 | 001 | Jul 01, 2002 | May | CAHN | |
| >D> | AB | | 30MG | A076164 | 002 | Jul 01, 2002 | May | CAHN | |
| >D> | AB | | 40MG | A076164 | 003 | Jul 01, 2002 | May | CAHN | |
| >A> | AB | PRINSTON PHARM LLC | 2.5MG | A076180 | 001 | Jul 01, 2002 | May | CAHN | |
| >A> | AB | | 5MG | A076180 | 002 | Jul 01, 2002 | May | CAHN | |
| >A> | AB | | 10MG | A076180 | 003 | Jul 01, 2002 | May | CAHN | |
| >A> | AB | | 20MG | A076164 | 001 | Jul 01, 2002 | May | CAHN | |
| >A> | AB | | 30MG | A076164 | 002 | Jul 01, 2002 | May | CAHN | |
| >A> | AB | | 40MG | A076164 | 003 | Jul 01, 2002 | May | CAHN | |
| | | LITHIUM CARBONATE | | | | | | | |
| | | TABLET, EXTENDED RELEASE; ORAL | | | | | | | |
| | | LITHIUM CARBONATE | | | | | | | |
| | AB | GLENMARK GENERICS | 450MG | A091616 | 001 | Feb 14, 2011 | Jan | NEWA | |
| | | LOSARTAN POTASSIUM | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | LOSARTAN POTASSIUM | | | | | | | |
| | AB | ALEMBIC PHARMS LTD | 25MG | A090428 | 001 | Oct 06, 2010 | Apr | CAHN | |
| | AB | | 50MG | A090428 | 002 | Oct 06, 2010 | Apr | NEWA | |
| | AB | | 100MG | A090428 | 003 | Oct 06, 2010 | Apr | CAHN | |
| >A> | AB | HUAHAI US INC | 25MG | A091497 | 001 | Jun 06, 2011 | May | NEWA | |
| >A> | AB | | 50MG | A091497 | 002 | Jun 06, 2011 | May | NEWA | |
| >A> | AB | | 100MG | A091497 | 003 | Jun 06, 2011 | May | NEWA | |
| | AB | MYLAN | 25MG | A091590 | 001 | Oct 06, 2010 | Jan | NEWA | |
| | AB | | 50MG | A091590 | 002 | Oct 06, 2010 | Jan | NEWA | |
| | AB | | 100MG | A091590 | 003 | Oct 06, 2010 | Jan | NEWA | |
| | | LOTEPREDNOL ETABONATE | | | | | | | |
| | | OINTMENT; OPHTHALMIC | | | | | | | |
| | | LOTEMAX | | | | | | | |
| | + | BAUSCH AND LOMB | 0.5% | N200738 | 001 | Apr 15, 2011 | Apr | NEWA | |
| | | MECLIZINE HYDROCHLORIDE | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | MECLIZINE HYDROCHLORIDE | | | | | | | |
| | AA | AMNEAL PHARMS | 12.5MG | A201451 | 001 | Feb 23, 2011 | Feb | NEWA | |
| | AA | | 25MG | A201451 | 002 | Feb 23, 2011 | Feb | NEWA | |
| | AA | | 50MG | A201451 | 003 | Feb 23, 2011 | Feb | NEWA | |
| | AA | JUBILANT CADISTA | 12.5MG | A040659 | 001 | Jun 04, 2010 | Jan | CAHN | |
| | AA | | 25MG | A040659 | 002 | Jun 04, 2010 | Jan | CAHN | |

MELOXICAM

TABLET; ORAL

MELOXICAM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | 7.5MG | A077934 | 001 | Jul 20, 2006 | Feb | CAHN |
| AB | | | 15MG | A077934 | 002 | Jul 20, 2006 | Feb | CAHN |

MEMANTINE HYDROCHLORIDE

TABLET; ORAL

MEMANTINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ SUN PHARM INDS (IN) | 5MG | A090058 | 001 | May 05, 2010 | May | CAHN |
| >D> | | @ | 10MG | A090058 | 002 | May 05, 2010 | May | CAHN |
| >A> | | @ SUN PHARMA GLOBAL | 5MG | A090058 | 001 | May 05, 2010 | May | CAHN |
| >A> | | @ | 10MG | A090058 | 002 | May 05, 2010 | May | CAHN |

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HYDROCHLORIDE PRESERVATIVE FREE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | ASTRAZENECA | 10MG/ML | A081002 | 001 | Jul 30, 1993 | May | CAHN |
| >A> | AP | BAXTER HLTHCARE CORP | 10MG/ML | A081002 | 001 | Jul 30, 1993 | May | CAHN |

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AA | ALEMBIC LTD | 400MG | A090122 | 002 | Feb 18, 2009 | May | CAHN |
| >A> | AA | ALEMBIC PHARMS LTD | 400MG | A090122 | 002 | Feb 18, 2009 | May | CAHN |
| >A> | AA | TARO | 200MG | A200998 | 001 | May 23, 2011 | May | NEWA |
| >A> | AA | | 400MG | A200998 | 002 | May 23, 2011 | May | NEWA |

MEQUINOL; TRETINOIN

SOLUTION; TOPICAL

SOLAGE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | AQUA PHARMS | 2%;0.01% | N020922 | 001 | Dec 10, 1999 | May | CAHN |
| >D> | + | STIEFEL LABS INC | 2%;0.01% | N020922 | 001 | Dec 10, 1999 | May | CAHN |

MEROPENEM

INJECTABLE; INJECTION

MEROPENEM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | SANDOZ | 500MG/VIAL | A091201 | 001 | Mar 29, 2011 | Mar | NEWA |
| AP | | | 1GM/VIAL | A091201 | 002 | Mar 29, 2011 | Mar | NEWA |

MERREM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | + | ASTRAZENECA | 500MG/VIAL | N050706 | 003 | Jun 21, 1996 | Mar | CTNA |
| AP | + | | 1GM/VIAL | N050706 | 001 | Jun 21, 1996 | Mar | CTNA |

METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | 500MG | A075973 | 001 | Jan 25, 2002 | Feb | CAHN |
| AB | | | 850MG | A075973 | 002 | Jan 25, 2002 | Feb | CAHN |
| AB | | | 1GM | A075973 | 003 | Jan 25, 2002 | Feb | CAHN |

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

ACTOPLUS MET

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | TAKEDA GLOBAL | 500MG;EQ 15MG BASE | N021842 | 001 | Aug 29, 2005 | Feb | CFTG |
| AB | + | | 850MG;EQ 15MG BASE | N021842 | 002 | Aug 29, 2005 | Feb | CFTG |

TABLET; ORAL
PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MYLAN | 500MG;EQ 15MG BASE | A090406 | 001 | Feb 25, 2011 | Feb | NEWA |
| AB | | 850MG;EQ 15MG BASE | A090406 | 002 | Feb 25, 2011 | Feb | NEWA |

METHYLERGONOVINE MALEATE

TABLET; ORAL
METHERGINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + NOVARTIS | 0.2MG | N006035 | 003 | | Apr | CTEC |

METHYLERGONOVINE MALEATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | NOVEL LABS INC | 0.2MG | A091577 | 001 | May 02, 2011 | Apr | NEWA |

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | JUBILANT CADISTA | 4MG | A040189 | 001 | Oct 31, 1997 | Jan | CAHN |
| AB | | 8MG | A040189 | 002 | Oct 31, 1997 | Jan | CAHN |
| AB | | 16MG | A040189 | 003 | Jul 20, 2007 | Jan | CAHN |
| AB | | 32MG | A040189 | 004 | Jul 20, 2007 | Jan | CAHN |

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-METHAPRED

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | HEMOFARM | EQ 40MG BASE/VIAL | A040793 | 001 | Nov 25, 2008 | Apr | CAHN |
| AP | | EQ 125MG BASE/VIAL | A040827 | 001 | Nov 25, 2008 | Apr | CAHN |
| | @ HOSPIRA | EQ 500MG BASE/VIAL | A089173 | 001 | Aug 18, 1987 | Feb | DISC |
| | @ | EQ 1GM BASE/VIAL | A089174 | 001 | Aug 18, 1987 | Feb | DISC |

METRONIDAZOLE

GEL; TOPICAL
METRONIDAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | G AND W LABS INC | 0.75% | A078178 | 001 | Jan 19, 2011 | Jan | NEWA |

TABLET; ORAL
METRONIDAZOLE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> AB | ALEMBIC LTD | 250MG | A079067 | 001 | Mar 13, 2009 | May | CAHN |
| >D> AB | | 500MG | A079067 | 002 | Mar 13, 2009 | May | CAHN |
| >A> AB | ALEMBIC PHARMS LTD | 250MG | A079067 | 001 | Mar 13, 2009 | May | CAHN |
| >A> AB | | 500MG | A079067 | 002 | Mar 13, 2009 | May | CAHN |

MICAFUNGIN SODIUM

INJECTABLE; IV (INFUSION)
MYCAMINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + ASTELLAS | 100MG/VIAL | N021506 | 003 | Jun 27, 2006 | Jan | CRLD |

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDOZALAM HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | SAGENT STRIDES | EQ 1MG BASE/ML | A090316 | 001 | May 04, 2011 | Apr | NEWA |
| AP | | EQ 5MG BASE/ML | A090316 | 002 | May 04, 2011 | Apr | NEWA |

MILRINONE LACTATE

INJECTABLE; INJECTION
MILRINONE LACTATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ HOSPIRA | EQ 1MG BASE/ML | A075884 | 001 | May 28, 2002 | Feb | DISC |

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL
MIRTAZAPINE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | ACTAVIS ELIZABETH | 15MG | A077959 | 001 | Feb 14, 2011 | Jan | NEWA |
| | AB | | | 30MG | A077959 | 002 | Feb 14, 2011 | Jan | NEWA |
| | AB | | | 45MG | A077959 | 003 | Feb 14, 2011 | Jan | NEWA |

MORPHINE SULFATE

INJECTABLE, LIPOSOMAL; EPIDURAL
DEPODUR

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >D> | | | EKR THERAP | 10MG/ML (10MG/ML) | N021671 | 001 | May 18, 2004 | May | CRLD |
| >A> | | + | | 10MG/ML (10MG/ML) | N021671 | 001 | May 18, 2004 | May | CRLD |
| >D> | | + | | 15MG/1.5ML (10MG/ML) | N021671 | 002 | May 18, 2004 | May | DISC |
| >A> | | | @ | 15MG/1.5ML (10MG/ML) | N021671 | 002 | May 18, 2004 | May | DISC |

MUPIROCIN

OINTMENT; TOPICAL
MUPIROCIN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | | GLENMARK PHARMS | 2% | A090480 | 001 | Jun 08, 2011 | May | NEWA |

MUPIROCIN CALCIUM

CREAM; TOPICAL
BACTROBAN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | + | GLAXOSMITHKLINE | EQ 2% BASE | N050746 | 001 | Dec 11, 1997 | Jan | CDFR |

NABUMETONE

TABLET; ORAL
NABUMETONE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | LUPIN LTD | 500MG | A090445 | 001 | Jan 12, 2011 | Jan | NEWA |
| | AB | | | 750MG | A090445 | 002 | Jan 12, 2011 | Jan | NEWA |
| >A> | AB | | WATSON LABS | 500MG | A091083 | 001 | Jun 13, 2011 | May | NEWA |
| >A> | AB | | | 750MG | A091083 | 002 | Jun 13, 2011 | May | NEWA |

NAFCILLIN SODIUM

INJECTABLE; INJECTION
NAFCILLIN SODIUM

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AP | | INSTITUTO BIOCHEMICO | EQ 10GM BASE/VIAL | A090005 | 001 | Apr 20, 2011 | Apr | NEWA |
| | AP | + | SANDOZ | EQ 10GM BASE/VIAL | A062527 | 004 | Aug 02, 1984 | Apr | CTEC |

NALTREXONE HYDROCHLORIDE

TABLET; ORAL
NALTREXONE HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | ELITE LABS | 50MG | A075274 | 001 | May 26, 1999 | Feb | CAHN |

NAPROXEN

TABLET; ORAL
NAPROXEN

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | AB | | MARKSANS PHARMA | 250MG | A091416 | 001 | Feb 14, 2011 | Jan | NEWA |
| | AB | | | 375MG | A091416 | 002 | Feb 14, 2011 | Jan | NEWA |
| | AB | | | 500MG | A091416 | 003 | Feb 14, 2011 | Jan | NEWA |

NARATRIPTAN

TABLET; ORAL
NARATRIPTAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | APOTEX CORP | EQ 1MG BASE | A091373 | 001 | Apr 22, 2011 | Apr | NEWA |
| AB | | | EQ 2.5MG BASE | A091373 | 002 | Apr 22, 2011 | Apr | NEWA |
| AB | | SUN PHARM INDS LTD | EQ 2.5MG BASE | A091552 | 001 | Feb 14, 2011 | Jan | NEWA |

NARATRIPTAN HYDROCHLORIDE

TABLET; ORAL
NARATRIPTAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | INDICUS PHARMA | EQ 1MG BASE | A200502 | 001 | Feb 28, 2011 | Feb | NEWA |
| AB | | | EQ 2.5MG BASE | A200502 | 002 | Feb 28, 2011 | Feb | NEWA |

NATEGLINIDE

TABLET; ORAL
NATEGLINIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | WATSON LABS | 60MG | A077462 | 001 | Mar 30, 2011 | Mar | NEWA |
| AB | | | 120MG | A077462 | 002 | Mar 30, 2011 | Mar | NEWA |

NEVIRAPINE

TABLET, EXTENDED RELEASE; ORAL
VIRAMUNE XR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | BOEHRINGER INGELHEIM | 400MG | N201152 | 001 | Mar 25, 2011 | Mar | NEWA |

NICARDIPINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDENE SR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | EKR THERAP | 45MG | N020005 | 002 | Feb 21, 1992 | May | DISC |
| >A> | @ | | 45MG | N020005 | 002 | Feb 21, 1992 | May | DISC |

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL
NIFEDIPINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB1 | | VALEANT INTL | 30MG | A075269 | 001 | Dec 04, 2000 | Apr | CAHN |
| AB2 | | | 30MG | A075289 | 002 | Feb 06, 2001 | Apr | CAHN |
| AB1 | | | 60MG | A075269 | 002 | Dec 04, 2000 | Apr | CAHN |
| AB2 | | | 60MG | A075289 | 001 | Sep 27, 2000 | Apr | CAHN |
| AB1 | | | 90MG | A076070 | 001 | Aug 16, 2002 | Apr | CAHN |

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
NISOLDIPINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | 8.5MG | A091001 | 001 | Jan 26, 2011 | Jan | NEWA |
| AB | | | 17MG | A091001 | 002 | Jan 26, 2011 | Jan | NEWA |
| AB | | | 25.5MG | A091001 | 003 | Jan 26, 2011 | Jan | NEWA |
| AB | | | 34MG | A091001 | 004 | Jan 26, 2011 | Jan | NEWA |

SULAR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | SHIONOGI PHARMA | 8.5MG | N020356 | 008 | Jan 02, 2008 | Jan | CFTG |
| AB | + | | 17MG | N020356 | 007 | Jan 02, 2008 | Jan | CFTG |
| AB | | | 25.5MG | N020356 | 006 | Jan 02, 2008 | Jan | CFTG |
| AB | + | | 34MG | N020356 | 005 | Jan 02, 2008 | Jan | CFTG |

NITROFURANTOIN

SUSPENSION; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | FURADANTIN | | | | | | |
| AB | + | SHIONOGI INC | 25MG/5ML | N009175 | 001 | | Apr | CFTG |
| | | NITROFURANTOIN | | | | | | |
| AB | | AMNEAL PHARMS | 25MG/5ML | A201679 | 001 | May 11, 2011 | Apr | NEWA |

NIZATIDINE

CAPSULE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | NIZATIDINE | | | | | | |
| AB | | MYLAN | 150MG | A075934 | 001 | Jul 09, 2002 | Feb | CAHN |
| AB | | | 300MG | A075934 | 002 | Jul 09, 2002 | Feb | CAHN |

NYSTATIN

SUSPENSION; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | NYSTATIN | | | | | | |
| AA | | VISTAPHARM | 100,000 UNITS/ML | A065422 | 001 | Mar 07, 2011 | Feb | NEWA |

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | OCTREOTIDE ACETATE | | | | | | |
| AP | | WOCKHARDT USA | EQ 0.2MG BASE/ML | A090986 | 001 | May 11, 2011 | Apr | NEWA |
| AP | | | EQ 1MG BASE/ML | A090986 | 002 | May 11, 2011 | Apr | NEWA |
| | | OCTREOTIDE ACETATE (PRESERVATIVE FREE) | | | | | | |
| AP | | BIONICHE PHARMA USA | EQ 0.05MG BASE/ML | A079198 | 001 | Feb 10, 2011 | Jan | NEWA |
| AP | | | EQ 0.1MG BASE/ML | A079198 | 002 | Feb 10, 2011 | Jan | NEWA |
| AP | | | EQ 0.5MG BASE/ML | A079198 | 003 | Feb 10, 2011 | Jan | NEWA |
| AP | | WOCKHARDT USA | EQ 0.05MG BASE/ML | A090985 | 001 | May 11, 2011 | Apr | NEWA |
| AP | | | EQ 0.1MG BASE/ML | A090985 | 002 | May 11, 2011 | Apr | NEWA |
| AP | | | EQ 0.5MG BASE/ML | A090985 | 003 | May 11, 2011 | Apr | NEWA |

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ONDANSETRON | | | | | | |
| AB | | RANBAXY | 4MG | A078602 | 001 | Feb 24, 2011 | Feb | NEWA |
| AB | | | 8MG | A078602 | 002 | Feb 24, 2011 | Feb | NEWA |

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ONDANSETRON HYDROCHLORIDE | | | | | | |
| >D> | AP | AKORN STRIDES | EQ 2MG BASE/ML | A078257 | 001 | Apr 23, 2008 | May | CAHN |
| >A> | AP | PFIZER | EQ 2MG BASE/ML | A078257 | 001 | Apr 23, 2008 | May | CAHN |
| | AP | TEVA | EQ 2MG BASE/ML | A076876 | 001 | Nov 22, 2006 | Jan | CMFD |
| | | ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER | | | | | | |
| | AP | + HOSPIRA | EQ 0.64MG BASE/ML | A077348 | 001 | Feb 01, 2007 | Apr | CRLD |
| | | ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE | | | | | | |
| >D> | AP | AKORN STRIDES | EQ 2MG BASE/ML | A078244 | 001 | Apr 23, 2008 | May | CAHN |
| >A> | AP | PFIZER | EQ 2MG BASE/ML | A078244 | 001 | Apr 23, 2008 | May | CAHN |

SOLUTION; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ONDANSETRON HYDROCHLORIDE | | | | | | |
| AA | | AMNEAL PHARMS | EQ 4MG BASE/5ML | A091483 | 001 | Jan 31, 2011 | Jan | NEWA |
| AA | | SILARX | EQ 4MG BASE/5ML | A091342 | 001 | Jan 27, 2011 | Jan | NEWA |

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ONDANSERTRON HYDROCHLORIDE | | | | | | |
| AB | | TARO | EQ 4MG BASE | A077729 | 001 | Mar 28, 2011 | Mar | NEWA |

TABLET; ORAL
ONDANSERTRON HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | TARO | EQ 8MG BASE | A077729 | 002 | Mar 28, 2011 | Mar | NEWA |
| AB | | EQ 24MG BASE | A077729 | 003 | Mar 28, 2011 | Mar | NEWA |

OXALIPLATIN

INJECTABLE; IV (INFUSION)
OXALIPLATIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | SANDOZ | 50MG/10ML (5MG/ML) | A078817 | 001 | Jan 24, 2011 | Jan | NEWA |
| AP | | 50MG/VIAL | A090849 | 001 | Apr 28, 2011 | Apr | NEWA |
| AP | | 100MG/VIAL | A090849 | 002 | Apr 28, 2011 | Apr | NEWA |
| AP | | 100MG/20ML (5MG/ML) | A078817 | 002 | Jan 24, 2011 | Jan | NEWA |

OXAPROZIN

TABLET; ORAL
OXAPROZIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MYLAN | 600MG | A075847 | 001 | Feb 28, 2001 | Feb | CAHN |

OXYCODONE HYDROCHLORIDE

TABLET; ORAL
OXYCODONE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | COASTAL PHARMS | 5MG | A091313 | 001 | Feb 18, 2011 | Feb | NEWA |
| AB | | 15MG | A091313 | 002 | Feb 18, 2011 | Feb | NEWA |
| AB | | 30MG | A091313 | 003 | Feb 18, 2011 | Feb | NEWA |
| AB | RHODES PHARMS | 5MG | A091490 | 001 | Mar 09, 2011 | Feb | NEWA |
| AB | | 10MG | A091490 | 002 | Mar 09, 2011 | Feb | NEWA |
| AB | | 15MG | A091490 | 003 | Mar 09, 2011 | Feb | NEWA |
| AB | | 20MG | A091490 | 004 | Mar 09, 2011 | Feb | NEWA |
| AB | | 30MG | A091490 | 005 | Mar 09, 2011 | Feb | NEWA |

OXYMETHOLONE

TABLET; ORAL
ANADROL-50

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + ALAVEN PHARM | 50MG | N016848 | 001 | | May | CAHN |
| >A> | + MEDA PHARMS | 50MG | N016848 | 001 | | May | CAHN |

OXYMORPHONE HYDROCHLORIDE

TABLET; ORAL
OXYMORPHONE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | TEVA | 5MG | A091443 | 002 | Feb 15, 2011 | Jan | NEWA |
| AB | | 10MG | A091443 | 001 | Feb 15, 2011 | Jan | NEWA |

TABLET, EXTENDED RELEASE; ORAL
OPANA ER

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ ENDO PHARMS | 7.5MG | N021610 | 005 | Feb 29, 2008 | Feb | DISC |
| | @ | 15MG | N021610 | 006 | Feb 29, 2008 | Feb | DISC |

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION
PAMIDRONATE DISODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | GENERAMEDIX | 30MG/10ML (3MG/ML) | A078373 | 001 | Dec 23, 2008 | May | CAHN |
| >D> | AP | | 90MG/10ML (9MG/ML) | A078373 | 002 | Dec 23, 2008 | May | CAHN |
| >A> | AP | MUSTAFA NEVZAT | 30MG/10ML (3MG/ML) | A078373 | 001 | Dec 23, 2008 | May | CAHN |
| >A> | AP | | 90MG/10ML (9MG/ML) | A078373 | 002 | Dec 23, 2008 | May | CAHN |

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL

PANTOPRAZOLE SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | ACTAVIS TOTOWA | EQ 20MG BASE | A090797 | 001 | Feb 07, 2011 | Jan | NEWA |
| AB | | | EQ 40MG BASE | A090797 | 002 | Feb 07, 2011 | Jan | NEWA |
| AB | | DR REDDYS LABS LTD | EQ 20MG BASE | A077619 | 001 | Jan 19, 2011 | Jan | NEWA |
| AB | | | EQ 40MG BASE | A077619 | 002 | Jan 19, 2011 | Jan | NEWA |
| AB | | KUDCO IRELAND | EQ 20MG BASE | A078281 | 001 | Jan 20, 2011 | Jan | NEWA |
| AB | | | EQ 40MG BASE | A078281 | 002 | Jan 20, 2011 | Jan | NEWA |
| AB | | MATRIX LABS LTD | EQ 20MG BASE | A090970 | 001 | Jan 19, 2011 | Jan | NEWA |
| AB | | | EQ 40MG BASE | A090970 | 002 | Jan 19, 2011 | Jan | NEWA |
| AB | | TORRENT PHARMS | EQ 20MG BASE | A090074 | 001 | Jan 19, 2011 | Jan | NEWA |
| AB | | | EQ 40MG BASE | A090074 | 002 | Jan 19, 2011 | Jan | NEWA |
| AB | | WOCKHARDT | EQ 20MG BASE | A091231 | 001 | Jan 19, 2011 | Jan | NEWA |
| AB | | | EQ 40MG BASE | A091231 | 002 | Jan 19, 2011 | Jan | NEWA |

PAROMOMYCIN SULFATE

CAPSULE; ORAL

HUMATIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | @ KING PHARMS | EQ 250MG BASE | A062310 | 001 | | May | CAHN |
| >A> | | @ MONARCH PHARMS | EQ 250MG BASE | A062310 | 001 | | May | CAHN |

PAROXETINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PAROXETINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | EQ 37.5MG BASE | A091427 | 001 | Apr 14, 2011 | Apr | NEWA |

PAXIL CR

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | GLAXOSMITHKLINE | EQ 37.5MG BASE | N020936 | 003 | Dec 06, 2000 | Apr | CTEC |

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

PENTOXIFYLLINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | VALEANT INTL | 400MG | A075028 | 001 | Jul 20, 1998 | Apr | CAHN |

PHENTERMINE HYDROCHLORIDE

TABLET; ORAL

PHENTERMINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | ELITE LABS | 37.5MG | A200272 | 001 | Jan 31, 2011 | May | CAHN |
| >D> | AA | EPIC PHARMA LLC | 37.5MG | A200272 | 001 | Jan 31, 2011 | May | CAHN |
| | AA | | 37.5MG | A200272 | 001 | Jan 31, 2011 | Jan | NEWA |

PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | HIKMA FARMACEUTICA | 50MG/ML | A040573 | 001 | Sep 13, 2006 | May | CAHN |
| >A> | AP | X-GEN PHARMS | 50MG/ML | A040573 | 001 | Sep 13, 2006 | May | CAHN |

PILOCARPINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC

CARPINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | ALCON | 1% | N200890 | 001 | Jun 22, 2010 | May | CTNA |
| >D> | | | 2% | N200890 | 002 | Jun 22, 2010 | May | CTNA |
| >D> | + | | 4% | N200890 | 003 | Jun 22, 2010 | May | CTNA |

ISOPTO CARPINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | ALCON RES | 1% | N200890 | 001 | Jun 22, 2010 | May | CTNA |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | SOLUTION; OPHTHALMIC | | | | | | | |
| >A> | | ISOPTO CARPINE | | | | | | | |
| >A> | | ALCON RES | 2% | N200890 | 002 | Jun 22, 2010 | May | CTNA | |
| >A> | | + | 4% | N200890 | 003 | Jun 22, 2010 | May | CTNA | |
| | | PIPERACILLIN SODIUM; TAZOBACTAM SODIUM | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | PIPERACILLIN AND TAZOBACTAM | | | | | | | |
| >A> | AP | AUROBINDO PHARMA LTD | EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL | A065498 | 001 | May 23, 2011 | May | NEWA | |
| >A> | AP | | EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL | A065498 | 002 | May 23, 2011 | May | NEWA | |
| >A> | AP | | EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL | A065498 | 003 | May 23, 2011 | May | NEWA | |
| | AP | HOSPIRA INC | EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL | A065386 | 001 | Sep 15, 2009 | Jan | CAHN | |
| | AP | | EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL | A065386 | 002 | Sep 15, 2009 | Jan | CAHN | |
| | AP | | EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL | A065386 | 003 | Sep 15, 2009 | Jan | CAHN | |
| | AP | | EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL | A065446 | 001 | Sep 15, 2009 | Jan | CAHN | |
| >A> | AP | INSTITUTO BIOCHEMICO | EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL | A065523 | 001 | May 31, 2011 | May | NEWA | |
| >A> | AP | | EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL | A065523 | 002 | May 31, 2011 | May | NEWA | |
| >A> | AP | | EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL | A065523 | 003 | May 31, 2011 | May | NEWA | |
| >A> | AP | | EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL | A090498 | 001 | May 31, 2011 | May | NEWA | |
| | | PIROXICAM | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | PIROXICAM | | | | | | | |
| | | @ MYLAN | 10MG | A074043 | 001 | Sep 22, 1992 | Feb | CAHN | |
| | | @ | 20MG | A074043 | 002 | Sep 22, 1992 | Feb | CAHN | |
| | | POTASSIUM CHLORIDE | | | | | | | |
| | | CAPSULE, EXTENDED RELEASE; ORAL | | | | | | | |
| | | POTASSIUM CHLORIDE | | | | | | | |
| >A> | AB | PADDOCK LABS | 8MEQ | A200185 | 001 | May 18, 2011 | May | NEWA | |
| >A> | AB | | 10MEQ | A200185 | 002 | May 18, 2011 | May | NEWA | |
| | | PREDNISOLONE SODIUM PHOSPHATE | | | | | | | |
| | | SOLUTION; ORAL | | | | | | | |
| | | PREDNISOLONE SODIUM PHOSPHATE | | | | | | | |
| >D> | AA | VINTAGE | EQ 5MG BASE/5ML | A078416 | 001 | Oct 31, 2007 | May | DISC | |
| >A> | | @ VINTAGE PHARMS | EQ 5MG BASE/5ML | A078416 | 001 | Oct 31, 2007 | May | DISC | |
| | | PREDNISONE | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | PREDNISONE | | | | | | | |
| | AB | JUBILANT CADISTA | 1MG | A040611 | 001 | Jun 06, 2005 | Jan | CAHN | |
| | AB | | 5MG | A040362 | 002 | Aug 29, 2001 | Jan | CAHN | |
| | AB | | 10MG | A040362 | 001 | Aug 29, 2001 | Jan | CAHN | |
| | AB | | 20MG | A040362 | 003 | Jun 29, 2005 | Jan | CAHN | |

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCOMP

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | JUBILANT CADISTA | EQ 5MG BASE | A040268 | 001 | Feb 27, 1998 | Jan | CAHN |
| AB | | EQ 10MG BASE | A040268 | 002 | Feb 27, 1998 | Jan | CAHN |

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> AP | HIKMA FARMACEUTICA | 25MG/ML | A040737 | 001 | Apr 24, 2008 | May | CAHN |
| >D> AP | | 50MG/ML | A040737 | 002 | Apr 24, 2008 | May | CAHN |
| >A> AP | X-GEN PHARMS | 25MG/ML | A040737 | 001 | Apr 24, 2008 | May | CAHN |
| >A> AP | | 50MG/ML | A040737 | 002 | Apr 24, 2008 | May | CAHN |

PROPANTHELINE BROMIDE

TABLET; ORAL
PROPANTHELINE BROMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| + | ROXANE | 15MG | A080927 | 002 | | Jan | CMFD |

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
DARVON

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | XANODYNE PHARM | 65MG | N010997 | 003 | | Jan | DISC |

PROPOXYPHENE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | TEVA | 65MG | A088615 | 001 | Oct 22, 1984 | Mar | DISC |
| @ | VINTAGE PHARMS | 65MG | A040908 | 001 | Jul 17, 2009 | Mar | DISC |
| @ | WEST WARD | 65MG | A083501 | 001 | | Jan | DISC |

PROPOXYPHENE NAPSYLATE

TABLET; ORAL
DARVON-N

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| @ | XANODYNE PHARM | 100MG | N016862 | 002 | | Jan | DISC |

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
PROPRANOLOL HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | ZYDUS PHARMS USA INC | 60MG | A090321 | 001 | Mar 25, 2011 | Mar | NEWA |
| AB | | 80MG | A090321 | 002 | Mar 25, 2011 | Mar | NEWA |
| AB | | 120MG | A090321 | 003 | Mar 25, 2011 | Mar | NEWA |
| AB | | 160MG | A090321 | 004 | Mar 25, 2011 | Mar | NEWA |

TABLET; ORAL
PROPRANOLOL HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MYLAN | 60MG | A070213 | 005 | Apr 08, 2011 | Mar | NEWA |

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL
QUINAPRIL HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | MYLAN | EQ 5MG BASE | A076036 | 001 | Jan 28, 2005 | Feb | CAHN |
| AB | | EQ 10MG BASE | A076036 | 002 | Jan 28, 2005 | Feb | CAHN |
| AB | | EQ 20MG BASE | A076036 | 003 | Jan 28, 2005 | Feb | CAHN |
| AB | | EQ 40MG BASE | A076036 | 004 | Jan 28, 2005 | Feb | CAHN |

RAMIPRIL

CAPSULE; ORAL
RAMIPRIL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | AUROBINDO PHARMA LTD | 1.25MG | A091604 | 001 | Jun 08, 2011 | May | NEWA |
| >A> | AB | | 2.5MG | A091604 | 002 | Jun 08, 2011 | May | NEWA |
| >A> | AB | | 5MG | A091604 | 003 | Jun 08, 2011 | May | NEWA |
| >A> | AB | | 10MG | A091604 | 004 | Jun 08, 2011 | May | NEWA |

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL
RANITIDINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ MYLAN | EQ 150MG BASE | A075564 | 001 | Oct 27, 2000 | Feb | CAHN |
| | | @ | EQ 300MG BASE | A075564 | 002 | Oct 27, 2000 | Feb | CAHN |

SYRUP; ORAL
RANITIDINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AA | HI TECH PHARMA | EQ 15MG BASE/ML | A091078 | 001 | Mar 22, 2011 | Mar | NEWA |
| >A> | AA | TARO | EQ 15MG BASE/ML | A077476 | 001 | Jun 13, 2011 | May | NEWA |

TABLET; ORAL
RANITIDINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | MYLAN | EQ 150MG BASE | A074023 | 001 | Aug 22, 1997 | Feb | CAHN |
| | AB | | EQ 300MG BASE | A074023 | 002 | Aug 22, 1997 | Feb | CAHN |

RIFAMPIN

INJECTABLE; INJECTION
RIFAMPIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | AKORN STRIDES | 600MG/VIAL | A065421 | 001 | May 22, 2008 | May | CAHN |
| >A> | AP | PFIZER | 600MG/VIAL | A065421 | 001 | May 22, 2008 | May | CAHN |

RIFAXIMIN

TABLET; ORAL
XIFAXAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | SALIX PHARMS | 550MG | N022554 | 001 | Mar 24, 2010 | Feb | CRLD |

>A> RILPIVIRINE HYDROCHLORIDE

>A> TABLET; ORAL
>A> EDURANT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | TIBOTEC | EQ 25MG BASE | N202022 | 001 | May 20, 2011 | May | NEWA |

RISPERIDONE

SOLUTION; ORAL
RISPERIDONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | AMNEAL PHARMS | 1MG/ML | A091384 | 001 | May 25, 2011 | May | NEWA |
| | AA | TARO | 1MG/ML | A090347 | 001 | Feb 07, 2011 | Jan | NEWA |

TABLET; ORAL
RISPERIDONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | CIPLA | 0.25MG | A077543 | 001 | May 18, 2011 | May | NEWA |
| >A> | AB | | 0.5MG | A077543 | 002 | May 18, 2011 | May | NEWA |
| >A> | AB | | 1MG | A077543 | 003 | May 18, 2011 | May | NEWA |
| >A> | AB | | 2MG | A077543 | 004 | May 18, 2011 | May | NEWA |
| >A> | AB | | 3MG | A077543 | 005 | May 18, 2011 | May | NEWA |
| >A> | AB | | 4MG | A077543 | 006 | May 18, 2011 | May | NEWA |
| | | @ RATIOPHARM | 0.25MG | A077784 | 001 | Jun 08, 2010 | Feb | DISC |
| | | @ | 0.5MG | A077784 | 002 | Jun 08, 2010 | Feb | DISC |
| | | @ | 1MG | A077784 | 003 | Jun 08, 2010 | Feb | DISC |
| | | @ | 2MG | A077784 | 004 | Jun 08, 2010 | Feb | DISC |

TABLET; ORAL
RISPERIDONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | RATIOPHARM | 3MG | A077784 | 005 | Jun 08, 2010 | Feb | DISC |
| | @ | | 4MG | A077784 | 006 | Jun 08, 2010 | Feb | DISC |

TABLET, ORALLY DISINTEGRATING; ORAL
RISPERIDONE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | 0.5MG | A091537 | 001 | Mar 30, 2011 | Mar | NEWA |
| AB | | | 1MG | A091537 | 002 | Mar 30, 2011 | Mar | NEWA |
| AB | | | 2MG | A091537 | 003 | Mar 30, 2011 | Mar | NEWA |
| AB | | | 3MG | A091537 | 004 | Mar 30, 2011 | Mar | NEWA |
| AB | | | 4MG | A091537 | 005 | Mar 30, 2011 | Mar | NEWA |
| AB | | WATSON LABS FLORIDA | 0.5MG | A076996 | 001 | Apr 19, 2011 | Apr | NEWA |
| AB | | | 1MG | A076996 | 002 | Apr 19, 2011 | Apr | NEWA |
| AB | | | 2MG | A076996 | 003 | Apr 19, 2011 | Apr | NEWA |
| AB | | | 3MG | A076996 | 004 | Apr 19, 2011 | Apr | NEWA |
| AB | | | 4MG | A076996 | 005 | Apr 19, 2011 | Apr | NEWA |

ROCURONIUM BROMIDE

INJECTABLE; INJECTION
ROCURONIUM BROMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | SAGENT STRIDES | 50MG/5ML (10MG/ML) | A091458 | 001 | Jul 28, 2010 | Jan | CAHN |
| AP | | | 100MG/10ML (10MG/ML) | A091458 | 002 | Jul 28, 2010 | Jan | CAHN |

ROFLUMILAST

TABLET; ORAL
DALIRESP

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | FOREST RES INST INC | 500MCG | N022522 | 001 | Feb 28, 2011 | Feb | NEWA |

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL
ROPINIROLE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AB | HUAHAI US INC | EQ 0.25MG BASE | A078110 | 001 | May 05, 2008 | May | CAHN |
| >D> | AB | | EQ 0.5MG BASE | A078110 | 002 | May 05, 2008 | May | CAHN |
| >D> | AB | | EQ 1MG BASE | A078110 | 003 | May 05, 2008 | May | CAHN |
| >D> | AB | | EQ 2MG BASE | A078110 | 004 | May 05, 2008 | May | CAHN |
| >D> | AB | | EQ 3MG BASE | A078110 | 005 | May 05, 2008 | May | CAHN |
| >D> | AB | | EQ 4MG BASE | A078110 | 006 | May 05, 2008 | May | CAHN |
| >A> | AB | PRINSTON PHARM LLC | EQ 0.25MG BASE | A078110 | 001 | May 05, 2008 | May | CAHN |
| >A> | AB | | EQ 0.5MG BASE | A078110 | 002 | May 05, 2008 | May | CAHN |
| >A> | AB | | EQ 1MG BASE | A078110 | 003 | May 05, 2008 | May | CAHN |
| >A> | AB | | EQ 2MG BASE | A078110 | 004 | May 05, 2008 | May | CAHN |
| >A> | AB | | EQ 3MG BASE | A078110 | 005 | May 05, 2008 | May | CAHN |
| >A> | AB | | EQ 4MG BASE | A078110 | 006 | May 05, 2008 | May | CAHN |

RUFINAMIDE

SUSPENSION; ORAL
BANZEL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | EISAI INC | 40MG/ML | N201367 | 001 | Mar 03, 2011 | Mar | NEWA |

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECONAL SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | MARATHON PHARMS | 50MG | A086101 | 001 | Oct 03, 1983 | Jan | CAHN |
| | + | | 100MG | A086101 | 002 | Oct 03, 1983 | Jan | CAHN |

SERTRALINE HYDROCHLORIDE

CONCENTRATE; ORAL

SERTRALINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | ROXANE | EQ 20MG BASE/ML | A076934 | 001 | Jun 30, 2006 | Mar | DISC |

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | IVAX SUB TEVA PHARMS | EQ 25MG BASE | A075719 | 003 | Jun 30, 2006 | Apr | DISC |
| | @ | | EQ 50MG BASE | A075719 | 001 | Jun 30, 2006 | Apr | DISC |
| | @ | | EQ 100MG BASE | A075719 | 002 | Jun 30, 2006 | Apr | DISC |
| AB | | MYLAN | EQ 25MG BASE | A076540 | 001 | Mar 20, 2007 | Feb | CAHN |
| AB | | | EQ 50MG BASE | A076540 | 002 | Mar 20, 2007 | Feb | CAHN |
| AB | | | EQ 100MG BASE | A076540 | 003 | Mar 20, 2007 | Feb | CAHN |
| | @ | ROXANE | EQ 25MG BASE | A076881 | 001 | Feb 06, 2007 | Mar | DISC |
| | @ | | EQ 50MG BASE | A076881 | 002 | Feb 06, 2007 | Mar | DISC |
| | @ | | EQ 100MG BASE | A076881 | 003 | Feb 06, 2007 | Mar | DISC |

SINECATECHINS

OINTMENT; TOPICAL

VEREGEN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | + | MEDIGENE | 15% | N021902 | 001 | Oct 31, 2006 | May | CAHN |
| >A> | + | MEDIGENE AG | 15% | N021902 | 001 | Oct 31, 2006 | May | CAHN |

SODIUM FERRIC GLUCONATE COMPLEX

INJECTABLE; INJECTION

FERRLECIT

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | SANOFI AVENTIS US | 62.5MG/5ML | N020955 | 001 | Feb 18, 1999 | Mar | CFTG |

SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | GENERAMEDIX | 62.5MG/5ML | A078215 | 001 | Mar 31, 2011 | Mar | NEWA |

SODIUM FLUORIDE F-18

INJECTABLE; INTRAVENOUS

SODIUM FLUORIDE F 18

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | NIH NCI DCTD | 10-200mCi/ML | N022494 | 001 | Jan 26, 2011 | Apr | DISC |
| | + | | 10-200mCi/ML | N022494 | 001 | Jan 26, 2011 | Jan | NEWA |

SODIUM NITRITE; SODIUM THIOSULFATE

SOLUTION, SOLUTION; INTRAVENOUS, INTRAVENOUS

NITHIODOTE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | HOPE PHARMS | 300MG/10ML(30MG/ML),N/A;N/A,12.5GM/50ML(250MG/ML) | N201444 | 001 | Jan 14, 2011 | Feb | CTNA |

SODIUM NITRITE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | HOPE PHARMS | 300MG/10ML(30MG/ML),N/A;N/A,12.5GM/50ML(250MG/ML) | N201444 | 001 | Jan 14, 2011 | Jan | NEWA |

SODIUM POLYSTYRENE SULFONATE

SUSPENSION; ORAL, RECTAL

SODIUM POLYSTYRENE SULFONATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AA | PADDOCK LABS | 15GM/60ML | A090590 | 001 | May 13, 2011 | May | NEWA |

SPINOSAD

SUSPENSION; TOPICAL

NATROBA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | PARAPRO PHARMS | 0.9% | N022408 | 001 | Jan 18, 2011 | Jan | NEWA |

SUMATRIPTAN SUCCINATE

TABLET; ORAL
SUMATRIPTAN SUCCINATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | @ | ROXANE | EQ 25MG BASE | A078241 | 001 | Aug 10, 2009 | Mar | DISC |
| | @ | | EQ 50MG BASE | A078241 | 002 | Aug 10, 2009 | Mar | DISC |
| | @ | | EQ 100MG BASE | A078241 | 003 | Aug 10, 2009 | Mar | DISC |

>A> TELAPREVIR

>A> TABLET; ORAL
>A> INCIVEK

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | + | VERTEX PHARMS | 375MG | N201917 | 001 | May 23, 2011 | May | NEWA |

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
TERAZOSIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | JUBILANT CADISTA | EQ 1MG BASE | A075317 | 001 | Dec 20, 2004 | Jan | CAHN |
| AB | | | EQ 2MG BASE | A075317 | 002 | Dec 20, 2004 | Jan | CAHN |
| AB | | | EQ 5MG BASE | A075317 | 003 | Dec 20, 2004 | Jan | CAHN |
| AB | | | EQ 10MG BASE | A075317 | 004 | Dec 20, 2004 | Jan | CAHN |

TERBINAFINE HYDROCHLORIDE

TABLET; ORAL
TERBINAFINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | EQ 250MG BASE | A077136 | 001 | Jul 02, 2007 | Feb | CAHN |
| | @ | ROXANE | EQ 250MG BASE | A077223 | 001 | Jul 02, 2007 | Feb | DISC |

TERBUTALINE SULFATE

TABLET; ORAL
TERBUTALINE SULFATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | + | IMPAX LABS | 5MG | A075877 | 002 | Jun 26, 2001 | Jan | CRLD |

TESTOSTERONE

GEL, METERED; TRANSDERMAL
ANDROGEL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | ABBOTT PRODS | 1.62% (20.25MG/1.25GM ACTIVATION) | N022309 | 001 | Apr 29, 2011 | Apr | NEWA |

FORTESTA

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | ENDO PHARMS | 10MG/0.5GM ACTIVATION | N021463 | 001 | Dec 29, 2010 | Mar | CPOT |

THEOPHYLLINE

SOLUTION; ORAL
THEOPHYLLINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | + | SILARX | 80MG/15ML | A091156 | 001 | Apr 13, 2011 | Mar | NEWA |

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
THIAMINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | HOSPIRA | 100MG/ML | A040079 | 001 | May 03, 1996 | May | DISC |
| >A> | | @ | 100MG/ML | A040079 | 001 | May 03, 1996 | May | DISC |

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLOPIDINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | MYLAN | 250MG | A075161 | 001 | Sep 13, 1999 | Feb | CAHN |

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AT | | FERA PHARMS | 0.3% | A065026 | 001 | Sep 11, 2001 | Mar | CAHN |

TOPOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

TOPOTECAN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | DR REDDYS LABS LTD | EQ 4MG BASE/VIAL | A201191 | 001 | Mar 09, 2011 | Feb | NEWA |
| AP | | SAGENT PHARMS | EQ 4MG BASE/VIAL | A091284 | 001 | Jan 26, 2011 | Jan | NEWA |

SOLUTION; INTRAVENOUS

TOPOTECAN

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AP | | HOSPIRA INC | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N200582 | 001 | Feb 02, 2011 | Feb | NEWA |
| | | SANDOZ | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N200199 | 001 | Feb 25, 2011 | Feb | NEWA |
| | | | EQ 3MG BASE/3ML (EQ 1MG BASE/ML) | N200199 | 002 | Feb 25, 2011 | Feb | NEWA |
| AP | + | | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N200199 | 003 | Feb 25, 2011 | Feb | NEWA |

TORSEMIDE

TABLET; ORAL

TORSEMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | VINTAGE PHARMS | 5MG | A090613 | 001 | Mar 22, 2011 | Mar | NEWA |
| AB | | | 10MG | A090613 | 002 | Mar 22, 2011 | Mar | NEWA |
| AB | | | 20MG | A090613 | 003 | Mar 22, 2011 | Mar | NEWA |
| AB | | | 100MG | A090613 | 004 | Mar 22, 2011 | Mar | NEWA |

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

TRAMADOL HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AB | | ZYDUS PHARMS USA INC | 50MG | A090404 | 001 | Jan 31, 2011 | Jan | NEWA |

TRAVOPROST

SOLUTION/DROPS; OPHTHALMIC

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | | TRAVATAN | | | | | | |
| >D> | + | ALCON | 0.004% | N021257 | 001 | Mar 16, 2001 | May | DISC |
| >A> | | @ | 0.004% | N021257 | 001 | Mar 16, 2001 | May | DISC |

TRAZODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OLEPTRO

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | ANGELINI LABOPHARM | 300MG | N022411 | 002 | Feb 02, 2010 | May | CAHN |
| >D> | | LABOPHARM | 300MG | N022411 | 002 | Feb 02, 2010 | May | CAHN |

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | LUITPOLD | 100MG/ML | A091330 | 001 | Mar 08, 2011 | May | CAHN |
| >D> | AP | PHARMAFORCE | 100MG/ML | A091330 | 001 | Mar 08, 2011 | May | CAHN |
| | AP | | 100MG/ML | A091330 | 001 | Mar 08, 2011 | Feb | NEWA |

TRIMETHOBENZAMIDE HYDROCHLORIDE PRESERVATIVE FREE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AP | LUITPOLD | 100MG/ML | A091329 | 001 | Mar 08, 2011 | May | CAHN |
| >D> | AP | PHARMAFORCE | 100MG/ML | A091329 | 001 | Mar 08, 2011 | May | CAHN |
| | AP | | 100MG/ML | A091329 | 001 | Mar 08, 2011 | Feb | NEWA |

TRIMETHOPRIM

TABLET; ORAL
TRIMETHOPRIM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | NOVEL LABS INC | 100MG | A091437 | 001 | Jun 15, 2011 | May | NEWA |

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | MIKAH PHARMA | EQ 25MG BASE | A077361 | 001 | Aug 02, 2006 | Feb | CAHN |
| | AB | | EQ 50MG BASE | A077361 | 002 | Aug 02, 2006 | Feb | CAHN |
| | AB | | EQ 100MG BASE | A077361 | 003 | Aug 02, 2006 | Feb | CAHN |

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL
VALACYCLOVIR HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | ACTAVIS PHARMA | EQ 500MG BASE | A090370 | 001 | Mar 16, 2011 | Feb | NEWA |
| | AB | | EQ 1GM BASE | A090370 | 002 | Mar 16, 2011 | Feb | NEWA |

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
VANCOMYCIN HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | AKORN STRIDES | EQ 500MG BASE/VIAL | A065397 | 001 | Dec 30, 2008 | May | CAHN |
| >D> | AP | | EQ 1GM BASE/VIAL | A065397 | 002 | Dec 30, 2008 | May | CAHN |
| >D> | AP | | EQ 5GM BASE/VIAL | A065432 | 001 | Dec 30, 2008 | May | CAHN |
| >A> | AP | PFIZER | EQ 500MG BASE/VIAL | A065397 | 001 | Dec 30, 2008 | May | CAHN |
| >A> | AP | | EQ 1GM BASE/VIAL | A065397 | 002 | Dec 30, 2008 | May | CAHN |
| >A> | AP | | EQ 5GM BASE/VIAL | A065432 | 001 | Dec 30, 2008 | May | CAHN |

VANDETANIB

TABLET; ORAL
VANDETANIB

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | IPR PHARMS INC | 100MG | N022405 | 001 | Apr 06, 2011 | Apr | NEWA |
| | + | | 300MG | N022405 | 002 | Apr 06, 2011 | Apr | NEWA |

VECURONIUM BROMIDE

INJECTABLE; INJECTION
VECURONIUM BROMIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >D> | AP | AKORN STRIDES | 10MG/VIAL | A090243 | 001 | May 11, 2010 | May | CAHN |
| >D> | AP | | 20MG/VIAL | A090243 | 002 | May 11, 2010 | May | CAHN |
| >A> | AP | PFIZER | 10MG/VIAL | A090243 | 001 | May 11, 2010 | May | CAHN |
| >A> | AP | | 20MG/VIAL | A090243 | 002 | May 11, 2010 | May | CAHN |

VENLAFAXINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
VENLAFAXINE HYDROCHLORIDE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AB | AUROBINDO PHARMA LTD | EQ 37.5MG BASE | A200834 | 001 | Apr 14, 2011 | Apr | NEWA |
| | AB | | EQ 75MG BASE | A200834 | 002 | Apr 14, 2011 | Apr | NEWA |
| | AB | | EQ 150MG BASE | A200834 | 003 | Apr 14, 2011 | Apr | NEWA |
| | AB | DR REDDYS LABS LTD | EQ 37.5MG BASE | A078421 | 001 | May 06, 2011 | Apr | NEWA |
| | AB | | EQ 75MG BASE | A078421 | 002 | May 06, 2011 | Apr | NEWA |
| | AB | | EQ 150MG BASE | A078421 | 003 | May 06, 2011 | Apr | NEWA |
| >A> | AB | MYLAN | EQ 37.5MG BASE | A078789 | 001 | Jun 01, 2011 | May | NEWA |
| >A> | AB | | EQ 75MG BASE | A078789 | 002 | Jun 01, 2011 | May | NEWA |
| >A> | AB | | EQ 150MG BASE | A078789 | 003 | Jun 01, 2011 | May | NEWA |
| >A> | AB | TORRENT PHARMS LLC | EQ 37.5MG BASE | A090899 | 001 | Jun 01, 2011 | May | NEWA |

CAPSULE, EXTENDED RELEASE; ORAL

VENLAFAXINE HYDROCHLORIDE

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| >A> | AB | TORRENT PHARMS LLC | EQ 75MG BASE | A090899 | 002 | Jun 01, 2011 | May | NEWA |
| >A> | AB | | EQ 150MG BASE | A090899 | 003 | Jun 01, 2011 | May | NEWA |
| | AB | VALEANT INTL | EQ 37.5MG BASE | A090071 | 001 | Apr 15, 2011 | Apr | NEWA |
| | AB | | EQ 75MG BASE | A090071 | 002 | Apr 15, 2011 | Apr | NEWA |
| | AB | | EQ 150MG BASE | A090071 | 003 | Apr 15, 2011 | Apr | NEWA |
| | AB | WOCKHARDT | EQ 37.5MG BASE | A078865 | 001 | Apr 14, 2011 | Apr | NEWA |
| | AB | | EQ 75MG BASE | A078865 | 002 | Apr 14, 2011 | Apr | NEWA |
| | AB | | EQ 150MG BASE | A078865 | 003 | Apr 14, 2011 | Apr | NEWA |
| | AB | ZYDUS PHARMS USA INC | EQ 37.5MG BASE | A090174 | 001 | Apr 14, 2011 | Apr | NEWA |
| | AB | | EQ 75MG BASE | A090174 | 002 | Apr 14, 2011 | Apr | NEWA |
| | AB | | EQ 150MG BASE | A090174 | 003 | Apr 14, 2011 | Apr | NEWA |

VILAZODONE HYDROCHLORIDE

TABLET; ORAL

VIIBRYD

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | | FOREST LABS INC | 10MG | N022567 | 001 | Jan 21, 2011 | May | CAHN |
| >A> | | | 20MG | N022567 | 002 | Jan 21, 2011 | May | CAHN |
| >A> | + | | 40MG | N022567 | 003 | Jan 21, 2011 | May | CAHN |
| >D> | | TROVIS PHARMS | 10MG | N022567 | 001 | Jan 21, 2011 | May | CAHN |
| | | | 10MG | N022567 | 001 | Jan 21, 2011 | Jan | NEWA |
| >D> | | | 20MG | N022567 | 002 | Jan 21, 2011 | May | CAHN |
| | | | 20MG | N022567 | 002 | Jan 21, 2011 | Jan | NEWA |
| >D> | + | | 40MG | N022567 | 003 | Jan 21, 2011 | May | CAHN |
| | + | | 40MG | N022567 | 003 | Jan 21, 2011 | Jan | NEWA |

VINCRISTINE SULFATE

INJECTABLE; INJECTION

VINCRISTINE SULFATE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ APP PHARMS | 1MG/ML | A076401 | 001 | Oct 28, 2003 | Jan | DISC |

WARFARIN SODIUM

TABLET; ORAL

WARFARIN SODIUM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| >A> | AB | INVAGEN PHARMS | 1MG | A090935 | 001 | May 25, 2011 | May | NEWA |
| >A> | AB | | 2MG | A090935 | 002 | May 25, 2011 | May | NEWA |
| >A> | AB | | 2.5MG | A090935 | 003 | May 25, 2011 | May | NEWA |
| >A> | AB | | 3MG | A090935 | 004 | May 25, 2011 | May | NEWA |
| >A> | AB | | 4MG | A090935 | 005 | May 25, 2011 | May | NEWA |
| >A> | AB | | 5MG | A090935 | 006 | May 25, 2011 | May | NEWA |
| >A> | AB | | 6MG | A090935 | 007 | May 25, 2011 | May | NEWA |
| >A> | AB | | 7.5MG | A090935 | 008 | May 25, 2011 | May | NEWA |
| >A> | AB | | 10MG | A090935 | 009 | May 25, 2011 | May | NEWA |

ZIDOVUDINE

INJECTABLE; INJECTION

ZIDOVUDINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | AP | LUITPOLD | 10MG/ML | A091457 | 001 | May 06, 2010 | Feb | CAHN |

TABLET; ORAL

ZIDOVUDINE

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | @ MATRIX LABS LTD | 100MG | N200732 | 001 | Feb 23, 2011 | Feb | NEWA |

ZOLPIDEM TARTRATE

TABLET; ORAL

ZOLPIDEM TARTRATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| AB | MYLAN | 5MG | A078016 | 001 | Apr 23, 2007 | Feb | CAHN |
| AB | | 10MG | A078016 | 002 | Apr 23, 2007 | Feb | CAHN |

TABLET, EXTENDED RELEASE; ORAL

ZOLPIDEM TARTRATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| AB | ANCHEN PHARMS | 6.25MG | A078148 | 002 | Apr 14, 2011 | Apr | NEWA |
| AB | SYNTHON PHARMS | 6.25MG | A078483 | 001 | Apr 12, 2011 | Apr | NEWA |

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SILARX | 5MG/5ML | A091130 | 001 | Apr 22, 2011 | Apr | NEWA |
| >A> | TARO | 5MG/5ML | A201546 | 001 | May 20, 2011 | May | NEWA |

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SILARX | 5MG/5ML | A091130 | 002 | Apr 22, 2011 | Apr | NEWA |
| >A> | TARO | 5MG/5ML | A201546 | 002 | May 20, 2011 | May | NEWA |

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SWAB; TOPICAL

CHLORAPREP ONE-STEP SEPP

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | CARDINAL HLTH | 2%;70% (0.67ML) | N021555 | 001 | Oct 07, 2002 | Apr | CAHN |

CHLORAPREP SINGLE SWABSTICK

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | CARDINAL HLTH | 2%;70% (1.75ML) | N021555 | 002 | May 10, 2005 | Apr | CAHN |

CHLORAPREP TRIPLE SWABSTICK

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | CARDINAL HLTH | 2%;70% (5.25ML) | N021555 | 003 | Jun 10, 2009 | Apr | NEWA |

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | MYLAN | 10MG | A075674 | 001 | Dec 21, 2001 | Feb | CAHN |

FEXOFENADINE HYDROCHLORIDE

SUSPENSION; ORAL

CHILDREN'S ALLEGRA ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | SANOFI AVENTIS US | 30MG/5ML | N201373 | 001 | Jan 24, 2011 | Jan | NEWA |

CHILDREN'S ALLEGRA HIVES

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | SANOFI AVENTIS US | 30MG/5ML | N201373 | 002 | Jan 24, 2011 | Jan | NEWA |

TABLET, ORALLY DISINTEGRATING; ORAL

CHILDREN'S ALLEGRA ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | SANOFI AVENTIS US | 30MG | N021909 | 002 | Jan 24, 2011 | Jan | NEWA |

CHILDREN'S ALLEGRA HIVES

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | SANOFI AVENTIS US | 30MG | N021909 | 003 | Jan 24, 2011 | Jan | NEWA |

TABLET; ORAL

ALLEGRA ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SANOFI AVENTIS US | 60MG | N020872 | 007 | Jan 24, 2011 | Jan | NEWA |
| + | | 180MG | N020872 | 010 | Jan 24, 2011 | Jan | NEWA |

ALLEGRA HIVES

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SANOFI AVENTIS US | 60MG | N020872 | 008 | Jan 24, 2011 | Jan | NEWA |
| + | | 180MG | N020872 | 009 | Jan 24, 2011 | Jan | NEWA |

CHILDREN'S ALLEGRA ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SANOFI AVENTIS US | 30MG | N020872 | 005 | Jan 24, 2011 | Jan | NEWA |

CHILDREN'S ALLEGRA HIVES

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SANOFI AVENTIS US | 30MG | N020872 | 006 | Jan 24, 2011 | Jan | NEWA |

CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | DR REDDYS LABS LTD | 30MG | A076502 | 004 | Apr 12, 2011 | Mar | NEWA |
| | TEVA | 30MG | A076447 | 004 | Apr 13, 2011 | Mar | NEWA |

CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | DR REDDYS LABS LTD | 30MG | A076502 | 005 | Apr 12, 2011 | Mar | NEWA |
| | TEVA | 30MG | A076447 | 005 | Apr 13, 2011 | Mar | NEWA |

FEXOFENADINE HYDROCHLORIDE ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | DR REDDYS LABS LTD | 60MG | A076502 | 006 | Apr 12, 2011 | Mar | NEWA |

TABLET; ORAL
FEXOFENADINE HYDROCHLORIDE ALLERGY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | DR REDDYS LABS LTD | 180MG | A076502 | 008 | Apr 12, 2011 | Mar | NEWA |
| | TEVA | 60MG | A076447 | 006 | Apr 13, 2011 | Mar | NEWA |
| | | 180MG | A076447 | 008 | Apr 13, 2011 | Mar | NEWA |

FEXOFENADINE HYDROCHLORIDE HIVES

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | DR REDDYS LABS LTD | 60MG | A076502 | 007 | Apr 12, 2011 | Mar | NEWA |
| | | 180MG | A076502 | 009 | Apr 12, 2011 | Mar | NEWA |
| | TEVA | 60MG | A076447 | 007 | Apr 13, 2011 | Mar | NEWA |
| | | 180MG | A076447 | 009 | Apr 13, 2011 | Mar | NEWA |

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
ALLEGRA-D 12 HOUR ALLERGY AND CONGESTION

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | SANOFI AVENTIS US | 60MG;120MG | N020786 | 002 | Jan 24, 2011 | Jan | NEWA |

ALLEGRA-D 24 HOUR ALLERGY AND CONGESTION

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | SANOFI AVENTIS US | 180MG;240MG | N021704 | 002 | Jan 24, 2011 | Jan | NEWA |

IBUPROFEN

TABLET; ORAL
IBUPROFEN

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >D> | ADVENT PHARMS | 200MG | A076460 | 001 | Nov 26, 2003 | May | CAHN |
| >A> | AVEMA PHARMA | 200MG | A076460 | 001 | Nov 26, 2003 | May | CAHN |
| | MARKSANS PHARMA | 200MG | A091237 | 001 | Feb 08, 2011 | Jan | NEWA |
| | | 200MG | A091239 | 001 | Feb 01, 2011 | Jan | NEWA |
| | MERRO PHARM | 200MG | A070985 | 001 | Oct 02, 1987 | Jan | CAHN |
| | SVADS HOLDINGS SA | 200MG | A079129 | 001 | Mar 28, 2011 | Mar | NEWA |
| | | 200MG | A091355 | 001 | Apr 04, 2011 | Mar | NEWA |

INSULIN SUSP ISOPHANE RECOMBINANT HUMAN

INJECTABLE; INJECTION
NOVOLIN N

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | NOVO NORDISK INC | 100 UNITS/ML | N019959 | 001 | Jul 01, 1991 | Jan | CRLD |

LEVONORGESTREL

TABLET; ORAL
PLAN B

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | TEVA WOMENS | 0.75MG | N021045 | 002 | Aug 24, 2006 | Feb | CAHN |

LOPERAMIDE HYDROCHLORIDE

SUSPENSION; ORAL
LOPERAMIDE HYDROCHLORIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| >A> | PERRIGO R AND D | 1MG/7.5ML | A091292 | 001 | May 20, 2011 | May | NEWA |

MINOXIDIL

AEROSOL, FOAM; TOPICAL
MINOXIDIL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | PERRIGO ISRAEL | 5% | A091344 | 001 | Apr 28, 2011 | Apr | NEWA |

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | MARKSANS PHARMA | EQ 200MG BASE | A090545 | 001 | Mar 16, 2011 | Feb | NEWA |
| >A> | RANBAXY LABS LTD | EQ 200MG BASE | A091183 | 001 | May 20, 2011 | May | NEWA |

POTASSIUM IODIDE

TABLET; ORAL

IOSAT

| | | | | | | |
|---|---|---|---|---|---|---|
| ANBEX | 65MG | N018664 | 002 | May 12, 2011 | Apr | NEWA |

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

| | | | | | | |
|---|---|---|---|---|---|---|
| MYLAN | EQ 75MG BASE | A075497 | 001 | Jan 14, 2000 | Feb | CAHN |
| PERRIGO R AND D | EQ 150MG BASE | A091429 | 001 | May 11, 2011 | Apr | NEWA |
| | EQ 150MG BASE | A091429 | 002 | May 11, 2011 | Apr | NEWA |

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

**CUMULATIVE SUPPLEMENT NUMBER 5 MAY 2011**

NO MAY 2011 APPROVALS

# ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of List of Orphan Designations and Approvals is available at:

http://www.fda.gov/orphan/designat/list.htm

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

NO MAY 2011 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2011

See List footnote for information regarding List content

| APPL/PROD NO | | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|---|---|---|---|---|---|---|
| ABIRATERONE ACETATE - ZYTIGA | | | | | | | |
| N202379 | 001 | **>A>** 5604213 | Feb 18, 2014 | DS DP U-1126 | | NCE | Apr 28, 2016 |
| ADAPALENE - DIFFERIN | | | | | | | |
| N021753 | 001 | 7868044 | Mar 12, 2023 | U-1078 | | | |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | | |
| N022545 | 001 | | | | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | | |
| N022545 | 002 | | | | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | | |
| N022545 | 003 | | | | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO | | | | | | | |
| N022545 | 004 | | | | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | | |
| N200045 | 001 | 5559111 | Jul 21, 2018 | DS DP U-3 | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | | |
| N200045 | 002 | 5559111 | Jul 21, 2018 | DS DP U-3 | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | | |
| N200045 | 003 | 5559111 | Jul 21, 2018 | DS DP U-3 | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | | |
| N200045 | 004 | 5559111 | Jul 21, 2018 | DS DP U-3 | | NCE | Mar 05, 2012 |
| ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE | | | | | | | |
| N200045 | 005 | 5559111 | Jul 21, 2018 | DS DP U-3 | | NCE | Mar 05, 2012 |
| ALVIMOPAN - ENTEREG | | | | | | | |
| N021775 | 001 | 5250542 | Mar 29, 2016 | DS DP U-878 | | | |
| AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE | | | | | | | |
| A078381 | 005 | | | | | PC | Jul 02, 2011 |
| AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE | | | | | | | |
| A078381 | 006 | | | | | PC | Jul 02, 2011 |
| AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 10 | | | | | | | |
| N021303 | 001 | RE42096 | Oct 21, 2018 | DP | | | |
| | | RE42096*PED | Apr 21, 2019 | | | | |
| AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 15 | | | | | | | |
| N021303 | 006 | RE42096 | Oct 21, 2018 | DP | | | |
| | | RE42096*PED | Apr 21, 2019 | | | | |
| AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 20 | | | | | | | |
| N021303 | 002 | RE42096 | Oct 21, 2018 | DP | | | |
| | | RE42096*PED | Apr 21, 2019 | | | | |
| AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 25 | | | | | | | |
| N021303 | 004 | RE42096 | Oct 21, 2018 | DP | | | |
| | | RE42096*PED | Apr 21, 2019 | | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2011

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|---|---|---|---|---|---|---|
| AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 30 | | | | | | |
| N021303 003 | RE42096 | Oct 21, 2018 | DP | | | |
| | RE42096*PED | Apr 21, 2019 | | | | |
| AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 5 | | | | | | |
| N021303 005 | RE42096 | Oct 21, 2018 | DP | | | |
| | RE42096*PED | Apr 21, 2019 | | | | |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021436 001 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021436 002 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021436 003 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021436 004 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021436 005 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021436 006 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021713 001 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021729 002 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021729 003 | | | | | I-633 | Feb 16, 2014 |
| ARIPIPRAZOLE - ABILIFY | | | | | | |
| N021866 001 | | | | | I-633 | Feb 16, 2014 |
| ATAZANAVIR SULFATE - REYATAZ | | | | | | |
| N021567 001 | | | | | D-130 | Feb 04, 2014 |
| ATAZANAVIR SULFATE - REYATAZ | | | | | | |
| N021567 002 | | | | | D-130 | Feb 04, 2014 |
| ATAZANAVIR SULFATE - REYATAZ | | | | | | |
| N021567 003 | | | | | D-130 | Feb 04, 2014 |
| ATAZANAVIR SULFATE - REYATAZ | | | | | | |
| N021567 004 | | | | | D-130 | Feb 04, 2014 |
| AZILSARTAN MEDOXOMIL - EDARBI | | | | | | |
| N200796 001 | 5583141 | Dec 10, 2013 | DS DP U-3 | | NCE | Feb 25, 2016 |
| | 5736555 | Jun 25, 2012 | DS DP U-3 | | | |
| | 5958961 | Jun 06, 2014 | DP U-3 | | | |
| | 7157584 | May 22, 2025 | DS | | | |
| | 7572920 | Jan 07, 2025 | DP U-3 | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2011

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|---|---|---|---|---|---|---|
| AZILSARTAN MEDOXOMIL - EDARBI | | | | | | |
| N200796 002 | 5583141 | Dec 10, 2013 | DS DP U-3 | | NCE | Feb 25, 2016 |
| | 5736555 | Jun 25, 2012 | DS DP U-3 | | | |
| | 5958961 | Jun 06, 2014 | DP U-3 | | | |
| | 7157584 | May 22, 2025 | DS | | | |
| | 7572920 | Jan 07, 2025 | DP U-3 | | | |
| AZITHROMYCIN - ZMAX | | | | | | |
| N050797 001 | 7887844 | Feb 14, 2024 | DP | | | |
| BOCEPREVIR - VICTRELIS | | | | | | |
| N202258 001 | **>A>** 7012066 | Feb 22, 2022 | DS DP U-1128 | | **>A>** NCE | May 13, 2016 |
| | **>A>** 7772178 | Nov 11, 2027 | DP U-1128 | | | |
| BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT | | | | | | |
| N021929 002 | 7897646 | Sep 09, 2018 | U-1118 | | | |
| CARBAMAZEPINE - CARBATROL | | | | | | |
| N020712 001 | **>A>** 5326570 | Jul 23, 2011 | U-215 | | | |
| CARBAMAZEPINE - CARBATROL | | | | | | |
| N020712 002 | **>A>** 5326570 | Jul 23, 2011 | U-215 | | | |
| CARBAMAZEPINE - CARBATROL | | | | | | |
| N020712 003 | **>A>** 5326570 | Jul 23, 2011 | U-215 | | | |
| CELECOXIB - CELEBREX | | | | | | |
| N020998 001 | 5760068 | Jun 02, 2015 | U-672 | | | |
| CELECOXIB - CELEBREX | | | | | | |
| N020998 002 | 5760068 | Jun 02, 2015 | U-672 | | | |
| CELECOXIB - CELEBREX | | | | | | |
| N020998 003 | 5760068 | Jun 02, 2015 | U-672 | | | |
| CHLORHEXIDINE GLUCONATE - CHLORHEXIDINE GLUCONATE | | | | | | |
| N021669 001 | **>A>** 7935093 | Oct 02, 2027 | DP U-1022 | | | |
| CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE - ADVIL ALLERGY SINUS | | | | | | |
| N021441 001 | 7863287 | Feb 28, 2027 | DP | | | |
| CINACALCET HYDROCHLORIDE - SENSIPAR | | | | | | |
| N021688 001 | | | | | I-634 | Feb 25, 2014 |
| | | | | | M-101 | Feb 25, 2014 |
| | | | | | ODE | Feb 25, 2018 |
| CINACALCET HYDROCHLORIDE - SENSIPAR | | | | | | |
| N021688 002 | | | | | I-634 | Feb 25, 2014 |
| | | | | | M-101 | Feb 25, 2014 |
| | | | | | ODE | Feb 25, 2018 |
| CINACALCET HYDROCHLORIDE - SENSIPAR | | | | | | |
| N021688 003 | | | | | I-634 | Feb 25, 2014 |
| | | | | | M-101 | Feb 25, 2014 |
| | | | | | ODE | Feb 25, 2018 |

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|---|---|---|---|---|---|---|
| CLOPIDOGREL BISULFATE - PLAVIX | | | | | | |
| N020839 001 | 4847265 | Nov 17, 2011 | DS DP | | >A> M-61 | May 06, 2014 |
| | 4847265*PED | May 17, 2012 | | | >A> PED | Nov 06, 2014 |
| | 5576328 | Jan 31, 2014 | U-432 | Y | | |
| | 5576328*PED | Jul 31, 2014 | | | | |
| | 6429210 | Jun 10, 2019 | DS DP | | | |
| | 6429210*PED | Dec 10, 2019 | | | | |
| | 6504030 | Jun 10, 2019 | DS | | | |
| | 6504030*PED | Dec 10, 2019 | | | | |
| CLOPIDOGREL BISULFATE - PLAVIX | | | | | | |
| N020839 002 | 4847265 | Nov 17, 2011 | DS DP | | >A> M-61 | May 06, 2014 |
| | 4847265*PED | May 17, 2012 | | | >A> PED | Nov 06, 2014 |
| | 6429210 | Jun 10, 2019 | DS DP | | | |
| | 6429210*PED | Dec 10, 2019 | | | | |
| | 6504030 | Jun 10, 2019 | DS | | | |
| | 6504030*PED | Dec 10, 2019 | | | | |
| COLCHICINE - COLCRYS | | | | | | |
| N022352 001 | 7906519 | Feb 17, 2029 | U-1116 | | | |
| | 7915269 | Feb 17, 2029 | U-1007 | | | |
| CYANOCOBALAMIN - NASCOBAL | | | | | | |
| N021642 001 | >A> 7879349 | Jun 01, 2024 | DP U-1152 | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N021976 001 | >A> 5843946 | Dec 01, 2015 | DP U-903 | | >A> D-129 | Dec 13, 2013 |
| | >A> 5843946 | Dec 01, 2015 | DP U-935 | | >A> D-119 | Dec 18, 2011 |
| | >A> 5843946 | Dec 01, 2015 | DP U-744 | | >A> I-578 | Oct 21, 2011 |
| | >A> 5843946*PED | Jun 01, 2016 | | | >A> NCE | Jun 23, 2011 |
| | >A> 6037157 | Jun 26, 2016 | U-935 | | >A> PED | Jun 13, 2014 |
| | >A> 6037157*PED | Dec 26, 2016 | | | >A> PED | Jun 18, 2012 |
| | >A> 6248775 | Aug 13, 2014 | DS | | >A> PED | Apr 21, 2012 |
| | >A> 6248775*PED | Feb 13, 2015 | | | >A> PED | Dec 23, 2011 |
| | >A> 6335460 | Aug 25, 2012 | DS DP U-903 | | | |
| | >A> 6335460 | Aug 25, 2012 | DS DP U-935 | | | |
| | >A> 6335460 | Aug 25, 2012 | DS DP U-744 | | | |
| | >A> 6335460*PED | Feb 25, 2013 | | | | |
| | >A> 6703403 | Jun 26, 2016 | U-935 | | | |
| | >A> 6703403*PED | Dec 26, 2016 | | | | |
| | >A> 7470506 | Jun 23, 2019 | U-935 | | | |
| | >A> 7470506*PED | Dec 23, 2019 | | | | |
| | >A> 7700645 | Dec 26, 2026 | DS DP | | | |
| | >A> 7700645*PED | Jun 26, 2027 | | | | |

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|---|---|---|---|---|---|---|
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N021976 002 | **>A>** 5843946 | Dec 01, 2015 | DP U-903 | | **>A>** D-129 | Dec 13, 2013 |
| | **>A>** 5843946 | Dec 01, 2015 | DP U-935 | | **>A>** D-119 | Dec 18, 2011 |
| | **>A>** 5843946 | Dec 01, 2015 | DP U-744 | | **>A>** I-578 | Oct 21, 2011 |
| | **>A>** 5843946*PED | Jun 01, 2016 | | | **>A>** NCE | Jun 23, 2011 |
| | **>A>** 6037157 | Jun 26, 2016 | U-935 | | **>A>** PED | Jun 13, 2014 |
| | **>A>** 6037157*PED | Dec 26, 2016 | | | **>A>** PED | Jun 18, 2012 |
| | **>A>** 6248775 | Aug 13, 2014 | DS | | **>A>** PED | Apr 21, 2012 |
| | **>A>** 6248775*PED | Feb 13, 2015 | | | **>A>** PED | Dec 23, 2011 |
| | **>A>** 6335460 | Aug 25, 2012 | DS DP U-903 | | | |
| | **>A>** 6335460 | Aug 25, 2012 | DS DP U-935 | | | |
| | **>A>** 6335460 | Aug 25, 2012 | DS DP U-744 | | | |
| | **>A>** 6335460*PED | Feb 25, 2013 | | | | |
| | **>A>** 6703403 | Jun 26, 2016 | U-935 | | | |
| | **>A>** 6703403*PED | Dec 26, 2016 | | | | |
| | **>A>** 7470506 | Jun 23, 2019 | U-935 | | | |
| | **>A>** 7470506*PED | Dec 23, 2019 | | | | |
| | **>A>** 7700645 | Dec 26, 2026 | DS DP | | | |
| | **>A>** 7700645*PED | Jun 26, 2027 | | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N021976 003 | **>A>** 5843946 | Dec 01, 2015 | DP U-903 | | **>A>** D-129 | Dec 13, 2013 |
| | **>A>** 5843946 | Dec 01, 2015 | DP U-935 | | **>A>** D-119 | Dec 18, 2011 |
| | **>A>** 5843946 | Dec 01, 2015 | DP U-744 | | **>A>** D-118 | Oct 21, 2011 |
| | **>A>** 5843946*PED | Jun 01, 2016 | | | **>A>** I-578 | Oct 21, 2011 |
| | **>A>** 6037157 | Jun 26, 2016 | U-935 | | **>A>** NCE | Jun 23, 2011 |
| | **>A>** 6037157*PED | Dec 26, 2016 | | | **>A>** PED | Jun 13, 2014 |
| | **>A>** 6248775 | Aug 13, 2014 | DS | | **>A>** PED | Jun 18, 2012 |
| | **>A>** 6248775*PED | Feb 13, 2015 | | | **>A>** PED | Apr 21, 2012 |
| | **>A>** 6335460 | Aug 25, 2012 | DS DP U-935 | | **>A>** PED | Dec 23, 2011 |
| | **>A>** 6335460 | Aug 25, 2012 | DS DP U-903 | | | |
| | **>A>** 6335460*PED | Feb 25, 2013 | | | | |
| | **>A>** 6703403 | Jun 26, 2016 | U-935 | | | |
| | **>A>** 6703403*PED | Dec 26, 2016 | | | | |
| | **>A>** 7470506 | Jun 23, 2019 | U-935 | | | |
| | **>A>** 7470506*PED | Dec 23, 2019 | | | | |
| | **>A>** 7700645 | Dec 26, 2026 | DS DP | | | |
| | **>A>** 7700645*PED | Jun 26, 2027 | | | | |

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|---|---|---|---|---|---|---|
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N021976 004 | **>A>** 5843946 | Dec 01, 2015 | DP U-935 | | **>A>** D-129 | Dec 13, 2013 |
| | **>A>** 5843946*PED | Jun 01, 2016 | | | **>A>** D-119 | Dec 18, 2011 |
| | **>A>** 6037157 | Jun 26, 2016 | U-935 | | **>A>** NS | Dec 18, 2011 |
| | **>A>** 6037157*PED | Dec 26, 2016 | | | **>A>** NCE | Jun 23, 2011 |
| | **>A>** 6248775 | Aug 13, 2014 | DS | | **>A>** PED | Jun 13, 2014 |
| | **>A>** 6248775*PED | Feb 13, 2015 | | | **>A>** PED | Jun 18, 2012 |
| | **>A>** 6335460 | Aug 25, 2012 | DS DP U-935 | | **>A>** PED | Dec 23, 2011 |
| | **>A>** 6335460*PED | Feb 25, 2013 | | | | |
| | **>A>** 6703403 | Jun 26, 2016 | U-935 | | | |
| | **>A>** 6703403*PED | Dec 26, 2016 | | | | |
| | **>A>** 7470506 | Jun 23, 2019 | U-935 | | | |
| | **>A>** 7470506*PED | Dec 23, 2019 | | | | |
| | **>A>** 7700645 | Dec 26, 2026 | DS DP | | | |
| | **>A>** 7700645*PED | Jun 26, 2027 | | | | |
| DARUNAVIR ETHANOLATE - PREZISTA | | | | | | |
| N021976 005 | **>A>** 5843946 | Dec 01, 2015 | DP U-935 | | **>A>** D-129 | Dec 13, 2013 |
| | **>A>** 5843946*PED | Jun 01, 2016 | | | **>A>** D-119 | Dec 18, 2011 |
| | **>A>** 6037157 | Jun 26, 2016 | U-935 | | **>A>** NS | Dec 18, 2011 |
| | **>A>** 6037157*PED | Dec 26, 2016 | | | **>A>** NCE | Jun 23, 2011 |
| | **>A>** 6248775 | Aug 13, 2014 | DS | | **>A>** PED | Jun 13, 2014 |
| | **>A>** 6248775*PED | Feb 13, 2015 | | | **>A>** PED | Jun 18, 2012 |
| | **>A>** 6335460 | Aug 25, 2012 | DS DP U-935 | | **>A>** PED | Dec 23, 2011 |
| | **>A>** 6335460*PED | Feb 25, 2013 | | | | |
| | **>A>** 6703403 | Jun 26, 2016 | U-935 | | | |
| | **>A>** 6703403*PED | Dec 26, 2016 | | | | |
| | **>A>** 7470506 | Jun 23, 2019 | U-935 | | | |
| | **>A>** 7470506*PED | Dec 23, 2019 | | | | |
| | **>A>** 7700645 | Dec 26, 2026 | DS DP | | | |
| | **>A>** 7700645*PED | Jun 26, 2027 | | | | |
| DESIRUDIN RECOMBINANT - IPRIVASK | | | | | | |
| N021271 001 | 6103515 | Aug 15, 2017 | DS | | | |
| DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR | | | | | | |
| N021802 007 | **>A>** 5837284 | Dec 04, 2015 | DP | | **>A>** D-121 | Oct 23, 2012 |
| | **>A>** 5908850 | Dec 04, 2015 | DP U-678 | | **>A>** M-80 | Oct 17, 2011 |
| | **>A>** 6228398 | Nov 01, 2019 | DP U-676 | | | |
| | **>A>** 6355656 | Dec 04, 2015 | DP | | | |
| | **>A>** 6528530 | Dec 04, 2015 | DP | | | |
| | **>A>** 6635284 | Dec 04, 2015 | DP U-677 | | | |
| | **>A>** 6730325 | Nov 01, 2019 | DP U-676 | | | |
| | **>A>** 7431944 | Dec 04, 2015 | DP | | | |

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|---|---|---|---|---|---|---|
| DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR | | | | | | |
| N021802 008 | **>A>** 5837284 | Dec 04, 2015 | DP | | **>A>** D-121 | Oct 23, 2012 |
| | **>A>** 5908850 | Dec 04, 2015 | DP U-678 | | **>A>** M-80 | Oct 17, 2011 |
| | **>A>** 6228398 | Nov 01, 2019 | DP U-676 | | | |
| | **>A>** 6355656 | Dec 04, 2015 | DP | | | |
| | **>A>** 6528530 | Dec 04, 2015 | DP | | | |
| | **>A>** 6635284 | Dec 04, 2015 | DP U-677 | | | |
| | **>A>** 6730325 | Nov 01, 2019 | DP U-676 | | | |
| | **>A>** 7431944 | Dec 04, 2015 | DP | | | |
| DICLOFENAC POTASSIUM - ZIPSOR | | | | | | |
| N022202 001 | 7884095 | Feb 24, 2029 | U-1111 | | | |
| | **>A>** 7939518 | Feb 24, 2029 | U-980 | | | |
| DICLOFENAC SODIUM - SOLARAZE | | | | | | |
| N021005 001 | 5929048 | Jun 17, 2014 | U-402 | | | |
| | 5985850 | Aug 11, 2015 | DP | | | |
| DIENOGEST; ESTRADIOL VALERATE - NATAZIA | | | | | | |
| N022252 001 | 6133251 | Oct 25, 2016 | DP U-828 | Y | | |
| | 6133251 | Oct 25, 2016 | DP U-112 | Y | | |
| | 6133251 | Oct 25, 2016 | DP U-1 | Y | | |
| | 6884793 | Oct 25, 2016 | DP | Y | | |
| DORIPENEM - DORIBAX | | | | | | |
| N022106 001 | 5317016 | Jun 05, 2015 | DS DP U-282 | | | |
| DORIPENEM - DORIBAX | | | | | | |
| N022106 002 | 5317016 | Jun 05, 2015 | DS DP U-282 | | | |
| DOXEPIN HYDROCHLORIDE - SILENOR | | | | | | |
| N022036 001 | 7915307 | Aug 24, 2027 | U-620 | | | |
| DOXEPIN HYDROCHLORIDE - SILENOR | | | | | | |
| N022036 002 | 7915307 | Aug 24, 2027 | U-620 | | | |
| DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - SAFYRAL | | | | | | |
| N022574 001 | 5798338 | Jul 10, 2015 | DP | | | |
| | 6441168 | Apr 17, 2020 | DS | | | |
| | 6958326 | Dec 20, 2021 | DP | | | |
| | 7163931 | Mar 03, 2022 | U-1 | | | |
| ELTROMBOPAG OLAMINE - PROMACTA | | | | | | |
| N022291 001 | 7547719 | Jul 13, 2025 | DS DP U-930 | | | |
| ELTROMBOPAG OLAMINE - PROMACTA | | | | | | |
| N022291 002 | 7547719 | Jul 13, 2025 | DS DP U-930 | | | |
| ELTROMBOPAG OLAMINE - PROMACTA | | | | | | |
| N022291 003 | 7547719 | Jul 13, 2025 | DS DP U-930 | | | |
| ESOMEPRAZOLE MAGNESIUM - NEXIUM | | | | | | |
| N021957 001 | | | | | **>A>** NPP | Feb 27, 2011 |
| | | | | | **>A>** PED | Aug 27, 2011 |
| ESOMEPRAZOLE MAGNESIUM - NEXIUM | | | | | | |
| N021957 002 | | | | | **>A>** NPP | Feb 27, 2011 |
| | | | | | **>A>** PED | Aug 27, 2011 |

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|---|---|---|---|---|---|---|
| ESOMEPRAZOLE MAGNESIUM - NEXIUM | | | | | | |
| N022101 001 | | | | | **>A>** M-86 | Jun 18, 2012 |
| | | | | | **>A>** PED | Dec 18, 2012 |
| ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO | | | | | | |
| N022511 001 | 5714504 | Feb 03, 2015 | DP U-1053 | | | |
| | 5714504*PED | Aug 03, 2015 | | | | |
| | 5900424 | May 04, 2016 | DS U-1053 | | | |
| | 5900424*PED | Nov 04, 2016 | | | | |
| | 6369085 | May 25, 2018 | DS DP U-1053 | | | |
| | 6369085*PED | Nov 25, 2018 | | | | |
| | 6875872 | May 27, 2014 | DS | | | |
| | 6875872*PED | Nov 27, 2014 | | | | |
| | 7411070 | May 25, 2018 | DS U-1053 | | | |
| | 7411070*PED | Nov 25, 2018 | | | | |
| ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO | | | | | | |
| N022511 002 | 5714504 | Feb 03, 2015 | DP U-1053 | | | |
| | 5714504*PED | Aug 03, 2015 | | | | |
| | 5900424 | May 04, 2016 | DS U-1053 | | | |
| | 5900424*PED | Nov 04, 2016 | | | | |
| | 6369085 | May 25, 2018 | DS DP U-1053 | | | |
| | 6369085*PED | Nov 25, 2018 | | | | |
| | 6875872 | May 27, 2014 | DS | | | |
| | 6875872*PED | Nov 27, 2014 | | | | |
| | 7411070 | May 25, 2018 | DS U-1053 | | | |
| | 7411070*PED | Nov 25, 2018 | | | | |
| ETHINYL ESTRADIOL; LEVONORGESTREL - LOSEASONIQUE | | | | | | |
| N022262 001 | 7855190 | Dec 05, 2028 | U-1 | | | |
| | 7858605 | Jun 23, 2023 | DP | | | |
| ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE | | | | | | |
| N021840 001 | 7855190 | Dec 05, 2028 | U-1 | | | |
| | 7858605 | Jun 23, 2023 | DP | | | |
| ETHINYL ESTRADIOL; NORETHINDRONE - NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE | | | | | | |
| N022573 001 | 5552394 | Jul 22, 2014 | U-828 | | | |
| | 6667050 | Apr 06, 2019 | DP U-828 | | | |
| ETRAVIRINE - INTELENCE | | | | | | |
| N022187 001 | 7887845 | Mar 25, 2019 | DP | | | |
| ETRAVIRINE - INTELENCE | | | | | | |
| N022187 002 | 6878717 | Nov 05, 2019 | U-1016 | | NCE | Jan 18, 2013 |
| | 7037917 | Nov 05, 2019 | DS DP U-1016 | | | |
| | 7887845 | Mar 25, 2019 | DP | | | |
| EVEROLIMUS - AFINITOR | | | | | | |
| N022334 001 | | | | | **>A>** I-638 | May 05, 2014 |
| | | | | | ODE | Oct 29, 2017 |
| EVEROLIMUS - AFINITOR | | | | | | |
| N022334 002 | | | | | **>A>** I-638 | May 05, 2014 |
| | | | | | ODE | Oct 29, 2017 |

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|---|---|---|---|---|---|---|
| EVEROLIMUS - AFINITOR | | | | | | |
| N022334 003 | | | | | >A> I-638 | May 05, 2014 |
| | | | | | NCE | Mar 30, 2014 |
| | | | | | ODE | Oct 29, 2017 |
| EXENATIDE SYNTHETIC - BYETTA | | | | | | |
| N021773 001 | 5424286 | Dec 01, 2016 | U-653 | | | |
| | 5424286 | Dec 01, 2016 | U-1108 | | | |
| EXENATIDE SYNTHETIC - BYETTA | | | | | | |
| N021773 002 | 5424286 | Dec 01, 2016 | U-653 | | | |
| | 5424286 | Dec 01, 2016 | U-1108 | | | |
| FAMCICLOVIR - FAMVIR | | | | | | |
| N020363 001 | | | | | M-98 | Jan 31, 2014 |
| FAMCICLOVIR - FAMVIR | | | | | | |
| N020363 002 | | | | | M-98 | Jan 31, 2014 |
| FAMCICLOVIR - FAMVIR | | | | | | |
| N020363 003 | | | | | M-98 | Jan 31, 2014 |
| FAMOTIDINE; IBUPROFEN - DUEXIS | | | | | | |
| N022519 001 | | | | | NC | Apr 23, 2014 |
| FENOFIBRATE - ANTARA (MICRONIZED) | | | | | | |
| N021695 001 | 7863331 | Aug 08, 2020 | U-1107 | | | |
| | 7863331 | Aug 08, 2020 | U-1106 | | | |
| FENOFIBRATE - ANTARA (MICRONIZED) | | | | | | |
| N021695 003 | 7863331 | Aug 08, 2020 | U-1107 | | | |
| | 7863331 | Aug 08, 2020 | U-1106 | | | |
| FENOFIBRIC ACID - FIBRICOR | | | | | | |
| N022418 001 | 7915247 | Aug 20, 2027 | U-1061 | | | |
| | 7915247 | Aug 20, 2027 | U-1059 | | | |
| | 7915247 | Aug 20, 2027 | U-1000 | | | |
| FENOFIBRIC ACID - FIBRICOR | | | | | | |
| N022418 002 | 7915247 | Aug 20, 2027 | U-1061 | | | |
| | 7915247 | Aug 20, 2027 | U-1059 | | | |
| | 7915247 | Aug 20, 2027 | U-1000 | | | |
| FENTANYL CITRATE - ABSTRAL | | | | | | |
| N022510 001 | 6759059 | Sep 24, 2019 | DP U-767 | | | |
| | 6761910 | Sep 24, 2019 | DP U-767 | | | |
| | 7910132 | Sep 24, 2019 | DP U-767 | | | |
| FENTANYL CITRATE - ABSTRAL | | | | | | |
| N022510 002 | 6759059 | Sep 24, 2019 | DP U-767 | | | |
| | 6761910 | Sep 24, 2019 | DP U-767 | | | |
| | 7910132 | Sep 24, 2019 | DP U-767 | | | |
| FENTANYL CITRATE - ABSTRAL | | | | | | |
| N022510 003 | 6759059 | Sep 24, 2019 | DP U-767 | | | |
| | 6761910 | Sep 24, 2019 | DP U-767 | | | |
| | 7910132 | Sep 24, 2019 | DP U-767 | | | |

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|---|---|---|---|---|---|---|---|
| FENTANYL CITRATE - ABSTRAL | | | | | | | |
| N022510 004 | | 6759059 | Sep 24, 2019 | DP U-767 | | | |
| | | 6761910 | Sep 24, 2019 | DP U-767 | | | |
| | | 7910132 | Sep 24, 2019 | DP U-767 | | | |
| FENTANYL CITRATE - ABSTRAL | | | | | | | |
| N022510 005 | | 6759059 | Sep 24, 2019 | DP U-767 | | | |
| | | 6761910 | Sep 24, 2019 | DP U-767 | | | |
| | | 7910132 | Sep 24, 2019 | DP U-767 | | | |
| FENTANYL CITRATE - ABSTRAL | | | | | | | |
| N022510 006 | | 6759059 | Sep 24, 2019 | DP U-767 | | | |
| | | 6761910 | Sep 24, 2019 | DP U-767 | | | |
| | | 7910132 | Sep 24, 2019 | DP U-767 | | | |
| FENTANYL CITRATE - FENTORA | | | | | | | |
| N021947 001 | | 7862832 | Jun 15, 2028 | DP | | | |
| | | 7862833 | Jun 15, 2028 | DP | | | |
| FENTANYL CITRATE - FENTORA | | | | | | | |
| N021947 002 | | 7862832 | Jun 15, 2028 | DP | | | |
| | | 7862833 | Jun 15, 2028 | DP | | | |
| FENTANYL CITRATE - FENTORA | | | | | | | |
| N021947 003 | | 7862832 | Jun 15, 2028 | DP | | | |
| | | 7862833 | Jun 15, 2028 | DP | | | |
| FENTANYL CITRATE - FENTORA | | | | | | | |
| N021947 004 | | 7862832 | Jun 15, 2028 | DP | | | |
| | | 7862833 | Jun 15, 2028 | DP | | | |
| FERUMOXYTOL - FERAHEME | | | | | | | |
| N022180 001 | | 7871597 | Mar 08, 2020 | DS DP | | | |
| FESOTERODINE FUMARATE - TOVIAZ | | | | | | | |
| N022030 001 | >A> | 7384980 | May 11, 2019 | DS DP U-913 | | | |
| | | 7855230 | May 11, 2019 | U-913 | | | |
| FESOTERODINE FUMARATE - TOVIAZ | | | | | | | |
| N022030 002 | >A> | 7384980 | May 11, 2019 | DS DP U-913 | | | |
| | | 7855230 | May 11, 2019 | U-913 | | | |
| FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE | | | | | | | |
| A079043 001 | | | | | | PC | Jul 27, 2011 |
| FIDAXOMICIN - DIFICID | | | | | | | |
| N201699 001 | | | | | | >A> NCE | May 27, 2016 |
| FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN - TRI-LUMA | | | | | | | |
| N021112 001 | | 7915243 | Mar 22, 2026 | DP | | | |
| | >A> | 7939516 | May 04, 2025 | DP | | | |
| FULVESTRANT - FASLODEX | | | | | | | |
| N021344 001 | | 6774122 | Jan 09, 2021 | U-596 | | D-126 | Sep 09, 2013 |
| | | 6774122*PED | Jul 09, 2021 | | | >A> M-103 | May 17, 2014 |
| | | 7456160 | Jan 09, 2021 | U-596 | | >A> PED | Nov 17, 2014 |
| | | 7456160*PED | Jul 09, 2021 | | | PED | Mar 09, 2014 |

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|---|---|---|---|---|---|---|
| GABAPENTIN - GABAPENTIN | | | | | | |
| A078974 001 | | | | | PC | Aug 22, 2011 |
| GABAPENTIN - GRALISE | | | | | | |
| N022544 001 | 6340475 | Sep 19, 2016 | DP | | NP | Jan 28, 2014 |
| | 6488962 | Jun 20, 2020 | DP | | | |
| | 6635280 | Sep 19, 2016 | DP | | | |
| | 6723340 | Oct 25, 2021 | DP | | | |
| | 7438927 | Feb 26, 2024 | U-1114 | | | |
| | 7731989 | Oct 25, 2022 | DP | | | |
| GABAPENTIN - GRALISE | | | | | | |
| N022544 002 | 6340475 | Sep 19, 2016 | DP | | NP | Jan 28, 2014 |
| | 6488962 | Jun 20, 2020 | DP | | | |
| | 6635280 | Sep 19, 2016 | DP | | | |
| | 6723340 | Oct 25, 2021 | DP | | | |
| | 7438927 | Feb 26, 2024 | U-1114 | | | |
| | 7731989 | Oct 25, 2022 | DP | | | |
| GABAPENTIN ENACARBIL - HORIZANT | | | | | | |
| N022399 001 | 6818787 | Nov 06, 2022 | DS DP | | NCE | Apr 06, 2016 |
| GADOBUTROL - GADAVIST | | | | | | |
| N201277 001 | 5980864 | Nov 09, 2016 | DS DP U-1119 | | NCE | Mar 14, 2016 |
| GADOBUTROL - GADAVIST | | | | | | |
| N201277 002 | 5980864 | Nov 09, 2016 | DS DP U-1119 | | NCE | Mar 14, 2016 |
| GADOBUTROL - GADAVIST | | | | | | |
| N201277 003 | 5980864 | Nov 09, 2016 | DS DP U-1119 | | NCE | Mar 14, 2016 |
| GADOBUTROL - GADAVIST | | | | | | |
| N201277 004 | 5980864 | Nov 09, 2016 | DS DP U-1119 | | NCE | Mar 14, 2016 |
| GADOBUTROL - GADAVIST | | | | | | |
| N201277 005 | 5980864 | Nov 09, 2016 | DS DP U-1119 | | NCE | Mar 14, 2016 |
| GADOFOSVESET TRISODIUM - ABLAVAR | | | | | | |
| N021711 001 | 5362475 | Nov 08, 2011 | DS | | | |
| | 6676929 | May 26, 2015 | DP | | | |
| | 7011815 | Feb 01, 2015 | U-1112 | | | |
| | 7060250 | May 26, 2015 | DS | | | |
| | 7229606 | May 26, 2015 | U-1112 | | | |
| GADOFOSVESET TRISODIUM - ABLAVAR | | | | | | |
| N021711 002 | 5362475 | Nov 08, 2011 | DS | | | |
| | 6676929 | May 26, 2015 | DP | | | |
| | 7011815 | Feb 01, 2015 | U-1112 | | | |
| | 7060250 | May 26, 2015 | DS | | | |
| | 7229606 | May 26, 2015 | U-1112 | | | |
| GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE | | | | | | |
| A077983 001 | | | | | PC | Jul 24, 2011 |
| GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE | | | | | | |
| A077983 002 | | | | | PC | Jul 24, 2011 |

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|---|---|---|---|---|---|---|
| GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE | | | | | | |
| A079183 001 | | | | | PC | May 14, 2011 |
| GRANISETRON HYDROCHLORIDE - KYTRIL | | | | | | |
| N020239 001 | | | | | M-102 | Apr 29, 2014 |
| GRANISETRON HYDROCHLORIDE - KYTRIL | | | | | | |
| N020239 002 | | | | | M-102 | Apr 29, 2014 |
| GRANISETRON HYDROCHLORIDE - KYTRIL | | | | | | |
| N020239 003 | | | | | M-102 | Apr 29, 2014 |
| GRANISETRON HYDROCHLORIDE - KYTRIL | | | | | | |
| N020239 004 | | | | | M-102 | Apr 29, 2014 |
| GUANFACINE HYDROCHLORIDE - INTUNIV | | | | | | |
| N022037 001 | | | | | I-635 | Feb 25, 2014 |
| GUANFACINE HYDROCHLORIDE - INTUNIV | | | | | | |
| N022037 002 | | | | | I-635 | Feb 25, 2014 |
| GUANFACINE HYDROCHLORIDE - INTUNIV | | | | | | |
| N022037 003 | | | | | I-635 | Feb 25, 2014 |
| GUANFACINE HYDROCHLORIDE - INTUNIV | | | | | | |
| N022037 004 | | | | | I-635 | Feb 25, 2014 |
| HYDROXOCOBALAMIN - CYANOKIT | | | | | | |
| N022041 001 | 5834448 | Nov 14, 2016 | DP | | ODE | Dec 15, 2013 |
| HYDROXYPROGESTERONE CAPROATE - MAKENA | | | | | | |
| N021945 001 | | | | | ODE | Feb 03, 2018 |
| IBUPROFEN LYSINE - NEOPROFEN | | | | | | |
| N021903 001 | **>A>** 6342530 | Nov 14, 2020 | DP U-794 | | | |
| | **>A>** 6342530 | Nov 14, 2020 | DP U-1127 | | | |
| | **>A>** 6344479 | Mar 20, 2021 | DS DP U-794 | Y | | |
| IMIQUIMOD - ZYCLARA | | | | | | |
| N022483 001 | | | | | I-636 | Mar 24, 2014 |
| INDIUM IN-111 PENTETREOTIDE KIT - OCTREOSCAN | | | | | | |
| N020314 001 | **>A>** 5384113 | Jan 24, 2012 | DP | | | |
| | **>A>** 5753627 | May 19, 2015 | U-1125 | | | |
| | **>A>** 5776894 | Jul 07, 2015 | DS DP | | | |
| INSULIN GLARGINE RECOMBINANT - LANTUS | | | | | | |
| N021081 001 | 7918833 | Sep 23, 2027 | DP | | | |
| | 7918833*PED | Mar 23, 2028 | | | | |
| INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR | | | | | | |
| N021629 003 | 7918833 | Sep 23, 2027 | DP | | | |
| INSULIN RECOMBINANT HUMAN - HUMULIN R | | | | | | |
| N018780 001 | | | | | NR | Mar 25, 2014 |
| INSULIN RECOMBINANT HUMAN - HUMULIN R PEN | | | | | | |
| N018780 005 | | | | | NR | Mar 25, 2014 |
| IOFLUPANE I-123 - DATSCAN | | | | | | |
| N022454 001 | | | | | NCE | Jan 14, 2016 |

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|---|---|---|---|---|---|---|
| IXABEPILONE - IXEMPRA KIT | | | | | | |
| N022065 001 | 6670384 | Jan 23, 2022 | DP U-960 | | NCE | Oct 16, 2012 |
| | 6670384 | Jan 23, 2022 | DP U-959 | | PED | Apr 16, 2013 |
| | 6670384*PED | Jul 23, 2022 | | | | |
| | 7022330 | Jan 23, 2022 | DP U-958 | | | |
| | 7022330*PED | Jul 23, 2022 | | | | |
| | 7125899 | May 26, 2018 | DS DP U-957 | | | |
| | 7125899*PED | Nov 26, 2018 | | | | |
| | 7312237 | Aug 21, 2024 | U-965 | | | |
| | 7312237*PED | Feb 21, 2025 | | | | |
| | RE41393 | Feb 08, 2022 | U-961 | | | |
| | RE41393*PED | Aug 08, 2022 | | | | |
| | RE41911 | May 26, 2018 | DS DP U-961 | | | |
| | RE41911*PED | Nov 26, 2018 | | | | |
| IXABEPILONE - IXEMPRA KIT | | | | | | |
| N022065 002 | 6670384 | Jan 23, 2022 | DP U-960 | | NCE | Oct 16, 2012 |
| | 6670384 | Jan 23, 2022 | DP U-959 | | PED | Apr 16, 2013 |
| | 6670384*PED | Jul 23, 2022 | | | | |
| | 7022330 | Jan 23, 2022 | DP U-958 | | | |
| | 7022330*PED | Jul 23, 2022 | | | | |
| | 7125899 | May 26, 2018 | DS DP U-957 | | | |
| | 7125899*PED | Nov 26, 2018 | | | | |
| | 7312237 | Aug 21, 2024 | U-965 | | | |
| | 7312237*PED | Feb 21, 2025 | | | | |
| | RE41393 | Feb 08, 2022 | U-961 | | | |
| | RE41393*PED | Aug 08, 2022 | | | | |
| | RE41911 | May 26, 2018 | DS DP U-961 | | | |
| | RE41911*PED | Nov 26, 2018 | | | | |
| LAMOTRIGINE - LAMICTAL ODT | | | | | | |
| N022251 001 | 7919115 | Jan 04, 2029 | DS DP | | | |
| LAMOTRIGINE - LAMICTAL ODT | | | | | | |
| N022251 002 | 7919115 | Jan 04, 2029 | DS DP | | | |
| LAMOTRIGINE - LAMICTAL ODT | | | | | | |
| N022251 003 | 7919115 | Jan 04, 2029 | DS DP | | | |
| LAMOTRIGINE - LAMICTAL ODT | | | | | | |
| N022251 004 | 7919115 | Jan 04, 2029 | DS DP | | | |
| LANREOTIDE ACETATE - SOMATULINE DEPOT | | | | | | |
| N022074 001 | 5595760 | Mar 08, 2020 | DP U-831 | | D-131 | Mar 04, 2014 |
| LANREOTIDE ACETATE - SOMATULINE DEPOT | | | | | | |
| N022074 002 | 5595760 | Mar 08, 2020 | DP U-831 | | D-131 | Mar 04, 2014 |
| LANREOTIDE ACETATE - SOMATULINE DEPOT | | | | | | |
| N022074 003 | 5595760 | Mar 08, 2020 | DP U-831 | | D-131 | Mar 04, 2014 |
| LANSOPRAZOLE - PREVACID | | | | | | |
| N021428 001 | 7875292 | May 17, 2019 | DP | | | |
| | 7875292*PED | Nov 17, 2019 | | | | |

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|---|---|---|---|---|---|---|
| LANSOPRAZOLE - PREVACID | | | | | | |
| N021428 002 | 7875292 | May 17, 2019 | DP | | | |
| | 7875292*PED | Nov 17, 2019 | | | | |
| LENALIDOMIDE - REVLIMID | | | | | | |
| N021880 001 | 7855217 | Nov 24, 2024 | DS DP | | | |
| LENALIDOMIDE - REVLIMID | | | | | | |
| N021880 002 | 7855217 | Nov 24, 2024 | DS DP | | | |
| LENALIDOMIDE - REVLIMID | | | | | | |
| N021880 004 | 7855217 | Nov 24, 2024 | DS DP | | | |
| LEVOLEUCOVORIN CALCIUM - FUSILEV | | | | | | |
| N020140 001 | | | | | **>A>** I-637 | Apr 29, 2014 |
| LEVOLEUCOVORIN CALCIUM - FUSILEV | | | | | | |
| N020140 002 | 6500829 | Dec 31, 2019 | DS DP | | **>A>** I-637 | Apr 29, 2014 |
| | | | | | ODE | Mar 07, 2015 |
| LEVOLEUCOVORIN CALCIUM - FUSILEV | | | | | | |
| N020140 003 | 6500829 | Dec 31, 2019 | DS DP | | **>A>** I-637 | Apr 29, 2014 |
| | | | | | ODE | Mar 07, 2015 |
| LINAGLIPTIN - TRADJENTA | | | | | | |
| N201280 001 | **>A>** 6303661 | Apr 24, 2017 | U-774 | | **>A>** NCE | May 20, 2016 |
| | **>A>** 6890898 | Feb 02, 2019 | U-493 | | | |
| | **>A>** 7078381 | Feb 02, 2019 | U-493 | | | |
| | **>A>** 7407955 | Aug 12, 2023 | DS DP | | | |
| | **>A>** 7459428 | Feb 02, 2019 | U-493 | | | |
| LOTEPREDNOL ETABONATE - LOTEMAX | | | | | | |
| N200738 001 | | | | | NDF | Apr 15, 2014 |
| | | | | | PED | Oct 15, 2014 |
| LOVASTATIN; NIACIN - ADVICOR | | | | | | |
| N021249 001 | **>A>** 6080428 | May 27, 2017 | U-1133 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-447 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1133 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1134 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-448 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-768 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1131 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1130 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1132 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1133 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1134 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-548 | | | |
| | **>A>** 6746691 | Sep 20, 2013 | DP U-586 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-712 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1135 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1136 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1137 | | | |

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| LOVASTATIN; NIACIN - ADVICOR | | | | | | |
| N021249 002 | **>A>** 6080428 | May 27, 2017 | U-1133 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-447 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1133 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1134 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-448 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-768 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1131 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1130 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1132 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1133 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1134 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-548 | | | |
| | **>A>** 6746691 | Sep 20, 2013 | DP U-586 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-712 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1135 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1136 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1137 | | | |
| LOVASTATIN; NIACIN - ADVICOR | | | | | | |
| N021249 003 | **>A>** 6080428 | May 27, 2017 | U-1133 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-447 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1133 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1134 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-448 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-768 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1131 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1130 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1132 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1133 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1134 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-548 | | | |
| | **>A>** 6746691 | Sep 20, 2013 | DP U-586 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-712 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1135 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1136 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1137 | | | |

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| LOVASTATIN; NIACIN - ADVICOR | | | | | | |
| N021249 004 | **>A>** 6080428 | May 27, 2017 | U-1133 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-447 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1133 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1134 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-448 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-768 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1131 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1130 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1132 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1133 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1134 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-548 | | | |
| | **>A>** 6746691 | Sep 20, 2013 | DP U-586 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-712 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1135 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1136 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1137 | | | |
| METFORMIN HYDROCHLORIDE - FORTAMET | | | | | | |
| N021574 001 | 7919116 | Mar 20, 2018 | DP | | | |
| METFORMIN HYDROCHLORIDE - FORTAMET | | | | | | |
| N021574 002 | 7919116 | Mar 20, 2018 | DP | | | |
| METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE - ACTOPLUS MET XR | | | | | | |
| N022024 001 | 7919116 | Mar 20, 2018 | U-973 | | | |
| | 7919116 | Mar 20, 2018 | U-1120 | | | |
| METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE - ACTOPLUS MET XR | | | | | | |
| N022024 002 | 7919116 | Mar 20, 2018 | U-973 | | | |
| | 7919116 | Mar 20, 2018 | U-1120 | | | |
| METRONIDAZOLE - VANDAZOLE | | | | | | |
| N021806 001 | 7456207 | Sep 22, 2024 | DP | | | |
| MILNACIPRAN HYDROCHLORIDE - SAVELLA | | | | | | |
| N022256 001 | 7888342 | Nov 05, 2021 | U-882 | | | |
| MILNACIPRAN HYDROCHLORIDE - SAVELLA | | | | | | |
| N022256 002 | 7888342 | Nov 05, 2021 | U-882 | | | |
| MILNACIPRAN HYDROCHLORIDE - SAVELLA | | | | | | |
| N022256 003 | 7888342 | Nov 05, 2021 | U-882 | | | |
| MILNACIPRAN HYDROCHLORIDE - SAVELLA | | | | | | |
| N022256 004 | 7888342 | Nov 05, 2021 | U-882 | | | |
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 001 | 7919483 | Feb 28, 2027 | U-1078 | | | |
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 002 | 7919483 | Feb 28, 2027 | U-1078 | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|---|---|---|---|---|---|
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 003 | 7919483 | Feb 28, 2027 | U-1078 | | | |
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 004 | 7919483 | Feb 28, 2027 | U-1078 | | | |
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 005 | 7919483 | Feb 28, 2027 | U-1078 | | | |
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 006 | 7919483 | Feb 28, 2027 | U-1078 | | | |
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 007 | 7919483 | Feb 28, 2027 | U-1078 | | | |
| MINOCYCLINE HYDROCHLORIDE - SOLODYN | | | | | | |
| N050808 008 | 7919483 | Feb 28, 2027 | U-1078 | | | |
| MOMETASONE FUROATE MONOHYDRATE - NASONEX | | | | | | |
| N020762 001 | | | | | M-99 | Jan 19, 2014 |
| MOXIFLOXACIN HYDROCHLORIDE - MOXEZA | | | | | | |
| N022428 001 | 7671070*PED | Mar 29, 2020 | | | | |
| MUPIROCIN CALCIUM - BACTROBAN | | | | | | |
| N050746 001 | 6025389 | Oct 20, 2014 | DP U-1122 | | | |
| NALTREXONE - VIVITROL | | | | | | |
| N021897 001 | **>A>** 7919499 | Oct 15, 2029 | U-1124 | | | |
| | **>A>** 7919499 | Oct 15, 2029 | U-1123 | | | |
| NEVIRAPINE - VIRAMUNE XR | | | | | | |
| N201152 001 | 5366972 | Nov 22, 2011 | DS DP U-167 | | NDF | Mar 25, 2014 |
| | 5366972*PED | May 22, 2012 | | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
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| NIACIN - NIASPAN | | | | | | |
| N020381 002 | >A> 6080428 | May 27, 2017 | U-1139 | | | |
| | >A> 6080428 | May 27, 2017 | U-1140 | | | |
| | >A> 6080428 | May 27, 2017 | U-1141 | | | |
| | >A> 6080428 | May 27, 2017 | U-331 | | | |
| | >A> 6080428 | May 27, 2017 | U-1138 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1138 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1139 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1140 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1141 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-354 | | | |
| | >A> 6406715 | Sep 20, 2013 | DP U-450 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1145 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1142 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1144 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-768 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1143 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1138 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1139 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1140 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1146 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-548 | | | |
| | >A> 6746691 | Sep 20, 2013 | DP U-586 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-712 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1140 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1141 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1147 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1148 | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
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| | >A> 6080428 | May 27, 2017 | U-1141 | | | |
| | >A> 6080428 | May 27, 2017 | U-331 | | | |
| | >A> 6080428 | May 27, 2017 | U-1138 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1138 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1139 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1140 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-1141 | | | |
| | >A> 6129930 | Sep 20, 2013 | DP U-354 | | | |
| | >A> 6406715 | Sep 20, 2013 | DP U-450 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1145 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1142 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1144 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-768 | | | |
| | >A> 6469035 | Mar 15, 2018 | U-1143 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1138 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1139 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1140 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1141 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-1146 | | | |
| | >A> 6676967 | Sep 20, 2013 | U-548 | | | |
| | >A> 6746691 | Sep 20, 2013 | DP U-586 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-712 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1140 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1141 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1147 | | | |
| | >A> 7011848 | Sep 20, 2013 | U-1148 | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
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| | **>A>** 6080428 | May 27, 2017 | U-331 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1138 | | | |
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| | **>A>** 6129930 | Sep 20, 2013 | DP U-1140 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1141 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-354 | | | |
| | **>A>** 6406715 | Sep 20, 2013 | DP U-450 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1145 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1142 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1144 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-768 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1143 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1138 | | | |
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| | **>A>** 6676967 | Sep 20, 2013 | U-1141 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1146 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-548 | | | |
| | **>A>** 6746691 | Sep 20, 2013 | DP U-586 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-712 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1140 | | | |
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| | **>A>** 7011848 | Sep 20, 2013 | U-1147 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1148 | | | |
| NIACIN; SIMVASTATIN - SIMCOR | | | | | | |
| N022078 001 | **>A>** 6080428 | May 27, 2017 | U-862 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
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| | **>A>** 6129930 | Sep 20, 2013 | DP U-862 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1134 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1132 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-863 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1149 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-862 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1134 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1132 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-862 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1151 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1150 | | | |

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| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1132 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-862 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1134 | | | |
| | **>A>** 6129930 | Sep 20, 2013 | DP U-1132 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-863 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1149 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-862 | | | |
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| | **>A>** 6676967 | Sep 20, 2013 | U-1132 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-862 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1151 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1150 | | | |
| NIACIN; SIMVASTATIN - SIMCOR | | | | | | |
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| | **>A>** 6129930 | Sep 20, 2013 | DP U-1134 | | | |
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| | **>A>** 6469035 | Mar 15, 2018 | U-863 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1149 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-862 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1134 | | | |
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| | **>A>** 7011848 | Sep 20, 2013 | U-1151 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1150 | | | |
| NIACIN; SIMVASTATIN - SIMCOR | | | | | | |
| N022078 004 | **>A>** 6080428 | May 27, 2017 | U-862 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1132 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-863 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1149 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-862 | | | |
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| | **>A>** 7011848 | Sep 20, 2013 | U-1150 | | | |

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| NIACIN; SIMVASTATIN - SIMCOR | | | | | | |
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| | **>A>** 6080428 | May 27, 2017 | U-1134 | | | |
| | **>A>** 6080428 | May 27, 2017 | U-1132 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-863 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1149 | | | |
| | **>A>** 6469035 | Mar 15, 2018 | U-1129 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-862 | | | |
| | **>A>** 6676967 | Sep 20, 2013 | U-1134 | | | |
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| | **>A>** 7011848 | Sep 20, 2013 | U-862 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1151 | | | |
| | **>A>** 7011848 | Sep 20, 2013 | U-1150 | | | |
| OLANZAPINE - ZYPREXA ZYDIS | | | | | | |
| N021086 001 | | | | | **>A>** NPP | Dec 04, 2012 |
| | | | | | **>A>** PED | Jun 04, 2013 |
| OLANZAPINE - ZYPREXA ZYDIS | | | | | | |
| N021086 002 | | | | | **>A>** NPP | Dec 04, 2012 |
| | | | | | **>A>** PED | Jun 04, 2013 |
| OLANZAPINE - ZYPREXA ZYDIS | | | | | | |
| N021086 003 | | | | | **>A>** NPP | Dec 04, 2012 |
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| OLANZAPINE - ZYPREXA ZYDIS | | | | | | |
| N021086 004 | | | | | **>A>** NPP | Dec 04, 2012 |
| | | | | | **>A>** PED | Jun 04, 2013 |
| OSELTAMIVIR PHOSPHATE - TAMIFLU | | | | | | |
| N021087 001 | 5952375 | Feb 27, 2015 | DS DP | | | |
| | 5952375*PED | Aug 27, 2015 | | | | |
| OSELTAMIVIR PHOSPHATE - TAMIFLU | | | | | | |
| N021087 002 | 5952375 | Feb 27, 2015 | DS DP | | | |
| | 5952375*PED | Aug 27, 2015 | | | | |
| OSELTAMIVIR PHOSPHATE - TAMIFLU | | | | | | |
| N021087 003 | 5952375 | Feb 27, 2015 | DS DP | | | |
| | 5952375*PED | Aug 27, 2015 | | | | |
| OSELTAMIVIR PHOSPHATE - TAMIFLU | | | | | | |
| N021246 001 | 5763483 | Dec 27, 2016 | DS U-376 | | | |
| | 5763483 | Dec 27, 2016 | DS U-1113 | | | |
| | 5952375 | Feb 27, 2015 | DS DP | | | |
| | 5952375*PED | Aug 27, 2015 | | | | |
| PACLITAXEL - ABRAXANE | | | | | | |
| N021660 001 | 7923536 | Dec 09, 2023 | U-1117 | | | |
| | RE41884 | Aug 14, 2016 | U-1117 | | | |
| PALIPERIDONE - INVEGA | | | | | | |
| N021999 001 | | | | | NPP | Apr 06, 2014 |
| | | | | | PED | Oct 06, 2014 |
| PALIPERIDONE - INVEGA | | | | | | |
| N021999 002 | | | | | NPP | Apr 06, 2014 |
| | | | | | PED | Oct 06, 2014 |

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| PALIPERIDONE - INVEGA | | | | | | |
| N021999 003 | | | | | NPP | Apr 06, 2014 |
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| PALIPERIDONE - INVEGA | | | | | | |
| N021999 004 | | | | | NPP | Apr 06, 2014 |
| | | | | | PED | Oct 06, 2014 |
| PALIPERIDONE - INVEGA | | | | | | |
| N021999 006 | | | | | NPP | Apr 06, 2014 |
| | | | | | PED | Oct 06, 2014 |
| PALONOSETRON HYDROCHLORIDE - ALOXI | | | | | | |
| N021372 001 | **>A>** 7947724 | Jan 30, 2024 | DP | | | |
| | **>A>** 7947725 | Jan 30, 2024 | DP | | | |
| PALONOSETRON HYDROCHLORIDE - ALOXI | | | | | | |
| N021372 002 | **>A>** 7947724 | Jan 30, 2024 | DP | | | |
| | **>A>** 7947725 | Jan 30, 2024 | DP | | | |
| PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE | | | | | | |
| A091427 001 | | | | | PC | Nov 01, 2011 |
| PEMETREXED DISODIUM - ALIMTA | | | | | | |
| N021462 001 | | | | | M-61 | Mar 17, 2014 |
| | | | | | PED | Sep 17, 2014 |
| PEMETREXED DISODIUM - ALIMTA | | | | | | |
| N021462 002 | | | | | M-61 | Mar 17, 2014 |
| | | | | | PED | Sep 17, 2014 |
| PERFLUTREN - DEFINITY | | | | | | |
| N021064 001 | 5527521 | Feb 22, 2015 | DP U-665 | | | |
| | 5585112 | Dec 17, 2013 | DP | | | |
| PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN | | | | | | |
| N050684 001 | 7915229 | Apr 14, 2023 | DP | | | |
| PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN | | | | | | |
| N050684 002 | 7915229 | Apr 14, 2023 | DP | | | |
| PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN | | | | | | |
| N050684 003 | 7915229 | Apr 14, 2023 | DP | | | |
| PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN | | | | | | |
| N050684 004 | 7915229 | Apr 14, 2023 | DP | | | |
| PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN IN PLASTIC CONTAINER | | | | | | |
| N050750 001 | 7915229 | Apr 14, 2023 | DP | | | |
| PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN IN PLASTIC CONTAINER | | | | | | |
| N050750 002 | 7915229 | Apr 14, 2023 | DP | | | |
| PIPERACILLIN SODIUM; TAZOBACTAM SODIUM - ZOSYN IN PLASTIC CONTAINER | | | | | | |
| N050750 003 | 7915229 | Apr 14, 2023 | DP | | | |
| PLERIXAFOR - MOZOBIL | | | | | | |
| N022311 001 | 7897590 | Jul 22, 2023 | U-936 | | | |
| | RE42152 | Dec 10, 2013 | DP | | | |
| RALTEGRAVIR POTASSIUM - ISENTRESS | | | | | | |
| N022145 001 | 7169780 | Oct 03, 2023 | DS DP | | | |

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| RANOLAZINE - RANEXA | | | | | | | |
| N021526 001 | | 6369062 | May 27, 2019 | DP | Y | | |
| RETAPAMULIN - ALTABAX | | | | | | | |
| N022055 001 | | 7875630 | Feb 14, 2027 | DS | | | |
| | | RE39128 | Apr 12, 2021 | DS DP U-805 | | | |
| RIFAXIMIN - XIFAXAN | | | | | | | |
| N021361 001 | | 7902206 | Jun 19, 2024 | DS DP | | | |
| | | 7906542 | Jun 01, 2025 | DS DP | | | |
| | | 7928115 | Jul 24, 2029 | U-1121 | | | |
| RIFAXIMIN - XIFAXAN | | | | | | | |
| N022554 001 | | 7612199 | Jun 19, 2024 | DS DP | | | |
| | | 7902206 | Jun 19, 2024 | DS DP | | | |
| | | 7906542 | Jun 01, 2025 | DS DP | | | |
| RILPIVIRINE HYDROCHLORIDE - EDURANT | | | | | | | |
| N202022 001 | **>A>** | 6838464 | Feb 26, 2021 | DS DP | | **>A>** NCE | May 20, 2016 |
| | **>A>** | 7067522 | Dec 20, 2019 | DS DP | | | |
| | **>A>** | 7125879 | Apr 14, 2023 | DS DP U-1153 | | | |
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| RIZATRIPTAN BENZOATE - MAXALT | | | | | | | |
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| N020864 002 | | 5602162 | Feb 11, 2014 | | Y | | |
| RIZATRIPTAN BENZOATE - MAXALT-MLT | | | | | | | |
| N020865 001 | | 5602162 | Feb 11, 2014 | U-240 | Y | | |
| RIZATRIPTAN BENZOATE - MAXALT-MLT | | | | | | | |
| N020865 002 | | 5602162 | Feb 11, 2014 | U-240 | Y | | |
| ROFLUMILAST - DALIRESP | | | | | | | |
| N022522 001 | | 5712298 | Jan 27, 2015 | DS DP U-1115 | | NCE | Feb 28, 2016 |
| ROPINIROLE HYDROCHLORIDE - REQUIP XL | | | | | | | |
| N022008 001 | **>A>** | 7927624 | Dec 02, 2021 | DP U-20 | | | |
| ROPINIROLE HYDROCHLORIDE - REQUIP XL | | | | | | | |
| N022008 002 | **>A>** | 7927624 | Dec 02, 2021 | DP U-20 | | | |
| ROPINIROLE HYDROCHLORIDE - REQUIP XL | | | | | | | |
| N022008 003 | **>A>** | 7927624 | Dec 02, 2021 | DP U-20 | | | |
| ROPINIROLE HYDROCHLORIDE - REQUIP XL | | | | | | | |
| N022008 004 | **>A>** | 7927624 | Dec 02, 2021 | DP U-20 | | | |
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| N022008 005 | **>A>** | 7927624 | Dec 02, 2021 | DP U-20 | | | |
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| N022008 006 | **>A>** | 7927624 | Dec 02, 2021 | DP U-20 | | | |
| ROTIGOTINE - NEUPRO | | | | | | | |
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See List footnote for information regarding List content

| APPL/PROD NO | | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|---|---|---|---|---|---|---|
| ROTIGOTINE - NEUPRO | | | | | | | |
| N021829 002 | | 6699498 | Nov 27, 2020 | DP | | | |
| ROTIGOTINE - NEUPRO | | | | | | | |
| N021829 003 | | 6699498 | Nov 27, 2020 | DP | | | |
| RUFINAMIDE - BANZEL | | | | | | | |
| N201367 001 | | 6740669 | Aug 17, 2020 | DS DP | | NCE | Nov 14, 2013 |
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| N201444 001 | | | | | | ODE | Jan 14, 2018 |
| SODIUM OXYBATE - XYREM | | | | | | | |
| N021196 001 | | 7668730 | Jun 16, 2024 | U-1110 | | | |
| | | 7895059 | Dec 17, 2022 | U-1110 | | | |
| SORAFENIB TOSYLATE - NEXAVAR | | | | | | | |
| N021923 001 | | 7897623 | Jan 12, 2020 | DP | | | |
| SPINOSAD - NATROBA | | | | | | | |
| N022408 001 | | 5496931 | Mar 05, 2013 | DS U-1105 | | NCE | Jan 18, 2016 |
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| | | 7030095 | Jul 02, 2021 | DP U-1105 | | | |
| SUMATRIPTAN SUCCINATE - SUMAVEL DOSEPRO | | | | | | | |
| N022239 001 | **>A>** | 7776007 | Nov 28, 2026 | DP | | | |
| | | 7901385 | Jul 31, 2026 | DP | | | |
| SUNITINIB MALATE - SUTENT | | | | | | | |
| N021938 001 | | | | | | **>A>** I-639 | May 20, 2014 |
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| TELAPREVIR - INCIVEK | | | | | | | |
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| TELBIVUDINE - TYZEKA | | | | | | | |
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| TESTOSTERONE - ANDROGEL | | | | | | | |
| N022309 001 | **>A>** | 6503894 | Aug 30, 2020 | U-1103 | | NP | Apr 29, 2014 |
| TESTOSTERONE - FORTESTA | | | | | | | |
| N021463 001 | | 6319913 | Nov 09, 2018 | U-490 | | | |
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| TESTOSTERONE - TESTIM | | | | | | | |
| N021454 001 | **>A>** | 7935690 | Apr 21, 2023 | U-1009 | | | |

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| THALIDOMIDE - THALOMID | | | | | | |
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| TIGECYCLINE - TYGACIL | | | | | | |
| N021821 001 | 7879828 | Feb 05, 2029 | DP | | | |
| TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA | | | | | | |
| N021395 001 | **>A>** 6908928 | Sep 24, 2021 | DS DP U-762 | | | |
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| | **>A>** 7694676 | Mar 12, 2027 | DP | | | |
| TRANEXAMIC ACID - LYSTEDA | | | | | | |
| N022430 001 | **>A>** 7947739 | Mar 04, 2025 | DP | | | |
| VANDETANIB - VANDETANIB | | | | | | |
| N022405 001 | 7173038 | Aug 14, 2021 | DS DP | | NCE | Apr 06, 2016 |
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| | **>A>** RE42353 | Sep 23, 2017 | DS DP | | ODE | Apr 06, 2018 |
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| N022567 001 | 5532241 | Sep 29, 2014 | DS DP | | NCE | Jan 21, 2016 |
| | 7834020 | Jun 05, 2022 | DS DP U-839 | | | |
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| N022567 003 | 5532241 | Sep 29, 2014 | DS DP | | NCE | Jan 21, 2016 |
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| N021817 001 | **>A>** 7932241 | Feb 05, 2028 | DP | | | |
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Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.
3. **** The expiration date for U.S. Patent No. 5,608,075 is March 4, 2009.

# 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, 31st 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/docs/pattermsall.cfm

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