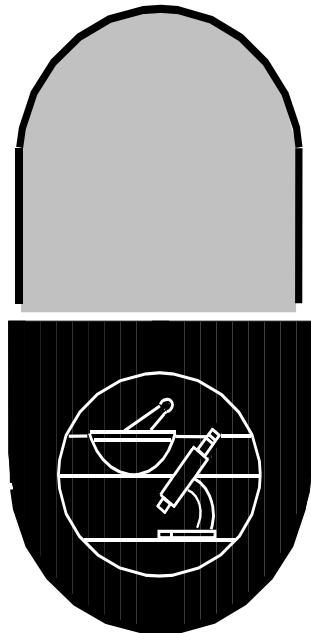


**CUMULATIVE  
SUPPLEMENT 9  
SEPTEMBER 2018**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**38th EDITION**

**Department of Health and Human Services**

Food and Drug Administration  
Office of Medical Products and Tobacco  
Center for Drug Evaluation and Research  
Office of Generic Drugs  
Office of Generic Drug Policy

2018

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**38<sup>th</sup> EDITION**

**Cumulative Supplement 9  
September 2018**

**CONTENTS**

	<i>PAGE</i>
<b>1.0 INTRODUCTION.....</b>	v
1.1 How to use the Cumulative Supplement.....	v
1.2 Cumulative Supplement Content .....	vi
1.3 Applicant Name Changes .....	vii
1.4 Levothyroxine Sodium.....	viii
1.5 Availability of the Edition .....	ix
1.6 Report of Counts for the Prescription Drug Product List.....	x
1.7 Cumulative Supplement Legend.....	xi
 <b>DRUG PRODUCT LISTS</b>	
Prescription Drug Product List .....	1-1
OTC Drug Product List .....	2-1
Drug Products with Approval under Section 505 of the Act	
Administered by the Center for Biologics Evaluation and Research List .....	3-1
Orphan Product Designations and Approvals List .....	4-1
Drug Products Which Must Demonstrate <i>in vivo</i> Bioavailability	
Only if Product Fails to Achieve Adequate Dissolution .....	5-1
 <b>PATENT AND EXCLUSIVITY INFORMATION ADDENDUM</b>	
A. Patent and Exclusivity Lists .....	A-1
B. Patent and Exclusivity Terms .....	B-1

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**38<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 9  
September 2018**

**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, 38th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; drug products with approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) administered by the Center for Biologics Evaluation and Research; and approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the

"@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the next Edition. The current Annual Edition Section 2.1, 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 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 [orangebook@fda.hhs.gov](mailto:orangebook@fda.hhs.gov).

mail to:  
FDA/CDER Orange Book Staff  
Office of Generic Drugs  
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)

IDT AUSTRALIA LTD  
(IDT AUSTRALIA LTD)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

ANI PHARMACEUTICALS INC  
(ANI PHARMS INC)

KREMERS URBAN PHARMACEUTICALS INC (KREMERS URBAN PHARMS)	LANNETT CO INC (LANNETT CO INC)
LANNETT HOLDINGS INC (LANNETT)	LANNETT CO INC (LANNETT CO INC)
LANNETT HOLDINGS INC (LANNETT HOLDINGS INC)	LANNETT CO INC (LANNETT CO INC)
SILARX PHARMACEUTICALS INC (SILARX)	LANNETT CO INC (LANNETT CO INC)
SILARX PHARMACEUTICALS INC (SILARX PHARMS INC)	LANNETT CO INC (LANNETT CO INC)
SAGENT AGILA LLIC (SAGENT AGILA)	MYLAN ASI LLC (MYLAN ASI)
SAGENT AGILA LLC (SAGENT AGILA LLC)	MYLAN ASI LLC (MYLAN ASI)
SAGENT STRIDES LLC (SAGENT STRIDESC)	MYLAN ASI LLC (MYLAN ASI)

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

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

Levo-T (Cediprof Inc NDA 021342), Unithroid (Jerome Stevens NDA 021210), and

Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

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

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

Trade Name	Applicant	Strength	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	021210	001
LEVOOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	076187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	021301	001
SYNTHROID	ABBVIE	0.025MG	AB1	021402	001
LEVO-T	CEDIPROF INC	0.025MG	AB1	021342	001
SYNTHROID	ABBVIE	0.025MG	AB2	021402	001
LEVOOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	076187	001
LEVO-T	CEDIPROF INC	0.025MG	AB2	021342	001
UNITHROID	STEVENS J	0.025MG	AB2	021210	001
LEVOXYL	KING PHARMS	0.025MG	AB3	021301	001
LEVO-T	CEDIPROF INC	0.025MG	AB3	021342	001
UNITHROID	STEVENS J	0.025MG	AB3	021210	001
LEVOOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	076187	001
LEVOOTHYROXINE SODIUM	MYLAN	0.025MG	AB4	076187	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 (December of the previous Annual Edition) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### **DEFINITIONS**

#### **Drug Product**

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

#### **New Molecular Entity**

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

combination.

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

<u>CATEGORIES COUNTED</u>	<u>DEC 2017</u>	<u>MAR 2018</u>	<u>JUN 2018</u>	<u>SEP 2018</u>	<u>DEC 2018</u>
DRUG PRODUCTS	19294	19359	19529	19793	
LISTED SINGLE SOURCE	2758 (14.3%)	2763 (14.3%)	2703 (13.8%)	2708 (13.7%)	
MULTISOURCE	16536 (85.7%)	16596 (85.7%)	16826 (86.2%)	17085 (86.3%)	
THERAPEUTICALLY EQUIVALENT	16431 (85.2%)	16501 (85.2%)	16735 (85.7%)	16997 (85.9%)	
NOT THERAPEUTICALLY EQUIVALENT	105 (0.5%)	95 (0.5%)	91 (0.5%)	88 (0.4%)	
EXCEPTIONS <sup>1</sup>	73 (0.4%)	72 (0.4%)	72 (0.4%)	72 (0.4%)	
NEW MOLECULAR ENTITIES APPROVED	25	6	26	23	
NUMBER OF APPLICANTS	1075	1084	1091	1103	

<sup>1</sup>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 of Administration and then by trade name (or established name of the active ingredient, if no trade name exists).

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, Reference Standard symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug

Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

Changes to currently listed products will list two records. The deleted product record will be 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.
CHRS	Change. Reference Standard.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

\*\*Note:

The Cumulative Supplement (CS) currently displays a condensed 20 character collapsed applicant holder firm name and the Electronic Orange Book (EOB) query may display up to a 240 character full applicant holder firm name. An applicant holder firm name change usually changes both the collapsed name and long name. On occasion, only the long name is changed resulting in the CS displaying only the collapsed name for the >D> and >A> action. The new firm long name will display in the EOB query.

ABACAVIR SULFATE

SOLUTION;ORAL  
ABACAVIR SULFATE  
AA AUROBINDO PHARMA LTD EQ 20MG BASE/ML A077950 001 Mar 14, 2018 Feb NEWA

ABIRATERONE ACETATE

TABLET;ORAL  
YONSA  
+! SUN PHARMA GLOBAL 125MG N210308 001 May 22, 2018 May NEWA  
ZYTIGA  
+ JANSSEN BIOTECH 250MG N202379 001 Apr 28, 2011 Feb CHRS  
+! 500MG N202379 002 Apr 14, 2017 Feb CHRS

ACEBUTOLOL HYDROCHLORIDE

CAPSULE;ORAL  
ACEBUTOLOL HYDROCHLORIDE  
AB ! AMNEAL PHARM EQ 200MG BASE A075047 001 Dec 30, 1999 Jun CHRS  
AB ! EQ 400MG BASE A075047 002 Dec 30, 1999 Jun CHRS  
SECTRAL  
+ @ PROMIUS PHARMA EQ 200MG BASE N018917 001 Dec 28, 1984 Jun DISC  
+ @ EQ 400MG BASE N018917 003 Dec 28, 1984 Jun DISC

ACETAMINOPHEN

SOLUTION;INTRAVENOUS  
ACETAMINOPHEN  
AP CUSTOPHARM INC 1GM/100ML (10MG/ML) A202605 001 Jun 13, 2016 Jun CDFR  
FRESENIUS KABI USA 1GM/100ML (10MG/ML) N204767 001 Oct 28, 2015 Jun CDFR  
AP SANDOZ INC 1GM/100ML (10MG/ML) A204052 001 Mar 22, 2016 Jun CDFR  
OFIRMEV  
AP +! MALLINCKRODT IP 1GM/100ML (10MG/ML) N022450 001 Nov 02, 2010 Jun CDFR

ACETAMINOPHEN; BENZHYDROCODONE HYDROCHLORIDE

TABLET;ORAL  
APADAZ  
+ KEMPHARM 325MG;EQ 6.12MG BASE N208653 001 Feb 23, 2018 Feb NEWA

ACETAMINOPHEN; BUTALBITAL

CAPSULE;ORAL  
BUTALBITAL AND ACETAMINOPHEN  
MAYNE PHARMA INC 300MG;50MG A207313 001 Dec 27, 2017 Mar CAHN  
TABLET;ORAL  
BUTALBITAL AND ACETAMINOPHEN  
>A> AA CNTY LINE PHARMS 300MG;50MG A207635 001 Jun 05, 2017 Sep CAHN  
>D> AA TEDOR PHARMA INC 300MG;50MG A207635 001 Jun 05, 2017 Sep CAHN

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE;ORAL  
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE  
>A> AA AUROLIFE PHARMA LLC 325MG;50MG;40MG A204733 001 Sep 26, 2018 Sep NEWA  
>D> ! MAYNE PHARMA INC 325MG;50MG;40MG A089007 001 Mar 17, 1986 Sep CTEC  
>A> AA ! 325MG;50MG;40MG A089007 001 Mar 17, 1986 Sep CTEC  
AA NUVO PHARMS INC 300MG;50MG;40MG A207118 001 Oct 28, 2016 Apr CTEC  
AA TEDOR PHARMA INC 300MG;50MG;40MG A206615 001 Aug 04, 2017 Apr CTEC  
TABLET;ORAL  
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE  
>A> AA ABHAI LLC 325MG;50MG;40MG A211106 001 Sep 26, 2018 Sep NEWA

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION;ORAL  
ACETAMINOPHEN AND CODEINE PHOSPHATE  
AA @ ACI HEALTHCARE LTD 120MG/5ML;12MG/5ML A086366 001 Aug CAHN  
AA LANNETT CO INC 120MG/5ML;12MG/5ML A091238 001 Nov 10, 2011 May CAHN  
TABLET;ORAL  
ACETAMINOPHEN AND CODEINE PHOSPHATE  
@ FOSUN PHARMA 300MG;30MG A081250 001 Jul 16, 1992 Jan CAHN  
@ 300MG;60MG A081249 001 Jul 16, 1992 Jan CAHN  
@ FRONTIDA BIOPHARM 300MG;15MG A089673 002 Feb 10, 1988 Aug CAHN  
@ 300MG;30MG A089673 003 Feb 10, 1988 Aug CAHN  
@ 300MG;60MG A089673 001 Feb 10, 1988 Aug CAHN

ACETAMINOPHEN; HYDROCODONE BITARTRATE

## SOLUTION;ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	GENUS LIFESCIENCES	325MG/15ML;7.5MG/15ML	A040894	001	Jul 19, 2011	Aug CAHN
	TABLET;ORAL					
		HYDROCODONE BITARTRATE AND ACETAMINOPHEN				
>A> AA	AUROLIFE PHARMA LLC	300MG;5MG	A207709	001	Sep 13, 2018	Sep NEWA
>A> AA		300MG;7.5MG	A207709	002	Sep 13, 2018	Sep NEWA
>A> AA		300MG;10MG	A207709	003	Sep 13, 2018	Sep NEWA
AA	EPIC PHARMA LLC	325MG;5MG	A203863	001	Mar 30, 2018	Mar NEWA
AA		325MG;7.5MG	A203863	002	Mar 30, 2018	Mar NEWA
AA		325MG;10MG	A203863	003	Mar 30, 2018	Mar NEWA
AA	PAR PHARM	325MG;5MG	A202935	002	Jun 15, 2016	Jul CAHN
AA		325MG;7.5MG	A202935	003	Jun 15, 2016	Jul CAHN
AA		325MG;10MG	A202935	004	Jun 15, 2016	Jul CAHN
AA	RHODES PHARMS	300MG;5MG	A207808	001	Mar 30, 2018	Mar NEWA
AA		300MG;7.5MG	A207808	002	Mar 30, 2018	Mar NEWA
AA		300MG;10MG	A207808	003	Mar 30, 2018	Mar NEWA

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

## SOLUTION;ORAL

OXYCODONE AND ACETAMINOPHEN

@ SPECGX LLC	325MG/5ML;5MG/5ML	A040680	001	Sep 29, 2006	Jan DISC
OXYCODONE HYDROCHLORIDE AND ACETAMINOPHEN		A203573	001	Dec 18, 2014	Jan DISC

## TABLET;ORAL

OXYCODONE AND ACETAMINOPHEN

AA	ABHAI LLC	325MG;2.5MG	A210644	001	Feb 09, 2018	Jan NEWA
AA		325MG;5MG	A210644	002	Feb 09, 2018	Jan NEWA
AA		325MG;7.5MG	A210644	003	Feb 09, 2018	Jan NEWA
AA		325MG;10MG	A210644	004	Feb 09, 2018	Jan NEWA
AA	ELITE LABS INC	325MG;5MG	A209385	001	Jul 02, 2018	Jun NEWA
AA		325MG;7.5MG	A209385	002	Jul 02, 2018	Jun NEWA
AA		325MG;10MG	A209385	003	Jul 02, 2018	Jun NEWA
AA	EPIC PHARMA LLC	325MG;5MG	A203864	001	Jul 02, 2018	Jun NEWA
AA		325MG;7.5MG	A203864	002	Jul 02, 2018	Jun NEWA
AA		325MG;10MG	A203864	003	Jul 02, 2018	Jun NEWA
AA	WES PHARMA INC	325MG;5MG	A207510	001	Mar 21, 2018	Mar NEWA
AA		325MG;7.5MG	A207510	002	Mar 21, 2018	Mar NEWA
AA		325MG;10MG	A207510	003	Mar 21, 2018	Mar NEWA

ACETIC ACID, GLACIAL

## SOLUTION;IRRIGATION, URETHRAL

ACETIC ACID 0.25% IN PLASTIC CONTAINER

AT	+! ICU MEDICAL INC	250MG/100ML	N017656	001		Mar CRLD
	SOLUTION/DROPS;OTIC					
	ACETIC ACID					
>A> AT	ANDA REPOSITORY	2%	A207280	001	Mar 09, 2018	Sep CAHN
AT	LANNETT CO INC	2%	A040607	001	Feb 24, 2005	May CAHN
>D> AT	RISING PHARMS	2%	A207280	001	Mar 09, 2018	Sep CAHN
AT		2%	A207280	001	Mar 09, 2018	Feb NEWA

ACETIC ACID, GLACIAL; HYDROCORTISONE

## SOLUTION/DROPS;OTIC

HYDROCORTISONE AND ACETIC ACID

AT	TARO PHARM INDs LTD	2%;1%	A088759	001	Mar 04, 1985	May CAHN
----	---------------------	-------	---------	-----	--------------	----------

ACETYLCYSTEINE

## INJECTABLE;INTRAVENOUS

ACETYLCYSTEINE

AP	ZYDUS PHARMS USA INC	6GM/30ML (200MG/ML)	A208166	001	Jul 20, 2018	Jul NEWA
----	----------------------	---------------------	---------	-----	--------------	----------

ACYCLOVIR

## CAPSULE;ORAL

ACYCLOVIR

AB	HERITAGE PHARMS INC	200MG	A074889	001	Oct 31, 1997	Mar CMFD
	OINTMENT;TOPICAL					
	ACYCLOVIR					
AB	ALEMBIC PHARMS LTD	5%	A209000	001	Apr 06, 2018	Mar NEWA

TABLET;ORALACYCLOVIR

@	MYLAN PHARMS INC	400MG	A075211	001	Sep 28, 1998	Jun DISC
@		800MG	A075211	002	Sep 28, 1998	Jun DISC
AB	YILING PHARM LTD	400MG	A210401	001	Mar 07, 2018	Feb NEWA
AB		800MG	A210401	002	Mar 07, 2018	Feb NEWA

ACYCLOVIR SODIUMINJECTABLE;INJECTIONACYCLOVIR SODIUM

@	FRESENIUS KABI USA	EQ 500MG BASE/VIAL	A075015	001	Apr 30, 1998	Jun DISC
@	HIKMA PHARMS	EQ 500MG BASE/VIAL	A205771	001	Feb 29, 2016	Jun DISC
@		EQ 1GM BASE/VIAL	A205771	002	Feb 29, 2016	Jun DISC
	ZYDUS PHARMS USA INC	EQ 500MG BASE/VIAL	A206535	001	Aug 31, 2018	Aug NEWA
@		EQ 500MG BASE/VIAL	A206606	001	Jun 13, 2017	Jun DISC
@		EQ 1GM BASE/VIAL	A206535	002	Aug 31, 2018	Aug NEWA
@		EQ 1GM BASE/VIAL	A206606	002	Jun 13, 2017	Jun DISC

ADAPALENESOLUTION;TOPICALADAPALENE

AB	CALL INC	0.1%	A203981	001	Sep 23, 2016	Jul CMFD
@		0.1%	A203981	001	Sep 23, 2016	Jun DISC
AB		0.1%	A204593	001	Jan 05, 2016	Jul CMFD
@		0.1%	A204593	001	Jan 05, 2016	Jun DISC

ADAPALENE; BENZOYL PEROXIDEGEL;TOPICALADAPALENE AND BENZOYL PEROXIDE

AB	PERRIGO ISRAEL	0.1%;2.5%	A205033	001	Jan 23, 2018	Jan NEWA
AB	TARO	0.1%;2.5%	A206959	001	Jan 24, 2018	Jan NEWA
AB	TOLMAR	0.1%;2.5%	A206164	001	May 23, 2018	May NEWA

ADEFOVIR DIPIVOXILTABLET;ORALADEFOVIR DIPIVOXIL

AB	APOTEX INC	10MG	A205459	001	Jul 06, 2018	Jun NEWA
----	------------	------	---------	-----	--------------	----------

ADENOSINEINJECTABLE;INJECTIONADENOCARD

+ @	ASTELLAS	3MG/ML	N019937	002	Oct 30, 1989	May DISC
AP	! AKORN	3MG/ML	A078076	001	Oct 31, 2008	May CHRS
AP	FRESENIUS KABI USA	3MG/ML	A205568	001	Apr 16, 2018	Apr NEWA
AP	GLAND PHARMA LTD	3MG/ML	A206778	001	Feb 16, 2018	Feb NEWA

SOLUTION;INTRAVENOUSADENOSCAN

+ @	ASTELLAS	60MG/20ML (3MG/ML)	N020059	001	May 18, 1995	Jun CDFR
+ @		90MG/30ML (3MG/ML)	N020059	002	May 18, 1995	Jun CDFR

ADENOSINE

AP	AKORN	60MG/20ML (3MG/ML)	A090450	001	Oct 02, 2014	Jun CDFR
AP		90MG/30ML (3MG/ML)	A090450	002	Oct 02, 2014	Jun CDFR
AP	AUROBINDO PHARMA LTD	60MG/20ML (3MG/ML)	A205331	001	Nov 02, 2017	Jun CDFR
AP		90MG/30ML (3MG/ML)	A205331	002	Nov 02, 2017	Jun CDFR
AP	EMCURE PHARMS LTD	60MG/20ML (3MG/ML)	A202313	001	Sep 15, 2014	Jun CDFR
AP		90MG/30ML (3MG/ML)	A202313	002	Sep 15, 2014	Jun CDFR
AP	FRESENIUS KABI USA	60MG/20ML (3MG/ML)	A077897	001	Nov 27, 2017	Jun CDFR
AP		90MG/30ML (3MG/ML)	A077897	002	Nov 27, 2017	Jun CDFR
AP	HOSPIRA INC	60MG/20ML (3MG/ML)	A203883	001	Mar 24, 2014	Jun CDFR
AP		90MG/30ML (3MG/ML)	A203883	002	Mar 24, 2014	Jun CDFR
AP	MYLAN ASI	60MG/20ML (3MG/ML)	A090212	001	Mar 28, 2014	Jun CDFR
AP		90MG/30ML (3MG/ML)	A090212	002	Mar 28, 2014	Jun CDFR
AP	! TEVA PHARMS USA	60MG/20ML (3MG/ML)	A077425	001	Aug 29, 2013	Jun CDFR
AP	!	90MG/30ML (3MG/ML)	A077425	002	Aug 29, 2013	Jun CDFR

ALBENDAZOLETABLET;ORALALBENDAZOLE

>A>	CIPLA LTD	200MG	A210434	001	Sep 21, 2018	Sep NEWA
>A> AB	ALBENZA					
>D>	+! IMPAX LABS INC	200MG	N020666	001	Jun 11, 1996	Sep CFTG

	TABLET;ORAL ALBENZA					
>A> AB	+!	200MG		N 020666	001	Jun 11, 1996 Sep CFTG
<b><u>ALBUTEROL SULFATE</u></b>						
	SOLUTION;INHALATION PROVENTIL					
+ @ SCHERING	EQ 0.083% BASE		N 019243	002	Jan 14, 1987	Jun CRLD
+ @	EQ 0.5% BASE		N 019243	001	Jan 14, 1987	Jun CRLD
	SYRUP;ORAL ALBUTEROL SULFATE					
AA	LANNETT CO INC	EQ 2MG BASE/5ML	A 078105	001	Dec 27, 2006	May CAHN
<b><u>TABLET;ORAL ALBUTEROL SULFATE</u></b>						
AB	AMNEAL PHARMS CO	EQ 2MG BASE	A 208804	001	May 21, 2018	May NEWA
AB		EQ 4MG BASE	A 208804	002	May 21, 2018	May NEWA
AB	APPCO PHARMA LLC	EQ 2MG BASE	A 207046	001	Jun 29, 2018	Jun NEWA
AB		EQ 4MG BASE	A 207046	002	Jun 29, 2018	Jun NEWA
AB	RISING PHARMS	EQ 2MG BASE	A 207046	001	Jun 29, 2018	Aug CAHN
AB		EQ 4MG BASE	A 207046	002	Jun 29, 2018	Aug CAHN
	@ YAOPHARMA CO LTD	EQ 2MG BASE	A 072151	001	Dec 05, 1989	Jan CAHN
	@	EQ 4MG BASE	A 072152	001	Dec 05, 1989	Jan CAHN
<b><u>TABLET, EXTENDED RELEASE;ORAL ALBUTEROL SULFATE</u></b>						
!	MYLAN	EQ 8MG BASE	A 078092	001	Jan 29, 2007	May CTEC
	VOSPIRE ER					
	@ DAVA PHARMS INC	EQ 8MG BASE	A 076130	003	Sep 26, 2002	May DISC
<b><u>ALBUTEROL SULFATE; IPRATROPIUM BROMIDE</u></b>						
<b>SOLUTION;INHALATION</b>						
	ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE					
@ FOSUN PHARMA	EQ 0.083% BASE;0.017%		A 076867	001	Dec 21, 2006	Jan CAHN
@ TEVA PHARMS	EQ 0.083% BASE;0.017%		A 076724	001	Dec 31, 2007	Aug DISC
<b><u>ALCOHOL</u></b>						
<b>SOLUTION;INTRA-ARTERIAL</b>						
	ABLYSINOL					
+ BELCHER PHARMS LLC	99% (1ML)		N 207987	001	Jun 21, 2018	Jun NEWA
+!	99% (5ML)		N 207987	002	Jun 21, 2018	Jun NEWA
<b><u>ALENDRONATE SODIUM</u></b>						
<b>TABLET;ORAL</b>						
	ALENDRONATE SODIUM					
AB	HANGZHOU BINJIANG	EQ 5MG BASE	A 090258	001	Sep 24, 2009	Jan CAHN
AB		EQ 10MG BASE	A 090258	002	Sep 24, 2009	Jan CAHN
AB		EQ 35MG BASE	A 090258	003	Sep 24, 2009	Jan CAHN
AB		EQ 70MG BASE	A 090258	004	Sep 24, 2009	Jan CAHN
	@ MYLAN	EQ 35MG BASE	A 076584	003	Aug 04, 2008	Apr DISC
	@	EQ 70MG BASE	A 076584	004	Aug 04, 2008	Apr DISC
AB	NEOPHARMA	EQ 5MG BASE	A 079049	003	Aug 04, 2008	Aug CAHN
AB		EQ 10MG BASE	A 079049	004	Aug 04, 2008	Aug CAHN
AB		EQ 35MG BASE	A 079049	001	Aug 04, 2008	Aug CAHN
AB		EQ 70MG BASE	A 079049	002	Aug 04, 2008	Aug CAHN
<b><u>ALISKIREN HEMIFUMARATE</u></b>						
<b>CAPSULE, PELLET;ORAL</b>						
	TEKTURNA					
+ @ NODEN PHARMA	EQ 37.5MG BASE		N 210709	001	Nov 14, 2017	Jun DISC
<b><u>ALLOPURINOL</u></b>						
<b>TABLET;ORAL</b>						
	ALLOPURINOL					
@ FOSUN PHARMA	100MG		A 070268	001	Dec 31, 1985	Jan CAHN
<b><u>ALOSETRON HYDROCHLORIDE</u></b>						
<b>TABLET;ORAL</b>						
	ALOSETRON HYDROCHLORIDE					
AB	PAR PHARM INC	EQ 0.5MG BASE	A 206113	001	Feb 23, 2018	Feb NEWA
AB		EQ 1MG BASE	A 206113	002	Feb 23, 2018	Feb NEWA

ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN K

SOLUTION; INTRAVENOUS

INFUVITE ADULT

+!	SANDOZ INC	2 IU/ML; 40MG/ML; 12MCG/ML; 40 IU/ML; 1MCG/ML; 3MG/ML; 120MCG/ML; 8MG /ML; 1.2MG/ML; 0.72MG/ML; 1.2MG/ML; 66 0 IU/ML; 0.03MG/ML	N 021163	001	May 18, 2000	Jun CDFR
+!		2 IU/ML; 40MG/ML; 12MCG/ML; 40 IU/ML; 1MCG/ML; 3MG/ML; 120MCG/ML; 8MG /ML; 1.2MG/ML; 0.72MG/ML; 1.2MG/ML; 66 0 IU/ML; 30MCG/ML	N 021559	001	Jun 16, 2003	Jun CDFR

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

AB	BRECKENRIDGE PHARM	0.25MG	A 207507	001	Jul 09, 2018	Aug CAHN
AB		0.5MG	A 207507	002	Jul 09, 2018	Aug CAHN
AB		1MG	A 207507	003	Jul 09, 2018	Aug CAHN
AB		2MG	A 207507	004	Jul 09, 2018	Aug CAHN
AB	CENTAUR PHARMS PVT	0.25MG	A 207507	001	Jul 09, 2018	Jun NEWA
AB		0.5MG	A 207507	002	Jul 09, 2018	Jun NEWA
AB		1MG	A 207507	003	Jul 09, 2018	Jun NEWA
AB		2MG	A 207507	004	Jul 09, 2018	Jun NEWA
AB	OXFORD PHARMS	0.25MG	A 078491	001	Sep 25, 2008	Jul CAHN
AB		0.5MG	A 078491	002	Sep 25, 2008	Jul CAHN
AB		1MG	A 078491	003	Sep 25, 2008	Jul CAHN
AB		2MG	A 078491	004	Dec 12, 2008	Jul CAHN

ALPROSTADIL

INJECTABLE; INJECTION

CAVERJECT

+ @ PHARMACIA AND UPJOHN 0.005MG/VIAL

N 020379 003 Jun 27, 1996 Jun DISC

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HYDROCHLORIDE

>A> AB	GRAVITI PHARMS	100MG	A 207570	001	Sep 30, 2016	Sep CAHN
@ LANNETT CO INC		100MG	A 209221	001	Jun 15, 2017	Jun DISC
>D> AB	NEWGEN PHARMS LLC	100MG	A 207570	001	Sep 30, 2016	Sep CAHN

TABLET; ORAL

AMANTADINE HYDROCHLORIDE

>A> AB	GRAVITI PHARMS	100MG	A 207571	001	Jan 31, 2017	Sep CAHN
AB	JUBILANT GENERICS	100MG	A 210403	001	Feb 07, 2018	Jan NEWA
>D> AB	NEWGEN PHARMS LLC	100MG	A 207571	001	Jan 31, 2017	Sep CAHN

TABLET, EXTENDED RELEASE; ORAL

OSMOLEX ER

+ OSMOTICA PHARM EQ 129MG BASE  
+ EQ 193MG BASE  
+! EQ 258MG BASE

N 209410 001 Feb 16, 2018 Feb NEWA  
N 209410 002 Feb 16, 2018 Feb NEWA  
N 209410 003 Feb 16, 2018 Feb NEWA

AMIKACIN SULFATE

SUSPENSION, LIPOSOMAL; INHALATION

>A>	ARIKAYCE KIT					
>A>	+! INSMED INC	EQ 590MG BASE/8.4ML	N 207356	001	Sep 28, 2018	Sep NEWA

AMILORIDE HYDROCHLORIDE

TABLET; ORAL

AMILORIDE HYDROCHLORIDE

>A> AB	USPHARMA WINDLAS	5MG	A 204180	001	Aug 07, 2015	Sep CAHN
>D> AB	WINDLAS HLTHCARE	5MG	A 204180	001	Aug 07, 2015	Sep CAHN

AMILORIDE HYDROCHLORIDE; HYDROCHLORTHIAZIDE

TABLET; ORAL

AMILORIDE HYDROCHLORIDE AND HYDROCHLORTHIAZIDE

@ YAOPHARMA CO LTD EQ 5MG ANHYDROUS; 50MG

A 073357 001 Nov 27, 1991 Jan CAHN

AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL

## EMULSION; INTRAVENOUS

## KABIVEN IN PLASTIC CONTAINER

+ FRESENIUS KABI USA	3.3%;29MG/100ML;9.8GM/100ML;96MG/1 00ML;174MG/100ML;239MG/100ML ;147MG/100ML;3.9GM/100ML (1026ML)	N 200656	004	Aug 25, 2014	Jul CDFR
+	3.3%;29MG/100ML;9.8GM/100ML;96MG/1 00ML;174MG/100ML;239MG/100ML;147MG /100ML;3.9GM/100ML (1540ML)	N 200656	005	Aug 25, 2014	Jul CDFR
+	3.3%;29MG/100ML;9.8GM/100ML;96MG/1 00ML;174MG/100ML;239MG/100ML;147MG /100ML;3.9GM/100ML (2053ML)	N 200656	006	Aug 25, 2014	Jul CDFR
+!	3.3%;29MG/100ML;9.8GM/100ML;96MG/1 00ML;174MG/100ML;239MG/100ML;147MG /100ML;3.9GM/100ML (2566ML)	N 200656	007	Aug 25, 2014	Jul CDFR

## PERIKABIVEN IN PLASTIC CONTAINER

+ FRESENIUS KABI USA	2.4%;20MG/100ML;6.8GM/100ML;68MG/1 00ML;124MG/100ML;170MG/100ML;105MG /100ML;3.5GM/100ML (1440ML)	N 200656	001	Aug 25, 2014	Jul CDFR
+	2.4%;20MG/100ML;6.8GM/100ML;68MG/1 00ML;124MG/100ML;170MG/100ML;105MG /100ML;3.5GM/100ML (1920ML)	N 200656	002	Aug 25, 2014	Jul CDFR
+	2.4%;20MG/100ML;6.8GM/100ML;68MG/1 00ML;124MG/100ML;170MG/100ML ;105MG/100ML;3.5GM/100ML (2400ML)	N 200656	003	Aug 25, 2014	Jul CDFR

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

## INJECTABLE; INJECTION

## AMINOSYN II 8.5% W/ ELECTROLYTES

@ ICU MEDICAL INC	8.5%;102MG/100ML;45MG/100ML;522MG/ 100ML;410MG/100ML	N 019437	005	Apr 03, 1986	May DISC
-------------------	---	----------	-----	--------------	----------

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

## INJECTABLE; INJECTION

## AMINOSYN 8.5% W/ELECTROLYTES

ICU MEDICAL INC	8.5%;102MG/100ML;487MG/100ML;28MG/ 100ML;425MG/100ML	N 017673	009	Oct 25, 2002	May NEWA
-----------------	---	----------	-----	--------------	----------

## AMINOSYN II 8.5% W/ELECTROLYTES

ICU MEDICAL INC	8.5%;102MG/100ML;492MG/100ML;60MG/ 100ML;425MG/100ML	N 019437	008	Oct 25, 2002	May NEWA
-----------------	---	----------	-----	--------------	----------

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

## INJECTABLE; INJECTION

## AMINOSYN 8.5% W/ ELECTROLYTES

@ ICU MEDICAL INC	8.5%;102MG/100ML;522MG/100ML;410MG /100ML	N 017673	005		May DISC
-------------------	--	----------	-----	--	----------

AMINOCAPROIC ACID

## SYRUP; ORAL

## AMICAR

>D> AA	+! CLOVER PHARMS	1.25GM/5ML	N 015230	002	Sep CTEC
>A>	+!	1.25GM/5ML	N 015230	002	Sep CTEC
>D>	AMINOCAPROIC ACID				
>D> AA	AKORN	1.25GM/5ML	A 074759	001	Sep 02, 1998
>A>	@	1.25GM/5ML	A 074759	001	Sep 02, 1998
	TABLET; ORAL				
	AMICAR				
+ CLOVER PHARMS	500MG		N 015197	001	
	AMINOCAPROIC				
@ AKORN	500MG		A 075602	001	May 24, 2001
					Jul DISC

AMIODARONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## AMIODARONE HYDROCHLORIDE

@ AKORN	50MG/ML	A 076232	001	Jul 05, 2006	Jun DISC
+ @ BAXTER HLTHCARE	50MG/ML	N 022325	001	Dec 24, 2008	Jun DISC

TABLET;ORAL  
CORDARONE

>A>	+ @ WYETH PHARMS	200MG	N 018972	001	Dec 24, 1985	Sep CAHN
>D>	+ @ WYETH PHARMS INC	200MG	N 018972	001	Dec 24, 1985	Sep CAHN

AMITRIPTYLINE HYDROCHLORIDE

## TABLET;ORAL

## AMITRIPTYLINE HYDROCHLORIDE

AB	SUN PHARM INDNS INC	10MG	A 089399	002	Jul 14, 1987	Jan CMFD
AB		25MG	A 089399	001	Jul 14, 1987	Jan CMFD
AB		50MG	A 089399	003	Jul 14, 1987	Jan CMFD
AB		75MG	A 089399	004	Jul 14, 1987	Jan CMFD
AB		100MG	A 089399	005	Jul 14, 1987	Jan CMFD
AB		150MG	A 089399	006	Jul 14, 1987	Jan CMFD

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

## TABLET;ORAL

## PERPHENAZINE AND AMITRIPTYLINE HYDROCHLORIDE

@ FOSUN PHARMA	10MG;2MG	A 071062	001	Nov 27, 1987	Jan CAHN
@	10MG;4MG	A 071862	001	Dec 21, 1987	Jan CAHN
@	25MG;2MG	A 071063	001	Nov 27, 1987	Jan CAHN
@	25MG;4MG	A 071064	001	Nov 27, 1987	Jan CAHN
@	50MG;4MG	A 071863	001	Dec 21, 1987	Jan CAHN

AMLODIPINE BESYLATE

## TABLET;ORAL

## AMLODIPINE BESYLATE

AB	OXFORD PHARMS	EQ 2.5MG BASE	A 078414	001	Apr 07, 2010	Jul CAHN
AB		EQ 5MG BASE	A 078414	002	Apr 07, 2010	Jul CAHN
AB		EQ 10MG BASE	A 078414	003	Apr 07, 2010	Jul CAHN
AB	SUNSHINE LAKE	EQ 2.5MG BASE	A 206524	001	May 04, 2018	Apr NEWA
AB		EQ 5MG BASE	A 206524	002	May 04, 2018	Apr NEWA
AB		EQ 10MG BASE	A 206524	003	May 04, 2018	Apr NEWA
@ YAO PHARMA CO LTD	EQ 2.5MG BASE	A 076859	001	Sep 10, 2007	Jan CAHN	
@	EQ 5MG BASE	A 076859	002	Sep 10, 2007	Jan CAHN	
@	EQ 10MG BASE	A 076859	003	Sep 10, 2007	Jan CAHN	

AMLODIPINE BESYLATE; CELECOXIB

## TABLET;ORAL

## CONSENSI

+	KITOV PHARMS LTD	EQ 2.5MG BASE;200MG	N 210045	001	May 31, 2018	May NEWA
+		EQ 5MG BASE;200MG	N 210045	002	May 31, 2018	May NEWA
+		EQ 10MG BASE;200MG	N 210045	003	May 31, 2018	May NEWA

AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL

## TABLET;ORAL

## AMLODIPINE AND OLMESARTAN MEDOXOMIL

AB	ACCORD HLTHCARE INC	EQ 5MG BASE;20MG	A 209600	001	Aug 30, 2018	Aug NEWA
AB		EQ 5MG BASE;40MG	A 209600	003	Aug 30, 2018	Aug NEWA
AB		EQ 10MG BASE;20MG	A 209600	002	Aug 30, 2018	Aug NEWA
AB		EQ 10MG BASE;40MG	A 209600	004	Aug 30, 2018	Aug NEWA

AMMONIA N-13

## INJECTABLE;INTRAVENOUS

## AMMONIA N 13

AP	SOFIE	18.8mCi-188mCi/5ML (3.75-37.5mCi/ML)	A 204667	001	Apr 22, 2015	Feb CAHN
	@ UNIV TX MD ANDERSON	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A 203933	001	Jun 27, 2014	Jun DISC

AMMONIUM LACTATE

## CREAM;TOPICAL

## LAC-HYDRIN

@ SUN PHARM INDNS INC	EQ 12% BASE	N 020508	001	Aug 29, 1996	Feb CAHN
-----------------------	-------------	----------	-----	--------------	----------

## LOTION;TOPICAL

## LAC-HYDRIN

+ @ SUN PHARM INDNS INC	EQ 12% BASE	N 019155	001	Apr 24, 1985	Feb CAHN
-------------------------	-------------	----------	-----	--------------	----------

AMOXAPINE

TABLET;ORAL

AMOXAPINE

WATSON LABS

25MG

50MG

100MG

A072691 002 Aug 28, 1992

Mar CMS1

A072691 003 Aug 28, 1992

Mar CMS1

A072691 004 Aug 28, 1992

Mar CMS1

AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE

CAPSULE, CAPSULE, DELAYED REL PELLETS, TABLET;ORAL

LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN

AB	! RISING PHARMS	500MG,N/A,N/A;N/A;N/A,500MG,N/A;N/A,N/A, A,30MG	A206006	001 Oct 07, 2016	Jun CHRS
	@ TEVA PHARMS USA	500MG,N/A,N/A;N/A;N/A,500MG,N/A;N/A,N/A, A,30MG	A200218	001 Aug 30, 2013	Jun DISC
	PREVPAC				
	+ @ TAKEDA PHARMS USA	500MG,N/A,N/A;N/A;N/A,500MG,N/A;N/A,N/A, A,30MG	N050757	001 Dec 02, 1997	Jun DISC

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE;ORAL

MYDAYIS

+! SHIRE DEV LLC

12.5MG;12.5MG;12.5MG;12.5MG

N022063 004

Jun 20, 2017 May CHRS

TABLET;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>A> AB	NUVO PHARM	1.25MG;1.25MG;1.25MG;1.25MG	A209799	001 Dec 28, 2017	Sep CAHN
>A> AB		1.875MG;1.875MG;1.875MG;1.875MG	A209799	002 Dec 28, 2017	Sep CAHN
>A> AB		2.5MG;2.5MG;2.5MG;2.5MG	A209799	003 Dec 28, 2017	Sep CAHN
>A> AB		3.125MG;3.125MG;3.125MG;3.125MG	A209799	004 Dec 28, 2017	Sep CAHN
>A> AB		3.75MG;3.75MG;3.75MG;3.75MG	A209799	005 Dec 28, 2017	Sep CAHN
>A> AB		5MG;5MG;5MG;5MG	A209799	006 Dec 28, 2017	Sep CAHN
>A> AB		7.5MG;7.5MG;7.5MG;7.5MG	A209799	007 Dec 28, 2017	Sep CAHN
>D> AB	SUNRISE PHARM INC	1.25MG;1.25MG;1.25MG;1.25MG	A209799	001 Dec 28, 2017	Sep CAHN
>D> AB		1.875MG;1.875MG;1.875MG;1.875MG	A209799	002 Dec 28, 2017	Sep CAHN
>D> AB		2.5MG;2.5MG;2.5MG;2.5MG	A209799	003 Dec 28, 2017	Sep CAHN
>D> AB		3.125MG;3.125MG;3.125MG;3.125MG	A209799	004 Dec 28, 2017	Sep CAHN
>D> AB		3.75MG;3.75MG;3.75MG;3.75MG	A209799	005 Dec 28, 2017	Sep CAHN
>D> AB		5MG;5MG;5MG;5MG	A209799	006 Dec 28, 2017	Sep CAHN
>D> AB		7.5MG;7.5MG;7.5MG;7.5MG	A209799	007 Dec 28, 2017	Sep CAHN

AMPHETAMINE SULFATE

TABLET;ORAL

AMPHETAMINE SULFATE

>A> AA	AMNEAL PHARMS	5MG	A211139	001 Sep 26, 2018	Sep NEWA
>A> AA		10MG	A211139	002 Sep 26, 2018	Sep NEWA
	EVEKEO				
>D>	ARBOR PHARMS LLC	5MG	A200166	001 Aug 09, 2012	Sep CTEC
>A> AA		5MG	A200166	001 Aug 09, 2012	Sep CTEC
>D>	!	10MG	A200166	002 Aug 09, 2012	Sep CTEC
>A> AA	!	10MG	A200166	002 Aug 09, 2012	Sep CTEC

AMPICILLIN SODIUM

INJECTABLE;INJECTION

AMPICILLIN SODIUM

@ AUROBINDO PHARMA

EQ 125MG BASE/VIAL

A065499 001 Aug 17, 2010

Aug DISC

@ ISTITUTO BIO ITA SPA

EQ 125MG BASE/VIAL

A062797 001 Jul 12, 1993

Mar DISC

ANASTROZOLE

TABLET;ORAL

ANASTROZOLE

>D> AB	DR REDDYS LABS LTD	1MG	A090732	001 Jun 28, 2010	Sep CAHN
>A> AB	NEOPHARMA	1MG	A090732	001 Jun 28, 2010	Sep CAHN
	ARIMIDEX				

AB	+! ANI PHARMS INC	1MG	N020541	001 Dec 27, 1995	Jan CAHN
----	-------------------	-----	---------	------------------	----------

ANGIOTENSIN II ACETATE

SOLUTION;INTRAVENOUS

GIAPREZA

+! LA JOLLA PHARM CO

EQ 2.5MG BASE/ML (EQ 2.5MG  
BASE/ML)

N209360 001 Dec 21, 2017

Jun CDFR

+!

EQ 5MG BASE/2ML (EQ 2.5MG BASE/ML)

N209360 002 Dec 21, 2017

Jun CDFR

+! LA JOLLA PHARMA

EQ 2.5MG BASE/ML (EQ 2.5MG  
BASE/ML)

N209360 001 Dec 21, 2017

Jun CAHN



ARIPIPRAZOLE LAUROXIL

SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR

ARISTADA INITIO KIT

+ ALKERMES INC 675MG/2.4ML

N209830 001 Jun 29, 2018 Jun NEWA

ARMODAFINIL

TABLET; ORAL

ARMODAFINIL

AB	AUROBINDO PHARMA LTD	50MG	A206069	001	Mar 06, 2018	Feb NEWA
AB		150MG	A206069	002	Mar 06, 2018	Feb NEWA
AB		250MG	A206069	003	Mar 06, 2018	Feb NEWA

ARSENIC TRIOXIDE

INJECTABLE; INJECTION

ARSENIC TRIOXIDE

FRESENIUS KABI USA

TRISENOX

+ @ CEPHALON 1MG/ML

A208231 001 Aug 31, 2018 Aug NEWA

N021248 001 Sep 25, 2000 Jul DISC

ASCORBIC ACID

SOLUTION; INTRAVENOUS

ASCOR

+! MCGUFF 25,000MG/50ML (500MG/ML)

N209112 001 Oct 02, 2017 Jul CDFR

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K

INJECTABLE; INTRAVENOUS

INFUVITE PEDIATRIC

+! SANDOZ INC	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14 MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/V IAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N021265	001	Feb 21, 2001	Aug CDFR
+! SANDOZ INC	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14 MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/V IAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N021646	001	Jan 29, 2004	Aug CDFR

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

FOR SOLUTION; INTRAVENOUS

M.V.I. PEDIATRIC

+! HOSPIRA	80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL ;5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL; 17MG/VIAL;0.2MG/VIAL;1MG/VIAL;1.4M G/VIAL;EQ 1.2MG BASE/VIAL;0.7MG/VIAL;7MG/VIAL	N018920	001	Sep 21, 2000	Aug CDFR
------------	--	---------	-----	--------------	----------

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K

INJECTABLE; INTRAVENOUS

M.V.I. ADULT

+! HOSPIRA	200MG/VIAL;0.06MG/VIAL;0.005MG/VIA L;15MG/VIAL;0.005MG/VIAL;0.6MG/VIA L;40MG/VIAL;6MG/VIAL;3.6MG/VIAL;6M G/VIAL;1MG/VIAL;10MG/VIAL;0.15MG/V IAL	N021625	001	Jan 30, 2004	Aug CDFR
------------	---	---------	-----	--------------	----------

M.V.I. ADULT (PHARMACY BULK PACKAGE)

+! HOSPIRA	200MG/5ML;0.06MG/5ML;0.005MG/5ML;1 5MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG /5ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG /5ML;10MG/5ML;0.15MG/5ML	N021643	001	Feb 18, 2004	Aug CDFR
------------	--	---------	-----	--------------	----------

ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE

FOR SOLUTION; ORAL

PLENUV

+! SALIX PHARMS INC	7.54GM;140GM;2.2GM;48.11GM;5.2GM;9 GM	N209381	001	May 04, 2018	May NEWA
---------------------	--	---------	-----	--------------	----------

ASENAPINE MALEATE

TABLET; SUBLINGUAL

ASENAPINE MALEATE

AB	SIGMAPHARM LABS LLC	EQ 5MG BASE	A206107	001	Jul 17, 2018	Jul NEWA
AB		EQ 10MG BASE	A206107	002	Jul 17, 2018	Jul NEWA
	SAPHRIS					
AB	+ FOREST LABS LLC	EQ 5MG BASE	N022117	001	Aug 13, 2009	Jul CFTG
AB	+!	EQ 10MG BASE	N022117	002	Aug 13, 2009	Jul CFTG

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ASPIRIN AND CAFFEINE

@ FOSUN PHARMA 325MG;50MG;40MG

A086398 002 Apr 06, 1984 Jan CAHN

ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

SYNALGOS-DC

+ @ SUN PHARM INDUSTRIES 356.4MG;30MG;16MG

N011483 004 Sep 06, 1983 Aug DISC

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENGESIC

@ GALT PHARMS 385MG;30MG;25MG

A075141 001 May 29, 1998 Feb CAHN

ORPHENGESIC FORTE

@ GALT PHARMS 770MG;60MG;50MG

A075141 002 May 29, 1998 Feb CAHN

ASPIRIN; DIPYRIDAMOLE

CAPSULE, EXTENDED RELEASE; ORAL

ASPIRIN AND DIPYRIDAMOLE

AB	ANI PHARMS INC	25MG;200MG	A206964	001	Jan 18, 2017	May CAHN
AB	SUN PHARMA GLOBAL	25MG;200MG	A208572	001	Aug 21, 2018	Aug NEWA

ATAZANAVIR SULFATE

CAPSULE; ORAL

ATAZANAVIR SULFATE

AB	AUROBINDO PHARMA LTD	EQ 100MG BASE	A204806	001	Jun 25, 2018	Jun NEWA
AB		EQ 150MG BASE	A204806	002	Jun 25, 2018	Jun NEWA
AB		EQ 200MG BASE	A204806	003	Jun 25, 2018	Jun NEWA
AB		EQ 300MG BASE	A204806	004	Jun 25, 2018	Jun NEWA
AB	Cipla LTD	EQ 100MG BASE	A200626	001	Aug 09, 2018	Jul NEWA
AB		EQ 150MG BASE	A200626	002	Aug 09, 2018	Jul NEWA
AB		EQ 200MG BASE	A200626	003	Aug 09, 2018	Jul NEWA
AB		EQ 300MG BASE	A200626	004	Aug 09, 2018	Jul NEWA
>A> AB	MYLAN PHARMS INC	EQ 150MG BASE	A208177	001	Sep 24, 2018	Sep NEWA
>A> AB		EQ 200MG BASE	A208177	002	Sep 24, 2018	Sep NEWA
>A> AB		EQ 300MG BASE	A208177	003	Sep 24, 2018	Sep NEWA
AB	TEVA PHARMS USA	EQ 100MG BASE	A091673	001	Apr 22, 2014	Jun CTEC

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

ATENOLOL AND CHLORTHALIDONE

AB	ALVOGEN MALTA	50MG;25MG	A072302	002	May 31, 1990	Jul CMS1
----	---------------	-----------	---------	-----	--------------	----------

ATOMOXETINE HYDROCHLORIDE

CAPSULE; ORAL

ATOMOXETINE HYDROCHLORIDE

AB	DR REDDYS LABS LTD	10MG	A090609	001	Feb 23, 2018	Feb NEWA
AB		18MG	A090609	002	Feb 23, 2018	Feb NEWA
AB		25MG	A090609	003	Feb 23, 2018	Feb NEWA
AB		40MG	A090609	004	Feb 23, 2018	Feb NEWA
AB		60MG	A090609	005	Feb 23, 2018	Feb NEWA
AB		80MG	A090609	006	Feb 23, 2018	Feb NEWA
AB		100MG	A090609	007	Feb 23, 2018	Feb NEWA

ATORVASTATIN CALCIUM

TABLET; ORAL

ATORVASTATIN CALCIUM

AB	ACCORD HLTHCARE	EQ 10MG BASE	A207687	001	Mar 30, 2018	Mar NEWA
AB		EQ 20MG BASE	A207687	002	Mar 30, 2018	Mar NEWA
AB		EQ 40MG BASE	A207687	003	Mar 30, 2018	Mar NEWA
AB		EQ 80MG BASE	A207687	004	Mar 30, 2018	Mar NEWA

TABLET;ORAL

## ATORVASTATIN CALCIUM

AB	GRAVITI PHARMS	EQ 10MG BASE	A209912	001	Jun 18, 2018	Jun NEWA
AB		EQ 20MG BASE	A209912	002	Jun 18, 2018	Jun NEWA
AB		EQ 40MG BASE	A209912	003	Jun 18, 2018	Jun NEWA
AB		EQ 80MG BASE	A209912	004	Jun 18, 2018	Jun NEWA

ATOVAQUONE

## SUSPENSION;ORAL

## ATOVAQUONE

AB	@ APOTEX INC	750MG/5ML	A209750	001	Oct 11, 2017	Jun DISC
	LUPIN LTD	750MG/5ML	A209105	001	Sep 11, 2018	Aug NEWA

ATROPINE

## SOLUTION;INTRAMUSCULAR

## ATROPINE (AUTOINJECTOR)

@ RAFA LABS LTD	EQ 2MG SULFATE/0.7ML (EQ 2MG SULFATE/0.7ML)	N212319	001	Jul 09, 2018	Jul NEWA
-----------------	--	---------	-----	--------------	----------

ATROPINE SULFATE

## SOLUTION;INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS, ENDOTRACHEAL

## ATROPINE SULFATE ANSYR PLASTIC SYRINGE

+ @ HOSPIRA	0.5MG/5ML (0.1MG/ML)	N021146	001	Jul 09, 2001	Jun DISC

## SOLUTION;IV (INFUSION), INTRAMUSCULAR, SUBCUTANEOUS, INTRAOSSEOUS, ENDOTRACHEAL

## ATROPINE SULFATE

+! FRESENIUS KABI USA	8MG/20ML (0.4MG/ML)	N209260	001	Jan 26, 2018	Jan NEWA
-----------------------	---------------------	---------	-----	--------------	----------

## SOLUTION/DROPS;OPHTHALMIC

## ISOPTO ATROPINE

ALCON LABS INC	1%	N208151	001	Dec 01, 2016	Jul CMFD
@	1%	N208151	001	Dec 01, 2016	Apr DISC
	1%	N208151	001	Dec 01, 2016	Feb CAHN

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

## TABLET;ORAL

## DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE

@ FOSUN PHARMA	0.025MG;2.5MG	A086173	001		Jan CAHN
UPSHER-SMITH LABS	0.025MG;2.5MG	A210571	001	Aug 31, 2018	Aug NEWA
LONOX					
@ FOSUN PHARMA	0.025MG;2.5MG	A085311	002		Jan CAHN

AVATROMBOPAG MALEATE

## TABLET;ORAL

## DOPELET

+! AKARX INC	EQ 20MG BASE	N210238	001	May 21, 2018	May NEWA
--------------	--------------	---------	-----	--------------	----------

AVIBACTAM SODIUM; CEFTAZIDIME

## POWDER;IV (INFUSION)

## AVYCAZ

+! ALLERGAN SALES LLC	EQ 0.5GM BASE;2GM/VIAL	N206494	001	Feb 25, 2015	Jan CAHN
-----------------------	------------------------	---------	-----	--------------	----------

AZACITIDINE

## POWDER;INTRAVENOUS, SUBCUTANEOUS

## AZACITIDINE

AP	ACCORD HLTHCARE	100MG/VIAL	A207475	001	Jul 02, 2018	Jun NEWA
AP	ACTAVIS LLC	100MG/VIAL	N208216	001	Apr 29, 2016	May CDFR
AP	CIPLA LTD	100MG/VIAL	A209540	001	May 04, 2018	May CDFR
AP	DR REDDYS LABS LTD	100MG/VIAL	A201537	001	Sep 16, 2013	May CDFR
AP	MYLAN INSTITUTIONAL	100MG/VIAL	A204949	001	Apr 28, 2016	May CDFR
AP	NATCO PHARMA LTD	100MG/VIAL	A207234	001	Jun 23, 2017	May CDFR
AP	SHILPA MEDICARE	100MG/VIAL	A207518	001	Sep 29, 2016	May CDFR
	VIDAZA					
AP	+! CELGENE	100MG/VIAL	N050794	001	May 19, 2004	May CDFR
	POWDER;IV (INFUSION), SUBCUTANEOUS					
	AZACITIDINE					
AP	CIPLA LTD	100MG/VIAL	A209540	001	May 04, 2018	Apr NEWA

AZELAIC ACID

AEROSOL, FOAM;TOPICAL

FINACEA

>D>	+!	BAYER HLTHCARE	15%	N207071	001	Jul 29, 2015	Sep CAHN
>A>	+!	LEO PHARMA AS	15%	N207071	001	Jul 29, 2015	Sep CAHN
		CREAM; TOPICAL					
		AZELEX					
>D>	+!	ALLERGAN	20%	N020428	001	Sep 13, 1995	Sep CAHN
>A>	+!	AQUA PHARMS LLC	20%	N020428	001	Sep 13, 1995	Sep CAHN
		GEL;TOPICAL					
		FINACEA					
>D>	+!	BAYER HLTHCARE	15%	N021470	001	Dec 24, 2002	Sep CAHN
>A>	+!	LEO PHARMA AS	15%	N021470	001	Dec 24, 2002	Sep CAHN

AZITHROMYCIN

FOR SUSPENSION;ORAL

AZITHROMYCIN

AB		AMNEAL PHARMS LLC	EQ 100MG BASE/5ML	A205666	001	Jul 19, 2018	Jul NEWA
AB			EQ 200MG BASE/5ML	A205666	002	Jul 19, 2018	Jul NEWA
>A> AB		AUROBINDO PHARMA LTD	EQ 100MG BASE/5ML	A209201	001	Oct 09, 2018	Sep NEWA
>A> AB			EQ 200MG BASE/5ML	A209201	002	Oct 09, 2018	Sep NEWA
AB		EPIC PHARMA LLC	EQ 100MG BASE/5ML	A207531	001	Apr 09, 2018	Mar NEWA
AB			EQ 200MG BASE/5ML	A207531	002	Apr 09, 2018	Mar NEWA
AB		ZYDUS WORLDWIDE	EQ 100MG BASE/5ML	A211147	001	Jul 31, 2018	Jul NEWA
AB			EQ 200MG BASE/5ML	A211147	002	Jul 31, 2018	Jul NEWA
		FOR SUSPENSION, EXTENDED RELEASE;ORAL					
		ZMAX					
	+ @	PF PRISM CV	EQ 2GM BASE/BOT	N050797	001	Jun 10, 2005	Jun DISC
		INJECTABLE; INJECTION					
		AZITHROMYCIN					
>A> AP		HAINAN POLY PHARM	EQ 500MG BASE/VIAL	A203412	001	Oct 09, 2018	Sep NEWA
		TABLET;ORAL					
		AZITHROMYCIN					
	@	APOTEX CORP	EQ 250MG BASE	A065507	001	Jul 13, 2011	Mar DISC
	@		EQ 500MG BASE	A065509	001	Jul 13, 2011	Mar DISC
	@		EQ 600MG BASE	A065508	001	Jul 13, 2011	Mar DISC
AB		AUROBINDO PHARMA LTD	EQ 250MG BASE	A207370	001	Jul 05, 2018	Jul NEWA
AB			EQ 500MG BASE	A207398	001	Jul 05, 2018	Jul NEWA
>A> AB		CSPC OUYI PHARM CO	EQ 600MG BASE	A207566	001	Sep 24, 2018	Sep NEWA

BACITRACIN

INJECTABLE; INJECTION

BACITRACIN

@	MYLAN ASI	50,000 UNITS/VIAL	A090211	001	May 11, 2010	Jan DISC
@	PHARMACIA AND UPJOHN	10,000 UNITS/VIAL	A060733	001		Jul DISC

BACLOFENINJECTABLE;INTRATHECAL  
BACLOFEN

AP		MYLAN LABS LTD	0.5MG/ML	A209592	001	Mar 21, 2018	Mar NEWA
AP			1MG/ML	A209594	001	Mar 06, 2018	Feb NEWA
AP			2MG/ML	A209592	002	Mar 21, 2018	Mar NEWA
		GABLOFEN					
AP	+!	PIRAMAL CRITICAL	1MG/ML	N022462	004	Jun 22, 2012	Feb CFTG

BARICITINIB

TABLET;ORAL

OLUMIANT

+!	ELI LILLY AND CO	2MG	N207924	001	May 31, 2018	May NEWA
----	------------------	-----	---------	-----	--------------	----------

BARIUM SULFATEFOR SUSPENSION;ORAL  
E-Z-HD

+!	BRACCO	98% (334GM/BOT)	N208036	001	Jan 11, 2016	Apr CPOT	
+!	BRACCO	96% (169GM/BOT)	N208036	002	Apr 07, 2017	Apr CPOT	
		PASTE;ORAL					
		VARIBAR PUDDING					
		BRACCO	40%	N208844	001	Oct 14, 2016	Jun CPOT
			40% (92GM/230ML)	N208844	001	Oct 14, 2016	Jun CTNA

SUSPENSION;ORAL

LIQUID E-Z-PAQUE

+! BRACCO	60% (213GM/BOT)	N 208143	003	Mar 01, 2017	Apr CPOT
READI-CAT 2					
+! BRACCO	2% (9GM/BOT)	N 208143	001	Jan 15, 2016	Apr CPOT
READI-CAT 2 SMOOTHIES					
+! BRACCO	2% (9GM/BOT)	N 208143	002	Jan 15, 2016	Apr CPOT
TAGITOL V					
+! BRACCO	40% (8GM/BOT)	N 208143	005	Aug 04, 2017	Apr CPOT
VARIBAR HONEY					
+! BRACCO	40% (100GM/250ML)	N 208143	007	Mar 26, 2018	Mar NEWA
VARIBAR THIN HONEY					
+! BRACCO	40% (100GM/250ML)	N 208143	006	Jan 23, 2018	Jan NEWA

BAZEDOXIFENE ACETATE; ESTROGENS, CONJUGATED

TABLET;ORAL

DUAVEE

+! WYETH PHARMS	EQ 20MG BASE;0.45MG	N 022247	001	Oct 03, 2013	Aug CAHN
-----------------	---------------------	----------	-----	--------------	----------

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED;INHALATION

QVAR 40

+ @ TEVA BRANDED PHARM	0.04MG/INH	N 020911	002	Sep 15, 2000	Jun DISC
QVAR 80					
+ @ TEVA BRANDED PHARM	0.08MG/INH	N 020911	001	Sep 15, 2000	Jun DISC
QVAR REDIHALER					
+ NORTON WATERFORD	0.04MG/INH	N 207921	001	Aug 03, 2017	Jul CMFD
+ @	0.04MG/INH	N 207921	001	Aug 03, 2017	Jun DISC
+!	0.04MG/INH	N 207921	001	Aug 03, 2017	Jan CHRS
+	0.08MG/INH	N 207921	002	Aug 03, 2017	Jul CMFD
+ @	0.08MG/INH	N 207921	002	Aug 03, 2017	Jun DISC

BELINOSTAT

POWDER; INTRAVENOUS

BELEODAQ

+! SPECTRUM PHARMS	500MG/VIAL	N 206256	001	Jul 03, 2014	Jun CDFR
--------------------	------------	----------	-----	--------------	----------

BENAZEPRIL HYDROCHLORIDE

TABLET;ORAL

BENAZEPRIL HYDROCHLORIDE

AB	CASI PHARMS INC	5MG	A 076402	001	Feb 11, 2004	Mar CAHN
AB		10MG	A 076402	002	Feb 11, 2004	Mar CAHN
AB		20MG	A 076402	003	Feb 11, 2004	Mar CAHN
AB		40MG	A 076402	004	Feb 11, 2004	Mar CAHN

BENDAMUSTINE HYDROCHLORIDE

POWDER; IV (INFUSION)

BENDAMUSTINE HYDROCHLORIDE

AP	MYLAN LABS LTD	25MG/VIAL	A 204104	001	Apr 26, 2018	Apr NEWA
AP		100MG/VIAL	A 204104	002	Apr 26, 2018	Apr NEWA
SOLUTION;IV (INFUSION)						
BENDAMUSTINE HYDROCHLORIDE						
+! EAGLE PHARMS	100MG/4ML (25MG/ML)	N 205580	001	May 15, 2018	Jul CHRS	
+	100MG/4ML (25MG/ML)	N 205580	001	May 15, 2018	May NEWA	
TREANDA						
+ @ CEPHALON	45MG/0.5ML (90MG/ML)	N 022249	003	Sep 13, 2013	May DISC	
+ @	180MG/2ML (90MG/ML)	N 022249	004	Sep 13, 2013	May DISC	

>D> BENZNIDAZOLE

&gt;D&gt; TABLET;ORAL

&gt;D&gt; BENZNIDAZOLE

>D>	+ CHEMO RESEARCH SL	12.5MG	N 209570	001	Aug 29, 2017	Sep DISC
>A>	+ @	12.5MG	N 209570	001	Aug 29, 2017	Sep DISC
>D>	+!	100MG	N 209570	002	Aug 29, 2017	Sep DISC
>A>	+ @	100MG	N 209570	002	Aug 29, 2017	Sep DISC

BENZONATATE

CAPSULE;ORAL

BENZONATATE

AA CSPC NBP PHARM CO 100MG A202765 002 Aug 25, 2017 Mar NEWA

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL;TOPICAL

CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE

AB TARO 3.75%;EQ 1.2% BASE A208683 001 Jun 05, 2018 May NEWA  
AB 5%;EQ 1% BASE A208776 001 May 25, 2018 May NEWA  
AB TARO PHARMS 5%;1.2% A206218 001 Dec 15, 2017 May CAHN  
ONEXTON  
AB +! DOW PHARM 3.75%;EQ 1.2% BASE N050819 002 Nov 24, 2014 May CTECBENZPHETAMINE HYDROCHLORIDE

TABLET;ORAL

BENZPHETAMINE HYDROCHLORIDE

>D> AA MIKART 25MG A090473 001 Sep 15, 2010 Sep CTEC  
>A> 25MG A090473 001 Sep 15, 2010 Sep CTEC  
>D> AA TEDOR PHARM 25MG A040747 002 Nov 20, 2015 Sep DISC  
>A> @ 25MG A040747 002 Nov 20, 2015 Sep DISC  
>D> AA 50MG A040747 001 Mar 30, 2007 Sep DISC  
>A> @ 50MG A040747 001 Mar 30, 2007 Sep DISC  
AA TWI PHARMS 50MG A040578 001 Apr 17, 2006 Jul CAHNBENZTROPINE MESYLATE

TABLET;ORAL

BENZTROPINE MESYLATE

@ CHARTWELL RX 1MG A081265 002 Jan 23, 1992 Aug CMS1  
@ 2MG A081265 001 Jan 23, 1992 Jan CAHNBETAINE

FOR SOLUTION;ORAL

CYSTADANE

+! ORPHAN EUROPE 1GM/SCOOPFUL N020576 001 Oct 25, 1996 May CAIN

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED;TOPICAL

BETAMETHASONE DIPROPIONATE

>A> AB ANDA REPOSITORY EQ 0.05% BASE A076603 001 Jan 23, 2004 Sep CAHN  
>D> AB TOLMAR EQ 0.05% BASE A076603 001 Jan 23, 2004 Sep CAHN  
LOTION;TOPICAL  
BETAMETHASONE DIPROPIONATE  
AB HI-TECH PHARMACAL EQ 0.05% BASE A209896 001 Feb 06, 2018 Jan NEWA  
LOTION, AUGMENTED;TOPICAL  
BETAMETHASONE DIPROPIONATE  
AB ! TARO EQ 0.05% BASE A077477 001 May 21, 2007 Aug CHRS  
AB TELIGENT PHARMA INC EQ 0.05% BASE A206389 001 Feb 13, 2018 Jan NEWA  
DIPROLENE  
+ @ MERCK SHARP DOHME EQ 0.05% BASE N019716 001 Aug 01, 1988 Aug DISCBETAMETHASONE VALERATE

LOTION;TOPICAL

BETA-VAL

@ G AND W LABS INC EQ 0.1% BASE A070072 001 Jun 27, 1985 Jan DISC

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

BETOPICTIC

AT +! SANDOZ INC EQ 0.5% BASE N019270 001 Aug 30, 1985 Jan CAHN

BEXAROTENE

CAPSULE;ORAL

BEXAROTENE

AB AMERIGEN PHARMS LTD 75MG A209861 001 May 08, 2018 Apr NEWA  
AB AMNEAL PHARMS NY 75MG A210105 001 Sep 04, 2018 Aug NEWA  
AB UPSHER-SMITH LABS 75MG A209886 001 Jul 25, 2018 Jul NEWA

BICALUTAMIDE

TABLET;ORAL  
CASODEX

AB +! ANI PHARMS INC 50MG N020498 001 Oct 04, 1995 Jan CAHN

BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE

TABLET;ORAL  
BIKTARVY  
+! GILEAD SCIENCES INC EQ 50MG BASE;200MG;EQ 25MG BASE N210251 001 Feb 07, 2018 Feb NEWA

BIMATOPROST

SOLUTION/DROPS;TOPICAL  
BIMATOPROST

>A> AT HI-TECH PHARMACAL 0.03% A203051 001 Oct 09, 2018 Sep NEWA

BINIMETINIB

TABLET;ORAL  
MEKTOVI

+! ARRAY BIOPHARMA INC 15MG N210498 001 Jun 27, 2018 Jun NEWA

BISACODYL; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION, TABLET, DELAYED RELEASE;ORAL  
PEG-3350, SODIUM CHLORIDE, SODIUM BICARBONATE, POTASSIUM CHLORIDE AND BISACODYL  
@ NOVEL LABS INC 5MG,N/A;N/A,210GM;N/A,0.74GM;N/A,2 A202217 001 Aug 20, 2014 May DISC  
.86GM;N/A,5.6GM

BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE

CAPSULE;ORAL  
PYLERA

+! ALLERGAN SALES LLC 140MG;125MG;125MG N050786 001 Sep 28, 2006 Jan CAHN

BISOPROLOL FUMARATE

TABLET;ORAL  
BISOPROLOL FUMARATE

AB CASI PHARMS INC	5MG	A075643	001	Nov 16, 2000	Mar CAHN
AB	10MG	A075643	002	Nov 16, 2000	Mar CAHN
ZEBETA					
+ @ TEVA WOMENS	5MG	N019982	002	Jul 31, 1992	Aug CRLD
+ @	10MG	N019982	001	Jul 31, 1992	Aug CRLD

BIVALIRUDIN

INJECTABLE;INTRAVENOUS  
ANGIOMAX

>A> AP +! SANDOZ INC	250MG/VIAL	N020873	001	Dec 15, 2000	Sep CAHN
>D> AP +! THE MEDICINES CO	250MG/VIAL	N020873	001	Dec 15, 2000	Sep CAHN

BIVALIRUDIN

AP AUROBINDO PHARMA LTD	250MG/VIAL	A205962	001	Jul 27, 2018	Jul NEWA
AP MYLAN INSTITUTIONAL	250MG/VIAL	A202471	001	Jun 01, 2018	May NEWA
AP SAGENT PHARMS	250MG/VIAL	A091602	001	Jul 16, 2018	Jul NEWA

SOLUTION;INTRAVENOUS

BIVALIRUDIN IN 0.9% SODIUM CHLORIDE

+! BAXTER HLTHCARE CORP	250MG/50ML (5MG/ML)	N208374	001	Dec 21, 2017	Jul CDFR
+!	500MG/100ML (5MG/ML)	N208374	002	Dec 21, 2017	Jul CDFR

SOLUTION;IV (INFUSION)

BIVALIRUDIN IN 0.9% SODIUM CHLORIDE

+! BAXTER HLTHCARE CORP	250MG/50ML (5MG/ML)	N208374	001	Dec 21, 2017	Jan CAHN
+!	500MG/100ML (5MG/ML)	N208374	002	Dec 21, 2017	Jan CAHN

BLEOMYCIN SULFATE

INJECTABLE;INJECTION  
BLEOMYCIN SULFATE

AP HONG KONG	EQ 15 UNITS BASE/VIAL	A205030	001	Apr 20, 2018	Apr NEWA
AP	EQ 30 UNITS BASE/VIAL	A205030	002	Apr 20, 2018	Apr NEWA

BORTEZOMIB

POWDER;INTRAVENOUS, SUBCUTANEOUS  
BORTEZOMIB

+! HOSPIRA INC 2.5MG/VIAL N209191 001 Jul 12, 2018 Jul NEWA

BRIGATINIB

TABLET;ORAL  
ALUNBRIG  
+ ARIAD 90MG N208772 002 Apr 28, 2017 Jun CHRS  
+! 180MG N208772 003 Oct 02, 2017 Jun CHRS

BROMFENAC SODIUM

SOLUTION/DROPS;OPHTHALMIC  
BROMFENAC SODIUM  
@ AMRING PHARMS EQ 0.09% ACID A202030 001 Jan 09, 2013 Jun DISC  
@ APOTEX INC EQ 0.09% ACID A202435 001 Jun 19, 2014 Jun DISC  
@ PADDOCK LLC EQ 0.09% ACID A201941 001 Feb 10, 2015 Jun DISC

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP;ORAL  
BROMFED-DM  
AA ! WOCKHARDT BIO AG 2MG/5ML;10MG/5ML;30MG/5ML A088811 001 Jun 07, 1985 Apr CAHN

BUDESONIDE

CAPSULE;ORAL  
BUDESONIDE  
AB RISING PHARMS 3MG A207367 001 Apr 07, 2017 Aug CAHN  
TABLET, EXTENDED RELEASE;ORAL  
BUDESONIDE  
AB ACTAVIS LABS FL INC 9MG A205457 001 Jul 03, 2018 Jun NEWA  
UCERIS  
AB +! VALEANT PHARMS INTL 9MG N203634 001 Jan 14, 2013 Jun CFTG

BUMETANIDE

INJECTABLE;INJECTION  
BUMETANIDE  
@ ATHENEX INC 0.25MG/ML A074441 001 Jan 27, 1995 Apr DISC  
AP ! WEST-WARD PHARMS INT 0.25MG/ML A079196 001 Apr 30, 2008 Apr CHRS  
TABLET;ORAL  
BUMETANIDE  
AB UPSHER-SMITH LABS 0.5MG A209916 001 Jan 23, 2018 Jan NEWA  
AB 1MG A209916 002 Jan 23, 2018 Jan NEWA  
AB 2MG A209916 003 Jan 23, 2018 Jan NEWA  
AB ZYDUS PHARMS USA INC 0.5MG A202900 001 Apr 30, 2018 Apr NEWA  
AB 1MG A202900 002 Apr 30, 2018 Apr NEWA  
AB 2MG A202900 003 Apr 30, 2018 Apr NEWA

BUPIVACAINE HYDROCHLORIDE

INJECTABLE;SPINAL  
SENSORCAINE  
@ FRESENIUS KABI USA 0.75% A071202 001 Apr 15, 1987 Jun DISC

BUPRENORPHINE

SOLUTION, EXTENDED RELEASE;SUBCUTANEOUS  
SUBLOCODE  
+ INDIVIOR INC 100MG/0.5ML (100MG/0.5ML) N209819 001 Nov 30, 2017 Jul CMS1  
+! 300MG/1.5ML (200MG/ML) N209819 002 Nov 30, 2017 Jul CMS1

BUPRENORPHINE HYDROCHLORIDE

IMPLANT;IMPLANTATION  
PROBUPHINE  
+! TITAN PHARMS EQ 80MG BASE/IMPLANT N204442 001 May 26, 2016 Jun CAHN  
TABLET;SUBLINGUAL  
BUPRENORPHINE HYDROCHLORIDE

AB CASI PHARMS INC EQ 2MG BASE A090279 001 Jun 10, 2015 Mar CAHN  
AB EQ 8MG BASE A090279 002 Jun 10, 2015 Mar CAHN

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

FILM;BUCCAL, SUBLINGUAL  
BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE  
AB DR REDDYS LABS SA EQ 2MG BASE;EQ 0.5MG BASE A205299 001 Jun 14, 2018 May NEWA  
AB EQ 4MG BASE;EQ 1MG BASE A205806 001 Jun 14, 2018 May NEWA  
AB EQ 8MG BASE;EQ 2MG BASE A205299 002 Jun 14, 2018 May NEWA  
AB EQ 12MG BASE;EQ 3MG BASE A205806 002 Jun 14, 2018 May NEWA  
AB MYLAN TECHNOLOGIES EQ 8MG BASE;EQ 2MG BASE A207607 001 Jun 14, 2018 May NEWA  
AB EQ 12MG BASE;EQ 3MG BASE A207607 002 Jun 14, 2018 May NEWA

FILM;BUCCAL, SUBLINGUAL  
SUBOXONE

AB	+ INDIVIOR INC	EQ 2MG BASE;EQ 0.5MG BASE	N 022410	001	Aug 30, 2010	May CFTG
AB	+	EQ 4MG BASE;EQ 1MG BASE	N 022410	003	Aug 10, 2012	May CFTG
AB	+	EQ 8MG BASE;EQ 2MG BASE	N 022410	002	Aug 30, 2010	May CFTG
AB	+!	EQ 12MG BASE;EQ 3MG BASE	N 022410	004	Aug 10, 2012	May CFTG
>A>	FILM;SUBLINGUAL					
>A>	CASSIPA					
>A>	+! TEVA PHARMS USA	EQ 16MG BASE;EQ 4MG BASE	N 208042	001	Sep 07, 2018	Sep NEWA

BUPROPION HYDROCHLORIDE

TABLET;ORAL  
BUPROPION HYDROCHLORIDE

AB	ALEMBIC PHARMS LTD	75MG	A 203013	001	Jun 08, 2018	May NEWA
AB		100MG	A 203013	002	Jun 08, 2018	May NEWA
	TABLET, EXTENDED RELEASE;ORAL					
	BUPROPION HYDROCHLORIDE					
AB2	SCIEGEN PHARMS INC	150MG	A 206122	001	Aug 17, 2016	Jan CAHN
AB3	YICHANG HUMANWELL	150MG	A 210015	001	Jun 14, 2018	Jun NEWA
AB3		300MG	A 210015	002	Jun 14, 2018	Jun NEWA
AB3	ZYDUS PHARMS USA INC	150MG	A 201567	002	Jul 23, 2018	Jul NEWA

BUPROPION HYDROCHLORIDE; NALTREXONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
CONTRAVE

+! NALPROPION 90MG;8MG

N 200063 001 Sep 10, 2014 Jul CAHN

BUSPIRONE HYDROCHLORIDE

TABLET;ORAL  
BUSPIRONE HYDROCHLORIDE

AB	AUROBINDO PHARMA LTD	5MG	A 078246	001	Feb 27, 2009	Feb CAHN
AB		10MG	A 078246	002	Feb 27, 2009	Feb CAHN
AB		15MG	A 078246	003	Feb 27, 2009	Feb CAHN
AB		30MG	A 078246	004	Feb 27, 2009	Feb CAHN
	@ FOSUN PHARMA	5MG	A 075413	001	Mar 19, 2002	Jan CAHN
	@	10MG	A 075413	002	Mar 19, 2002	Jan CAHN
	@	15MG	A 075413	003	Mar 19, 2002	Jan CAHN
AB	INVENTIA HLTHCARE	5MG	A 209696	001	May 03, 2018	Apr NEWA
AB		7.5MG	A 209696	002	May 03, 2018	Apr NEWA
AB		10MG	A 209696	003	May 03, 2018	Apr NEWA
AB		15MG	A 209696	004	May 03, 2018	Apr NEWA
AB		30MG	A 209696	005	May 03, 2018	Apr NEWA

BUSULFAN

INJECTABLE;INJECTION  
BUSULFAN

AP	HOSPIRA INC	6MG/ML	A 205672	001	Jul 31, 2018	Jul NEWA
AP	MYLAN LABS LTD	6MG/ML	A 205184	001	Jul 13, 2018	Jul NEWA
>D> AP	SANDOZ INC	6MG/ML	A 205106	001	Jul 07, 2017	Sep CMS1
>A> AP		6MG/ML	A 205106	001	Sep 21, 2018	Sep CMS1

BUTORPHANOL TARTRATE

INJECTABLE;INJECTION  
BUTORPHANOL TARTRATE PRESERVATIVE FREE

AP	! HOSPIRA	1MG/ML	A 074626	001	Jan 23, 1997	Mar CHRS
AP	!	2MG/ML	A 074626	002	Jan 23, 1997	Mar CHRS
	STADOL					
+ @ APOTHECON		2MG/ML	N 017857	004		Mar CRLD
	STADOL PRESERVATIVE FREE					
+ @ APOTHECON		1MG/ML	N 017857	001		Mar CRLD
+ @		2MG/ML	N 017857	002		Mar CRLD

CABAZITAXEL

SOLUTION;INTRAVENOUS  
JEVTANA KIT

+! SANOFI AVENTIS US 60MG/1.5ML (40MG/ML)

N 201023 001 Jun 17, 2010 Jul CDFR

CABERGOLINE

TABLET;ORAL  
CABERGOLINE  
@ APOTEX CORP 0.5MG A201503 001 Mar 08, 2013 Mar DISC  
AB INGENUS PHARMS LLC 0.5MG A204735 001 Aug 01, 2018 Jul NEWA

CABOZANTINIB S-MALATE

CAPSULE;ORAL  
COMETRIQ  
+! EXELIXIS EQ 20MG BASE N203756 001 Nov 29, 2012 Jun CHRS  
+ EQ 80MG BASE N203756 002 Nov 29, 2012 Jun CHRS

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY;RECTAL  
MIGERGOT  
! HZNP 100MG;2MG A086557 001 Oct 04, 1983 Aug CAHN

CALCIUM ACETATE

CAPSULE;ORAL  
CALCIUM ACETATE  
AB LOTUS PHARM CO LTD 667MG A203298 001 Jul 26, 2016 Jun CAHN  
TABLET;ORAL  
ELIPHOS  
@ CYPRESS PHARM 667MG A078502 001 Nov 25, 2008 Apr DISC

CALCIUM CHLORIDE

INJECTABLE;INJECTION  
CALCIUM CHLORIDE 10%  
AP INTL MEDICATION SYS 100MG/ML A203477 001 May 09, 2018 Apr NEWA

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

SOLUTION;IRRIGATION  
BSS PLUS  
+! ALCON 0.154MG/ML;0.92MG/ML;0.184MG/ML;0. N018469 001 Aug CTEC  
2MG/ML;0.38MG/ML;2.1MG/ML;7.14MG/M  
L;0.42MG/ML  
METHOTREXATE SODIUM  
@ AKORN 0.154MG/ML;0.92MG/ML;0.184MG/ML;0. N020079 001 Feb 26, 1999 Aug DISC  
2MG/ML;0.38MG/ML;2.1MG/ML;7.14MG/M  
L;0.42MG/ML

CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

INJECTABLE;INJECTION  
PRISMASOL B22GK 2/0 IN PLASTIC CONTAINER  
+ @ BAXTER HLTHCARE CORP N/A/1000ML;20GM/1000ML;5.4GM/1000M N021703 010 Oct 10, 2008 Jun DISC  
L;3.05GM/1000ML;0.157GM/1000ML;2.2  
1GM/1000ML;7.07GM/1000ML (5000ML)

PRISMASOL B22GK 4/2.5 IN PLASTIC CONTAINER  
+ @ BAXTER HLTHCARE CORP 3.68GM/1000ML;20GM/1000ML;5.4GM/1000M N021703 013 Oct 10, 2008 Jun DISC  
00ML;3.05GM/1000ML;0.314GM/1000ML;  
2.21GM/1000ML;7.07GM/1000ML  
(5000ML)  
PRISMASOL BK 0/3.5 IN PLASTIC CONTAINER  
+ @ BAXTER HLTHCARE CORP 5.15GM/1000ML;N/A/1000ML;5.4GM/100 N021703 001 Oct 25, 2006 Jun DISC  
0ML;2.03GM/1000ML;N/A/1000ML;3.09G  
M/1000ML;6.46GM/1000ML (5000ML)

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE;INJECTION  
DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER  
@ B BRAUN 33MG/100ML;5GM/100ML;30MG/100ML;86 N020000 001 Apr 17, 1992 Aug DISC  
0MG/100ML

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE;INJECTION  
POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER  
+ @ ICU MEDICAL INC 20MG/100ML;5GM/100ML;104MG/100ML;6 N019685 005 Oct 17, 1988 Jan CRLD  
00MG/100ML;310MG/100ML  
+ @ 20MG/100ML;5GM/100ML;179MG/100ML; N019685 006 Oct 17, 1988 Jan CRLD

INJECTABLE; INJECTION

	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER 600MG/100ML; 310MG/100ML				
	POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER + @ ICU MEDICAL INC 20MG/100ML; 5GM/100ML; 254MG/100ML; 6 N019685 007 Oct 17, 1988 Jan CRLD				
AP	+ ICU MEDICAL INC 20MG/100ML; 5GM/100ML; 254MG/100ML; 6 N019685 002 Oct 17, 1988 Jan CRLD				
	+ @ 20MG/100ML; 5GM/100ML; 328MG/100ML; 6 N019685 008 Oct 17, 1988 Jan DISC				
	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER + @ ICU MEDICAL INC 20MG/100ML; 5GM/100ML; 179MG/100ML; 6 N019685 003 Oct 17, 1988 Jan CRLD				
	POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER + @ ICU MEDICAL INC 20MG/100ML; 5GM/100ML; 328MG/100ML; 6 N019685 004 Oct 17, 1988 Jan DISC				
	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER + @ ICU MEDICAL INC 20MG/100ML; 5GM/100ML; 104MG/100ML; 6 N019685 001 Oct 17, 1988 Jan CRLD				

CALCIUM GLUCONATE

SOLUTION; INTRAVENOUS  
CALCIUM GLUCONATE

+! FRESENIUS KABI USA	1GM/10ML (100MG/ML)	N208418	001	Jun 15, 2017	May CDFR
+!	5GM/50ML (100MG/ML)	N208418	002	Jun 15, 2017	May CDFR
+!	10GM/100ML (100MG/ML)	N208418	003	Jun 15, 2017	May CDFR

CANDESARTAN CILEXETIL

TABLET; ORAL  
ATACAND

AB	+ ANI PHARMS INC	4MG	N020838	001	Jun 04, 1998	Jan CAHN
AB	+ !	8MG	N020838	002	Jun 04, 1998	Jan CAHN
AB	+ !	16MG	N020838	003	Jun 04, 1998	Jan CAHN
AB	+ !	32MG	N020838	004	Jun 04, 1998	Jan CAHN
	CANDESARTAN CILEXETIL					
	@ APOTEX INC	4MG	A202079	001	Jan 10, 2014	Mar DISC
	@	8MG	A202079	002	Jan 10, 2014	Mar DISC
	@	16MG	A202079	003	Jan 10, 2014	Mar DISC
	@	32MG	A202079	004	Jan 10, 2014	Mar DISC
AB	MYLAN PHARMS INC	4MG	A078702	001	May 03, 2013	Apr CAHN
AB		8MG	A078702	002	May 03, 2013	Apr CAHN
AB		16MG	A078702	003	May 03, 2013	Apr CAHN
AB		32MG	A078702	004	May 03, 2013	Apr CAHN

CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL  
ATACAND HCT

AB	+ ANI PHARMS INC	16MG; 12.5MG	N021093	001	Sep 05, 2000	Feb CAHN
AB	+ !	32MG; 12.5MG	N021093	002	Sep 05, 2000	Feb CAHN
AB	+ !	32MG; 25MG	N021093	003	May 16, 2008	Feb CAHN
	CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE					
	@ APOTEX INC	16MG; 12.5MG	A202884	001	Dec 04, 2012	Mar DISC
	@	32MG; 12.5MG	A202884	002	Dec 04, 2012	Mar DISC
	@	32MG; 25MG	A202884	003	Jun 03, 2013	Mar DISC
AB	PRINSTON INC	16MG; 12.5MG	A207455	001	Apr 11, 2018	Mar NEWA
AB		32MG; 12.5MG	A207455	002	Apr 11, 2018	Mar NEWA
AB		32MG; 25MG	A207455	003	Apr 11, 2018	Mar NEWA

CANGRELOR

POWDER; INTRAVENOUS  
KENCREAL

+! CHIESI USA INC	50MG/VIAL				
		N204958	001	Jun 22, 2015	Jul CDFR

CAPECITABINE

TABLET; ORAL  
CAPECITABINE

AB	EUGIA PHARMA	150MG	A210604	001	Apr 17, 2018	Apr NEWA
AB		500MG	A210604	002	Apr 17, 2018	Apr NEWA
AB	MSN LABS PVT LTD	150MG	A209365	001	Jul 02, 2018	Jun NEWA
AB		500MG	A209365	002	Jul 02, 2018	Jun NEWA

CAPTOPRIL

TABLET;ORAL

Captopril

@ OXFORD PHARMS	12.5MG	A074418	001	Feb 13, 1996	Jul CAHN
@	25MG	A074418	002	Feb 13, 1996	Jul CAHN
@	50MG	A074418	003	Feb 13, 1996	Jul CAHN
@	100MG	A074418	004	Feb 13, 1996	Jul CAHN
@ YAOPHARMA CO LTD	12.5MG	A074363	001	Nov 09, 1995	Jan CAHN
@	12.5MG	A074519	001	Feb 13, 1996	Jan CAHN
@	25MG	A074363	002	Nov 09, 1995	Jan CAHN
@	25MG	A074519	002	Feb 13, 1996	Jan CAHN
@	50MG	A074363	003	Nov 09, 1995	Jan CAHN
@	50MG	A074519	003	Feb 13, 1996	Jan CAHN
@	100MG	A074363	004	Nov 09, 1995	Jan CAHN
@	100MG	A074519	004	Feb 13, 1996	Jan CAHN

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET;ORAL

Captopril And Hydrochlorothiazide

@ G AND W LABS INC	25MG;15MG	A074827	001	Dec 29, 1997	Jan DISC
@	25MG;25MG	A074827	002	Dec 29, 1997	Jan DISC
@	50MG;15MG	A074827	004	Dec 29, 1997	Jan DISC
@	50MG;25MG	A074827	003	Dec 29, 1997	Jan DISC
MYLAN	25MG;15MG	A074896	001	Dec 29, 1997	Jan CTEC
!	25MG;25MG	A074896	002	Dec 29, 1997	Jan CTEC
!	50MG;15MG	A074896	004	Dec 29, 1997	Jan CTEC
	50MG;25MG	A074896	003	Dec 29, 1997	Jan CTEC

CARBAMAZEPINE

SOLUTION;INTRAVENOUS

CARNEXIV

+ @ LUNDBECK PHARMS LLC	200MG/20ML (10MG/ML)	N206030	001	Oct 07, 2016	Jul CDFR
-------------------------	----------------------	---------	-----	--------------	----------

SOLUTION;IV (INFUSION)

CARNEXIV

+ @ LUNDBECK PHARMS LLC	200MG/20ML (10MG/ML)	N206030	001	Oct 07, 2016	Jun DISC
-------------------------	----------------------	---------	-----	--------------	----------

CARBIDOPA

TABLET;ORAL

Carbidopa

AB	ZYDUS PHARMS USA INC	25MG	A209910	001	May 07, 2018	Apr NEWA
----	----------------------	------	---------	-----	--------------	----------

CARBINOXAMINE MALEATE

SOLUTION;ORAL

Carbinoxamine Maleate

@ CYPRESS PHARM	4MG/5ML	A090418	001	May 04, 2010	Apr DISC
TABLET;ORAL	Carbinoxamine Maleate				
@ CYPRESS PHARM	4MG	A090417	001	Aug 23, 2010	Apr DISC

CARBOPLATIN

INJECTABLE;IV (INFUSION)

Carboplatin

AP	EUGIA PHARMA	50MG/5ML (10MG/ML)	A205487	001	Mar 28, 2016	Apr CAHN
AP		150MG/15ML (10MG/ML)	A205487	002	Mar 28, 2016	Apr CAHN
AP		450MG/45ML (10MG/ML)	A205487	003	Mar 28, 2016	Apr CAHN
	@ MYLAN LABS LTD	1GM/100ML (10MG/ML)	A091478	001	Nov 23, 2011	May DISC

CARFILZOMIB

POWDER;INTRAVENOUS

Kyprolis

+ ONYX THERAP	10MG/VIAL	N202714	003	Jun 07, 2018	Jun NEWA
---------------	-----------	---------	-----	--------------	----------

CARIPRAZINE HYDROCHLORIDE

CAPSULE;ORAL

Vraylar

+ ALLERGAN SALES LLC	EQ 1.5MG BASE	N204370	001	Sep 17, 2015	Jan CAHN
+	EQ 3MG BASE	N204370	002	Sep 17, 2015	Jan CAHN
+	EQ 4.5MG BASE	N204370	003	Sep 17, 2015	Jan CAHN
+!	EQ 6MG BASE	N204370	004	Sep 17, 2015	Jan CAHN

CARISOPRODOL

CAPSULE;ORAL	SOMA	+ @ MYLAN SPECIALITY LP	250MG	N 011792	003	Aug CRLD	
TABLET;ORAL	CARISOPRODOL	@ FOSUN PHARMA	350MG	A 081025	001	Apr 13, 1989	Jan CAHN
>D> AA	INGENUS PHARMS NJ	350MG	A 040823	001	Oct 22, 2008	Sep CAHN	
>A> AA	NOVAST LABS	350MG	A 040823	001	Oct 22, 2008	Sep CAHN	

CARMUSTINE

INJECTABLE;INJECTION	BICNU	AP +! EMCURE PHARMS LTD	100MG/VIAL	N 017422	001	Aug CFTG	
AP	CARMUSTINE	NAVINTA LLC	100MG/VIAL	A 210179	001	Sep 11, 2018	Aug NEWA

CARVEDILOL

TABLET;ORAL	CARVEDILOL	AB CHARTWELL MOLECULAR	3.125MG	A 077474	001	Sep 05, 2007	Mar CAHN
AB	6.25MG		6.25MG	A 077474	002	Sep 05, 2007	Mar CAHN
AB	12.5MG		12.5MG	A 077474	003	Sep 05, 2007	Mar CAHN
AB	25MG		25MG	A 077474	004	Sep 05, 2007	Mar CAHN

CARVEDILOL PHOSPHATE

CAPSULE, EXTENDED RELEASE;ORAL	CARVEDILOL PHOSPHATE	AB IMPAX LABS INC	10MG	A 204717	001	May 07, 2018	Apr NEWA
AB	20MG		20MG	A 204717	002	May 07, 2018	Apr NEWA
AB	40MG		40MG	A 204717	003	May 07, 2018	Apr NEWA
AB	80MG		80MG	A 204717	004	May 07, 2018	Apr NEWA

CASPOFUNGIN ACETATE

POWDER;INTRAVENOUS	CANCIDAS	AP +! MERCK	50MG/VIAL	N 021227	001	Jan 26, 2001	May CDFR
AP +!	CASPOFUNGIN ACETATE	CIPLA LTD	50MG/VIAL	A 209489	001	Jul 12, 2018	Jul NEWA
AP	70MG/VIAL		70MG/VIAL	A 209489	002	Jul 12, 2018	Jul NEWA
AP	FRESENIUS KABI USA	50MG/VIAL	50MG/VIAL	N 206110	001	Dec 30, 2016	May CDFR
AP	GLAND PHARMA LTD	50MG/VIAL	70MG/VIAL	N 206110	002	Dec 30, 2016	May CDFR
AP	MYLAN LABS LTD	50MG/VIAL	50MG/VIAL	A 207092	001	Sep 29, 2017	May CDFR
AP	SANDOZ INC	50MG/VIAL	70MG/VIAL	A 207092	002	Sep 29, 2017	May CDFR
AP	XELLIA PHARMS APS	50MG/VIAL	50MG/VIAL	A 207650	001	Sep 29, 2017	May CDFR
AP		70MG/VIAL	70MG/VIAL	A 207650	002	Sep 29, 2017	May CDFR
AP		50MG/VIAL	50MG/VIAL	A 200833	001	Jun 28, 2018	Jun NEWA
AP		70MG/VIAL	70MG/VIAL	A 200833	002	Jun 28, 2018	Jun NEWA
AP		50MG/VIAL	50MG/VIAL	A 205923	001	Jul 02, 2018	Jun NEWA
AP		70MG/VIAL	70MG/VIAL	A 205923	002	Jul 02, 2018	Jun NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE;ORAL	CEFADROXIL	@ CSPC OUYI PHARM CO	EQ 500MG BASE	A 205072	001	Jul 28, 2017	Jun DISC
--------------	------------	----------------------	---------------	----------	-----	--------------	----------

CEFAZOLIN SODIUM

INJECTABLE;INJECTION	ANCEF IN PLASTIC CONTAINER	@ BAXTER HLTHCARE	EQ 10MG BASE/ML	A 063002	001	Mar 28, 1991	Jun DISC
----------------------	----------------------------	-------------------	-----------------	----------	-----	--------------	----------

CEFEPIME HYDROCHLORIDE

INJECTABLE;INJECTION	CEFEPIME HYDROCHLORIDE	@ FOSUN PHARMA	EQ 500MG BASE/VIAL	A 090291	001	Dec 21, 2010	Jan CAHN
@		EQ 1GM BASE/VIAL	EQ 1GM BASE/VIAL	A 090291	002	Dec 21, 2010	Jan CAHN
@		EQ 2GM BASE/VIAL	EQ 2GM BASE/VIAL	A 090291	003	Dec 21, 2010	Jan CAHN

POWDER; INTRAVENOUS  
 CEFEPIME HYDROCHLORIDE IN PLASTIC CONTAINER  
 SAMSON MEDCL EQ 100GM BASE

A209408 001 Aug 21, 2018 Aug NEWA

CEFIXIME

CAPSULE; ORAL				
>A>	CEFIXIME			
>A> AB	ALKEM LABS LTD	400MG		A210574 001 Oct 09, 2018 Sep NEWA
	SUPRAX			
>D>	+! LUPIN LTD	400MG		N203195 001 Jun 01, 2012 Sep CFTG
>A> AB	+!	400MG		N203195 001 Jun 01, 2012 Sep CFTG

CEFOTAXIME SODIUM

INJECTABLE; INJECTION				
CEFOTAXIME				
AP ! HIKMA	EQ 500MG BASE/VIAL			A065072 001 Nov 20, 2002 Apr CHRS
AP !	EQ 1GM BASE/VIAL			A065072 002 Nov 20, 2002 Apr CHRS
AP !	EQ 2GM BASE/VIAL			A065072 003 Nov 20, 2002 Apr CHRS
AP !	EQ 10GM BASE/VIAL			A065071 001 Nov 20, 2002 Apr CHRS
CLAFORAN				
+ @ US PHARM HOLDINGS	EQ 500MG BASE/VIAL			N050547 001
+ @	EQ 1GM BASE/VIAL			N050547 002
+ @	EQ 2GM BASE/VIAL			N050547 003
+ @	EQ 10GM BASE/VIAL			N050547 004 Dec 29, 1983 Apr DISC

CEFOXITIN SODIUM

POWDER; INTRAVENOUS  
 CEFOXITIN IN PLASTIC CONTAINER  
 SAMSON MEDCL EQ 100GM BASE

A200938 001 Nov 16, 2015 Jul CDFR

CEFPROZIL

TABLET; ORAL				
CEFPROZIL				
AB CASI PHARMS INC	250MG			A065235 001 Nov 14, 2005 Mar CAHN
AB	500MG			A065235 002 Nov 14, 2005 Mar CAHN

CEFTAROLINE FOSAMIL

POWDER; INTRAVENOUS				
TEFLARO				
+ ALLERGAN SALES LLC	400MG/VIAL			N200327 001 Oct 29, 2010 Jul CDFR
+!	600MG/VIAL			N200327 002 Oct 29, 2010 Jul CDFR
POWDER; IV (INFUSION)				
TEFLARO				
+ ALLERGAN SALES LLC	400MG/VIAL			N200327 001 Oct 29, 2010 Jan CAHN
+!	600MG/VIAL			N200327 002 Oct 29, 2010 Jan CAHN

CEFTAZIDIME

INJECTABLE; INJECTION  
 CEFTAZIDIME  
 @ ACS DOBFAR 500MG/VIAL

A062640 001 Nov 20, 1985 Jun DISC

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION  
 FORTAZ IN PLASTIC CONTAINER  
 + @ TELIGENT EQ 20MG BASE/ML  
 + @ EQ 40MG BASE/ML

N050634 002 Apr 28, 1989 May DISC  
N050634 003 Apr 28, 1989 May DISCCEFTIBUTEN DIHYDRATE

CAPSULE; ORAL				
CEDAX				
@ SI PHARMS	EQ 400MG BASE			N050685 002 Dec 20, 1995 Jan CAHN
FOR SUSPENSION; ORAL				
CEDAX				
+ @ SI PHARMS	EQ 90MG BASE/5ML			N050686 001 Dec 20, 1995 Jan CAHN
+ @	EQ 180MG BASE/5ML			N050686 002 Dec 20, 1995 Jan CAHN

CEFTOLOZANE SULFATE; TAZOBACTAM SODIUM

POWDER; INTRAVENOUS

ZERBAXA

+! CUBIST PHARMS LLC EQ 1GM BASE/VIAL;EQ 0.5GM  
BASE/VIAL

N206829 001 Dec 19, 2014 Jul CDFR

CEFTRIAZONE SODIUMINJECTABLE; INTRAMUSCULAR, INTRAVENOUS  
CEFTRIAZONEAP SAGENT PHARMS EQ 250MG BASE/VIAL  
AP EQ 500MG BASE/VIAL  
AP EQ 1GM BASE/VIAL  
AP EQ 2GM BASE/VIALA091049 001 Jun 11, 2018 May NEWA  
A091049 002 Jun 11, 2018 May NEWA  
A091049 003 Jun 11, 2018 May NEWA  
A091049 004 Jun 11, 2018 May NEWACEFUROXIME AXETILFOR SUSPENSION; ORAL  
CEFTIN+ @ GLAXOSMITHKLINE EQ 125MG BASE/5ML  
+ @ EQ 250MG BASE/5MLN050672 001 Jun 30, 1994 Jul DISC  
N050672 002 Apr 29, 1997 Jul DISCTABLET; ORAL  
CEFTIN+ @ GLAXOSMITHKLINE EQ 125MG BASE  
+ @ EQ 250MG BASE  
+ @ EQ 500MG BASEN050605 001 Dec 28, 1987 May DISC  
N050605 002 Dec 28, 1987 May DISC  
N050605 003 Dec 28, 1987 May DISC

CEFUROXIME AXETIL

@ FOSUN PHARMA EQ 250MG BASE  
@ EQ 500MG BASEA065126 001 Oct 28, 2003 Jan CAHN  
A065126 002 Oct 28, 2003 Jan CAHN  
A065135 002 Jul 25, 2003 May CHRS

AB ! LUPIN EQ 500MG BASE

CEFUROXIME SODIUMINJECTABLE; INJECTION  
ZINACEF IN PLASTIC CONTAINER

+ @ TELIGENT EQ 30MG BASE/ML

N050643 002 Apr 28, 1989 May DISC

CELECOXIBCAPSULE; ORAL  
CELECOXIBAB AMNEAL PHARMS 50MG  
AB 100MG  
AB 200MG  
AB 400MG  
AB CSPC OUYI PHARM CO 50MG  
AB 100MG  
AB 200MG  
AB MICRO LABS 50MG  
AB 100MG  
AB 200MG  
AB 400MGA208833 001 May 31, 2018 May NEWA  
A208833 002 May 31, 2018 May NEWA  
A208833 003 May 31, 2018 May NEWA  
A208833 004 May 31, 2018 May NEWA  
A210071 001 Jan 23, 2018 Jan NEWA  
A210071 002 Jan 23, 2018 Jan NEWA  
A210071 003 Jan 23, 2018 Jan NEWA  
A204776 001 Apr 30, 2018 Apr NEWA  
A204776 002 Apr 30, 2018 Apr NEWA  
A204776 003 Apr 30, 2018 Apr NEWA  
A204776 004 Apr 30, 2018 Apr NEWACETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CETIRIZINE HYDROCHLORIDE

>D> AA ALLIED 5MG/5ML  
>A> AA ANDA REPOSITORY 5MG/5ML  
AA LANNETT CO INC 5MG/5ML  
>A> AA SAPTALIS PHARMS 5MG/5MLA090191 001 Nov 12, 2009 Sep CAHN  
A090191 001 Nov 12, 2009 Sep CAHN  
A078496 001 Sep 25, 2009 May CAHN  
A090191 001 Nov 12, 2009 Sep CAHNCEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL

CEVIMELINE HYDROCHLORIDE

@ APOTEX INC 30MG

A091260 001 Aug 25, 2011 Mar DISC

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

CHLORHEXIDINE GLUCONATE

>D> @ APOTEX INC 0.12%  
>A> @ BAJAJ 0.12%A075561 001 Nov 14, 2000 Sep CAHN  
A075561 001 Nov 14, 2000 Sep CAHN

CHLORPHENIRAMINE MALEATE; CODEINE PHOSPHATE

TABLET, EXTENDED RELEASE;ORAL

TUXARIN ER

@ SPIRIASO LLC

8MG;54.3MG

N206323 001 Jun 22, 2015 Jul CTNA

CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE

SOLUTION;ORAL

HYDROCODONE BITARTRATE, CHLORPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE HYDROCHLORIDE

&gt;A&gt; AA MAYNE PHARMA INC 4MG/5ML;5MG/5ML;60MG/5ML A205657 001 Aug 03, 2015 Sep CMS1

HYDROCODONE BITARTRATE,CHLORPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE HYDROCHLORIDE

&gt;D&gt; AA MAYNE PHARMA INC 4MG/5ML;5MG/5ML;60MG/5ML A205657 001 Aug 03, 2015 Sep CMS1

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENSION, EXTENDED RELEASE;ORAL

CODEPREX

@ LANNETT CO INC

EQ 4MG MALEATE/5ML;EQ 20MG  
BASE/5ML

N021369 001 Jun 21, 2004 Aug CAHN

&gt;D&gt; TUZISTRA XR

&gt;D&gt; +! TRIS PHARMA INC

EQ 2.8MG BASE/5ML;EQ 14.7MG  
BASE/5ML

N207768 001 Apr 30, 2015 Sep DISC

&gt;A&gt; + @

EQ 2.8MG BASE/5ML;EQ 14.7MG  
BASE/5ML

N207768 001 Apr 30, 2015 Sep DISC

+!

EQ 2.8MG BASE/5ML;EQ 14.7MG  
BASE/5ML

N207768 001 Apr 30, 2015 Jul CMFD

+ @

EQ 2.8MG BASE/5ML;EQ 14.7MG  
BASE/5ML

N207768 001 Apr 30, 2015 Jun DISC

+!

EQ 2.8MG BASE/5ML;EQ 14.7MG  
BASE/5ML

N207768 001 Apr 30, 2015 Jun CAHN

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENSION, EXTENDED RELEASE;ORAL

HYDROCODONE POLISTIREX AND CHLORPHENIRAMNE POLISTIREX

AB ! NEOS THERAP INC EQ 8MG MALEATE/5ML;EQ 10MG  
BITARTRATE/5ML A091671 001 Jun 29, 2012 Apr CHRS

TUSSIONEX PENNKNETIC

+ @ UCB INC

EQ 8MG MALEATE/5ML;EQ 10MG  
BITARTRATE/5ML

N019111 001 Dec 31, 1987 Apr DISC

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE;ORAL

SONAZINE

@ FOSUN PHARMA

30MG/ML

A080983 004

Jan CAHN

@

100MG/ML

A080983 005

Jan CAHN

SYRUP;ORAL

SONAZINE

@ FOSUN PHARMA

10MG/5ML

A083040 001

Jan CAHN

TABLET;ORAL

CHLORPROMAZINE HYDROCHLORIDE

AB AMNEAL PHARMS CO 10MG A209755 001 Sep 10, 2018 Aug NEWA

AB 25MG A209755 002 Sep 10, 2018 Aug NEWA

AB 50MG A209755 003 Sep 10, 2018 Aug NEWA

AB 100MG A209755 004 Sep 10, 2018 Aug NEWA

AB 200MG A209755 005 Sep 10, 2018 Aug NEWA

AB USL PHARMA 10MG A083386 001 Aug CTEC

AB ! 25MG A084112 001 Aug CTEC

AB 50MG A084113 001 Aug CTEC

AB ! 100MG A084114 001 Aug CTEC

AB 200MG A084115 001 Aug CTEC

CHLORPROPAMIDE

TABLET;ORAL

CHLORPROPAMIDE

@ ANI PHARMS INC

100MG

A088921 001 Apr 12, 1985 Jul DISC

@

250MG

A088922 001 Apr 12, 1985 Jul DISC

MYLAN

100MG

A088549 002 Jun 01, 1984 Jul CTEC

!

250MG

A088549 001 Jun 01, 1984 Jul CTEC

AB ! 250MG A088549 001 Jun 01, 1984 Jul CHRS

DIABINESE

+ @ PFIZER

100MG

N011641 003 Jul DISC

+ @

250MG

N011641 006 Jul DISC

GLUCAMIDE

@ ANI PHARMS INC

250MG

A088641 001 Oct 11, 1984 Jul DISC

CHLORTHALIDONE

	TABLET;ORAL						
	CHLORTHALIDONE						
AB	UMEDICA LABS PVT LTD	25MG		A207222	001	May 24, 2018	May NEWA
AB		50MG		A207222	002	May 24, 2018	May NEWA
	THALITONE						
+ @	CASPER PHARMA LLC	15MG		N019574	001	Dec 20, 1988	Apr CRLD

CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE

	TABLET;ORAL						
	CLORPRES						
@	MYLAN	15MG;0.1MG		A071325	003	Feb 09, 1987	Mar DISC
@		15MG;0.2MG		A071325	002	Feb 09, 1987	Mar DISC
@		15MG;0.3MG		A071325	001	Feb 09, 1987	Mar DISC

CHOLESTYRAMINE

	POWDER;ORAL						
	CHOLESTYRAMINE						
AB	ANI PHARMS INC	EQ 4GM RESIN/PACKET		A074554	001	Oct 02, 1996	Jun CMFD
AB		EQ 4GM RESIN/SCOOPFUL		A074554	002	Oct 02, 1996	Jun CMFD
AB	ZYDUS PHARMS USA INC	EQ 4GM RESIN/SCOOPFUL		A202901	001	Jul 02, 2018	Jun NEWA

CICLOPIROX

	SHAMPOO;TOPICAL						
	CICLOPIROX						
AT	TELIGENT PHARMA INC	1%		A209975	001	Apr 05, 2018	Mar NEWA
	SOLUTION;TOPICAL						
	CICLOPIROX						
AT	INGENUS PHARMS LLC	8%		A078124	001	Sep 18, 2007	Jan CAHN

CILASTATIN SODIUM; IMIPENEM

	POWDER;INTRAVENOUS						
	IMIPENEM AND CILASTATIN						
!	ACS DOBFAR	EQ 250MG BASE/VIAL;250MG/VIAL		A090577	001	Dec 21, 2011	Apr CHRS
@	HOSPIRA INC	EQ 250MG BASE/VIAL;250MG/VIAL		A090825	001	Nov 16, 2011	Apr DISC
	PRIMAXIN						
+ @	MERCK	EQ 250MG BASE/VIAL;250MG/VIAL		N050587	001	Nov 26, 1985	Apr DISC

CILOSTAZOL

	TABLET;ORAL						
	CILOSTAZOL						
AB	CASI PHARMS INC	50MG		A077310	001	Nov 08, 2005	Mar CAHN
AB		100MG		A077021	001	Nov 23, 2004	Mar CAHN
AB	FRONTIDA BIOPHARM	50MG		A077208	002	Mar 29, 2006	Aug CMFD
AB		100MG		A077208	001	Mar 29, 2006	Aug CMFD

CIMETIDINE

	TABLET;ORAL						
	CIMETIDINE						
@	CHARTWELL MOLECULES	200MG		A074329	002	May 17, 1994	Jan CMS1
@		300MG		A074329	003	May 17, 1994	Jan CMS1
@		400MG		A074329	004	May 17, 1994	Jan CMS1
@	YAOPHARMA CO LTD	200MG		A074100	001	Jan 31, 1995	Jan CAHN
@		300MG		A074100	002	Jan 31, 1995	Jan CAHN
@		400MG		A074100	003	Jan 31, 1995	Jan CAHN
@		800MG		A074100	004	Jan 31, 1995	Jan CAHN

CIMETIDINE HYDROCHLORIDE

	SOLUTION;ORAL						
	CIMETIDINE HYDROCHLORIDE						
@	LANNETT CO INC	EQ 300MG BASE/5ML		A074251	001	Dec 22, 1994	May CAHN

CINACALCET HYDROCHLORIDE

	TABLET;ORAL						
	CINACALCET HYDROCHLORIDE						
AB	AUROBINDO PHARMA LTD	EQ 30MG BASE		A206125	001	Mar 08, 2018	Feb NEWA
AB		EQ 60MG BASE		A206125	002	Mar 08, 2018	Feb NEWA
AB		EQ 90MG BASE		A206125	003	Mar 08, 2018	Feb NEWA
AB	CIPLA LTD	EQ 30MG BASE		A208915	001	Mar 08, 2018	Feb NEWA
AB		EQ 60MG BASE		A208915	002	Mar 08, 2018	Feb NEWA
AB		EQ 90MG BASE		A208915	003	Mar 08, 2018	Feb NEWA

TABLET;ORAL

## CINACALCET HYDROCHLORIDE

AB	PIRAMAL HLTHCARE UK	EQ 30MG BASE	A210207	001	Aug 01, 2018	Jul NEWA
AB		EQ 60MG BASE	A210207	002	Aug 01, 2018	Jul NEWA
AB		EQ 90MG BASE	A210207	003	Aug 01, 2018	Jul NEWA
AB	STRIDES PHARMA	EQ 30MG BASE	A209226	001	Apr 30, 2018	Apr NEWA
AB		EQ 60MG BASE	A209226	002	Apr 30, 2018	Apr NEWA
AB		EQ 90MG BASE	A209226	003	Apr 30, 2018	Apr NEWA
AB	ZYDUS PHARMS USA INC	EQ 30MG BASE	A208971	001	Apr 23, 2018	Apr NEWA
AB		EQ 60MG BASE	A208971	002	Apr 23, 2018	Apr NEWA
AB		EQ 90MG BASE	A208971	003	Apr 23, 2018	Apr NEWA
	SENSIPAR					
AB	+ AMGEN	EQ 30MG BASE	N021688	001	Mar 08, 2004	Feb CFTG
AB	+!	EQ 60MG BASE	N021688	002	Mar 08, 2004	Feb CFTG
AB		EQ 90MG BASE	N021688	003	Mar 08, 2004	Feb CFTG

CIPROFLOXACIN

## INJECTABLE; INJECTION

## CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	INFORLIFE	200MG/100ML	A078252	001	Mar 18, 2008	Jan CAHN
AP		400MG/200ML	A078252	002	Mar 18, 2008	Jan CAHN

CIPROFLOXACIN HYDROCHLORIDE

## SOLUTION/DROPS; OPHTHALMIC

## CIPROFLOXACIN HYDROCHLORIDE

AT	ALTAIRE PHARMS INC	EQ 0.3% BASE	A204613	001	May 03, 2018	Apr NEWA
>A> AT	ANDA REPOSITORY	EQ 0.3% BASE	A077689	001	Dec 13, 2006	Sep CAHN
>D> AT	RISING PHARMS	EQ 0.3% BASE	A077689	001	Dec 13, 2006	Sep CAHN
	TABLET;ORAL					
	CIPRO					
+ @	BAYER HLTHCARE	EQ 100MG BASE	N019537	001	Apr 08, 1996	Mar DISC
+ @		EQ 750MG BASE	N019537	004	Oct 22, 1987	Mar DISC
	CIPROFLOXACIN HYDROCHLORIDE					
@	FOSUN PHARMA	EQ 250MG BASE	A076593	002	Jun 09, 2004	Jan CAHN
@		EQ 500MG BASE	A076593	003	Jun 09, 2004	Jan CAHN
@		EQ 750MG BASE	A076593	004	Jun 09, 2004	Jan CAHN
@	MYLAN	EQ 100MG BASE	A075817	001	Jun 25, 2007	Jun DISC
@		EQ 250MG BASE	A075817	002	Jun 09, 2004	Jun DISC
@		EQ 750MG BASE	A075817	004	Jun 09, 2004	Jun DISC
AB	YILING PHARM LTD	EQ 250MG BASE	A208921	001	Jun 22, 2018	Jun NEWA
AB		EQ 500MG BASE	A208921	002	Jun 22, 2018	Jun NEWA

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## CIPROFLOXACIN EXTENDED RELEASE

@ FOSUN PHARMA 212.6MG;EQ 287.5MG BASE

A078712 001 Dec 11, 2007 Jan CAHN

CISATRACURIUM BESYLATE

## INJECTABLE; INJECTION

## CISATRACURIUM BESYLATE

AP	HOSPIRA INC	EQ 2MG BASE/ML	A203236	001	Mar 30, 2018	Mar NEWA
AP		EQ 2MG BASE/ML	A203238	001	Mar 30, 2018	Mar NEWA
AP		EQ 10MG BASE/ML	A203236	002	Mar 30, 2018	Mar NEWA

CITALOPRAM HYDROBROMIDE

## TABLET;ORAL

## CELEXA

AB	+ ALLERGAN SALES LLC	EQ 10MG BASE	N020822	001	Apr 27, 2000	Jan CAHN
AB	+!	EQ 20MG BASE	N020822	002	Jul 17, 1998	Jan CAHN
AB		EQ 40MG BASE	N020822	003	Jul 17, 1998	Jan CAHN
	@	EQ 60MG BASE	N020822	004	Jul 17, 1998	Jan CAHN
	CITALOPRAM HYDROBROMIDE					
AB	CHARTWELL MOLECULAR	EQ 10MG BASE	A077044	001	Nov 05, 2004	Mar CAHN
AB		EQ 20MG BASE	A077044	002	Nov 05, 2004	Mar CAHN
AB		EQ 40MG BASE	A077044	003	Nov 05, 2004	Mar CAHN
	@ FOSUN PHARMA	EQ 10MG BASE	A077035	001	Oct 28, 2004	Jan CAHN
	@	EQ 10MG BASE	A077040	001	Aug 17, 2005	Jan CAHN
	@	EQ 20MG BASE	A077035	002	Oct 28, 2004	Jan CAHN
	@	EQ 20MG BASE	A077040	002	Aug 17, 2005	Jan CAHN
	@	EQ 40MG BASE	A077035	003	Oct 28, 2004	Jan CAHN
	@	EQ 40MG BASE	A077040	003	Aug 17, 2005	Jan CAHN

CITRIC ACID; MAGNESIUM OXIDE; SODIUM PICOSULFATE

SOLUTION;ORAL

CLENPIQ

+! FERRING PHARMS INC

12GM/BOT;3.5GM/BOT;10MG/BOT

N209589 001 Nov 28, 2017 Apr CPOT

CLARITHROMYCIN

FOR SUSPENSION;ORAL

BIAxin

+ @ ABBVIE

125MG/5ML

N050698 001 Dec 23, 1993 Apr DISC

+ @

250MG/5ML

N050698 002 Dec 23, 1993 Apr DISC

CLARITHROMYCIN

AB ! SANDOZ 250MG/5ML

A065283 003 Sep 04, 2007 Apr CHRS

TABLET, EXTENDED RELEASE;ORAL

CLARITHROMYCIN

AB SUNSHINE LAKE 500MG

A208987 001 Jul 09, 2018 Jun NEWA

CLEMASTINE FUMARATE

SYRUP;ORAL

CLEMASTINE FUMARATE

! TEVA

EQ 0.5MG BASE/5ML

A073399 001 Jun 30, 1994 May CTEC

@ WOCKHARDT BIO AG

EQ 0.5MG BASE/5ML

A074863 001 Mar 13, 1998 May DISC

AA TABLET;ORAL

TAVIST

+ @ NOVARTIS

2.68MG

A074863 001 Mar 13, 1998 May CAHN

CLEVIDIPINE

EMULSION;INTRAVENOUS

CLEVIPREX

+ @ CHIESI USA INC

125MG/250ML (0.5MG/ML)

N022156 003 Nov 08, 2013 Jun DISC

CLINDAMYCIN PALMITATE HYDROCHLORIDE

FOR SOLUTION;ORAL

CLINDAMYCIN PALMITATE HYDROCHLORIDE

&gt;D&gt; AA APPCO PHARMA LLC EQ 75MG BASE/5ML

A207047 001 May 11, 2018 Sep CAHN

AA EQ 75MG BASE/5ML

A207047 001 May 11, 2018 Apr NEWA

&gt;A&gt; AA HERITAGE PHARMS INC EQ 75MG BASE/5ML

A207047 001 May 11, 2018 Sep CAHN

CLINDAMYCIN PHOSPHATE

INJECTABLE;INJECTION

CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER

@ ABBOTT LABS EQ 6MG BASE/ML

A065027 001 Jun 29, 2001 Mar CAHN

@ EQ 12MG BASE/ML

A065027 002 Jun 29, 2001 Mar CAHN

@ EQ 18MG BASE/ML

A065027 003 Jun 29, 2001 Mar CAHN

SOLUTION;TOPICAL

CLINDAMYCIN PHOSPHATE

AT GLASSHOUSE PHARMS EQ 1% BASE

A209846 001 Feb 08, 2018 Jan NEWA

@ WOCKHARDT BIO AG EQ 1% BASE

A063304 001 Jul 15, 1997 May DISC

AT EQ 1% BASE

A063304 001 Jul 15, 1997 May CAHN

AT ZYDUS PHARMS USA INC EQ 1% BASE

A208767 001 Jul 16, 2018 Jul NEWA

CLOBETASOL PROPIONATE

AEROSOL, FOAM;TOPICAL

CLOBETASOL PROPIONATE

&gt;A&gt; AB1 TARO PHARM 0.05%

A208779 001 Oct 04, 2018 Sep NEWA

CREAM;TOPICAL

CLOBETASOL PROPIONATE

AB1 CHEMO RESEARCH SL 0.05%

A210034 001 Jun 15, 2018 Jun NEWA

AB1 GLENMARK PHARMS 0.05%

A209095 001 May 10, 2018 Apr NEWA

AB1 LUPIN LTD 0.05%

A210208 001 Jan 30, 2018 Jan NEWA

AB1 TELIGENT PHARMA INC 0.05%

A209974 001 Apr 17, 2018 Apr NEWA

IMPOYZ

+! ENCORE DERMAT 0.025%

N209483 001 Nov 28, 2017 Jan CAHN

OINTMENT;TOPICAL

CLOBETASOL PROPIONATE

AB AMNEAL PHARMS LLC 0.05%

A210551 001 Aug 21, 2018 Aug NEWA

AB CHEMO RESEARCH SL 0.05%

A209701 001 Apr 17, 2018 Apr NEWA

AB NOVEL LABS INC 0.05%

A208841 001 May 04, 2018 Apr NEWA

SOLUTION;TOPICAL CLOBETASOL PROPIONATE				A210190	001	Apr 18, 2018	Apr NEWA
AT	GLENMARK PHARMS LTD	0.05%					
SPRAY;TOPICAL CLOBETASOL PROPIONATE				A209004	001	Mar 26, 2018	Mar NEWA
AT	GLENMARK PHARMS	0.05%		A208125	001	Mar 26, 2018	Mar NEWA
AT	LUPIN LTD	0.05%		A208842	001	Mar 26, 2018	Mar NEWA
AT	TARO	0.05%					
<b>CLOFARABINE</b>							
SOLUTION;INTRAVENOUS CLOFARABINE							
AP	ABON PHARMS LLC	20MG/20ML (1MG/ML)		A204029	001	May 09, 2017	May CDFR
AP	AMNEAL PHARMS CO	20MG/20ML (1MG/ML)		A208857	001	Nov 06, 2017	May CDFR
AP	DR REDDYS LABS LTD	20MG/20ML (1MG/ML)		A205375	001	Nov 06, 2017	May CDFR
>A>	AP	INGENUS PHARMS LLC	20MG/20ML (1MG/ML)	A210270	001	Sep 14, 2018	Sep NEWA
AP	MSN LABS PVT LTD	20MG/20ML (1MG/ML)		A209775	001	Dec 06, 2017	May CDFR
AP	MYLAN LABS LTD	20MG/20ML (1MG/ML)		A208860	001	Nov 06, 2017	May CDFR
CLOLAR							
AP	+! GENZYME	20MG/20ML (1MG/ML)		N021673	001	Dec 28, 2004	May CDFR
<b>CLOMIPHENE CITRATE</b>							
TABLET;ORAL CLOMID							
+ @	SANOFI AVENTIS US	50MG		N016131	002		Jul DISC
CLOMIPHENE CITRATE							
!	PAR PHARM	50MG		A075528	001	Aug 30, 1999	Jul CHRS
		50MG		A075528	001	Aug 30, 1999	Jul CTEC
<b>CLONIDINE HYDROCHLORIDE</b>							
INJECTABLE;INJECTION CLONIDINE HYDROCHLORIDE							
AP	X-GEN PHARMS INC	1MG/10ML (0.1MG/ML)		A203167	001	Oct 29, 2013	May CAHN
AP		5MG/10ML (0.5MG/ML)		A203167	002	Oct 29, 2013	May CAHN
TABLET;ORAL CLONIDINE HYDROCHLORIDE							
@	AUROLIFE PHARMA LLC	0.1MG		A070886	002	Aug 31, 1988	Jan CMS1
@		0.3MG		A070886	003	Aug 31, 1988	Jan CMS1
@	CHARTWELL MOLECULES	0.1MG		A071785	002	Apr 05, 1988	Apr CMS1
@		0.2MG		A071785	003	Apr 05, 1988	Apr CMS1
TABLET, EXTENDED RELEASE;ORAL CLONIDINE HYDROCHLORIDE							
AB1	JUBILANT GENERICS	0.1MG		A210338	001	Jan 29, 2018	Jan NEWA
AB1	MAYNE PHARMA INC	0.1MG		A210680	001	Apr 30, 2018	Apr NEWA
<b>CLOPIDOGREL BISULFATE</b>							
TABLET;ORAL CLOPIDOGREL BISULFATE							
AB	PRINSTON INC	EQ 75MG BASE		A206376	001	May 07, 2018	Apr NEWA
AB		EQ 300MG BASE		A206376	002	May 07, 2018	Apr NEWA
<b>CLORAZEPATE DIPOTASSIUM</b>							
>D>	CAPSULE;ORAL						
>D>	CLORAZEPATE DIPOTASSIUM						
>D>	AUROLIFE PHARMA LLC	3.75MG		A072112	002	Aug 11, 2017	Sep DISC
>A>	@	3.75MG		A072112	002	Aug 11, 2017	Sep DISC
>D>		7.5MG		A072112	003	Aug 11, 2017	Sep DISC
>A>	@	7.5MG		A072112	003	Aug 11, 2017	Sep DISC
<b>CLOZAPINE</b>							
TABLET;ORAL CLOZAPINE							
	IVAX SUB TEVA PHARMS	12.5MG		A074949	003	Jul 31, 2003	Jul CTEC
@	MYLAN	12.5MG		A075417	003	Apr 15, 2010	Jul DISC
TABLET, ORALLY DISINTEGRATING;ORAL CLOZAPINE							
AB	BARR LABS INC	12.5MG		A090308	003	Apr 09, 2018	Mar NEWA
	FAZACLO ODT						
AB	+ JAZZ PHARMS III	12.5MG		N021590	004	May 30, 2007	Mar CTEC

COBICISTAT; DARUNAVIR ETHANOLATE; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE

TABLET;ORAL

SYMTUZA

+! JANSSEN PRODS 150MG;EQ 800MG BASE;200MG;EQ 10MG N210455 001 Jul 17, 2018 Jul NEWA  
BASE

COLCHICINE; PROBENECID

TABLET;ORAL

PROBENECID AND COLCHICINE

>D> AB INGENUS PHARMS NJ 0.5MG;500MG A040618 001 May 13, 2008 Sep CAHN  
>A> AB NOVAST LABS 0.5MG;500MG A040618 001 May 13, 2008 Sep CAHN

COLESEVELAM HYDROCHLORIDE

FOR SUSPENSION;ORAL

COLESEVELAM HYDROCHLORIDE

AB GLENMARK PHARMS LTD	1.875GM/PACKET	A202190	001	Jul 16, 2018	Jul NEWA
AB	3.75GM/PACKET	A202190	002	Jul 16, 2018	Jul NEWA
WELCHOL					
AB + DAIICHI SANKYO	1.875GM/PACKET	N022362	001	Oct 02, 2009	Jul CFTG
AB +!	3.75GM/PACKET	N022362	002	Oct 02, 2009	Jul CFTG
TABLET;ORAL					
COLESEVELAM HYDROCHLORIDE					
>A> AB ALKEM LABS LTD	625MG	A209038	001	Oct 05, 2018	Sep NEWA
>A> AB DR REDDYS LABS LTD	625MG	A210889	001	Oct 05, 2018	Sep NEWA
AB GLENMARK PHARMS LTD	625MG	A203480	001	May 18, 2018	May NEWA
AB IMPAX LABS INC	625MG	A091600	001	May 16, 2018	Apr NEWA
WELCHOL					
AB +! DAIICHI SANKYO	625MG	N021176	001	May 26, 2000	Apr CFTG

COLISTIMETHATE SODIUM

INJECTABLE;INJECTION

COLISTIMETHATE SODIUM

AP NEXUS PHARMS EQ 150MG BASE/VIAL A065177 001 Mar 19, 2004 Jun CAHN

CONIVAPTAN HYDROCHLORIDE

INJECTABLE;INTRAVENOUS

VAPRISOL

@ CUMBERLAND PHARMS 20MG/4ML (5MG/ML)  
VAPRISOL IN 5% DEXTROSE IN PLASTIC CONTAINER  
+! CUMBERLAND PHARMS 20MG/100ML (0.2MG/ML)

N021697 001 Dec 29, 2005 Aug CDFR  
N021697 002 Oct 08, 2008 Aug CDFR

COPANLISIB DIHYDROCHLORIDE

POWDER;INTRAVENOUS

ALIQOPA

+! BAYER HEALTHCARE 60MG/VIAL N209936 001 Sep 14, 2017 Jul CDFR

CROFETELEMER

TABLET, DELAYED RELEASE;ORAL

MYTESI

+! NAPO PHARMS INC 125MG N202292 001 Dec 31, 2012 Mar CTNA

CROMOLYN SODIUM

SOLUTION;INHALATION

CROMOLYN SODIUM

@ FERA PHARMS LLC 10MG/ML A075437 001 Apr 21, 2000 Mar CAHN

SOLUTION/DROPS;OPHTHALMIC

CROMOLYN SODIUM

AT SANDOZ INC 4% A075282 001 Jun 16, 1999 Jan CAHN

CROTAMITON

CREAM;TOPICAL

EURAX

+! SUN PHARM INDs INC 10% N006927 001 Feb CAHN

LOTION;TOPICAL

EURAX

AT +! SUN PHARM INDs INC 10% N009112 003 Feb CAHN

CYCLOBENZAPRINE HYDROCHLORIDE

	CAPSULE, EXTENDED RELEASE;ORAL AMRIX						
AB	+ TEVA PHARMS INTL	15MG	N021777	001	Feb 01, 2007	Jul CFTG	
AB	+!	30MG	N021777	002	Feb 01, 2007	Jul CFTG	
	CYCLOBENZAPRINE HYDROCHLORIDE						
AB	APOTEX INC	15MG	A206703	001	Jul 24, 2018	Jul NEWA	
AB		30MG	A206703	002	Jul 24, 2018	Jul NEWA	

CYCLOPENTOLATE HYDROCHLORIDE

	SOLUTION/DROPS;OPHTHALMIC CYCLOGYL						
AT	! ALCON LABS INC	0.5%	A084109	001		Feb CAHN	
AT	!	1%	A084110	001		Feb CAHN	
	!	2%	A084108	001		Feb CAHN	

CYCLOPENTOLATE HYDROCHLORIDE; PHENYLEPHRINE HYDROCHLORIDE

	SOLUTION/DROPS;OPHTHALMIC CYCLOMYDRIL						
	! ALCON LABS INC	0.2%;1%	A084300	001		Feb CAHN	

CYCLOPHOSPHAMIDE

	CAPSULE;ORAL CYCLOPHOSPHAMIDE						
AB	AMERIGEN PHARMS LTD	25MG	A207014	001	Mar 19, 2018	Mar NEWA	
AB		50MG	A207014	002	Mar 19, 2018	Mar NEWA	
AB	STI PHARMA LLC	25MG	A209872	001	May 07, 2018	Apr NEWA	
AB		50MG	A209872	002	May 07, 2018	Apr NEWA	
AB	+ WEST-WARD PHARMS INT	25MG	N203856	001	Sep 16, 2013	Mar CFTG	
AB	+!	50MG	N203856	002	Sep 16, 2013	Mar CFTG	
	INJECTABLE;INJECTION CYCLOPHOSPHAMIDE						
AP	AMNEAL PHARMS CO	500MG/VIAL	A210046	001	May 25, 2018	May NEWA	
AP		1GM/VIAL	A210046	002	May 25, 2018	May NEWA	
AP		2GM/VIAL	A210046	003	May 25, 2018	May NEWA	

CYCLOSPORINE

	CAPSULE;ORAL CYCLOSPORINE						
	IVAX SUB TEVA PHARMS	50MG	A065110	001	Mar 29, 2005	May CTEC	
	GENGRAF						
	@ ABBVIE	50MG	A065003	002	May 12, 2000	May DISC	
	SOLUTION;OPHTHALMIC CEQUA						
	+! SUN PHARMA GLOBAL	0.09%	N210913	001	Aug 14, 2018	Aug NEWA	

CYPROHEPTADINE HYDROCHLORIDE

	TABLET;ORAL CYPROHEPTADINE HYDROCHLORIDE						
AA	APNAR PHARMA LP	4MG	A207555	001	Jan 31, 2017	Apr CAHN	
>D> AA	APPCO PHARMA LLC	4MG	A206553	001	Nov 29, 2016	Sep CAHN	
	@ FOSUN PHARMA	4MG	A086808	001		Jan CAHN	
>D> AA	INGENUS PHARMS NJ	4MG	A205087	001	Sep 23, 2015	Sep CAHN	
AA	MOUNTAIN	4MG	A040537	001	Sep 30, 2003	Jan CAHN	
>A> AA	NOVAST LABS	4MG	A205087	001	Sep 23, 2015	Sep CAHN	
AA	STRIDES PHARMA	4MG	A209172	001	Apr 11, 2018	Mar NEWA	
>A> AA	TWI PHARMS	4MG	A206553	001	Nov 29, 2016	Sep CAHN	

CYTARABINE

	INJECTABLE;INJECTION CYTARABINE						
AP	HONG KONG	100MG/ML	A205696	001	Jul 17, 2018	Jul NEWA	
AP	MYLAN LABS LTD	20MG/ML	A200916	001	Dec 13, 2011	Jan CAHN	
	INJECTABLE, LIPOSOMAL;INJECTION DEPOCYT						
	+ @ PACIRA PHARMS INC	10MG/ML	N021041	001	Apr 01, 1999	Aug DISC	

CYTARABINE; DAUNORUBICIN

POWDER; INTRAVENOUS  
VYXEOS  
+! CELATOR PHARMS 100MG;44MG N209401 001 Aug 03, 2017 Jul CDFR

DACLATASVIR DIHYDROCHLORIDE

TABLET; ORAL  
DAKLINZA  
+ BRISTOL-MYERS SQUIBB EQ 60MG BASE N206843 002 Jul 24, 2015 Jun CHRS  
+! EQ 90MG BASE N206843 003 Apr 13, 2016 Jun CHRS

>A> DACOMITINIB

>A> TABLET; ORAL  
>A> VIZIMPRO  
>A> + PFIZER INC 15MG N211288 001 Sep 27, 2018 Sep NEWA  
>A> + 30MG N211288 002 Sep 27, 2018 Sep NEWA  
>A> +! 45MG N211288 003 Sep 27, 2018 Sep NEWA

DALBAVANCIN HYDROCHLORIDE

POWDER; INTRAVENOUS  
DALVANCE  
+! ALLERGAN SALES LLC EQ 500MG BASE/VIAL N021883 001 May 23, 2014 Jul CDFR

DALFAMPRIDINE

TABLET, EXTENDED RELEASE; ORAL  
DALFAMPRIDINE  
AB ACCORD HLTHCARE 10MG A206863 001 Jul 11, 2018 Jun NEWA  
AB ALKEM LABS LTD 10MG A206765 001 Jul 30, 2018 Jul NEWA

DALFOPRISTIN; QUINUPRISTIN

INJECTABLE; INTRAVENOUS  
SYNCERID  
+! KING PHARMS 350MG/VIAL;150MG/VIAL N050748 001 Sep 21, 1999 Aug CDFR  
@ 420MG/VIAL;180MG/VIAL N050748 002 Aug 24, 2000 Aug CDFR

DAPAGLIFLOZIN

TABLET; ORAL  
FARXIGA  
+ ASTRAZENECA AB 5MG N202293 001 Jan 08, 2014 Mar CAIN  
+! 10MG N202293 002 Jan 08, 2014 Mar CAIN

DAPAGLIFLOZIN; METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
XIGDUO XR  
+ ASTRAZENECA AB 2.5MG;1GM N205649 005 Jul 28, 2017 Mar CAIN  
+ 5MG;500MG N205649 001 Oct 29, 2014 Mar CAIN  
+ 5MG;1GM N205649 002 Oct 29, 2014 Mar CAIN  
+ 10MG;500MG N205649 003 Oct 29, 2014 Mar CAIN  
+! 10MG;1GM N205649 004 Oct 29, 2014 Mar CAIN

DAPAGLIFLOZIN; SAXagliptin HYDROCHLORIDE

TABLET; ORAL  
QTERN  
+! ASTRAZENECA AB 10MG;EQ 5MG BASE N209091 001 Feb 27, 2017 Mar CAIN

DAPSONE

GEL;TOPICAL  
ACZONE  
>D> +! ALLERGAN INC 7.5% N207154 001 Feb 24, 2016 Sep CAHN  
>A> +! AQUA PHARMS LLC 7.5% N207154 001 Feb 24, 2016 Sep CAHN

DAPTOMYCIN

POWDER; INTRAVENOUS  
DAPTOMYCIN  
AP FRESENIUS KABI USA 500MG/VIAL A206077 001 Apr 11, 2018 Mar NEWA  
AP MYLAN LABS LTD 500MG/VIAL A205037 001 Jun 05, 2018 May NEWA  
AP TEVA PHARMS USA 500MG/VIAL A091039 001 Mar 25, 2016 Feb CAHN

DECITABINE

INJECTABLE; INTRAVENOUS

DECITABINE

AP SAGENT PHARMS 50MG/VIAL A207100 001 Mar 16, 2018 Mar NEWA

DEFERIPRONE

SOLUTION; ORAL

FERRIPROX

+ APOPHARMA INC 80MG/ML N208030 002 Apr 20, 2018 Apr NEWA

DEFIBROTIDE SODIUM

SOLUTION; INTRAVENOUS

DEFITELIO

+! JAZZ PHARMS INC 200MG/2.5ML (80MG/ML) N208114 001 Mar 30, 2016 Jul CDFR

DELAFLOXACIN MEGLUMINE

POWDER; INTRAVENOUS

BAXDELA

+! MELINTA EQ 300MG BASE/VIAL N208611 001 Jun 19, 2017 Jul CDFR

DESFLURANE

LIQUID; INHALATION

DESFLURANE

AN SHANGHAI HENGRI 100% A208234 001 Feb 26, 2018 Feb NEWA  
SUPRANE

AN +! BAXTER HLTHCARE 100% N020118 001 Sep 18, 1992 Feb CFTG

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HYDROCHLORIDE

AB ANI PHARMS INC 10MG A205153 001 Oct 28, 2016 May CAHN  
@ 25MG A071803 002 Dec 08, 1987 Apr CMS1  
AB @ 25MG A205153 002 Oct 28, 2016 May CAHN  
AB @ 50MG A071803 003 Dec 08, 1987 Apr CMS1  
AB @ 50MG A205153 003 Oct 28, 2016 May CAHN  
AB @ 75MG A071803 004 Dec 08, 1987 Apr CMS1  
AB @ 75MG A205153 004 Oct 28, 2016 May CAHN  
AB 100MG A205153 005 Oct 28, 2016 May CAHN  
AB @ 150MG A071803 005 May 29, 1997 Apr CMS1  
AB 150MG A205153 006 Oct 28, 2016 May CAHN  
AB MOUNTAIN 10MG A205153 001 Oct 28, 2016 Feb CAHN  
AB 25MG A205153 002 Oct 28, 2016 Feb CAHN  
AB 50MG A205153 003 Oct 28, 2016 Feb CAHN  
AB 75MG A205153 004 Oct 28, 2016 Feb CAHN  
AB 100MG A205153 005 Oct 28, 2016 Feb CAHN  
AB 150MG A205153 006 Oct 28, 2016 Feb CAHN>D> DESIRUDIN RECOMBINANT

&gt;D&gt; INJECTABLE; SUBCUTANEOUS

&gt;D&gt; IPRIVASK

&gt;D&gt; +! VALEANT PHARMS NORTH 15MG/VIAL

N021271 001 Apr 04, 2003 Sep DISC

&gt;A&gt; + @ 15MG/VIAL N021271 001 Apr 04, 2003 Sep DISC

DESMOPRESSIN ACETATE

TABLET; SUBLINGUAL

NOCDURNA

+ FERRING PHARMS INC 0.0277MG

N022517 001 Jun 21, 2018 Jun NEWA

+! 0.0553MG

N022517 002 Jun 21, 2018 Jun NEWA

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

DESOGESTREL AND ETHINYL ESTRADIOL

&gt;A&gt; AB ACCORD HLTHCARE 0.15MG; 0.03MG

A207067 001 Sep 13, 2018 Sep NEWA

DESONIDE

GEL; TOPICAL

DESONATE

&gt;D&gt; +! BAYER HLTHCARE 0.05%

N021844 001 Oct 20, 2006 Sep CAHN

&gt;A&gt; +! LEO PHARMA AS 0.05%

N021844 001 Oct 20, 2006 Sep CAHN

DESOXIMETASONE

CREAM;TOPICAL

DESOXIMETASONE

>A>	AB	ANDA REPOSITORY	0.25%	A205594	001	Jul 02, 2018	Sep CAHN
	AB	GROUPE PARIMA INC	0.25%	A205594	001	Jul 02, 2018	Jun NEWA
>D>	AB	RISING PHARMS	0.25%	A205594	001	Jul 02, 2018	Sep CAHN
	AB		0.25%	A205594	001	Jul 02, 2018	Jul CAHN
>A>	AB	ZYDUS PHARMS USA INC	0.25%	A205620	001	Sep 28, 2018	Sep NEWA
		TOPICORT					
	AB	! TARO PHARM INDS LTD	0.05%	A073210	001	Nov 30, 1990	May CAHN
	AB	! + @ TOPICORT LP	0.25%	A073193	001	Nov 30, 1990	May CAHN
		+ @ TARO PHARM INDS LTD	0.05%	N017856	001		May CAHN
		GEL;TOPICAL					
		DESOXIMETASONE					
>A>	AB	ANDA REPOSITORY	0.05%	A204675	001	Aug 12, 2016	Sep CAHN
>D>	AB	RISING PHARMS	0.05%	A204675	001	Aug 12, 2016	Sep CAHN
		TOPICORT					
	AB	! TARO PHARM INDS LTD	0.05%	A074904	001	Jul 14, 1998	May CAHN
		+ @	0.05%	N018586	001	Mar 29, 1982	May CAHN
		OINTMENT;TOPICAL					
		DESOXIMETASONE					
>A>	AB	ANDA REPOSITORY	0.25%	A204272	001	Nov 30, 2016	Sep CAHN
>D>	AB	RISING PHARMS	0.25%	A204272	001	Nov 30, 2016	Sep CAHN
		TOPICORT					
	AB	+! TARO PHARM INDS LTD	0.05%	N018594	001	Jan 17, 1985	May CAHN
	AB	!	0.25%	A074286	001	Jun 07, 1996	May CAHN
		+ @	0.25%	N018763	001	Sep 30, 1983	May CAHN
		SPRAY;TOPICAL					
		DESOXIMETASONE					
AT		LUPIN ATLANTIS	0.25%	A208124	001	Mar 16, 2018	Mar NEWA
		TOPICORT					
AT		+! TARO PHARMS	0.25%	N204141	001	Apr 11, 2013	May CAHN

DESVENLAFAXINE FUMARATE

TABLET, EXTENDED RELEASE;ORAL

DESVENLAFAXINE

+ @ SUN PHARMA GLOBAL	EQ 50MG BASE	N205583	001	Jan 28, 2014	Jun DISC
+ @	EQ 100MG BASE	N205583	002	Jan 28, 2014	Jun DISC

DESVENLAFAXINE SUCCINATE

TABLET, EXTENDED RELEASE;ORAL

DESVENLAFAXINE SUCCINATE

>A>	AB	ALEMBIC PHARMS LTD	EQ 25MG BASE	A204003	003	Sep 14, 2018	Sep NEWA
	AB	CASI PHARMS INC	EQ 50MG BASE	A204028	001	Jun 29, 2015	Mar CAHN
	AB		EQ 100MG BASE	A204028	002	Jun 29, 2015	Mar CAHN
>A>	AB	YICHANG HUMANWELL	EQ 50MG BASE	A210014	001	Oct 01, 2018	Sep NEWA
>A>	AB		EQ 100MG BASE	A210014	002	Oct 01, 2018	Sep NEWA

DEXAMETHASONE

ELIXIR;ORAL

DEXAMETHASONE

AA		LANNETT CO INC	0.5MG/5ML	A091188	001	May 11, 2011	May CAHN
		HEXDROL		N012674	001		Feb CAHN
		@ ASPEN GLOBAL INC	0.5MG/5ML				
		SUSPENSION;INTRAOOCULAR					
		DEXYCU KIT					
		+! EYEPOINT PHARMS	9%	N208912	001	Feb 09, 2018	Apr CAHN
		+! ICON BIOSCIENCE	9%	N208912	001	Feb 09, 2018	Feb NEWA
		TABLET;ORAL					
		DEXAMETHASONE					
BP		FERA PHARMS LLC	0.5MG	A088481	002	Apr 28, 1983	May CMS1
BP			0.75MG	A088481	003	Apr 28, 1983	May CMS1
BP			4MG	A088481	004	Apr 28, 1983	May CMS1
BP			6MG	A088481	001	Nov 28, 1983	Jan CAHN

DEXAMETHASONE SODIUM PHOSPHATE

## INJECTABLE; INJECTION

## DEXAMETHASONE SODIUM PHOSPHATE

AP	AMNEAL PHARMS CO	EQ 4MG PHOSPHATE/ML	A208689	001	Aug 22, 2018	Aug NEWA
AP	FRESENIUS KABI USA	EQ 10MG PHOSPHATE/ML	A209192	001	Jul 06, 2018	Jun NEWA
AP	SOMERSET THERAPS LLC	EQ 4MG PHOSPHATE/ML	A207521	001	Jun 08, 2018	May NEWA
		DEXAMETHASONE SODIUM PHOSPHATE PRESERVATIVE FREE				
AP	AMNEAL PHARMS CO	EQ 10MG PHOSPHATE/ML	A208690	001	Aug 22, 2018	Aug NEWA
AP	SOMERSET THERAPS LLC	EQ 10MG PHOSPHATE/ML	A207442	001	Apr 19, 2018	Apr NEWA
		HEXADROL				
+ @	ASPEN GLOBAL INC	EQ 4MG PHOSPHATE/ML	N014694	002		Feb CAHN
+ @		EQ 10MG PHOSPHATE/ML	N014694	003		Feb CAHN
@		EQ 20MG PHOSPHATE/ML	N014694	004		Feb CAHN

DEXCHLORPHENIRAMINE MALEATE

## SYRUP; ORAL

## DEXCHLORPHENIRAMINE MALEATE

AA	! WOCKHARDT BIO AG	2MG/5ML	A088251	001	Mar 23, 1984	Jul CTEC
AA	POLMON					
AA	CAPELLO PHARMS LLC	2MG/5ML	A202520	001	Jul 16, 2018	Jul NEWA

DEXMEDETOMIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## DEXMEDETOMIDINE HYDROCHLORIDE

AP	BAXTER HLTHCARE CORP	EQ 200MCG BASE/50ML (EQ 4MCG BASE/ML)	A208532	001	Aug 21, 2018	Aug NEWA
AP		EQ 400MCG BASE/100ML (EQ 4MCG BASE/ML)	A208532	002	Aug 21, 2018	Aug NEWA
AP	ZYDUS PHARMS USA INC	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)	A206798	001	Feb 27, 2018	Feb NEWA
		PRECEDEX				
AP	+! HOSPIRA	EQ 200MCG BASE/50ML (EQ 4MCG BASE/ML)	N021038	002	Mar 13, 2013	Aug CFTG
AP	+!	EQ 400MCG BASE/100ML (EQ 4MCG BASE/ML)	N021038	003	Mar 13, 2013	Aug CFTG
		SOLUTION; IV (INFUSION)				
		DEXMEDETOMIDINE HYDROCHLORIDE				
+ !	HQ SPCLT PHARMA	EQ 200MG BASE/50ML (EQ 4MCG BASE/ML)	N206628	003	Jun 22, 2018	Jun NEWA
+ !		EQ 400MG BASE/100ML (EQ 4MCG BASE/ML)	N206628	004	Jun 22, 2018	Jun NEWA

DEXMETHYLPHENIDATE HYDROCHLORIDE

## CAPSULE, EXTENDED RELEASE; ORAL

## DEXMETHYLPHENIDATE HYDROCHLORIDE

>A> AB	ADARE PHARMS INC	5MG	A210279	001	Oct 09, 2018	Sep NEWA
>A> AB		10MG	A210279	002	Oct 09, 2018	Sep NEWA
>A> AB		15MG	A210279	003	Oct 09, 2018	Sep NEWA
>A> AB		20MG	A210279	004	Oct 09, 2018	Sep NEWA
>A> AB		25MG	A210279	005	Oct 09, 2018	Sep NEWA
>A> AB		30MG	A210279	006	Oct 09, 2018	Sep NEWA
>A> AB		35MG	A210279	007	Oct 09, 2018	Sep NEWA
>A> AB		40MG	A210279	008	Oct 09, 2018	Sep NEWA
		TABLET; ORAL				
		DEXMETHYLPHENIDATE HYDROCHLORIDE				
>A> AB	CEDIPROF INC	5MG	A209211	001	Sep 19, 2018	Sep NEWA
>A> AB		10MG	A209211	002	Sep 19, 2018	Sep NEWA

DEXTROAMPHETAMINE SULFATE

## TABLET; ORAL

## DEXTROAMPHETAMINE SULFATE

AA	ARBOR PHARMS LLC	2.5MG	A090533	001	Oct 25, 2011	Apr CAHN
		5MG	A090533	002	Oct 25, 2011	Apr CAHN
		7.5MG	A090533	003	Oct 25, 2011	Apr CAHN
AA		10MG	A090533	004	Oct 25, 2011	Apr CAHN
		15MG	A090533	005	Oct 25, 2011	Apr CAHN
		20MG	A090533	006	Oct 25, 2011	Apr CAHN
		30MG	A090533	007	Oct 25, 2011	Apr CAHN
>A> AA	NUVO PHARM	5MG	A210059	001	Oct 18, 2017	Sep CAHN
>A> AA		10MG	A210059	002	Oct 18, 2017	Sep CAHN
>D> AA	SUNRISE PHARM INC	5MG	A210059	001	Oct 18, 2017	Sep CAHN
>D> AA		10MG	A210059	002	Oct 18, 2017	Sep CAHN

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETH W/ DEXTROMETHORPHAN

@ G AND W LABS INC 15MG/5ML; 6.25MG/5ML

A088762 001 Oct 31, 1984 Jan DISC

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

AP	FRESENIUS KABI USA	10GM/100ML	A209448	001	Jul 16, 2018	Jul NEWA
	DEXTROSE 20% IN PLASTIC CONTAINER					
+ @	BAXTER HLTHCARE	20GM/100ML	N017521	004		Jun DISC
+!	ICU MEDICAL INC	20GM/100ML	N018564	001	Mar 23, 1982	Jun CTEC
	DEXTROSE 30% IN PLASTIC CONTAINER					
+ @	BAXTER HLTHCARE	30GM/100ML	N017521	003		Jun DISC
+!	ICU MEDICAL INC	30GM/100ML	N019345	001	Jan 26, 1985	Jun CTEC
	DEXTROSE 40% IN PLASTIC CONTAINER					
+ @	BAXTER HLTHCARE	40GM/100ML	N017521	002		Jun DISC
+!	ICU MEDICAL INC	40GM/100ML	N018562	001	Mar 23, 1982	Jun CTEC
	DEXTROSE 5% IN PLASTIC CONTAINER					
+ @	ICU MEDICAL INC	50MG/ML	N019222	001	Jul 13, 1984	Mar DISC
+!		50MG/ML	N019222	001	Jul 13, 1984	Feb CAHN
	DEXTROSE 50% IN PLASTIC CONTAINER					
+ @	BAXTER HLTHCARE	50GM/100ML	N017521	001		Jun DISC
	DEXTROSE 60% IN PLASTIC CONTAINER					
+ @	BAXTER HLTHCARE	60GM/100ML	N017521	005	Mar 26, 1982	Jun DISC
	DEXTROSE 70% IN PLASTIC CONTAINER					
AP	+! B BRAUN	70GM/100ML	N019626	005	Feb 18, 2015	Feb NEWA

>D> DEXTROSE; MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE

>D>	INJECTABLE; INJECTION					
>D>	PLASMA-LYTE 56 AND DEXTROSE 5% IN PLASTIC CONTAINER					
>D>	BAXTER HLTHCARE	5GM/100ML; 32MG/100ML; 128MG/100ML; 2 34MG/100ML	N017385	001		Sep DISC
>A>	@	5GM/100ML; 32MG/100ML; 128MG/100ML; 2 34MG/100ML	N017385	001		Sep DISC

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	+! ICU MEDICAL INC	5GM/100ML; 74.5MG/100ML; 450MG/100ML	N018362	009	Jul 05, 1983	Mar CHRS
AP	+!	5GM/100ML; 149MG/100ML; 450MG/100ML	N018362	005	Mar 28, 1988	Mar CPOT
	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER					
	BAXTER HLTHCARE	5GM/100ML; 75MG/100ML; 900MG/100ML	N019308	004	Apr 05, 1985	Mar CTEC
		5GM/100ML; 150MG/100ML; 900MG/100ML	N019308	002	Apr 05, 1985	Mar CTEC
+ @	ICU MEDICAL INC	5GM/100ML; 74.5MG/100ML; 900MG/100ML	N019691	002	Mar 24, 1988	Mar DISC
+ @		5GM/100ML; 149MG/100ML; 900MG/100ML	N019691	004	Mar 24, 1988	Mar DISC
	POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER					
+ @	ICU MEDICAL INC	5GM/100ML; 224MG/100ML; 450MG/100ML	N018362	006	Mar 28, 1988	Mar DISC
	POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER					
+ @	ICU MEDICAL INC	5GM/100ML; 224MG/100ML; 900MG/100ML	N019691	006	Mar 24, 1988	Mar DISC
	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER					
AP	+! ICU MEDICAL INC	5GM/100ML; 149MG/100ML; 450MG/100ML	N018362	010	Jul 05, 1983	Mar CHRS
AP	+ @	5GM/100ML; 298MG/100ML; 450MG/100ML	N018362	007	Mar 28, 1988	Mar DISC
	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER					
	BAXTER HLTHCARE	5GM/100ML; 300MG/100ML; 900MG/100ML	N019308	003	Apr 05, 1985	Mar CTEC
AP	+! ICU MEDICAL INC	5GM/100ML; 149MG/100ML; 900MG/100ML	N019691	005	Mar 24, 1988	Mar CRLD
AP	+ @	5GM/100ML; 298MG/100ML; 900MG/100ML	N019691	008	Mar 24, 1988	Mar DISC
	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER					
AP	+! ICU MEDICAL INC	5GM/100ML; 224MG/100ML; 450MG/100ML	N018362	002		Mar CHRS
	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER					
	BAXTER HLTHCARE	5GM/100ML; 224MG/100ML; 900MG/100ML	N019308	006	Apr 05, 1985	Mar CTEC
+ @	ICU MEDICAL INC	5GM/100ML; 224MG/100ML; 900MG/100ML	N019691	007	Mar 24, 1988	Mar DISC
	POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER					
AP	+! ICU MEDICAL INC	5GM/100ML; 298MG/100ML; 450MG/100ML	N018362	003		Mar CHRS
	POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER					
AP	+! ICU MEDICAL INC	5GM/100ML; 298MG/100ML; 900MG/100ML	N019691	009	Mar 24, 1988	Mar CRLD
	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER					
	BAXTER HLTHCARE	5GM/100ML; 150MG/100ML; 450MG/100ML	N018008	004		Mar CTEC
+ @	ICU MEDICAL INC	5GM/100ML; 74.5MG/100ML; 450MG/100ML	N018362	008	Mar 28, 1988	Mar DISC
+ @		5GM/100ML; 149MG/100ML; 450MG/100ML	N018362	004	Mar 28, 1988	Mar DISC

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER	BAXTER HLTHCARE	5GM/100ML;150MG/100ML;900MG/100ML	N 019308	001	Apr 05, 1985	Mar CTEC
+ @ ICU MEDICAL INC		5GM/100ML;74.5MG/100ML;900MG/100ML	N 019691	001	Mar 24, 1988	Mar DISC
+ @		5GM/100ML;149MG/100ML;900MG/100ML	N 019691	003	Mar 24, 1988	Mar DISC

DEXTROSE; SODIUM CHLORIDEINJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP + ICU MEDICAL INC	5GM/100ML;450MG/100ML	N 017607	001	Jan CRLD
----------------------	-----------------------	----------	-----	----------

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUMINJECTABLE; INJECTION

RENOGRAFIN-76

+ @ BRACCO	66%;10%	N 010040	001	May DISC
------------	---------	----------	-----	----------

DIATRIZOATE MEGLUMINE; IODIPAMIDE MEGLUMINESOLUTION; INTRAUTERINE

SINOGRAPHIN

+ @ BRACCO	52.7%;26.8%	N 011324	002	May DISC
------------	-------------	----------	-----	----------

DIAZEPAMTABLET; ORAL

DIAZEPAM

@ DAVA PHARMS INC	2MG	A 070228	002	Sep 26, 1985	Apr CMS1
-------------------	-----	----------	-----	--------------	----------

@	5MG	A 070228	003	Sep 26, 1985	Apr CMS1
---	-----	----------	-----	--------------	----------

DICLOFENAC POTASSIUMCAPSULE; ORAL

ZIPSOR

AB +! ASSERTIO FOR SOLUTION; ORAL CAMBIA	25MG	N 022202	001	Jun 16, 2009	Aug CAHN
--	------	----------	-----	--------------	----------

AB +! ASSERTIO TABLET; ORAL DICLOFENAC POTASSIUM	50MG	N 022165	001	Jun 17, 2009	Aug CAHN
--	------	----------	-----	--------------	----------

AB CASI PHARMS INC	50MG	A 075229	001	Nov 20, 1998	Mar CAHN
--------------------	------	----------	-----	--------------	----------

DICLOFENAC SODIUMGEL; TOPICAL

DICLOFENAC SODIUM

AB CIPLA LTD	1%	A 209903	001	Aug 03, 2018	Jul NEWA
--------------	----	----------	-----	--------------	----------

>D> AB GAGE DEVELOPMENT	3%	A 210893	001	Jul 27, 2018	Sep CAHN
-------------------------	----	----------	-----	--------------	----------

AB	3%	A 210893	001	Jul 27, 2018	Jul NEWA
----	----	----------	-----	--------------	----------

>A> AB PERRIGO UK FINCO	3%	A 210893	001	Jul 27, 2018	Sep CAHN
-------------------------	----	----------	-----	--------------	----------

SOLUTION; INTRAVENOUS

DYLOJECT

+ @ JAVELIN PHARMS INC	37.5MG/ML (37.5MG/ML)	N 022396	001	Dec 23, 2014	Jun DISC
------------------------	-----------------------	----------	-----	--------------	----------

SOLUTION; TOPICAL

DICLOFENAC SODIUM

AT TWI PHARMS	1.5%	A 202393	001	Nov 24, 2014	Jul CAHN
---------------	------	----------	-----	--------------	----------

AT ZYDUS PHARMS USA INC	1.5%	A 206411	001	Apr 17, 2018	Apr NEWA
-------------------------	------	----------	-----	--------------	----------

PENNSAID

+! HZNP	2%	N 204623	001	Jan 16, 2014	Aug CAHN
---------	----	----------	-----	--------------	----------

SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM

>A> AT ANDA REPOSITORY	0.1%	A 078553	001	Dec 28, 2007	Sep CAHN
------------------------	------	----------	-----	--------------	----------

>D> AT RISING PHARMS	0.1%	A 078553	001	Dec 28, 2007	Sep CAHN
----------------------	------	----------	-----	--------------	----------

TABLET, DELAYED RELEASE; ORAL

DICLOFENAC SODIUM

AB ! CASI PHARMS INC	25MG	A 074376	001	Sep 28, 1995	Mar CAHN
----------------------	------	----------	-----	--------------	----------

AB !	50MG	A 074376	002	Sep 28, 1995	Mar CAHN
------	------	----------	-----	--------------	----------

AB !	75MG	A 074394	001	Nov 30, 1995	Mar CAHN
------	------	----------	-----	--------------	----------

DICYCLOMINE HYDROCHLORIDECAPSULE; ORAL

BENTYL

AB +! ALLERGAN SALES LLC	10MG	N 007409	003	Oct 15, 1984	Jan CAHN
--------------------------	------	----------	-----	--------------	----------

DICYCLOMINE HYDROCHLORIDE

>D> @ HIKMA PHARMS	10MG	A 040204	001	Feb 28, 1997	Sep CMFD
--------------------	------	----------	-----	--------------	----------

>A> AB WEST WARD	10MG	A 040204	001	Feb 28, 1997	Sep CMFD
------------------	------	----------	-----	--------------	----------

INJECTABLE; INJECTION

BENTYL

AP	+!	ALLERGAN SALES LLC	10MG/ML	N 008370	001	Oct 15, 1984	Jan CAHN
		BENTYL PRESERVATIVE FREE					
AP	+!	ALLERGAN SALES LLC	10MG/ML	N 008370	002	Oct 15, 1984	Jan CAHN
		DICYCLOMINE HYDROCHLORIDE					
AP		AKORN INC	10MG/ML	A 207084	001	May 04, 2018	Apr NEWA
AP		APC PHARMS LLC	10MG/ML	A 210979	001	Jul 02, 2018	Jun NEWA
		TABLET; ORAL					
		BENTYL					
AB	+!	ALLERGAN SALES LLC	20MG	N 007409	001	Oct 15, 1984	Jan CAHN

DIDANOSINECAPSULE, DELAYED REL PELLETS; ORAL  
DIDANOSINE

@ BARR	200MG	A 077167	001	Dec 03, 2004	Mar DISC
@	250MG	A 077167	002	Dec 03, 2004	Mar DISC
@	400MG	A 077167	003	Dec 03, 2004	Mar DISC

DIETHYLPROPION HYDROCHLORIDETABLET; ORAL  
TENUATE

>D> AA	+!	ACTAVIS LABS UT INC	25MG	N 011722	002		Sep CAHN
>A> AA	+!	TEVA BRANDED PHARM	25MG	N 011722	002		Sep CAHN
		TABLET, EXTENDED RELEASE; ORAL					
		TENUATE DOSPAN					
>D> AB	+!	ACTAVIS LABS UT INC	75MG	N 012546	001		Sep CAHN
>A> AB	+!	TEVA BRANDED PHARM	75MG	N 012546	001		Sep CAHN

DIFLORASONE DIACETATEOINTMENT; TOPICAL  
DIFLORASONE DIACETATE

>D> AB	RICONPHARMA LLC	0.05%	A 207440	001	Feb 27, 2017	Sep CAHN
>A> AB	RISING PHARMS	0.05%	A 207440	001	Feb 27, 2017	Sep CAHN
AB	TELIGENT PHARMA INC	0.05%	A 210753	001	Jun 12, 2018	May NEWA

DIFLUNISALTABLET; ORAL  
DIFLUNISAL  
@ SOCORRO 250MG  
@ 500MG

A 073562	001	Nov 27, 1992	Jun CAHN
A 073563	001	Nov 27, 1992	Jul CAHN

DIGOXINTABLET; ORAL  
LANOXIN  
+ @ CONCORDIA PHARMS INC 0.1875MG

N 020405	003	Sep 30, 1997	May DISC
----------	-----	--------------	----------

DIHYDROERGOTAMINE MESYLATEINJECTABLE; INJECTION  
DIHYDROERGOTAMINE MESYLATE

AP	SAGENT PHARMS	1MG/ML	A 207264	001	Jul 11, 2018	Jun NEWA
----	---------------	--------	----------	-----	--------------	----------

DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORAL  
DILTIAZEM HYDROCHLORIDE

AB3	PAR PHARM	360MG	A 209766	001	May 30, 2018	May NEWA
AB3	TWI PHARMS	120MG	A 205231	001	Aug 30, 2018	Aug NEWA
AB3		180MG	A 205231	002	Aug 30, 2018	Aug NEWA
AB3		240MG	A 205231	003	Aug 30, 2018	Aug NEWA
AB3		300MG	A 205231	004	Aug 30, 2018	Aug NEWA
AB3		360MG	A 205231	005	Aug 30, 2018	Aug NEWA

DIPHENHYDRAMINE HYDROCHLORIDECAPSULE; ORAL  
DIPHENHYDRAMINE HYDROCHLORIDE  
@ FOSUN PHARMA 25MG  
@ 25MG  
@ 50MG  
@ 50MG

A 080832	001		Jan CAHN
A 080845	002		Jan CAHN
A 080832	002		Jan CAHN
A 080845	001		Jan CAHN

INJECTABLE; INJECTION

DIPHENYDRAMINE HYDROCHLORIDE

AP MICRO LABS 50MG/ML A205723 001 Aug 22, 2018 Aug NEWA

DIVALPROEX SODIUM

TABLET, DELAYED RELEASE; ORAL

DIVALPROEX SODIUM

AB APOTEX INC EQ 125MG VALPROIC ACID A077615 003 Jul 29, 2008 Apr CAHN  
AB EQ 250MG VALPROIC ACID A077615 002 Jul 29, 2008 Apr CAHN  
AB EQ 500MG VALPROIC ACID A077615 001 Jul 29, 2008 Apr CAHNDOCETAXEL

INJECTABLE; INJECTION

DOCETAXEL

+ @ ACCORD HLTHCARE 20MG/0.5ML (40MG/ML) N201195 001 Jun 08, 2011 Jun DISC  
+ @ 80MG/2ML (40MG/ML) N201195 002 Jun 08, 2011 Jun DISC  
AP AMNEAL PHARMS CO 20MG/ML (20MG/ML) A209640 001 Jan 19, 2018 Jan NEWA  
AP 80MG/4ML (20MG/ML) A209640 002 Jan 19, 2018 Jan NEWA  
AP 160MG/8ML (20MG/ML) A209640 003 Jan 19, 2018 Jan NEWA  
AP CIPLA LTD 20MG/2ML (10MG/ML) A209634 001 Aug 24, 2018 Aug NEWA  
AP 80MG/8ML (10MG/ML) A209634 002 Aug 24, 2018 Aug NEWA  
AP 160MG/16ML (10MG/ML) A209634 003 Aug 24, 2018 Aug NEWA  
AP EAGLE PHARMS 20MG/ML (20MG/ML) N205934 001 Dec 22, 2015 Jun CTEC  
20MG/ML (20MG/ML) N205934 001 Dec 22, 2015 Jun CDFR  
AP 80MG/4ML (20MG/ML) N205934 002 Dec 22, 2015 Jun CTEC  
80MG/4ML (20MG/ML) N205934 002 Dec 22, 2015 Jun CDFR  
AP 160MG/8ML (20MG/ML) N205934 003 Dec 22, 2015 Jun CTEC  
160MG/8ML (20MG/ML) N205934 003 Dec 22, 2015 Jun CDFR  
AP MYLAN LABS LTD 20MG/2ML (10MG/ML) A210072 001 Jul 02, 2018 Jun NEWA  
AP 80MG/8ML (10MG/ML) A210848 001 Jul 06, 2018 Jun NEWADOCETAXEL

INJECTABLE; INJECTION

DOCETAXEL

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

DOFETILIDE

CAPSULE; ORAL

DOFETILIDE

AB APICORE US 0.125MG A208625 001 Apr 10, 2018 Mar NEWA  
AB 0.25MG A208625 002 Apr 10, 2018 Mar NEWA  
AB 0.5MG A208625 003 Apr 10, 2018 Mar NEWA  
AB BIONPHARMA INC 0.125MG A208625 001 Apr 10, 2018 May CAHN  
AB 0.25MG A208625 002 Apr 10, 2018 May CAHN  
AB 0.5MG A208625 003 Apr 10, 2018 May CAHN  
>A> AB PAR PHARM INC 0.125MG A208519 001 Oct 09, 2018 Sep NEWA  
>A> AB 0.25MG A208519 002 Oct 09, 2018 Sep NEWA  
>A> AB 0.5MG A208519 003 Oct 09, 2018 Sep NEWA  
AB SIGMAPHARM LABS LLC 0.125MG A207746 001 Mar 26, 2018 Mar NEWA  
AB 0.25MG A207746 002 Mar 26, 2018 Mar NEWA  
AB 0.5MG A207746 003 Mar 26, 2018 Mar NEWA  
>A> AB SUN PHARMA GLOBAL 0.125MG A210466 001 Oct 09, 2018 Sep NEWA  
>A> AB 0.25MG A210466 002 Oct 09, 2018 Sep NEWA  
>A> AB 0.5MG A210466 003 Oct 09, 2018 Sep NEWADONEPEZIL HYDROCHLORIDE

TABLET; ORAL

DONEPEZIL HYDROCHLORIDE

@ APOTEX 5MG A078841 001 Jun 02, 2011 Mar DISC  
@ 10MG A078841 002 Jun 02, 2011 Mar DISC  
AB HISUN PHARM HANGZHOU 23MG A202410 001 Mar 24, 2017 Aug CAHN  
@ SUN PHARM INDs LTD 5MG A076786 001 Nov 26, 2010 Apr DISC  
@ 10MG A076786 002 Nov 26, 2010 Apr DISC

TABLET, ORALLY DISINTEGRATING; ORAL

ARICEPT ODT

+ @ EISAI INC 5MG N021720 001 Oct 18, 2004 Aug DISC  
+ @ 10MG N021720 002 Oct 18, 2004 Aug DISC

DONEPEZIL HYDROCHLORIDE

@ BARR 5MG A078388 002 Nov 26, 2010 Aug DISC  
@ 10MG A078388 001 Nov 26, 2010 Aug DISC  
AB HISUN PHARM HANGZHOU 5MG A205269 001 Jul 27, 2018 Jul NEWA  
AB 10MG A205269 002 Jul 27, 2018 Jul NEWA  
AB ! SANDOZ 10MG A091198 002 May 10, 2011 Aug CHRS

TABLET, ORALLY DISINTEGRATING;ORAL  
DONEPEZIL HYDROCHLORIDE

@ ZYDUS PHARMS USA INC	5MG	A090175	001	May 10, 2011	Aug DISC
@	10MG	A090175	002	May 10, 2011	Aug DISC

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL  
NAMZARIC

AB + ALLERGAN SALES LLC	10MG;7MG	N206439	003	Jul 18, 2016	Jun CAHN
AB +	10MG;14MG	N206439	001	Dec 23, 2014	Jun CAHN
AB +	10MG;21MG	N206439	004	Jul 18, 2016	Jun CAHN
AB +!	10MG;28MG	N206439	002	Dec 23, 2014	Jun CAHN

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
DOPAMINE HYDROCHLORIDE

AP HIKMA INTL PHARMS	40MG/ML	A207707	001	Apr 11, 2018	Mar NEWA
AP	80MG/ML	A207707	002	Apr 11, 2018	Mar NEWA
AP @ LUITPOLD	160MG/ML	A070826	001	Feb 11, 1987	Aug DISC

DORAVIRINE

TABLET;ORAL  
PIFELTRO  
+! MSD MERCK CO 100MG

N210806	001	Aug 30, 2018	Aug NEWA
---------	-----	--------------	----------

DORAVIRINE; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL  
DELSTRIGO  
+! MSD MERCK CO 100MG;300MG;300MG

N210807	001	Aug 30, 2018	Aug NEWA
---------	-----	--------------	----------

DORIPENEM

>A> INJECTABLE; INTRAVENOUS					
>A> DORIBAX					
>A> + @ SHIONOGI INC	250MG/VIAL	N022106	002	Oct 05, 2010	Sep CDFR
>A> + @	500MG/VIAL	N022106	001	Oct 12, 2007	Sep CDFR
>D> INJECTABLE; IV (INFUSION)					
>D> DORIBAX					
>D> + @ SHIONOGI INC	250MG/VIAL	N022106	002	Oct 05, 2010	Sep CDFR
>D> + @	500MG/VIAL	N022106	001	Oct 12, 2007	Sep CDFR

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC  
DORZOLAMIDE HYDROCHLORIDE  
@ TEVA PHARMS EQ 2% BASE  
@ WATSON LABS INC EQ 2% BASE

A078756	001	Dec 04, 2008	Jun DISC
A202053	001	Sep 11, 2014	May DISC

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC  
COSOPT PF  
AT +! OAK PHARMS INC EQ 2% BASE;EQ 0.5% BASE  
DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE  
AT AUROBINDO PHARMA LTD EQ 2% BASE;EQ 0.5% BASE  
@ WATSON LABS INC EQ 2% BASE;EQ 0.5% BASE

N202667	001	Feb 01, 2012	Jul CFTG
A207630	001	Jul 24, 2018	Jul NEWA
A202054	001	Sep 03, 2014	May DISC

DOXAZOSIN MESYLATE

TABLET;ORAL  
DOXAZOSIN MESYLATE  
>D> AB APPCO PHARMA LLC EQ 1MG BASE A209013 001 Apr 17, 2018 Sep CAHN  
AB EQ 1MG BASE A209013 001 Apr 17, 2018 Apr NEWA  
>D> AB EQ 2MG BASE A209013 002 Apr 17, 2018 Sep CAHN  
AB EQ 2MG BASE A209013 002 Apr 17, 2018 Apr NEWA  
>D> AB EQ 4MG BASE A209013 003 Apr 17, 2018 Sep CAHN  
AB EQ 4MG BASE A209013 003 Apr 17, 2018 Apr NEWA  
>D> AB EQ 8MG BASE A209013 004 Apr 17, 2018 Sep CAHN  
AB EQ 8MG BASE A209013 004 Apr 17, 2018 Apr NEWA  
AB HERITAGE PHARMA EQ 1MG BASE A205210 001 Feb 13, 2018 Jan NEWA  
AB EQ 2MG BASE A205210 002 Feb 13, 2018 Jan NEWA  
AB EQ 4MG BASE A205210 003 Feb 13, 2018 Jan NEWA  
AB EQ 8MG BASE A205210 004 Feb 13, 2018 Jan NEWA  
>A> AB UPSHER-SMITH LABS EQ 1MG BASE A209013 001 Apr 17, 2018 Sep CAHN  
>A> AB EQ 2MG BASE A209013 002 Apr 17, 2018 Sep CAHN  
>A> AB EQ 4MG BASE A209013 003 Apr 17, 2018 Sep CAHN

TABLET;ORAL  
DOXAZOSIN MESYLATE

>A> AB		EQ 8MG BASE	A209013	004	Apr 17, 2018	Sep CAHN
	@ YAOPHARMA CO LTD	EQ 1MG BASE	A075646	001	Oct 18, 2000	Jan CAHN
	@	EQ 2MG BASE	A075646	002	Oct 18, 2000	Jan CAHN
	@	EQ 4MG BASE	A075646	003	Oct 18, 2000	Jan CAHN
	@	EQ 8MG BASE	A075646	004	Oct 18, 2000	Jan CAHN

DOXEPEPIN HYDROCHLORIDE

TABLET;ORAL  
DOXEPEPIN HYDROCHLORIDE  
@ ACTAVIS ELIZABETH  
@ SILENOR  
+ PERNIX THERAPS LLC  
+!

	EQ 3MG BASE	A201951	001	Jul 26, 2013	Jan DISC
	EQ 6MG BASE	A201951	002	Jul 26, 2013	Jan DISC
	EQ 3MG BASE	N022036	001	Mar 17, 2010	Jan CTEC
	EQ 6MG BASE	N022036	002	Mar 17, 2010	Jan CTEC

DOXERCALCIFEROL

CAPSULE;ORAL  
DOXERCALCIFEROL

>A> AB	ANDA REPOSITORY	0.5MCG	A201518	001	Sep 09, 2016	Sep CAHN
>A> AB		1MCG	A201518	002	Sep 09, 2016	Sep CAHN
>A> AB		2.5MCG	A201518	003	Sep 09, 2016	Sep CAHN
>D> AB	RISING PHARMS	0.5MCG	A201518	001	Sep 09, 2016	Sep CAHN
>D> AB		1MCG	A201518	002	Sep 09, 2016	Sep CAHN
>D> AB		2.5MCG	A201518	003	Sep 09, 2016	Sep CAHN
	HECTOROL					
AB	+ SANOFI	0.5MCG	N020862	002	Apr 23, 2004	Aug CAHN
AB	+	1MCG	N020862	003	Jul 13, 2009	Aug CAHN
AB	+!	2.5MCG	N020862	001	Jun 09, 1999	Aug CAHN
	INJECTABLE;INJECTION					
	DOXERCALCIFEROL					
AP	+ HOSPIRA INC	4MCG/2ML (2MCG/ML)	N208614	001	Jul 24, 2018	Jul NEWA
	+!	10MCG/5ML (2MCG/ML)	N208614	002	Jul 24, 2018	Jul NEWA
	HECTOROL					
AP	+ SANOFI	2MCG/ML (2MCG/ML)	N021027	002	Apr 06, 2000	Aug CAHN
AP	+!	4MCG/2ML (2MCG/ML)	N021027	001	Apr 06, 2000	Aug CAHN

DOXORUBICIN HYDROCHLORIDE

INJECTABLE;INJECTION  
DOXORUBICIN HYDROCHLORIDE

>D> AP	MYLAN LABS LTD	10MG/VIAL	A200170	001	Oct 28, 2011	Sep DISC
>A>	@	10MG/VIAL	A200170	001	Oct 28, 2011	Sep DISC

DOXYCYCLINE

TABLET;ORAL  
DOXYCYCLINE

AB	SUN PHARM INDNS LTD	EQ 150MG BASE	A065356	004	Jul 29, 2010	Jul NEWA
----	---------------------	---------------	---------	-----	--------------	----------

DOXYCYCLINE HYCLATE

CAPSULE;ORAL  
ACTICLATE CAP

+ @ AQUA PHARMS	DOXYCYCLINE HYCLATE	EQ 75MG BASE	N208253	001	Apr 26, 2016	May DISC
>A> AB	AJANTA PHARMA LTD	EQ 50MG BASE	A211012	001	Sep 24, 2018	Sep NEWA
>A> AB		EQ 100MG BASE	A211012	002	Sep 24, 2018	Sep NEWA
AB	ALEMBIC PHARMS LTD	EQ 50MG BASE	A210527	001	Jun 13, 2018	May NEWA
AB		EQ 100MG BASE	A210527	002	Jun 13, 2018	May NEWA
	@ HIKMA INTL PHARMS	EQ 20MG BASE	A065103	001	May 13, 2005	Jul DISC
AB	SUN PHARM INDUSTRIES	EQ 50MG BASE	A062676	002	Jul 10, 1986	Jun CMS1
AB	ZYDUS PHARMS USA INC	EQ 50MG BASE	A207774	001	May 31, 2018	May NEWA
AB		EQ 100MG BASE	A207774	002	May 31, 2018	May NEWA

TABLET;ORAL  
DOXYCYCLINE HYCLATE

CARIBE HOLDINGS	EQ 50MG BASE	A062269	003	Oct 05, 1983	Jul CMS1
>D> LYMEPAK					
>D> +! CHARTWELL PHARMA	EQ 100MG BASE	N209844	001	Jun 15, 2018	Sep DISC
>A> + @	EQ 100MG BASE	N209844	001	Jun 15, 2018	Sep DISC
	EQ 100MG BASE	N209844	001	Jun 15, 2018	Jun NEWA

## TABLET, DELAYED RELEASE;ORAL

DORYX

+ @ MAYNE PHARMA	EQ 80MG BASE	N 050795	004	Apr 11, 2013	Apr DISC
DOXYCYCLINE HYCLATE					
AB ACTAVIS ELIZABETH	EQ 50MG BASE	A 090134	003	May 22, 2018	May NEWA
	EQ 200MG BASE	A 090134	004	May 22, 2018	May NEWA

@ MYLAN

EQ 80MG BASE

A 090431 004 Apr 29, 2016 Apr DISC

DRONABINOL

CAPSULE;ORAL

DRONABINOL

AB LANNETT CO INC	2.5MG	A 201463	001	May 18, 2018	May NEWA
	5MG	A 201463	002	May 18, 2018	May NEWA
	10MG	A 201463	003	May 18, 2018	May NEWA

DROSPIRENONE; ETHINYL ESTRADIOL

TABLET;ORAL

DROSPIRENONE AND ETHINYL ESTRADIOL

AB JUBILANT CADISTA	3MG;0.02MG	A 209423	001	Dec 22, 2017	Mar CAHN
LO-ZUMANDIMINE					

AB AUROBINDO PHARMA LTD	3MG;0.02MG	A 209632	001	Feb 27, 2018	Feb NEWA
TABLET;ORAL-28					

DROSPIRENONE AND ETHINYL ESTRADIOL

>A> AB CYNDEA PHARMA	3MG;0.03MG	A 210017	001	Sep 10, 2018	Sep NEWA
>A> AB JUBILANT CADISTA	3MG;0.03MG	A 210017	001	Sep 10, 2018	Sep CAHN

ZUMANDIMINE

AB AUROBINDO PHARMA LTD	3MG;0.03MG	A 209407	001	Mar 26, 2018	Mar NEWA
-------------------------	------------	----------	-----	--------------	----------

DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM

TABLET;ORAL

DROSPIRENONE, ETHINYL ESTRADIOL AND LEVOMEFOLATE CALCIUM

AB LUPIN LTD	3MG,N/A;0.02MG,N/A;0.451MG,0.451MG	A 205947	001	Jun 13, 2018	May NEWA
--------------	------------------------------------	----------	-----	--------------	----------

DULOXETINE HYDROCHLORIDE

CAPSULE, DELAYED REL PELLETS;ORAL

DULOXETINE HYDROCHLORIDE

AB BRECKENRIDGE PHARM	EQ 40MG BASE	A 203088	004	May 18, 2018	May NEWA
AB LUPIN LTD	EQ 40MG BASE	A 090694	003	Dec 11, 2013	May CTEC
AB MARKSANS PHARMA	EQ 20MG BASE	A 090723	001	Dec 11, 2013	Jul CAHN
	EQ 30MG BASE	A 090723	002	Dec 11, 2013	Jul CAHN
	EQ 60MG BASE	A 090723	003	Dec 11, 2013	Jul CAHN

DUTASTERIDE

CAPSULE;ORAL

DUTASTERIDE

>A> AB BRECKENRIDGE PHARM	0.5MG	A 208227	001	Jun 22, 2018	Sep CAHN
>D> AB HAUPPT PHARMA	0.5MG	A 207935	001	Oct 13, 2017	Sep CAHN
>A> AB HERITAGE PHARMS INC	0.5MG	A 207935	001	Oct 13, 2017	Sep CAHN
@ MYLAN PHARMS INC	0.5MG	A 203241	001	Jun 14, 2016	Jun DISC
>D> AB PHARMACEUTICS	0.5MG	A 208227	001	Jun 22, 2018	Sep CAHN
AB	0.5MG	A 208227	001	Jun 22, 2018	Jun NEWA

DUTASTERIDE; TAMSULOSIN HYDROCHLORIDE

CAPSULE;ORAL

DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE

AB ZYDUS PHARMS USA INC	0.5MG;0.4MG	A 207769	001	May 24, 2018	May NEWA
-------------------------	-------------	----------	-----	--------------	----------

>A> DUVELISIB

&gt;A&gt; CAPSULE;ORAL

&gt;A&gt; COPIKTRA

>A> + VERASTEM INC	15MG	N 211155	001	Sep 24, 2018	Sep NEWA
>A> +!	25MG	N 211155	002	Sep 24, 2018	Sep NEWA

ECONAZOLE NITRATE

CREAM;TOPICAL

ECONAZOLE NITRATE

AB CASI PHARMS INC	1%	A 076075	001	Nov 26, 2002	Mar CAHN
AB MYLAN PHARMS INC	1%	A 210364	001	Apr 18, 2018	Apr NEWA

EDARAVONE

SOLUTION; INTRAVENOUS  
RADICAVA  
+! MITSUBISHI TANABE 30MG/100ML (0.3MG/ML) N209176 001 May 05, 2017 Jul CDFR

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION  
>D> ENLON  
>D> ! MYLAN INSTITUTIONAL 10MG/ML A088873 001 Aug 06, 1985 Sep DISC  
>A> @ 10MG/ML A088873 001 Aug 06, 1985 Sep DISC

EFAVIRENZ

TABLET; ORAL  
EFAVIRENZ  
>A> AB AUROBINDO PHARMA LTD 600MG A077673 001 Sep 21, 2018 Sep NEWA  
AB 600MG A205322 001 Aug 30, 2018 Aug NEWA  
AB CIPLA LTD 600MG A204766 001 Jun 15, 2018 Jun NEWA  
AB HETERO LABS LTD III 600MG A078886 001 Apr 27, 2018 Apr NEWA  
AB STRIDES PHARMA 600MG A204869 001 Mar 12, 2018 Feb NEWA

EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET; ORAL  
ATRIPLA  
AB +! GILEAD SCIENCES 600MG;200MG;300MG N021937 001 Jul 12, 2006 Aug CFTG  
+! 600MG;200MG;300MG N021937 001 Jul 12, 2006 Mar CAHN  
EFAVIRENZ, EMTRICITABINE, AND TENOFOVIR DISOPROXIL FUMARATE  
AB AUROBINDO PHARMA LTD 600MG;200MG;300MG A203041 001 Sep 04, 2018 Aug NEWA

EFAVIRENZ; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET; ORAL  
EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE  
AUROBINDO PHARMA LTD 600MG;300MG;300MG N022343 001 Aug 15, 2018 Aug NEWA  
SYMFI  
+! MYLAN LABS LTD 600MG;300MG;300MG N022142 001 Mar 22, 2018 Mar NEWA  
SYMFI LO  
+! MYLAN PHARMS INC 400MG;300MG;300MG N208255 001 Feb 05, 2018 Feb NEWA

ELAGOLIX SODIUM

TABLET; ORAL  
ORILISSA  
+! ABBVIE INC EQ 150MG BASE N210450 001 Jul 23, 2018 Jul NEWA  
+! EQ 200MG BASE N210450 002 Jul 23, 2018 Jul NEWA

ELETRIPTAN HYDROBROMIDE

TABLET; ORAL  
ELETRIPTAN HYDROBROMIDE  
AB AMNEAL PHARMS CO EQ 20MG BASE A206787 001 May 25, 2018 May NEWA  
AB EQ 40MG BASE A206787 002 May 25, 2018 May NEWA

ELTROMBOGOL OLAMINE

FOR SUSPENSION; ORAL  
>D> PROMACTA  
>D> +! NOVARTIS PHARMS CORP EQ 25MG ACID/PACKET N207027 001 Aug 24, 2015 Sep CTNA  
PROMACTA KIT  
>A> +! NOVARTIS PHARMS CORP EQ 12.5MG ACID/PACKET N207027 002 Sep 27, 2018 Sep NEWA  
>A> +! EQ 25MG ACID/PACKET N207027 001 Aug 24, 2015 Sep CTNA

EMTRICITABINE

CAPSULE; ORAL  
EMTRICITABINE  
AB CIPLA LTD 200MG A091168 001 Jul 02, 2018 Jun NEWA  
EMTRIVA  
AB +! GILEAD 200MG N021500 001 Jul 02, 2003 Jun CFTG

EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET; ORAL  
EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE  
AB AMNEAL PHARMS CO 100MG;150MG A209721 001 Aug 22, 2018 Aug NEWA  
AB 133MG;200MG A209721 002 Aug 22, 2018 Aug NEWA  
AB 167MG;250MG A209721 003 Aug 22, 2018 Aug NEWA  
AB 200MG;300MG A209721 004 Aug 22, 2018 Aug NEWA

TABLET;ORAL

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

AB	AUROBINDO PHARMA LTD	200MG;300MG	A090513	001	Jan 26, 2018	Jan NEWA
AB	MYLAN PHARMS INC	200MG;300MG	A206436	001	Apr 09, 2018	Mar NEWA
	TRUVADA					
AB	+ GILEAD	100MG;150MG	N021752	002	Mar 10, 2016	Aug CFTG
AB	+ +	133MG;200MG	N021752	003	Mar 10, 2016	Aug CFTG
AB	+ +	167MG;250MG	N021752	004	Mar 10, 2016	Aug CFTG

ENCORAFENIB

CAPSULE;ORAL

BRAFTOVI

+ +	ARRAY BIOPHARMA INC	50MG
+ !		75MG

N210496	001	Jun 27, 2018	Jun NEWA
N210496	002	Jun 27, 2018	Jun NEWA

ENOXAPARIN SODIUM

INJECTABLE;SUBCUTANEOUS

ENOXAPARIN SODIUM (PRESERVATIVE FREE)

>A> AP	APOTEX INC	30MG/0.3ML (100MG/ML)	A078990	001	Sep 28, 2018	Sep NEWA
>A> AP		40MG/0.4ML (100MG/ML)	A078990	002	Sep 28, 2018	Sep NEWA
>A> AP		60MG/0.6ML (100MG/ML)	A078990	003	Sep 28, 2018	Sep NEWA
>A> AP		80MG/0.8ML (100MG/ML)	A078990	004	Sep 28, 2018	Sep NEWA
>A> AP		100MG/ML (100MG/ML)	A078990	005	Sep 28, 2018	Sep NEWA
>A> AP		120MG/0.8ML (150MG/ML)	A078990	006	Sep 28, 2018	Sep NEWA
>A> AP		150MG/ML (150MG/ML)	A078990	007	Sep 28, 2018	Sep NEWA

ENTACAPONE

TABLET;ORAL

ENTACAPONE

>A> AB	SUNSHINE LAKE	200MG	A206669	001	Oct 03, 2018	Sep NEWA
--------	---------------	-------	---------	-----	--------------	----------

ENTECAVIR

TABLET;ORAL

ENTECAVIR

AB	BRECKENRIDGE PHARM	0.5MG	A208721	001	Mar 15, 2018	Apr NEWA
AB		1MG	A208721	002	Mar 15, 2018	Apr NEWA
AB	CASI PHARMS INC	0.5MG	A206672	001	May 11, 2017	Mar CAHN
AB		1MG	A206672	002	May 11, 2017	Mar CAHN

EPHEDRINE SULFATE

SOLUTION;INTRAVENOUS

CORPHEDRA

AP	PAR STERILE PRODUCTS	50MG/ML (50MG/ML)	N208943	001	Jan 27, 2017	Apr CDFR
----	----------------------	-------------------	---------	-----	--------------	----------

EPINASTINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

EPINASTINE HYDROCHLORIDE

AT	CASI PHARMS INC	0.05%	A203384	001	Dec 07, 2016	Mar CAHN
----	-----------------	-------	---------	-----	--------------	----------

EPINEPHRINE

INJECTABLE;INTRAMUSCULAR, SUBCUTANEOUS

ADRENAClick

BX	+! IMPAX	EQ 0.15MG/DELIVERY	N020800	003	Nov 25, 2009	Aug CAHN
BX	+!	EQ 0.3MG/DELIVERY	N020800	004	Nov 25, 2009	Aug CAHN
	EPINEPHRINE (AUTOINJECTOR)					
AB	TEVA PHARMS USA	0.15MG/DELIVERY	A090589	002	Aug 16, 2018	Jul NEWA
AB		0.3MG/DELIVERY	A090589	001	Aug 16, 2018	Jul NEWA
	EPIPEN					
AB	+! MYLAN SPECIALITY LP	0.3MG/DELIVERY	N019430	001	Dec 22, 1987	Jul CFTG
	EPIPEN JR.					
AB	+! MYLAN SPECIALITY LP	0.15MG/DELIVERY	N019430	002	Dec 22, 1987	Jul CFTG
	TWINJECT 0.15					
	@ IMPAX	EQ 0.15MG/DELIVERY	N020800	002	May 28, 2004	Aug CAHN
	TWINJECT 0.3					
	@ IMPAX	EQ 0.3MG/DELIVERY	N020800	001	May 30, 2003	Aug CAHN
	SOLUTION;INTRAMUSCULAR, SUBCUTANEOUS					
	ADRENALIN					
AP	+! PAR STERILE PRODUCTS	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	N204200	001	Dec 07, 2012	Jun CFTG
	EPINEPHRINE					
AP	LUITPOLD	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A207568	001	Jul 06, 2018	Jun NEWA

SOLUTION; INTRAMUSCULAR, SUBCUTANEOUS  
SYMJEPI

>A> +! ADAMIS PHARMS CORP 0.15MG/0.3ML (0.15MG/0.3ML) N207534 002 Sep 27, 2018 Sep NEWA  
SOLUTION; IV (INFUSION), INTRAOCULAR, INTRAMUSCULAR, SUBCUTANEOUS  
EPINEPHRINE  
+! BELCHER PHARMS LLC EQ 1MG BASE/ML (EQ 1MG BASE/ML) N205029 001 Jul 29, 2014 Apr CRLD

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE  
@ EASTMAN KODAK 0.01MG/ML; 2% A040057 002 Feb 26, 1993 Mar DISC  
@ 0.02MG/ML; 2% A040057 001 Feb 26, 1993 Mar DISC

EPIRUBICIN HYDROCHLORIDE

>D> INJECTABLE; IV (INFUSION)  
>D> EPIRUBICIN HYDROCHLORIDE  
>D> @ HOSPIRA 50MG/VIAL N050807 001 Sep 15, 2006 Sep CDFR  
>D> @ 200MG/VIAL N050807 002 Sep 15, 2006 Sep CDFR  
>A> POWDER; INTRAVENOUS  
>A> EPIRUBICIN HYDROCHLORIDE  
>A> @ HOSPIRA 50MG/VIAL N050807 001 Sep 15, 2006 Sep CDFR  
>A> @ 200MG/VIAL N050807 002 Sep 15, 2006 Sep CDFR

EPLERENONE

TABLET; ORAL  
EPLERENONE  
>A> AB BRECKENRIDGE PHARM 25MG A208283 001 Sep 14, 2018 Sep NEWA  
>A> AB 50MG A208283 002 Sep 14, 2018 Sep NEWA

EPROSARTAN MESYLATE

TABLET; ORAL  
EPROSARTAN MESYLATE  
AB ! MYLAN PHARMS INC TEVETEN EQ 600MG BASE A202012 002 Nov 16, 2011 Mar CHRS  
+ @ ABBVIE EQ 400MG BASE N020738 005 Dec 22, 1997 Mar DISC  
+ @ EQ 600MG BASE N020738 006 May 27, 1999 Mar DISC

EPTIFIBATIDE

INJECTABLE; INJECTION  
EPTIFIBATIDE  
AP MYLAN LABS LTD 2MG/ML A203258 001 Jul 20, 2018 Jul NEWA  
AP 75MG/100ML A203258 002 Jul 20, 2018 Jul NEWA  
AP SAGENT PHARMS 2MG/ML A204693 001 Mar 07, 2018 Feb NEWA  
AP 75MG/100ML A204693 002 Mar 07, 2018 Feb NEWA

ERAVACYCLINE DIHYDROCHLORIDE

POWDER; INTRAVENOUS  
XERAVA  
+! TETRAPHASE PHARMS EQ 50MG BASE/VIAL N211109 001 Aug 27, 2018 Aug NEWA

ERTAPENEM SODIUM

INJECTABLE; INTRAMUSCULAR, IV (INFUSION)  
ERTAPENEM SODIUM  
AP ACS DOBFAR SPA EQ 1GM BASE/VIAL A208790 001 Apr 16, 2018 Apr NEWA  
AP AUROBINDO PHARMA LTD EQ 1GM BASE/VIAL A209133 001 Jun 25, 2018 Jun NEWA  
INVANZ  
AP +! MERCK SHARP DOHME EQ 1GM BASE/VIAL N021337 001 Nov 21, 2001 Apr CFTG

ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE

TABLET; ORAL  
STEGLUJAN  
+! MERCK SHARP DOHME 5MG; EQ 100MG BASE N209805 001 Dec 19, 2017 Jan CMS1  
+! 15MG; EQ 100MG BASE N209805 002 Dec 19, 2017 Jan CMS1

ERYTHROMYCIN

SOLUTION; TOPICAL  
ERYTHRA-DERM  
>A> @ ANDA REPOSITORY 2% A062687 001 Feb 05, 1988 Sep CAHN  
>D> @ SAPTALIS PHARMS 2% A062687 001 Feb 05, 1988 Sep CAHN

TABLET;ORAL

## ERYTHROMYCIN

AB	AMNEAL PHARMS CO	250MG	A209720	001	Mar 09, 2018	Feb NEWA
AB		500MG	A209720	002	Mar 09, 2018	Feb NEWA
AB	ARBOR PHARMS LLC	250MG	A061621	001		Feb CTEC
AB	!	500MG	A061621	002		Feb CTEC
	TABLET, COATED PARTICLES;ORAL					
	PCE					
+ @	ARBOR PHARMS LLC	333MG	N050611	001	Sep 09, 1986	Jun DISC
+ @		500MG	N050611	002	Aug 22, 1990	Jun DISC

ERYTHROMYCIN LACTOBIONATE

## INJECTABLE;INJECTION

## ERYTHROCIN

## @ HOSPIRA

EQ 1GM BASE/VIAL

A062638 002 Oct 31, 1986 Jul DISC

ESCITALOPRAM OXALATE

## SOLUTION;ORAL

## LEXAPRO

AA	+! ALLERGAN SALES LLC	EQ 5MG BASE/5ML	N021365	001	Nov 27, 2002	Jan CAHN
	TABLET;ORAL					
	ESCITALOPRAM OXALATE					
>A> AB	PHARM ASSOC	EQ 5MG BASE	A077512	001	Sep 12, 2012	Sep CAHN
>A> AB		EQ 10MG BASE	A077512	002	Sep 12, 2012	Sep CAHN
>A> AB		EQ 20MG BASE	A077512	003	Sep 12, 2012	Sep CAHN
>D> AB	STI PHARMA LLC	EQ 5MG BASE	A077512	001	Sep 12, 2012	Sep CAHN
>D> AB		EQ 10MG BASE	A077512	002	Sep 12, 2012	Sep CAHN
>D> AB		EQ 20MG BASE	A077512	003	Sep 12, 2012	Sep CAHN
	LEXAPRO					
AB	+ ALLERGAN SALES LLC	EQ 5MG BASE	N021323	001	Aug 14, 2002	Jan CAHN
AB	+	EQ 10MG BASE	N021323	002	Aug 14, 2002	Jan CAHN
AB	+!	EQ 20MG BASE	N021323	003	Aug 14, 2002	Jan CAHN

ESMOLOL HYDROCHLORIDE

## INJECTABLE;INJECTION

## ESMOLOL HYDROCHLORIDE

AP	MYLAN LABS LTD	10MG/ML	A206608	001	Jun 08, 2018	May NEWA
AP		20MG/ML	A206608	002	Jun 08, 2018	May NEWA
AP	SAGENT PHARMS	10MG/ML	A207107	001	Jun 08, 2018	May NEWA
AP		20MG/ML	A207107	002	Jun 08, 2018	May NEWA

ESOMEPRAZOLE MAGNESIUM

## CAPSULE, DELAYED REL PELLETS;ORAL

## ESOMEPRAZOLE MAGNESIUM

AB	HEC PHARM	EQ 20MG BASE	A207265	002	May 18, 2018	Aug CAHN
AB		EQ 40MG BASE	A207265	001	May 18, 2018	Aug CAHN
AB	HEC PHARM CO LTD	EQ 20MG BASE	A207265	002	May 18, 2018	May NEWA
AB		EQ 40MG BASE	A207265	001	May 18, 2018	May NEWA
AB	SUN PHARM INDs LTD	EQ 20MG BASE	A209735	001	Apr 30, 2018	Apr NEWA
AB		EQ 40MG BASE	A209735	002	Apr 30, 2018	Apr NEWA

ESOMEPRAZOLE MAGNESIUM; NAPROXEN

## TABLET, DELAYED RELEASE;ORAL

## VIMOVO

AB	+ HORIZON	EQ 20MG BASE;375MG	N022511	002	Apr 30, 2010	Aug CTEC
AB	+	EQ 20MG BASE;375MG	N022511	002	Apr 30, 2010	Aug CAHN
AB	+!	EQ 20MG BASE;500MG	N022511	001	Apr 30, 2010	Aug CTEC
AB	+!	EQ 20MG BASE;500MG	N022511	001	Apr 30, 2010	Aug CAHN

ESTRADIOL

## CREAM;VAGINAL

## ESTRADIOL

AB	ALVOGEN PINE BROOK	0.01%	A209767	001	Mar 05, 2018	Feb NEWA
AB	PERRIGO UK FINCO	0.01%	A210194	001	Jan 22, 2018	Jan NEWA
AB	TEVA PHARMS USA	0.01%	A210488	001	Mar 30, 2018	Mar NEWA
	FILM, EXTENDED RELEASE;TRANSDERMAL					
	ESTRADIOL					
AB	MYLAN TECHNOLOGIES	0.025MG/24HR	A206685	001	Aug 15, 2018	Jul NEWA
AB		0.0375MG/24HR	A206685	002	Aug 15, 2018	Jul NEWA
AB		0.05MG/24HR	A206685	003	Aug 15, 2018	Jul NEWA
AB		0.075MG/24HR	A206685	004	Aug 15, 2018	Jul NEWA
AB		0.1MG/24HR	A206685	005	Aug 15, 2018	Jul NEWA

	FILM, EXTENDED RELEASE;TRANSDERMAL MINIVELLE					
AB	+ NOVEN	0.025MG/24HR	N 203752	005	Sep 23, 2014	Jul CFTG
AB	+	0.0375MG/24HR	N 203752	001	Oct 29, 2012	Jul CFTG
AB	+	0.05MG/24HR	N 203752	003	Oct 29, 2012	Jul CFTG
AB	+	0.075MG/24HR	N 203752	002	Oct 29, 2012	Jul CFTG
AB	+!	0.1MG/24HR	N 203752	004	Oct 29, 2012	Jul CFTG
	GEL;TRANSDERMAL DIVIGEL					
	+ VERTICAL PHARMS LLC	0.1%	N 022038	001	Jun 04, 2007	Jul CPOT
	INSERT;VAGINAL IMVEXXY					
	+ THERAPEUTICSMD INC	0.004MG	N 208564	001	May 29, 2018	May NEWA
	+!	0.01MG	N 208564	002	May 29, 2018	May NEWA
	TABLET;VAGINAL ESTRADIOL					
>A> AB	GLENMARK PHARMS LTD	10MCG	A 210264	001	Sep 14, 2018	Sep NEWA
	<u>ESTRADIOL ACETATE</u>					
	INSERT, EXTENDED RELEASE;VAGINAL FEMRING					
	+ MILLICENT	EQ 0.05MG BASE/24HR	N 021367	001	Mar 20, 2003	May CAHN
	+!	EQ 0.1MG BASE/24HR	N 021367	002	Mar 20, 2003	May CAHN
	<u>ESTRADIOL HEMIHYDRATE</u>					
	EMULSION;TOPICAL ESTRASORB					
	+ @ EXELTIS USA INC	0.25%	N 021371	001	Oct 09, 2003	Jun DISC
	<u>ESTRADIOL VALERATE</u>					
	INJECTABLE;INJECTION ESTRADIOL VALERATE					
	@ FOSUN PHARMA	10MG/ML	A 040628	001	Oct 04, 2007	Jan CAHN
	@	20MG/ML	A 040628	002	Oct 04, 2007	Jan CAHN
	@	40MG/ML	A 040628	003	Oct 04, 2007	Jan CAHN
	<u>ESTRADIOL; NORETHINDRONE ACETATE</u>					
	TABLET;ORAL ESTRADIOL AND NORETHINDRONE ACETATE					
AB	ACCORD HLTHCARE	1MG;0.5MG	A 210233	001	Feb 28, 2018	Feb NEWA
	<u>ESTROGENS, CONJUGATED</u>					
	CREAM;TOPICAL, VAGINAL PREMARIN					
	+! WYETH PHARMS	0.625MG/GM	N 020216	001		Jun CAHN
	INJECTABLE;INJECTION PREMARIN					
	+! WYETH PHARMS	25MG/VIAL	N 010402	001		Jun CAHN
	TABLET;ORAL PREMARIN					
	+ WYETH PHARMS	0.3MG	N 004782	003		Jun CAHN
	+	0.45MG	N 004782	006	Jul 16, 2003	Jun CAHN
	+!	0.625MG	N 004782	004		Jun CAHN
	+!	0.9MG	N 004782	005	Jan 26, 1984	Jun CAHN
	+!	1.25MG	N 004782	001		Jun CAHN
	@	2.5MG	N 004782	002		Jun CAHN
	<u>ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE</u>					
	TABLET;ORAL-28 PREMPHASE 14/14					
	+! WYETH PHARMS	0.625MG,0.625MG;N/A,5MG	N 020527	002	Nov 17, 1995	Jun CAHN
	PREMPRO					
	+! WYETH PHARMS	0.3MG;1.5MG	N 020527	005	Jun 04, 2003	Jun CAHN
	+!	0.45MG;1.5MG	N 020527	004	Mar 12, 2003	Jun CAHN
	+!	0.625MG;2.5MG	N 020527	001	Nov 17, 1995	Jun CAHN
	+!	0.625MG;5MG	N 020527	003	Jan 09, 1998	Jun CAHN

ETEPLIRSEN

SOLUTION; INTRAVENOUS  
EXONDYS 51

+! SAREPTA THERAPS INC 100MG/2ML (50MG/ML)  
+! 500MG/10ML (50MG/ML)

N206488 001 Sep 19, 2016 Jul CDFR  
N206488 002 Sep 19, 2016 Jul CDFR

ETHACRYNIC ACID

TABLET; ORAL  
ETHACRYNIC ACID

AB ALVOGEN 25MG  
AB AMNEAL PHARMS CO 25MG

A205709 001 Jul 24, 2018 Jul NEWA  
A208805 001 May 08, 2018 Apr NEWA

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET; ORAL-28  
MALMOREDE

AB NOVAST LABS 0.05MG; 1MG

A209547 001 Jul 25, 2018 Jul NEWA

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL  
BALCOLTRA

AVION PHARMS 0.02MG; 0.1MG  
NEUVOSYN LABS LLC 0.02MG; 0.1MG

N208612 001 Jan 09, 2018 Feb CAHN  
N208612 001 Jan 09, 2018 Jan NEWA

AB AUROBINDO PHARMA LTD 0.03MG; 0.15MG  
LEVONORGESTREL AND ETHINYL ESTRADIOL AND ETHINYL ESTRADIOL

A206850 001 Jun 29, 2018 Jun NEWA

AB LABS LEON FARMA 0.02MG, 0.1MG; 0.01MG, N/A  
AB LUPIN LTD 0.02MG, 0.1MG; 0.01MG, N/A

A205131 001 Dec 14, 2017 Apr CPOT  
A091674 001 Oct 26, 2011 Apr CPOT

AB MAYNE PHARMA 0.02MG, 0.1MG; 0.01MG, N/A  
AB MYLAN LABS LTD 0.02MG, 0.1MG; 0.01MG, N/A

A200407 001 Oct 25, 2011 Apr CPOT  
A200493 001 Jun 17, 2015 Apr CPOT

LO SIMPESSE

AB AUROBINDO PHARMA LTD 0.02MG, 0.1MG; 0.01MG, N/A

A206852 001 Apr 28, 2017 Apr CPOT

LOSEASONIQUE

AB TEVA BRANDED PHARM 0.02MG, 0.1MG; 0.01MG, N/A

N022262 001 Oct 24, 2008 Apr CPOT

TABLET; ORAL-21

ALESSE

+ @ WYETH PHARMS 0.02MG; 0.1MG

N020683 001 Mar 27, 1997 May CAHN

TRIPHASICL-21

+ @ WYETH PHARMS 0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075M G, 0.125MG

N019192 001 Nov 01, 1984 May CAHN

TABLET; ORAL-28

ALESSE

+ @ WYETH PHARMS 0.02MG; 0.1MG

N020683 002 Mar 27, 1997 May CAHN

LEVONORGESTREL AND ETHINYL ESTRADIOL

AB MYLAN LABS LTD 0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075M G, 0.125MG

A202970 001 Mar 23, 2018 Mar NEWA

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

BALZIVA-28

AB ! BARR 0.035MG; 0.4MG

A076238 001 Apr 22, 2004 Aug CHRS

MODICON 28

+ @ JANSSEN PHARMS 0.035MG; 0.5MG

N017735 001 Feb DISC

NORETHINDRONE AND ETHINYL ESTRADIOL

@ MYLAN LABS LTD 0.035MG; 0.4MG

A200897 001 May 11, 2015 Aug DISC

WERA

AB ! NOVAST LABS LTD 0.035MG; 0.5MG

A091204 001 Mar 27, 2012 Feb CHRS

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

LO LOESTRIN FE

+! APIL 0.01MG, 0.01MG; 1MG, N/A

N022501 001 Oct 21, 2010 Apr CTEC

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

@ MYLAN LABS LTD 0.01MG, 0.01MG; 1MG, N/A

A205049 001 May 31, 2016 Apr DISC

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

>D> AB APOTEX INC 0.02MG; 1MG

A208639 001 Mar 21, 2018 Sep DISC

>A> @ 0.02MG; 1MG

A208639 001 Mar 21, 2018 Sep DISC

AB 0.02MG; 1MG

A208639 001 Mar 21, 2018 Mar NEWA

TABLET; ORAL-28

HAILEY 1.5/30

AB GLENMARK PHARMS 0.03MG; 1.5MG

A209297 001 Jun 05, 2018 May NEWA

## TABLET;ORAL-28

HAILEY FE 1.5/30

AB	GLENMARK PHARMS	0.03MG;1.5MG	A209031	001	Jun 05, 2018	May NEWA
AB	NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL					
AB	MYLAN LABS LTD	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	A205069	001	Jun 22, 2018	Jun NEWA
	TABLET, CHEWABLE;ORAL					
	NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE					
AB	CHEMO RESEARCH SL	0.02MG;1MG	A209609	001	Jul 16, 2018	Jul NEWA
	TABLET, CHEWABLE, TABLET;ORAL					
	LO MINASTRIN FE					
+ @ APIL		0.01MG,0.01MG,N/A;1MG,N/A,N/A	N204654	001	Jul 24, 2013	Jan DISC

ETHINYLMESTRADIOL; NORGESTIMATE

>D>	TABLET;ORAL					
>D>	NORGESTIMATE AND ETHINYLMESTRADIOL					
>D> AB	GLENMARK GENERICS	0.035MG,0.035MG,0.035MG;0.18MG,0.2 15MG,0.25MG	A200494	001	Jun 17, 2011	Sep CDFR
>A>	TABLET;ORAL-28					
>A>	NORGESTIMATE AND ETHINYLMESTRADIOL					
>A> AB	GLENMARK GENERICS	0.035MG,0.035MG,0.035MG;0.18MG,0.2 15MG,0.25MG	A200494	001	Jun 17, 2011	Sep CDFR

ETHINYLMESTRADIOL; SEGESTERONE ACETATE

	RING;VAGINAL					
	ANNOVERA					
>D>	+! POPULATION COUNCIL	0.013MG/24HR;0.15MG/24HR	N209627	001	Aug 10, 2018	Sep CAHN
	+!	0.013MG/24HR;0.15MG/24HR	N209627	001	Aug 10, 2018	Aug NEWA
>A>	+! THERAPEUTICSMD INC	0.013MG/24HR;0.15MG/24HR	N209627	001	Aug 10, 2018	Sep CAHN

ETHIONAMIDE

	TABLET;ORAL					
	TRECATOR					
	+! WYETH PHARMS	250MG	N013026	002		May CAHN

ETODOLAC

	TABLET;ORAL					
	ETODOLAC					
AB	AMNEAL PHARMS CO	400MG	A208834	001	Jun 07, 2018	May NEWA
AB		500MG	A208834	002	Jun 07, 2018	May NEWA

EVEROLIMUS

	TABLET;ORAL					
	EVEROLIMUS					
AB	WEST-WARD PHARMS INT	0.25MG	A206133	001	Apr 12, 2018	Apr NEWA
AB		0.5MG	A206133	002	Apr 12, 2018	Apr NEWA
AB		0.75MG	A206133	003	Apr 12, 2018	Apr NEWA
	ZORTRESS					
AB	+ NOVARTIS	0.25MG	N021560	001	Apr 20, 2010	Apr CFTG
AB	+	0.5MG	N021560	002	Apr 20, 2010	Apr CFTG
AB	+!	0.75MG	N021560	003	Apr 20, 2010	Apr CFTG

EXEMESTANE

	TABLET;ORAL					
	EXEMESTANE					
AB	CIPRA LTD	25MG	A210323	001	Apr 27, 2018	Apr NEWA
>A> AB	ZYDUS PHARMS USA INC	25MG	A202602	001	Oct 03, 2018	Sep NEWA

EZETIMIBE; SIMVASTATIN

	TABLET;ORAL					
	EZETIMIBE AND SIMVASTATIN					
AB	ANI PHARMS INC	10MG;10MG	A201890	001	Apr 26, 2017	May CAHN
AB		10MG;20MG	A201890	002	Apr 26, 2017	May CAHN
AB		10MG;40MG	A201890	003	Apr 26, 2017	May CAHN
AB		10MG;80MG	A201890	004	Apr 26, 2017	May CAHN

FAMOTIDINE

	TABLET;ORAL					
	FAMOTIDINE					
@ PLD ACQUISITIONS		20MG	A075302	001	Apr 16, 2001	Feb CAHN
@		40MG	A075302	002	Apr 16, 2001	Feb CAHN

FAMOTIDINE; IBUPROFEN

TABLET;ORAL

DUEXIS

+! HORIZON

26.6MG;800MG

N022519 001 Apr 23, 2011 Aug CAHN

FELBAMATE

TABLET;ORAL

FELBAMATE

AB ANI PHARMS INC

400MG

A202284 001 Nov 04, 2015

May CAHN

AB

600MG

A202284 002 Nov 04, 2015

May CAHN

FENOFLIBRATE

CAPSULE;ORAL

FENOFLIBRATE (MICRONIZED)

AB AJANTA PHARMA LTD

67MG

A210705 001 Sep 10, 2018

Aug NEWA

AB

134MG

A210705 002 Sep 10, 2018

Aug NEWA

AB

200MG

A210705 003 Sep 10, 2018

Aug NEWA

AB AMERIGEN PHARMS LTD

67MG

A209504 001 Apr 30, 2018

Apr NEWA

AB

134MG

A209504 002 Apr 30, 2018

Apr NEWA

AB

200MG

A209504 003 Apr 30, 2018

Apr NEWA

AB TORRENT PHARMS LTD

67MG

A210782 001 Jun 26, 2018

Jun NEWA

AB

134MG

A210782 002 Jun 26, 2018

Jun NEWA

AB

200MG

A210782 003 Jun 26, 2018

Jun NEWA

TABLET;ORAL

FENOFLIBRATE

AB AJANTA PHARMA LTD

54MG

A210138 001 Jul 23, 2018

Jul NEWA

AB

160MG

A210138 002 Jul 23, 2018

Jul NEWA

AB AMNEAL PHARMS LLC

48MG

A209951 001 Feb 09, 2018

Jan NEWA

AB

54MG

A209950 001 Mar 19, 2018

Mar NEWA

AB

145MG

A209951 002 Feb 09, 2018

Jan NEWA

AB

160MG

A209950 002 Mar 19, 2018

Mar NEWA

AB GRAVITI PHARMS

54MG

A210606 001 Aug 17, 2018

Aug NEWA

AB

160MG

A210606 002 Aug 17, 2018

Aug NEWA

AB PRINSTON INC

48MG

A211080 001 Aug 28, 2018

Aug NEWA

AB

145MG

A211080 002 Aug 28, 2018

Aug NEWA

FENOPROFEN CALCIUM

CAPSULE;ORAL

NALFON

+ XSPIRE PHARMA

EQ 200MG BASE

N017604 003

Jun CHRS

+!

EQ 400MG BASE

N017604 004 Jul 21, 2009

Jun CHRS

FENTANYL

FILM, EXTENDED RELEASE;TRANSDERMAL

DURAGESIC-37

+ JANSSEN PHARMS

37.5MCG/HR

N019813 006 Jan 24, 2018

Jan NEWA

FENTANYL-100

&gt;D&gt; AB ACTAVIS LABS UT INC

100MCG/HR

A076709 004 Aug 20, 2007

Sep DISC

&gt;A&gt; @

100MCG/HR

A076709 004 Aug 20, 2007

Sep DISC

FENTANYL-25

&gt;D&gt; AB ACTAVIS LABS UT INC

25MCG/HR

A076709 001 Aug 20, 2007

Sep DISC

&gt;A&gt; @

25MCG/HR

A076709 001 Aug 20, 2007

Sep DISC

FENTANYL-50

&gt;D&gt; AB ACTAVIS LABS UT INC

50MCG/HR

A076709 002 Aug 20, 2007

Sep DISC

&gt;A&gt; @

50MCG/HR

A076709 002 Aug 20, 2007

Sep DISC

FENTANYL-75

&gt;D&gt; AB ACTAVIS LABS UT INC

75MCG/HR

A076709 003 Aug 20, 2007

Sep DISC

&gt;A&gt; @

75MCG/HR

A076709 003 Aug 20, 2007

Sep DISC

FENTANYL CITRATE

TROCHE/LOZENGE;TRANSMUCOSAL

FENTANYL CITRATE

@ PAR PHARM

EQ 0.2MG BASE

A077312 001 Oct 30, 2009

Jun DISC

@

EQ 0.4MG BASE

A077312 002 Oct 30, 2009

Jun DISC

@

EQ 0.6MG BASE

A077312 003 Oct 30, 2009

Jun DISC

@

EQ 0.8MG BASE

A077312 004 Oct 30, 2009

Jun DISC

@

EQ 1.2MG BASE

A077312 005 Oct 30, 2009

Jun DISC

@

EQ 1.6MG BASE

A077312 006 Oct 30, 2009

Jun DISC

FENTANYL HYDROCHLORIDE

SYSTEM; IONTOPHORESIS, TRANSDERMAL  
IONSYS

+ @ THE MEDICINES CO EQ 40MCG BASE/ACTIVATION N021338 001 May 22, 2006 Jun DISC

FERRIC PYROPHOSPHATE CITRATE

SOLUTION; INTRAVENOUS  
TRIFERIC

+! ROCKWELL MEDICAL INC 27.2MG IRON/5ML (5.44MG IRON/ML) N206317 001 Jan 23, 2015 Jul CDFR

+ @ 272MG IRON/50ML (5.44MG IRON/ML) N206317 002 Sep 04, 2015 Jul CDFR

SOLUTION; IV (INFUSION)  
TRIFERIC

+ @ ROCKWELL MEDICAL INC 272MG IRON/50ML (5.44MG IRON/ML) N206317 002 Sep 04, 2015 May DISC

FEXOFENADINE HYDROCHLORIDE

SUSPENSION; ORAL  
ALLEGRA

+ @ SANOFI AVENTIS US 30MG/5ML

N021963 001 Oct 16, 2006 May DISC

FEXOFENADINE HYDROCHLORIDE

@ ACTAVIS MID ATLANTIC 30MG/5ML

A201311 001 Jul 25, 2012 Aug DISC

! 30MG/5ML

A201311 001 Jul 25, 2012 May CHRS

FINAFLOXACIN

SUSPENSION/DROPS; OTIC  
XTORO

+! MERLION PHARMS GMBH 0.3%

N206307 001 Dec 17, 2014 Jul CAHN

FINASTERIDE

TABLET; ORAL  
FINASTERIDE

@ MYLAN PHARMS INC 1MG

A078161 001 Nov 05, 2013 Jul DISC

FINGOLIMOD HYDROCHLORIDE

CAPSULE; ORAL  
GILENYA

+ NOVARTIS EQ 0.25MG BASE

N022527 002 May 11, 2018 May NEWA

+! EQ 0.5MG BASE

N022527 001 Sep 21, 2010 May CAIN

FISH OIL TRIGLYCERIDES

EMULSION; INTRAVENOUS  
OMEGAVEN

+! FRESENIUS KABI USA 5GM/50ML (0.1GM/ML)

N210589 001 Jul 27, 2018 Jul NEWA

+! 10GM/100ML (0.1GM/ML)

N210589 002 Jul 27, 2018 Jul NEWA

FISH OIL; MEDIUM CHAIN TRIGLYCERIDES; OLIVE OIL; SOYBEAN OIL

EMULSION; INTRAVENOUS  
SMOFLIPID 20%

+! FRESENIUS KABI USA 3GM/100ML; 6GM/100ML; 5GM/100ML; 6GM/100ML (1000ML) N207648 004 Aug 10, 2018 Aug NEWA

FLOXURIDINE

INJECTABLE; INJECTION  
FLOXURIDINE

AP LUITPOLD 500MG/VIAL A203008 001 Nov 22, 2017 Jul CAHN

FLUCONAZOLE

INJECTABLE; INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ! INFORLIFE 200MG/100ML (2MG/ML) A079104 001 Jul 30, 2009 Jan CAHN

AP ! 400MG/200ML (2MG/ML) A079104 002 Jul 30, 2009 Jan CAHN

FLUCYTOSINE

CAPSULE; ORAL  
FLUCYTOSINE

AB RECIPHARM 250MG A207536 001 Jun 18, 2018 Jun NEWA

AB 500MG A207536 002 Jun 18, 2018 Jun NEWA

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION  
FLUDARABINE PHOSPHATE

AP AREVA PHARMS 50MG/2ML (25MG/ML) A090724 001 Sep 27, 2010 Jul CAHN

FLUDEOXYGLUCOSE F-18

INJECTABLE; INTRAVENOUS  
FLUDEOXYGLUCOSE F18

+ @ FEINSTEIN 20-200mCi/ML N021870 001 Aug 19, 2005 May DISC  
@ MIDWEST MEDCLL 20-200mCi/ML A203736 001 Nov 19, 2015 May DISC  
AP ! PETNET 20-200mCi/ML A079086 001 Feb 25, 2011 May CHRS

FLUNISOLIDE

SPRAY, METERED; NASAL  
FLUNISOLIDE  
@ APOTEX INC 0.029MG/SPRAY

A077436 001 Aug 09, 2007 Jun DISC

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL  
FLUOCINOLONE ACETONIDE  
@ G AND W LABS 0.025%  
OIL/DROPS; OTIC  
FLAC

A089525 001 Jul 26, 1988 Jan DISC

AT PATRIN PHARMA INC 0.01% A210736 001 Apr 11, 2018 Mar NEWA  
SOLUTION; TOPICAL  
FLUOCINOLONE ACETONIDE  
@ G AND W LABS INC 0.01% A207441 001 Sep 28, 2016 Jan DISC

FLUOCINONIDE

CREAM; TOPICAL  
FLUOCINONIDE  
AB1 AMNEAL PHARMS LLC 0.05% A210554 001 Aug 21, 2018 Aug NEWA  
AB 0.1% A211111 001 Jun 04, 2018 May NEWA  
FLUOCINONIDE EMULSIFIED BASE  
AB2 ! TARO PHARM IND LTD 0.05% A072494 001 Jan 19, 1989 May CAHN  
GEL; TOPICAL  
FLUOCINONIDE  
AB TELIGENT PHARMA INC 0.05% A209030 001 Jun 19, 2018 Jun NEWA  
OINTMENT; TOPICAL  
FLUOCINONIDE  
>A> AB TELIGENT PHARMA INC 0.05% A207680 001 Sep 28, 2018 Sep NEWA  
SOLUTION; TOPICAL  
FLUOCINONIDE  
AT GLASSHOUSE PHARMS 0.05% A209118 001 Apr 23, 2018 Apr NEWA  
AT MACLEODS PHARMS LTD 0.05% A209283 001 Apr 23, 2018 Apr NEWA  
AT ZYDUS PHARMS USA INC 0.05% A208948 001 Jul 17, 2018 Jul NEWA

FLUORESCIN SODIUM

INJECTABLE; INTRAVENOUS  
FLUORESCITE  
AP +! ALCON LABS INC EQ 500MG BASE/5ML (EQ 100MG  
BASE/ML)

N021980 001 Mar 28, 2006 Feb CAHN

FLUOROURACIL

CREAM; TOPICAL  
FLUOROURACIL  
AB MAYNE PHARMA 5% A077524 001 Apr 11, 2008 Jul CAHN

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL  
FLUOXETINE HYDROCHLORIDE  
AB1 MARKSANS PHARMA EQ 10MG BASE A075465 001 Jan 29, 2002 Jul CAHN  
AB1 EQ 20MG BASE A075465 002 Jan 29, 2002 Jul CAHN  
AB EQ 40MG BASE A075465 003 Aug 02, 2001 Jul CAHN

TABLET; ORAL  
FLUOXETINE HYDROCHLORIDE  
AB DR REDDYS LABS LTD EQ 10MG BASE A076006 001 Jan 30, 2002 Apr CAHN  
AB EQ 20MG BASE A076006 002 Apr 23, 2018 Apr NEWA  
AB EQ 20MG BASE A076006 002 Apr 23, 2018 Apr CAHN  
@ FOSUN PHARMA EQ 10MG BASE A076024 001 Jan 29, 2002 Jan CAHN

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION  
FLUPHENAZINE DECANOATE

AO MYLAN LABS LTD 25MG/ML A075918 001 Aug 17, 2001 Jun CMFD

FLURANDRENOLIDE

TAPE; TOPICAL  
CORDRAN

>D> +! ALLERGAN SALES LLC 0.004MG/SQ CM N016455 001 Sep CAHN  
>A> +! AQUA PHARMS LLC 0.004MG/SQ CM N016455 001 Sep CAHN

FLUTAMIDE

CAPSULE; ORAL  
FLUTAMIDE  
@ YAOPHARMA CO LTD 125MG

A075818 001 Sep 18, 2001 Jan CAHN

FLUTEMETAMOL F-18

INJECTABLE; INTRAVENOUS  
VIZAMYL  
+ @ GE HEALTHCARE 40.5mCi/10ML (4.05mCi/ML)

N203137 001 Oct 25, 2013 Jun DISC

FLUTICASONE FUROATE

POWDER; INHALATION  
ARNUITY ELLIPTA  
+! GLAXOSMITHKLINE 0.05MG/INH

N205625 003 May 17, 2018 May NEWA

FLUTICASONE PROPIONATE

CREAM; TOPICAL  
FLUTICASONE PROPIONATE

>A> AB ANDA REPOSITORY 0.05% A076633 001 May 14, 2004 Sep CAHN  
>D> AB TOLMAR 0.05% A076633 001 May 14, 2004 Sep CAHN

OINTMENT; TOPICAL

>D> CUTIVATE

>D> AB +! FOUGERA PHARMS 0.005%

N019957 001 Dec 14, 1990 Sep DISC

>A> + @ 0.005%

N019957 001 Dec 14, 1990 Sep DISC

FLUTICASONE PROPIONATE

>D> AB FOUGERA PHARMS 0.005%

A076300 001 May 14, 2004 Sep DISC

>A> @ 0.005%

A076300 001 May 14, 2004 Sep DISC

>D> AB PERRIGO NEW YORK 0.005%

A076668 001 May 14, 2004 Sep CHRS

>A> AB ! 0.005%

A076668 001 May 14, 2004 Sep CHRS

SPRAY, METERED; NASAL

FLONASE

+ @ GLAXOSMITHKLINE 0.05MG/SPRAY

N020121 001 Oct 19, 1994 Jul CAHN

XHANCE

+! OPTINOSE US INC 0.093MG

N209022 001 Sep 18, 2017 Jan CMS1

FOLIC ACID

TABLET; ORAL  
FOLIC ACID

>D> AA AIPING PHARM INC 1MG A091145 001 Jul 12, 2013 Sep CAHN

>A> AA ANBISON LAB 1MG A091145 001 Jul 12, 2013 Sep CAHN

AA CHARTWELL MOLECULAR 1MG A090035 001 Jun 09, 2009 Jun CAHN

FONDAPARINUX SODIUM

INJECTABLE; SUBCUTANEOUS  
FONDAPARINUX SODIUM

AP JIANGSU HENGRIUI MED 2.5MG/0.5ML A206812 001 May 15, 2018 Apr NEWA

AP 5MG/0.4ML A206812 002 May 15, 2018 Apr NEWA

AP 7.5MG/0.6ML A206812 003 May 15, 2018 Apr NEWA

AP 10MG/0.8ML A206812 004 May 15, 2018 Apr NEWA

FOSFOMYCIN TROMETHAMINE

FOR SOLUTION; ORAL  
MONUROL

+! ZAMBON SPA EQ 3GM BASE/PACKET

N050717 001 Dec 19, 1996 Aug CDFR

FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET;ORAL

FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE

AB	EMCURE PHARMS LTD	10MG;12.5MG	A079025	001	Sep 17, 2010	Jan CAHN
AB	!	20MG;12.5MG	A079025	002	Sep 17, 2010	Jan CAHN

FOSNETUPITANT CHLORIDE HYDROCHLORIDE; PALONOSETRON HYDROCHLORIDE

POWDER;INTRAVENOUS

AKYNZEOTM

+!	HELSINN HLTHCARE	EQ 235MG BASE;EQ 0.25MG BASE	N210493	001	Apr 19, 2018	Apr NEWA
----	------------------	------------------------------	---------	-----	--------------	----------

FOSTAMATINIB DISODIUM

TABLET;ORAL

TAVALISSE

+!	RIGEL PHARMS INC	EQ 100MG BASE	N209299	001	Apr 17, 2018	Apr NEWA
+!		EQ 150MG BASE	N209299	002	Apr 17, 2018	Apr NEWA

GABAPENTIN

CAPSULE;ORAL

GABAPENTIN

AB	ACI HEALTHCARE LTD	100MG	A206943	001	May 14, 2018	Apr NEWA
AB		300MG	A206943	002	May 14, 2018	Apr NEWA
AB		400MG	A206943	003	May 14, 2018	Apr NEWA

TABLET;ORAL

GABAPENTIN

AB	LUPIN LTD	600MG	A209306	001	Aug 24, 2018	Aug NEWA
AB		800MG	A209306	002	Aug 24, 2018	Aug NEWA

GRALISE

BX	+! ASSERTIO	300MG	N022544	001	Jan 28, 2011	Aug CAHN
BX	+!	600MG	N022544	002	Jan 28, 2011	Aug CAHN

GADOVERSETAMIDE

INJECTABLE;INJECTION

OPTIMARK

+ @	LIEBEL-FLARSHEIM	1654.5MG/5ML (330.9MG/ML)	N020937	001	Dec 08, 1999	Aug DISC
+ @		3309MG/10ML (330.9MG/ML)	N020937	002	Dec 08, 1999	Aug DISC
+ @		4963.5MG/15ML (330.9MG/ML)	N020937	003	Dec 08, 1999	Aug DISC
+ @		6618MG/20ML (330.9MG/ML)	N020937	004	Dec 08, 1999	Aug DISC
+ @		16.545GM/50ML (330.9MG/ML)	N020975	001	Dec 08, 1999	Aug DISC

OPTIMARK IN PLASTIC CONTAINER

+ @	LIEBEL-FLARSHEIM	3309MG/10ML (330.9MG/ML)	N020976	002	Dec 08, 1999	Aug DISC
+ @		4963.5MG/15ML (330.9MG/ML)	N020976	003	Dec 08, 1999	Aug DISC
+ @		6618MG/20ML (330.9MG/ML)	N020976	004	Dec 08, 1999	Aug DISC
+ @		9927MG/30ML (330.9MG/ML)	N020976	001	Dec 08, 1999	Aug DISC

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE;ORAL

GALANTAMINE HYDROBROMIDE

@	MYLAN	EQ 8MG BASE	A090900	001	Jan 24, 2011	Jun DISC
@		EQ 16MG BASE	A090900	002	Jan 24, 2011	Jun DISC
@		EQ 24MG BASE	A090900	003	Jan 24, 2011	Jun DISC

GANCICLOVIR

&gt;A&gt; SOLUTION;INTRAVENOUS

GANCICLOVIR

>A>	+! EXELA PHARMA SCS LLC	500MG/250ML (2MG/ML)	N209347	001	Feb 17, 2017	Sep CDFR
-----	-------------------------	----------------------	---------	-----	--------------	----------

&gt;D&gt; SOLUTION;IV (INFUSION)

GANCICLOVIR

>D>	+! EXELA PHARMA SCS LLC	500MG/250ML (2MG/ML)	N209347	001	Feb 17, 2017	Sep CDFR
-----	-------------------------	----------------------	---------	-----	--------------	----------

GATIFLOXACIN

SOLUTION/DROPS;OPHTHALMIC

GATIFLOXACIN

AT	MICRO LABS	0.5%	A206446	001	Jun 08, 2018	May NEWA
AT	MYLAN PHARMS INC	0.5%	A206446	001	Jun 08, 2018	Aug CAHN

GEMCITABINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## GEMCITABINE HYDROCHLORIDE

AP	SAGENT PHARMS	200MG/5.26ML (38MG/ML)	A209077	001	Jul 20, 2018	Jul NEWA
AP		1GM/26.3ML (38MG/ML)	A209077	002	Jul 20, 2018	Jul NEWA
AP		2GM/52.6ML (38MG/ML)	A209077	003	Jul 20, 2018	Jul NEWA
>A>	SOLUTION; INTRAVENOUS					
>A>	GEMCITABINE HYDROCHLORIDE					
>A>	+! ACCORD HLTHCARE	1GM/10ML (100MG/ML)	N209604	002	Aug 03, 2017	Sep CDFR
>A>	+!	1.5GM/15ML (100MG/ML)	N209604	003	Aug 03, 2017	Sep CDFR
>A>	+!	2GM/20ML (100MG/ML)	N209604	004	Aug 03, 2017	Sep CDFR
>A>	+!	200MG/2ML (100MG/ML)	N209604	001	Aug 03, 2017	Sep CDFR
	INFUGEM					
	+! SUN PHARM INDs INC	EQ 1200MG BASE/120ML (EQ 10MG BASE/ML)	N208313	001	Jul 16, 2018	Jul NEWA
	+!	EQ 1300MG BASE/130ML (EQ 10MG BASE/ML)	N208313	002	Jul 16, 2018	Jul NEWA
	+!	EQ 1400MG BASE/140ML (EQ 10MG BASE/ML)	N208313	003	Jul 16, 2018	Jul NEWA
	+!	EQ 1500MG BASE/150ML (EQ 10MG BASE/ML)	N208313	004	Jul 16, 2018	Jul NEWA
	+!	EQ 1600MG BASE/160ML (EQ 10MG BASE/ML)	N208313	005	Jul 16, 2018	Jul NEWA
	+!	EQ 1700MG BASE/170ML (EQ 10MG BASE/ML)	N208313	006	Jul 16, 2018	Jul NEWA
	+!	EQ 1800MG BASE/180ML (EQ 10MG BASE/ML)	N208313	007	Jul 16, 2018	Jul NEWA
	+!	EQ 1900MG BASE/190ML (EQ 10MG BASE/ML)	N208313	008	Jul 16, 2018	Jul NEWA
	+!	EQ 2000MG BASE/200ML (EQ 10MG BASE/ML)	N208313	009	Jul 16, 2018	Jul NEWA
	+!	EQ 2200MG BASE/220ML (EQ 10MG BASE/ML)	N208313	010	Jul 16, 2018	Jul NEWA
	+! SUN PHARM INDs LTD	EQ 1200MG BASE/120ML (EQ 10MG BASE/ML)	N208313	001	Jul 16, 2018	Aug CAHN
	+!	EQ 1300MG BASE/130ML (EQ 10MG BASE/ML)	N208313	002	Jul 16, 2018	Aug CAHN
	+!	EQ 1400MG BASE/140ML (EQ 10MG BASE/ML)	N208313	003	Jul 16, 2018	Aug CAHN
	+!	EQ 1500MG BASE/150ML (EQ 10MG BASE/ML)	N208313	004	Jul 16, 2018	Aug CAHN
	+!	EQ 1600MG BASE/160ML (EQ 10MG BASE/ML)	N208313	005	Jul 16, 2018	Aug CAHN
	+!	EQ 1700MG BASE/170ML (EQ 10MG BASE/ML)	N208313	006	Jul 16, 2018	Aug CAHN
	+!	EQ 1800MG BASE/180ML (EQ 10MG BASE/ML)	N208313	007	Jul 16, 2018	Aug CAHN
	+!	EQ 1900MG BASE/190ML (EQ 10MG BASE/ML)	N208313	008	Jul 16, 2018	Aug CAHN
	+!	EQ 2000MG BASE/200ML (EQ 10MG BASE/ML)	N208313	009	Jul 16, 2018	Aug CAHN
	+!	EQ 2200MG BASE/220ML (EQ 10MG BASE/ML)	N208313	010	Jul 16, 2018	Aug CAHN
>D>	SOLUTION; IV (INFUSION)					
>D>	GEMCITABINE HYDROCHLORIDE					
>D>	+! ACCORD HLTHCARE	1GM/10ML (100MG/ML)	N209604	002	Aug 03, 2017	Sep CDFR
>D>	+!	1.5GM/15ML (100MG/ML)	N209604	003	Aug 03, 2017	Sep CDFR
>D>	+!	2GM/20ML (100MG/ML)	N209604	004	Aug 03, 2017	Sep CDFR
>D>	+!	200MG/2ML (100MG/ML)	N209604	001	Aug 03, 2017	Sep CDFR

GEMFIBROZIL

## TABLET; ORAL

## GEMFIBROZIL

@ YAOPHARMA CO LTD	600MG	A074615	001	Sep 29, 1995	Jan CAHN
AB ZYDUS PHARMS USA INC	600MG	A204189	001	Aug 28, 2018	Aug NEWA

GENTAMICIN SULFATE

## OINTMENT; TOPICAL

## GENTAMICIN SULFATE

AT G AND W LABS INC	EQ 0.1% BASE	A064054	001	Apr 29, 1994	Jan CMFD
---------------------	--------------	---------	-----	--------------	----------

GLATIRAMER ACETATE

INJECTABLE; SUBCUTANEOUS  
GLATOPA

AP	SANDOZ INC	40MG/ML	A206921	001	Feb 12, 2018	Jan NEWA
----	------------	---------	---------	-----	--------------	----------

GLIMEPIRIDE; ROSIGLITAZONE MALEATE

TABLET; ORAL

ROSIGLITAZONE MALEATE AND GLIMEPIRIDE

@ TEVA PHARMS USA	1MG; 4MG	A078709	001	Apr 01, 2016	Jul DISC
@	2MG; 4MG	A078709	002	Apr 01, 2016	Jul DISC
@	2MG; 8MG	A078709	004	Apr 01, 2016	Jul DISC
@	4MG; 4MG	A078709	003	Apr 01, 2016	Jul DISC
@	4MG; 8MG	A078709	005	Apr 01, 2016	Jul DISC

GLIPIZIDE

TABLET; ORAL

GLIPIZIDE

@ OXFORD PHARMS	5MG	A074378	001	Nov 28, 1994	Jul CAHN
@	10MG	A074378	002	Nov 28, 1994	Jul CAHN

TABLET, EXTENDED RELEASE; ORAL

GLIPIZIDE

AB	ZYDUS PHARMS USA INC	2.5MG	A203499	001	Jul 16, 2018	Jul NEWA
AB		5MG	A203499	002	Jul 16, 2018	Jul NEWA
AB		10MG	A203499	003	Jul 16, 2018	Jul NEWA

GLUCAGON

INJECTABLE; INJECTION

GLUCAGON

+! LILLY	1MG/VIAL	N020928	001	Sep 11, 1998	Apr CAIN
----------	----------	---------	-----	--------------	----------

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION

GLUCAGEN

+! NOVO NORDISK	EQ 1MG BASE/VIAL	N020918	001	Jun 22, 1998	Apr CAIN
-----------------	------------------	---------	-----	--------------	----------

GLYBURIDE

TABLET; ORAL

GLYBURIDE (MICRONIZED)

@ YAOPHARMA CO LTD	1.5MG	A075174	001	Jun 22, 1998	Jan CAHN
@	3MG	A075174	002	Jun 22, 1998	Jan CAHN

GLYCINE

SOLUTION; IRRIGATION

AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER

AT	+! BAXTER HLTHCARE	1.5GM/100ML	N017865	001		Mar CRLD
----	--------------------	-------------	---------	-----	--	----------

GLCOPYRROLATE

SOLUTION; INTRAMUSCULAR, INTRAVENOUS

GLYRX-PF

EXELA PHARMA SCS LLC	0.2MG/ML (0.2MG/ML)	N210997	001	Jul 11, 2018	Jul NEWA
	0.4MG/2ML (0.2MG/ML)	N210997	002	Jul 11, 2018	Jul NEWA

TABLET; ORAL

GLCOPYRROLATE

>A> AA	ANDA REPOSITORY	1MG	A040821	001	Dec 29, 2008	Sep CAHN
>A> AA		2MG	A040821	002	Dec 29, 2008	Sep CAHN
AA	OXFORD PHARMS	1MG	A090020	001	Oct 19, 2011	Jul CAHN
AA		2MG	A090020	002	Oct 19, 2011	Jul CAHN
AA !	PAR PHARM	1MG	A040653	001	Aug 31, 2006	May CHRS
AA !		2MG	A040653	002	Aug 31, 2006	May CHRS
	@ RENATA	1MG	A040568	001	Dec 22, 2004	Apr CAHN
	@	2MG	A040568	002	Dec 22, 2004	Apr CAHN
>D> AA	RISING PHARMS	1MG	A040821	001	Dec 29, 2008	Sep CAHN
>D> AA		2MG	A040821	002	Dec 29, 2008	Sep CAHN
	ROBINUL					
+ @	CASPER PHARMA LLC	1MG	N012827	001		May DISC
	ROBINUL FORTE					
+ @	CASPER PHARMA LLC	2MG	N012827	002		May DISC

GLYCOPYRRONIUM TOSYLATE

CLOTH;TOPICAL

QBREXZA

+! DERMIRA INC

EQ 2.4% BASE

N210361 001 Jun 28, 2018 Jun NEWA

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

>D> AP	BIONPHARMA INC	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A078863	001	Jun 30, 2008	Sep CAHN
>D> AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A078880	001	Jun 30, 2008	Sep CAHN
>A> AP	BLUEPHARMA	EQ 0.1IMG BASE/ML (EQ 0.1IMG BASE/ML)	A078863	001	Jun 30, 2008	Sep CAHN
>A> AP	@ TEVA PHARMS USA	EQ 4MG BASE/4ML (EQ 1MG BASE/ML) EQ 1MG BASE/ML (EQ 1MG BASE/ML) GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE	A078880	001	Jun 30, 2008	Sep CAHN
>D> AP	BIONPHARMA INC	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A078863	002	Jun 30, 2008	Sep CAHN
>A> AP	BLUEPHARMA	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A078863	002	Jun 30, 2008	Sep CAHN
	TABLET; ORAL					
	GRANISETRON HYDROCHLORIDE					
AB	CHARTWELL MOLECULAR	EQ 1MG BASE	A078037	001	Feb 27, 2008	Mar CAHN

GRISEOFULVIN, ULTRAMICROSIZE

TABLET; ORAL

GRISEOFULVIN, ULTRAMICROSIZE

AB	MOUNTAIN	125MG	A204371	001	Jan 09, 2014	Jan CAHN
AB		250MG	A204371	002	Jan 09, 2014	Jan CAHN

GUAIFENESIN; HYDROCODONE BITARTRATE

SOLUTION;ORAL

FLOWTUSS

@ BKK PHARMS

200MG/5ML;2.5MG/5ML

N022424

001 May 14, 2015 Aug DISC

200MG/5ML;2.5MG/5ML

N022424

001 May 14, 2015 May CAHN

OBREDON

>D>	+ @ SOVEREIGN PHARMS	200MG/5ML;2.5MG/5ML	N205474	001	Nov 14, 2014	Sep CMFD
>A>	+!	200MG/5ML;2.5MG/5ML	N205474	001	Nov 14, 2014	Sep CMFD

TABLET;ORAL

HYDROCODONE BITARTRATE AND GUAIFENESIN

+! ECT PHARMS LLC 400MG;5MG

N208085 001 Apr 25, 2018 Apr NEWA

GUAIFENESIN; HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE

SOLUTION;ORAL

HYCOFENIX

+ @ BKK PHARMS

200MG/5ML;2.5MG/5ML;30MG/5ML

N022279

001 May 14, 2015 Aug DISC

+!

200MG/5ML;2.5MG/5ML;30MG/5ML

N022279

001 May 14, 2015 May CAHN

GUANABENZ ACETATE

TABLET;ORAL

GUANABENZ ACETATE

@ YAOPHARMA CO LTD

EQ 4MG BASE

A074517

001 Sep 30, 1998 Jan CAHN

@

EQ 8MG BASE

A074517

002 Sep 30, 1998 Jan CAHN

GUANFACINE HYDROCHLORIDE

TABLET;ORAL

GUANFACINE HYDROCHLORIDE

AB	! MYLAN	EQ 1MG BASE	A074796	001	Jan 27, 1997	Jun CHRS
AB	!	EQ 2MG BASE	A074796	002	Jan 27, 1997	Jun CHRS
	TENEX					
	+ @ PROMIUS PHARMA	EQ 1MG BASE	N019032	001	Oct 27, 1986	Jun DISC
	+ @	EQ 2MG BASE	N019032	002	Nov 07, 1988	Jun DISC
	TABLET, EXTENDED RELEASE;ORAL					
	GUANFACINE HYDROCHLORIDE					
AB	APOTEX INC	EQ 1MG BASE	A205430	001	Jul 25, 2018	Jul NEWA
AB		EQ 2MG BASE	A205430	002	Jul 25, 2018	Jul NEWA
AB		EQ 3MG BASE	A205430	003	Jul 25, 2018	Jul NEWA
AB		EQ 4MG BASE	A205430	004	Jul 25, 2018	Jul NEWA

HALCINONIDE

CREAM;TOPICAL

HALOG

+! SUN PHARM INDs INC 0.1%

N017556 001

Feb CAHN

HALOBETASOL PROPIONATE

AEROSOL, FOAM;TOPICAL

HALOBETASOL PROPIONATE

+! THERAPS INC 0.05%

N210566 001 May 24, 2018 May NEWA

CREAM;TOPICAL

ULTRAVATE

AB + SUN PHARM INDs INC 0.05%

N019967 001 Dec 27, 1990 Feb CAHN

OINTMENT;TOPICAL

HALOBETASOL PROPIONATE

AB TELIGENT PHARMA INC 0.05%

A209978 001 Mar 20, 2018 Mar NEWA

ULTRAVATE

AB + SUN PHARM INDs INC 0.05%

N019968 001 Dec 17, 1990 Feb CAHN

HALOPERIDOL DECANOATE

INJECTABLE;INJECTION

HALOPERIDOL DECANOATE

AO SOMERSET THERAPS LLC EQ 50MG BASE/ML

A209101 001 Jul 03, 2018 Jun NEWA

AO EQ 100MG BASE/ML

A209101 002 Jul 03, 2018 Jun NEWA

HALOPERIDOL LACTATE

INJECTABLE;INJECTION

HALOPERIDOL

@ FOSUN PHARMA

EQ 5MG BASE/ML

A076464 001 Sep 29, 2004 Jan CAHN

HEPARIN SODIUM

INJECTABLE;INJECTION

HEPARIN SODIUM

AP CASI PHARMS INC 5,000 UNITS/ML

A091659 001 Jun 08, 2011 Mar CAHN

+ @ WEST-WARD PHARMS INT 1,000 UNITS/ML

N017007 001 Aug CRLD

+ @ 2,500 UNITS/ML

N017007 007 Aug CRLD

+ @ 5,000 UNITS/ML

N017007 002 Aug CRLD

+ @ 5,000 UNITS/0.5ML

N017007 010 Aug CRLD

+ @ 7,500 UNITS/ML

N017007 003 Aug CRLD

+ @ 10,000 UNITS/ML

N017007 004 Aug CRLD

+ @ 15,000 UNITS/ML

N017007 005 Aug CRLD

+ @ 20,000 UNITS/ML

N017007 006 Aug CRLD

HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

&gt;D&gt; AP HOSPIRA 200 UNITS/100ML

N018916 010 Jun 23, 1989 Sep CRLD

&gt;A&gt; AP +! 200 UNITS/100ML

N018916 010 Jun 23, 1989 Sep CHRS

&gt;A&gt; AP + 200 UNITS/100ML

N018916 010 Jun 23, 1989 Sep CRLD

HEPARIN SODIUM 2,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

&gt;D&gt; AP HOSPIRA 200 UNITS/100ML

N018916 011 Jun 23, 1989 Sep CRLD

&gt;A&gt; AP +! 200 UNITS/100ML

N018916 011 Jun 23, 1989 Sep CHRS

&gt;A&gt; AP + 200 UNITS/100ML

N018916 011 Jun 23, 1989 Sep CRLD

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP;ORAL

HYCODAN

+ @ GENUS LIFESCIENCES 1.5MG/5ML;5MG/5ML

N005213 002 Jul 26, 1988 Aug CAHN

TABLET;ORAL

HYCODAN

+ @ GENUS LIFESCIENCES 1.5MG;5MG

N005213 001 Jul 26, 1988 Aug CAHN

HYDRALAZINE HYDROCHLORIDE

TABLET;ORAL

HYDRALAZINE HYDROCHLORIDE

AA APPCO PHARMA LLC 10MG

A209251 001 Jul 09, 2018 Jun NEWA

AA 25MG

A209251 002 Jul 09, 2018 Jun NEWA

AA 50MG

A209251 003 Jul 09, 2018 Jun NEWA

AA 100MG

A209251 004 Jul 09, 2018 Jun NEWA

AA SCIEGEN PHARMS INC 10MG

A205236 001 May 26, 2017 Feb CAHN

AA 25MG

A205236 002 May 26, 2017 Feb CAHN

AA 50MG

A205236 003 May 26, 2017 Feb CAHN

AA 100MG

A205236 004 May 26, 2017 Feb CAHN

HYDROCHLOROTHIAZIDE

CAPSULE;ORAL

HYDROCHLOROTHIAZIDE

© APOTEX 12.5MG

A078389 001 May 16, 2008 Mar DISC

TABLET;ORAL

HYDROCHLOROTHIAZIDE

© APOTEX 25MG

A040774 001 Oct 03, 2007 Mar DISC

© 50MG

A040774 002 Oct 03, 2007 Mar DISC

© DAVA PHARMS INC 100MG

A087060 001 Jul CAHN

AB OXFORD PHARMS 25MG

A087059 001 Jul CAHN

AB 50MG

A087068 001 Jul CAHN

AB SCIEGEN PHARMS INC 25MG

A203018 001 Jul 23, 2014 Jan CAHN

AB 50MG

A203018 002 Jul 23, 2014 Jan CAHN

© YAOPHARMA CO LTD 25MG

A087565 001 Mar 09, 1982 Jan CAHN

© 50MG

A084912 001 Jan CAHN

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET;ORAL

IRBESARTAN AND HYDROCHLOROTHIAZIDE

© ATLAS PHARMS LLC 12.5MG;150MG

A203036 001 Jan 15, 2016 Aug DISC

© 12.5MG;300MG

A203036 002 Jan 15, 2016 Aug DISC

© 25MG;300MG

A203036 003 Jan 15, 2016 Aug DISC

AB HISUN PHARM HANGZHOU 12.5MG;150MG

A207896 001 Oct 14, 2016 Aug CAHN

AB 12.5MG;300MG

A207896 002 Oct 14, 2016 Aug CAHN

© MYLAN PHARMS INC 12.5MG;150MG

A077969 001 Sep 27, 2012 Jun DISC

© 12.5MG;300MG

A077969 002 Sep 27, 2012 Jun DISC

© 25MG;300MG

A077969 003 Jul 20, 2016 Jun DISC

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET;ORAL

LISINOPRIL AND HYDROCHLOROTHIAZIDE

© APOTEX INC 12.5MG;10MG

A076674 001 Oct 05, 2004 Apr DISC

© 12.5MG;20MG

A076674 002 Oct 05, 2004 Apr DISC

© 25MG;20MG

A076674 003 Oct 05, 2004 Apr DISC

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET;ORAL

HYZAAR

+ © MERCK SHARP DOHME 12.5MG;50MG

N020387 001 Apr 28, 1995 Apr DISC

+ © 25MG;100MG

N020387 002 Nov 10, 1998 Apr DISC

LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

© APOTEX 12.5MG;50MG

A090150 001 Oct 06, 2010 Mar DISC

© 12.5MG;100MG

A090150 002 Aug 11, 2010 Mar DISC

© 25MG;100MG

A090150 003 Oct 06, 2010 Mar DISC

AB ! AUROBINDO PHARMA 25MG;100MG

A091629 003 Jan 06, 2010 Apr CHRS

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET;ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

© YAOPHARMA CO LTD 15MG;250MG

A070182 001 Jan 15, 1986 Jan CAHN

© 25MG;250MG

A070183 001 Jan 15, 1986 Jan CAHN

© 30MG;500MG

A070543 001 Jan 15, 1986 Jan CAHN

© 50MG;500MG

A070544 001 Jan 15, 1986 Jan CAHN

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET;ORAL

PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

© YAOPHARMA CO LTD 25MG;40MG

A071060 001 Aug 26, 1987 Jan CAHN

© 25MG;80MG

A071061 001 Aug 26, 1987 Jan CAHN

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET;ORAL

SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

© YAOPHARMA CO LTD 25MG;25MG

A086881 001 Jan CAHN

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE;ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB ! CASI PHARMS INC 25MG;50MG

A073191 001 Jul 31, 1991 Mar CAHN

TABLET;ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE  
 AB ZYDUS PHARMS USA INC 25MG;37.5MG  
 AB 50MG;75MG

A208360 001 Jun 29, 2018 Jun NEWA  
 A208360 002 Jun 29, 2018 Jun NEWA

HYDROCHLOROTHIAZIDE; VALSARTANTABLET;ORAL

VALSARTAN AND HYDROCHLOROTHIAZIDE  
 @ APOTEX INC 12.5MG;80MG  
 @ 12.5MG;160MG  
 @ 12.5MG;320MG  
 @ 25MG;160MG  
 @ 25MG;320MG  
 @ WATSON LABS TEVA 12.5MG;80MG  
 @ 12.5MG;160MG  
 @ 12.5MG;320MG  
 @ 25MG;160MG  
 @ 25MG;320MG

A203026 001 Mar 21, 2013 Mar DISC  
 A203026 002 Mar 21, 2013 Mar DISC  
 A203026 003 Mar 21, 2013 Mar DISC  
 A203026 004 Mar 21, 2013 Mar DISC  
 A203026 005 Mar 21, 2013 Mar DISC  
 A091519 001 Mar 21, 2013 Aug DISC  
 A091519 002 Mar 21, 2013 Aug DISC  
 A091519 003 Mar 21, 2013 Aug DISC  
 A091519 004 Mar 21, 2013 Aug DISC  
 A091519 005 Mar 21, 2013 Aug DISC

HYDROCORTISONECREAM;TOPICAL

HYDROCORTISONE

AT LANNETT CO INC	2.5%	A040503 001 Mar 12, 2004 May CAHN
@ TARO PHARM INDS LTD	1%	A086155 001 May CAHN
	2.5%	A088799 001 Nov 09, 1984 May CAHN
	2.5%	A088799 001 Nov 09, 1984 May CAHN
AT TELIGENT PHARMA INC	2.5%	A203810 001 Jul 23, 2018 Jul NEWA

LOTION;TOPICAL

HYDROCORTISONE

AT LANNETT CO INC	2.5%	A040417 001 Jul 30, 2003 May CAHN
AT TELIGENT PHARMA INC	2.5%	A203804 001 Jul 27, 2018 Jul NEWA

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDEAEROSOL, METERED;TOPICAL

HYDROCORTISONE ACETATE 1% AND PRAMOXINE HYDROCHLORIDE 1%  
 @ GENUS LIFESCIENCES 1%;1%

A089440 001 May 17, 1988 Aug CAHN

HYDROCORTISONE BUTYRATELOTION;TOPICAL

HYDROCORTISONE BUTYRATE

AB LUPIN LTD	0.1%	A210209 001 Aug 17, 2018 Aug NEWA
--------------	------	-----------------------------------

HYDROCORTISONE VALERATECREAM;TOPICAL

WESTCORT

+ @ SUN PHARM INDS INC	0.2%	N017950 001 Mar CAHN
OINTMENT;TOPICAL		
WESTCORT		
+ @ SUN PHARM INDS INC	0.2%	N018726 001 Aug 08, 1983 Feb CAHN

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATESOLUTION/DROPS;OTIC  
CORTISPORIN

+ @ MONARCH PHARMS	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N050479 001 Aug DISC
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE		
@ AMRING PHARMS	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	A065216 001 Oct 31, 2005 Aug DISC
AT ! BAUSCH AND LOMB	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	A064053 001 Dec 29, 1995 Aug CHRS

HYDROMORPHONE HYDROCHLORIDEINJECTABLE;INJECTION

DILAUDID

+ @ FRESENIUS KABI USA	4MG/ML	N019034 005 Apr 30, 2009 Aug DISC
DILAUDID-HP		
+ @ FRESENIUS KABI USA	10MG/ML	N019034 001 Jan 11, 1984 Aug DISC
HYDROMORPHONE HYDROCHLORIDE		

AP EUROHLTH INTL SARL	2MG/ML	A202159 001 Apr 27, 2018 Apr NEWA
-----------------------	--------	-----------------------------------

TABLET;ORAL

HYDROMORPHONE HYDROCHLORIDE

AB ASCENT PHARMS INC	2MG	A210506 001 Jan 17, 2018 Jan NEWA
----------------------	-----	-----------------------------------

**TABLET;ORAL**  
**HYDROMORPHONE HYDROCHLORIDE**

AB		4MG	A210506	002	Jan 17, 2018	Jan NEWA
AB		8MG	A210506	003	Jan 17, 2018	Jan NEWA

**HYDROXYCHLOROQUINE SULFATE**

**TABLET;ORAL**  
**HYDROXYCHLOROQUINE SULFATE**

AB	ALKALOIDA ZRT	200MG	A201691	001	May 08, 2018	Apr NEWA
AB	AMNEAL PHARMS CO	200MG	A210577	001	May 15, 2018	Apr NEWA
>D> AB	APPCO PHARMA LLC	200MG	A210441	001	May 01, 2018	Sep CAHN
AB		200MG	A210441	001	May 01, 2018	Apr NEWA
AB	LUPIN LTD	200MG	A210543	001	Jul 06, 2018	Jun NEWA
>A> AB	TWI PHARMS	200MG	A210441	001	May 01, 2018	Sep CAHN

**HYDROXYPROGESTERONE CAPROATE**

**SOLUTION;INTRAMUSCULAR**  
**HYDROXYPROGESTERONE CAPROATE**

AP	LUITPOLD	250MG/ML (250MG/ML)	A210723	001	Jun 21, 2018	Jun NEWA
	MAKENA PRESERVATIVE FREE					
AP	+! AMAG PHARMA USA	250MG/ML (250MG/ML)	N021945	002	Feb 19, 2016	Jun CFTG
	SOLUTION;SUBCUTANEOUS					
	MAKENA (AUTOINJECTOR)					
+!	AMAG PHARMA USA	275MG/1.1ML (250MG/ML)	N021945	004	Feb 14, 2018	Feb NEWA

**HYDROXYZINE HYDROCHLORIDE**

**INJECTABLE;INJECTION**  
**HYDROXYZINE HYDROCHLORIDE**

@	FRESENIUS KABI USA	25MG/ML	A087329	001		Aug DISC
@		50MG/ML	A087329	002		Aug DISC
!	LUITPOLD	25MG/ML	A087408	001		Aug CHRS
		25MG/ML	A087408	001		Aug CTEC
!		50MG/ML	A087408	002		Aug CHRS
		50MG/ML	A087408	002		Aug CTEC

**TABLET;ORAL**  
**ATARAX**

+ @	PFIZER	10MG	N010392	001		Feb CRLD
+ @		25MG	N010392	004		Feb CRLD
+ @		50MG	N010392	006		Feb CRLD
+ @		100MG	N010392	005		Feb CRLD

**IBRUTINIB****TABLET;ORAL****IMBRUVICA**

+	PHARMACYCLICS INC	140MG	N210563	001	Feb 16, 2018	Feb NEWA
+		280MG	N210563	002	Feb 16, 2018	Feb NEWA
+		420MG	N210563	003	Feb 16, 2018	Feb NEWA
!+		560MG	N210563	004	Feb 16, 2018	Feb NEWA

**IBUPROFEN****SUSPENSION;ORAL****IBUPROFEN**

	AUROBINDO PHARMA LTD	100MG/5ML	A209178	001	Feb 16, 2018	Feb NEWA
--	----------------------	-----------	---------	-----	--------------	----------

**TABLET;ORAL**  
**IBUPROFEN**

>D> AB	AIPING PHARM INC	400MG	A202413	001	Nov 23, 2016	Sep CAHN
>D> AB		600MG	A202413	002	Nov 23, 2016	Sep CAHN
>D> AB		800MG	A202413	003	Nov 23, 2016	Sep CAHN
AB	HEC PHARM	400MG	A204062	001	Sep 10, 2018	Aug NEWA
AB		600MG	A204062	002	Sep 10, 2018	Aug NEWA
AB		800MG	A204062	003	Sep 10, 2018	Aug NEWA
>A> AB	SHANDONG XINHUA	400MG	A202413	001	Nov 23, 2016	Sep CAHN
>A> AB		600MG	A202413	002	Nov 23, 2016	Sep CAHN
>A> AB		800MG	A202413	003	Nov 23, 2016	Sep CAHN

**IBUPROFEN LYSINE****INJECTABLE;INTRAVENOUS****IBUPROFEN LYSINE**

>D> AP	EXELA PHARMA SCIENCE	EQ 20MG BASE/2ML (EQ 10MG BASE/ML)	A202402	001	Mar 30, 2016	Sep CAHN
>A> AP	X-GEN PHARMS INC	EQ 20MG BASE/2ML (EQ 10MG BASE/ML)	A202402	001	Mar 30, 2016	Sep CAHN

IBUTILIDE FUMARATE

INJECTABLE; INJECTION  
IBUTILIDE FUMARATE  
@ MYLAN INSTITUTIONAL 0.1MG/ML

A090924 001 Jan 11, 2010 Jan DISC

IFOSFAMIDE

INJECTABLE; INJECTION  
IFOSFAMIDE  
>D> AP FRESENIUS KABI USA 1GM/20ML (50MG/ML)  
>A> @ 1GM/20ML (50MG/ML)  
>D> AP 3GM/60ML (50MG/ML)  
>A> @ 3GM/60ML (50MG/ML)

A090181 001 Sep 22, 2009 Sep DISC  
A090181 001 Sep 22, 2009 Sep DISC  
A090181 002 Sep 22, 2009 Sep DISC  
A090181 002 Sep 22, 2009 Sep DISC

IMATINIB MESYLATE

TABLET; ORAL  
IMATINIB MESYLATE  
AB DR REDDYS LABS LTD EQ 100MG BASE  
AB EQ 400MG BASE  
AB WEST-WARD PHARMS INT EQ 100MG BASE  
AB EQ 400MG BASE

A206547 001 Aug 13, 2018 Jul NEWA  
A206547 002 Aug 13, 2018 Jul NEWA  
A207586 001 Jul 13, 2018 Jul NEWA  
A207586 002 Jul 13, 2018 Jul NEWA

IMIQUIMOD

CREAM; TOPICAL  
IMIQUIMOD  
>A> AB ANDA REPOSITORY 5%  
@ G AND W LABS INC 5%  
@ STRIDES PHARMA 5%  
>D> AB TOLMAR 5%

A091044 001 Feb 28, 2011 Sep CAHN  
A200481 001 Apr 18, 2011 Jan DISC  
A202002 001 Jun 24, 2014 Jun DISC  
A091044 001 Feb 28, 2011 Sep CAHN

INDAPAMIDE

TABLET; ORAL  
INDAPAMIDE  
@ YAOPHARMA CO LTD 1.25MG  
@ 2.5MG

A074594 001 May 23, 1996 Jan CAHN  
A074594 002 May 23, 1996 Jan CAHN

INDIUM IN-111 OXYQUINOLINE

INJECTABLE; INJECTION  
INDIUM IN 111 OXYQUINOLINE  
>A> @ BWXT ITG 1mCi/ML  
>D> AP +! GE HEALTHCARE 1mCi/ML  
>A> +! 1mCi/ML  
AP +! 1mCi/ML  
>D> AP NORDION INC 1mCi/ML  
>A> @ 1mCi/ML  
AP 1mCi/ML

A202586 001 Jul 25, 2018 Sep CAHN  
N019044 001 Dec 24, 1985 Sep CTEC  
N019044 001 Dec 24, 1985 Sep CTEC  
N019044 001 Dec 24, 1985 Jul CFTG  
A202586 001 Jul 25, 2018 Sep DISC  
A202586 001 Jul 25, 2018 Sep DISC  
A202586 001 Jul 25, 2018 Jul NEWA

INSULIN ASPART RECOMBINANT

INJECTABLE; SUBCUTANEOUS  
NOVOLOG FLEXTOUCH  
+ @ NOVO NORDISK INC 300 UNITS/3ML (100 UNITS/ML)

N020986 005 Oct 31, 2013 Jun DISC

INSULIN GLARGINE RECOMBINANT

SOLUTION; SUBCUTANEOUS  
TOUJEO MAX SOLOSTAR  
+! SANOFI US SERVICES 900 UNITS/3ML (300 UNITS/ML)  
TOUJEO SOLOSTAR  
+! SANOFI US SERVICES 450 UNITS/1.5ML (300 UNITS/ML)

N206538 002 Mar 26, 2018 Mar NEWA  
N206538 001 Feb 25, 2015 Mar CPOT

INSULIN GLULISINE RECOMBINANT

INJECTABLE; IV (INFUSION), SUBCUTANEOUS  
APIDRA  
>D> +! SANOFI AVENTIS US 300 UNITS/3ML (100 UNITS/ML)  
>A> + @ 300 UNITS/3ML (100 UNITS/ML)

N021629 002 Dec 20, 2005 Sep DISC  
N021629 002 Dec 20, 2005 Sep DISC

IOBENGUANE I-131

SOLUTION; INTRAVENOUS  
AZEDRA  
+! PROGENICS PHARMS INC 15mCi/ML

N209607 001 Jul 30, 2018 Jul NEWA

IOTHEXOL

SOLUTION; INJECTION, ORAL, RECTAL OMNIPQUE 240	51.8%	N 020608 001 Oct 24, 1995	May DISC
@ GE HEALTHCARE			
SOLUTION; ORAL OMNIPQUE 12	2.6%	N 018956 009 Apr 17, 2018	Jun NEWA
+! GE HEALTHCARE			
OMNIPQUE 9			
+! GE HEALTHCARE	1.9%	N 018956 008 Apr 17, 2018	Jun NEWA

IOTHALAMATE MEGLUMINE

INJECTABLE; INJECTION CONRAY 30	30%	N 016983 001	Aug DISC
+ @ LIEBEL-FLARSHEIM			

IPRATROPIUM BROMIDE

SPRAY, METERED; NASAL IPRATROPIUM BROMIDE			
AB ! WEST-WARD PHARMS INT	0.021MG/SPRAY	A 076664 001 Nov 05, 2003	Jan CHRS
AB !	0.042MG/SPRAY	A 076598 001 Nov 05, 2003	Jan CHRS

IRBESARTAN

TABLET; ORAL IRBESARTAN			
AB AMNEAL PHARMS	75MG	A 204740 001 Apr 17, 2018	Apr NEWA
AB	150MG	A 204740 002 Apr 17, 2018	Apr NEWA
AB	300MG	A 204740 003 Apr 17, 2018	Apr NEWA
@ APOTEX INC	75MG	A 200832 001 Oct 15, 2012	Mar DISC
@	150MG	A 200832 002 Oct 15, 2012	Mar DISC
@	300MG	A 200832 003 Oct 15, 2012	Mar DISC
AB CHARTWELL MOLECULAR	75MG	A 077205 001 Nov 14, 2012	Apr CAHN
AB	150MG	A 077205 002 Nov 14, 2012	Apr CAHN
AB	300MG	A 077205 003 Nov 14, 2012	Apr CAHN
AB HISUN PHARM HANGZHOU	75MG	A 206194 001 Jun 14, 2016	Aug CAHN
AB	150MG	A 206194 002 Jun 14, 2016	Aug CAHN
AB	300MG	A 206194 003 Jun 14, 2016	Aug CAHN
AB NEOPHARMA	75MG	A 203161 001 Sep 27, 2012	Aug CAHN
AB	150MG	A 203161 002 Sep 27, 2012	Aug CAHN
AB	300MG	A 203161 003 Sep 27, 2012	Aug CAHN

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION IRINOTECAN HYDROCHLORIDE			
AP NEOPHARMA	40MG/2ML (20MG/ML)	A 078953 001 Apr 15, 2010	Aug CAHN
AP	100MG/5ML (20MG/ML)	A 078953 002 Apr 15, 2010	Aug CAHN
>A> INJECTABLE, LIPOSOMAL; INTRAVENOUS			
>A> ONIVYDE			
>A> +! IPSEN INC	EQ 43MG BASE/10ML (EQ 4.3MG BASE/ML)	N 207793 001 Oct 22, 2015	Sep CDFR
>D> INJECTABLE, LIPOSOMAL; IV (INFUSION)			
>D> ONIVYDE			
>D> +! IPSEN INC	EQ 43MG BASE/10ML (EQ 4.3MG BASE/ML)	N 207793 001 Oct 22, 2015	Sep CDFR

ISAVUCONAZONIUM SULFATE

>A> POWDER; INTRAVENOUS			
>A> CRESEMPA			
>A> +! ASTELLAS	372MG	N 207501 001 Mar 06, 2015	Sep CDFR
>D> POWDER; IV (INFUSION)			
>D> CRESEMPA			
>D> +! ASTELLAS	372MG	N 207501 001 Mar 06, 2015	Sep CDFR

ISOFLURANE

LIQUID; INHALATION ISOFLURANE			
>D> AN HOSPIRA	99.9%	A 074097 001 Jan 25, 1993	Sep DISC
>A> @	99.9%	A 074097 001 Jan 25, 1993	Sep DISC

ISOPROTERENOL HYDROCHLORIDE

INJECTABLE; INJECTION

ISOPROTERENOL HYDROCHLORIDE

AP	AMPHASTAR PHARMS INC	0.2MG/ML	A210106	001	Jun 18, 2018	Jun NEWA
AP	CIPRA LTD	0.2MG/ML	A210322	001	Jun 12, 2018	May NEWA

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

ISOSORBIDE MONONITRATE

@	ACCORD HLTHCARE	30MG	A209684	001	Oct 24, 2017	Apr DISC
@		60MG	A209684	002	Oct 24, 2017	Apr DISC
@		120MG	A209684	003	Oct 24, 2017	Apr DISC

AB	DEXCEL LTD	120MG	A210822	001	Aug 29, 2018	Aug NEWA
----	------------	-------	---------	-----	--------------	----------

ITRACONAZOLE

CAPSULE; ORAL

ITRACONAZOLE

AB	TORRENT PHARMS LTD	100MG	A209460	001	Aug 24, 2018	Aug NEWA
AA	SOLUTION; ORAL ITRACONAZOLE		A205573	001	Oct 30, 2015	Aug CMFD

AA	AMNEAL PHARMS SPORANOX	10MG/ML	N020657	001	Feb 21, 1997	Aug CTEC
----	---------------------------	---------	---------	-----	--------------	----------

IVACAFTOR; IVACAFTOR, TEZACAFTOR

TABLET, TABLET; ORAL

SYMDEKO (COPACKAGED)

+!	VERTEX PHARMS INC	150MG,N/A;150MG, 100MG	N210491	001	Feb 12, 2018	Feb NEWA
----	-------------------	------------------------	---------	-----	--------------	----------

IVACAFTOR; LUMACAFTOR

GRANULE; ORAL

ORKAMBI

+!	VERTEX PHARMS INC	125MG/PACKET;100MG/PACKET	N211358	001	Aug 07, 2018	Aug NEWA
+!		188MG/PACKET;150MG/PACKET	N211358	002	Aug 07, 2018	Aug NEWA

IVOSIDENIB

TABLET; ORAL

TIBSOVO

+!	AGIOS PHARMS INC	250MG	N211192	001	Jul 20, 2018	Jul NEWA
----	------------------	-------	---------	-----	--------------	----------

IXABEPILONE

>A>	INJECTABLE; INTRAVENOUS IXEMTRA KIT					
>A>	+! R-PHARM US LLC	15MG/VIAL	N022065	001	Oct 16, 2007	Sep CDER
>A>	+!	45MG/VIAL	N022065	002	Oct 16, 2007	Sep CDER
>D>	INJECTABLE; IV (INFUSION) IXEMTRA KIT					
>D>	+! R-PHARM US LLC	15MG/VIAL	N022065	001	Oct 16, 2007	Sep CDER
>D>	+!	45MG/VIAL	N022065	002	Oct 16, 2007	Sep CDER

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

@	FRESENIUS KABI USA	EQ 500MG BASE/2ML	A065111	001	Dec 17, 2002	Jun DISC
@		EQ 1GM BASE/3ML	A065111	002	Dec 17, 2002	Jun DISC

KETOCONAZOLE

TABLET; ORAL

KETOCONAZOLE

AB	STRIDES PHARMA	200MG	A210457	001	Jun 18, 2018	Jun NEWA
----	----------------	-------	---------	-----	--------------	----------

KETOPROFEN

CAPSULE; ORAL

KETOPROFEN

@	MYLAN	50MG	A074035	002	Dec 31, 1996	Jun DISC
@		75MG	A074035	003	Dec 31, 1996	Jun DISC

CAPSULE, EXTENDED RELEASE; ORAL KETOPROFEN			A075270	002	Mar 24, 1999	Jun DISC
@ ACTAVIS LABS FL INC	100MG					

## CAPSULE, EXTENDED RELEASE;ORAL

KETOPROFEN

@	150MG	A075270	003	Mar 24, 1999	Jun DISC
@	200MG	A075270	001	Mar 24, 1999	Jun DISC
@ MYLAN	100MG	A075679	003	Feb 20, 2002	Jun DISC
@	150MG	A075679	002	Feb 20, 2002	Jun DISC
!	200MG	A075679	001	Feb 20, 2002	Jun CTEC

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINE

AP	CYCLE PHARMS LTD	15MG/ML	A209900	002	Jul 25, 2018	Jul NEWA
	SOLUTION/DROPS;OPHTHALMIC					
	KETOROLAC TROMETHAMINE					
AT	SANDOZ INC	0.4%	A078721	001	Nov 05, 2009	Jan CAHN

TABLET;ORAL

KETOROLAC TROMETHAMINE

AB	CYCLE PHARMS LTD	10MG	A210616	001	Aug 16, 2018	Aug NEWA
----	------------------	------	---------	-----	--------------	----------

LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION

LABETALOL HYDROCHLORIDE

@ AKORN INC	5MG/ML	A075524	001	Nov 29, 1999	Aug DISC	
	TABLET;ORAL					
	LABETALOL HYDROCHLORIDE					
AB	APPCO PHARMA LLC	100MG	A209603	001	Jun 20, 2018	Jun NEWA
AB		200MG	A209603	002	Jun 20, 2018	Jun NEWA
AB		300MG	A209603	003	Jun 20, 2018	Jun NEWA
AB	TWI PHARMS	100MG	A209603	001	Jun 20, 2018	Aug CAHN
AB		200MG	A209603	002	Jun 20, 2018	Aug CAHN
AB		300MG	A209603	003	Jun 20, 2018	Aug CAHN

LACTULOSE

SOLUTION;ORAL

LACTULOSE

AA	BIO-PHARM INC	10GM/15ML	A207786	001	Jun 11, 2018	May NEWA
AA	LANNETT CO INC	10GM/15ML	A075993	001	Jul 26, 2001	May CAHN

LAMIVUDINE

TABLET;ORAL

LAMIVUDINE

>D> AB	APPCO PHARMA LLC	150MG	A206974	001	Nov 21, 2016	Sep CAHN
>D> AB		300MG	A206974	002	Nov 21, 2016	Sep CAHN
>A> AB	ARISE PHARMS	150MG	A206974	001	Nov 21, 2016	Sep CAHN
>A> AB		300MG	A206974	002	Nov 21, 2016	Sep CAHN
AB	STRIDES PHARMA	150MG	A090457	001	Apr 19, 2018	Apr NEWA
AB		300MG	A090457	002	Apr 19, 2018	Apr NEWA

LAMIVUDINE; NEVIRAPINE; ZIDOVUDINE

TABLET;ORAL

LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE

+ @ MICRO LABS	150MG;200MG;300MG	N205626	001	Aug 13, 2018	Aug NEWA
----------------	-------------------	---------	-----	--------------	----------

LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL

CIMDUO

+! MYLAN LABS LTD	300MG;300MG	N022141	001	Feb 28, 2018	Feb NEWA
	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE				
@ AUROBINDO PHARMA LTD	300MG;300MG	N022344	001	May 15, 2018	Jul DISC

300MG;300MG

N022344 001 May 15, 2018 May NEWA

LAMIVUDINE; ZIDOVUDINE

TABLET;ORAL

LAMIVUDINE AND ZIDOVUDINE

AB	CIPLA LTD	150MG;300MG	A077411	001	Sep 07, 2018	Aug NEWA
AB	MACLEODS PHARMS LTD	150MG;300MG	A090679	001	Aug 29, 2018	Aug NEWA
@ PHARMACARE		150MG;300MG	N022018	001	Mar 17, 2017	Jun DISC
AB	SHANGHAI DESANO	150MG;300MG	A206375	001	Apr 10, 2018	Mar NEWA

LATANOPROST

>A> EMULSION;OPHTHALMIC  
 >A> XELPROS  
 >A> +! SUN PHARMA GLOBAL 0.005% N 206185 001 Sep 12, 2018 Sep NEWA

LEFLUNOMIDE

TABLET;ORAL  
 LEFLUNOMIDE  
 @ FOSUN PHARMA 10MG A 077087 001 Sep 13, 2005 Jan CAHN  
 @ 20MG A 077087 002 Sep 13, 2005 Jan CAHN

LETHERMOVIR

>A> SOLUTION;INTRAVENOUS  
 >A> PREVYMIS  
 >A> +! MERCK SHARP DOHME 240MG/12ML (20MG/ML) N 209940 001 Nov 08, 2017 Sep CDFR  
 >A> +! 480MG/24ML (20MG/ML) N 209940 002 Nov 08, 2017 Sep CDFR  
 >D> SOLUTION;IV (INFUSION)  
 >D> PREVYMIS  
 >D> +! MERCK SHARP DOHME 240MG/12ML (20MG/ML) N 209940 001 Nov 08, 2017 Sep CDFR  
 >D> +! 480MG/24ML (20MG/ML) N 209940 002 Nov 08, 2017 Sep CDFR

LETROZOLE

TABLET;ORAL  
 LETROZOLE  
 @ MYLAN 2.5MG A 078190 001 Dec 24, 2008 Jun DISC

LEUCOVORIN CALCIUM

INJECTABLE;INJECTION  
 LEUCOVORIN CALCIUM  
 FRESENIUS KABI USA EQ 10MG BASE/ML A 207241 001 Mar 14, 2018 Mar NEWA  
 LEUCOVORIN CALCIUM  
 AP FRESENIUS KABI USA EQ 10MG BASE/ML A 207226 001 Jul 27, 2018 Jul NEWA  
 LEUCOVORIN CALCIUM PRESERVATIVE FREE  
 AP ! WEST-WARD PHARMS INT EQ 10MG BASE/ML A 040347 001 Apr 25, 2000 Jul CTEC

LEUPROLIDE ACETATE

FOR SUSPENSION;INTRAMUSCULAR  
 LUTRATE DEPOT KIT  
 +! GP-PHARM SA 22.5MG/VIAL N 205054 001 Aug 28, 2018 Aug NEWA  
 INJECTABLE;INJECTION  
 LUPRON  
 + @ ABBVIE ENDOCRINE INC 1MG/0.2ML N 019010 001 Apr 09, 1985 Feb CRLD  
 LUPRON DEPOT  
 + ABBVIE ENDOCRINE INC 22.5MG/VIAL N 020517 001 Dec 22, 1995 Jun CHRS  
 +! 45MG/VIAL N 020517 003 Jun 17, 2011 Jun CHRS

LEVETIRACETAM

INJECTABLE;IV (INFUSION)  
 LEVETIRACETAM  
 AP AKORN 500MG/5ML (100MG/ML) A 209934 001 May 04, 2018 Apr NEWA  
 AP HAINAN POLY PHARM 500MG/5ML (100MG/ML) A 209781 001 Mar 20, 2018 Mar NEWA  
 SOLUTION;ORAL  
 LEVETIRACETAM  
 AA ACI HEALTHCARE LTD 100MG/ML A 078582 001 Jan 15, 2009 May CAHN  
 AA LANNEOTT CO INC 100MG/ML A 090079 001 Apr 11, 2012 May CAHN  
 TABLET;ORAL  
 LEVETIRACETAM  
 @ FOSUN PHARMA 250MG A 077324 001 Jan 15, 2009 Jan CAHN  
 @ 500MG A 077324 002 Jan 15, 2009 Jan CAHN  
 @ 750MG A 077324 003 Jan 15, 2009 Jan CAHN  
 @ 1GM A 077324 004 Jan 15, 2009 Jan CAHN  
 AB OXFORD PHARMS 250MG A 077319 001 Mar 20, 2009 Jul CAHN  
 AB 500MG A 077319 002 Mar 20, 2009 Jul CAHN  
 AB 750MG A 077319 003 Mar 20, 2009 Jul CAHN  
 TABLET, EXTENDED RELEASE;ORAL  
 LEVETIRACETAM  
 @ VIRTUS PHARMS 500MG A 091291 001 Sep 12, 2011 Jun DISC  
 @ 750MG A 091291 002 Sep 12, 2011 Jun DISC

LEVOCARNITINE

TABLET;ORAL

LEVOCARNITINE

>A>	AB	ANDA REPOSITORY	330MG	A076858	001	Sep 20, 2004	Sep CAHN
>D>	AB	RISING PHARMS	330MG	A076858	001	Sep 20, 2004	Sep CAHN

LEVOSETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOSETIRIZINE DIHYDROCHLORIDE

@	FOSUN PHARMA	5MG	A090486	001	Mar 26, 2013	Jan CAHN
AB	NEOPHARMA	5MG	A204323	001	Dec 20, 2016	Aug CAHN

LEVOFLOXACIN

INJECTABLE;INJECTION

LEVAQUIN

+ @	JANSSEN PHARMS	EQ 500MG/20ML (EQ 25MG/ML)	N020635	001	Dec 20, 1996	Feb DISC
+ @		EQ 750MG/30ML (EQ 25MG/ML)	N020635	004	Dec 20, 1996	Feb DISC

LEVOFLOXACIN

AP	! AUROBINDO PHARMA LTD	EQ 500MG/20ML (EQ 25MG/ML)	A202328	001	Jan 24, 2013	Mar CHRS
AP	! EMCURE PHARMS LTD	EQ 750MG/30ML (EQ 25MG/ML)	A202328	002	Jan 24, 2013	Mar CHRS
	@	EQ 500MG/20ML (EQ 25MG/ML)	A202590	001	Jan 24, 2013	Mar DISC
	@	EQ 750MG/30ML (EQ 25MG/ML)	A202590	002	Jan 24, 2013	Mar DISC
@	MYLAN ASI	EQ 500MG/20ML (EQ 25MG/ML)	A200560	001	Jun 20, 2011	Jun DISC
@		EQ 750MG/30ML (EQ 25MG/ML)	A200560	002	Jun 20, 2011	Jun DISC
@	ZYDUS PHARMS USA INC	EQ 500MG/20ML (EQ 25MG/ML)	A205968	001	Jun 01, 2017	Feb DISC
@		EQ 750MG/30ML (EQ 25MG/ML)	A205968	002	Jun 01, 2017	Feb DISC

LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	! INFORLIFE	EQ 250MG/50ML (EQ 5MG/ML)	A090343	001	Jul 07, 2011	Jan CAHN
AP	!	EQ 500MG/100ML (EQ 5MG/ML)	A090343	002	Jul 07, 2011	Jan CAHN
AP	!	EQ 750MG/150ML (EQ 5MG/ML)	A090343	003	Jul 07, 2011	Jan CAHN

SOLUTION;ORAL

LEVOFLOXACIN

AA	! HI TECH PHARMA	250MG/10ML	A091678	001	Jun 20, 2011	May CTEC
AA	LANNETT CO INC	250MG/10ML	A205222	001	May 25, 2018	May NEWA

SOLUTION/DROPS;OPHTHALMIC

LEVOFLOXACIN

>A>	AT	! ANDA REPOSITORY	0.5%	A077700	001	Dec 20, 2010	Sep CAHN
>D>	AT	! RISING PHARMS	0.5%	A077700	001	Dec 20, 2010	Sep CAHN

TABLET;ORAL

LEVAQUIN

+ @	JANSSEN PHARMS	250MG	N020634	001	Dec 20, 1996	Feb DISC
+ @		500MG	N020634	002	Dec 20, 1996	Feb DISC
+ @		750MG	N020634	003	Sep 08, 2000	Feb DISC

AB	! AUROBINDO PHARMA LTD	750MG	A201043	003	Jun 20, 2011	Feb CHRS
----	------------------------	-------	---------	-----	--------------	----------

LEVOLEUCOVORIN CALCIUM

POWDER;INTRAVENOUS

FUSILEV

AP	+! SPECTRUM PHARMS	EQ 50MG BASE/VIAL	N020140	001	Mar 07, 2008	May CDFR
AP	LEVOLEUCOVORIN CALCIUM					

AP	ACTAVIS LLC	EQ 50MG BASE/VIAL	A206516	001	Feb 13, 2017	May CDFR
AP	+!	EQ 175MG BASE/VIAL	N208723	001	Sep 29, 2016	May CDFR

AP	AMNEAL PHARMS CO	EQ 50MG BASE/VIAL	A207547	001	Feb 13, 2017	May CDFR
AP	WEST-WARD PHARMS INT	EQ 50MG BASE/VIAL	A206263	001	Jun 16, 2016	May CDFR

SOLUTION;INTRAVENOUS

FUSILEV

+ @	SPECTRUM PHARMS	EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML)	N020140	002	Apr 29, 2011	May CDFR
+ @		EQ 250MG BASE/25ML (EQ 10MG BASE/ML)	N020140	003	Apr 29, 2011	May CDFR

AP	LEVOLEUCOVORIN CALCIUM					
AP	AMNEAL PHARMS CO	EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML)	A207548	001	Sep 08, 2017	May CDFR

>A>	AP	GLAND PHARMA LTD	EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML)	A210892	001	Sep 14, 2018	Sep NEWA
>A>	AP		EQ 250MG BASE/25ML (EQ 10MG BASE/ML)	A210892	002	Sep 14, 2018	Sep NEWA

AP	INGENUS PHARMS LLC	EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML)	A210623	001	May 03, 2018	May CDFR
AP		EQ 250MG BASE/25ML (EQ 10MG BASE/ML)	A210623	002	May 03, 2018	May CDFR



TABLET;ORAL  
NOVOTHYROX

>D>	@	0.1MG	N 021292	005	May 31, 2002	Sep CTNA
>D>	@	0.112MG	N 021292	006	May 31, 2002	Sep CTNA
>D>	@	0.125MG	N 021292	007	May 31, 2002	Sep CTNA
>D>	@	0.137MG	N 021292	008	May 31, 2002	Sep CTNA
>D>	@	0.15MG	N 021292	009	May 31, 2002	Sep CTNA
>D>	@	0.175MG	N 021292	010	May 31, 2002	Sep CTNA
>D>	@	0.2MG	N 021292	011	May 31, 2002	Sep CTNA
>D>	@	0.3MG	N 021292	012	May 31, 2002	Sep CTNA

LIDOCAINE

OINTMENT;TOPICAL  
LIDOCAINE

AT	TEVA PHARMS USA	5%	A 210256	001	Jan 16, 2018	Jan NEWA
	PATCH;TOPICAL ZTLIDO					
+!	SCILEX PHARMS INC	1.8%	N 207962	001	Feb 28, 2018	Feb NEWA

LIDOCAINE HYDROCHLORIDE

INJECTABLE;INJECTION  
LIDOCAINE HYDROCHLORIDE

AP	B BRAUN MEDICAL INC	1%	A 208474	001	Aug 03, 2018	Jul NEWA
AP	SPECTRA MDCL DEVICES	1%	A 208017	001	Apr 18, 2018	Apr NEWA
	LIDOCAINE HYDROCHLORIDE	PRESERVATIVE FREE				
	@ INTL MEDICATION	20%	N 017702	001		Jun DISC

JELLY;TOPICAL  
ANESTACON

>D>	@ BIONPHARMA INC	2%	A 080429	001		Sep CAHN
>A>	@ BLUEPHARMA	2%	A 080429	001		Sep CAHN
	LIDOCAINE HYDROCHLORIDE					
	@ WATSON LABS INC	2%	A 040837	001	Mar 23, 2011	Aug DISC

SOLUTION;ORAL  
LIDOCAINE HYDROCHLORIDE VISCOUS

AT	! LANNETT CO INC	2%	A 040708	001	Feb 27, 2007	May CAHN
	SOLUTION;TOPICAL LIDOCAINE HYDROCHLORIDE					
AT	LANNETT CO INC	4%	A 040710	001	Feb 27, 2007	May CAHN

LIDOCAINE; PRILOCAINE

CREAM;TOPICAL  
LIDOCAINE AND PRILOCAINE

AB	TELIGENT PHARMA INC	2.5%;2.5%	A 205887	001	Jun 29, 2018	Jun NEWA
----	---------------------	-----------	----------	-----	--------------	----------

LINACLOTIDE

CAPSULE;ORAL  
LINZESS

+	ALLERGAN SALES LLC	72MCG	N 202811	003	Jan 25, 2017	Jan CAHN
+		145MCG	N 202811	001	Aug 30, 2012	Jan CAHN
+		290MCG	N 202811	002	Aug 30, 2012	Jan CAHN

LINDANE

LOTION;TOPICAL  
LINDANE

!	OLTA PHARMS	1%	A 087313	001		Jun CHRS
		1%	A 087313	001		Jun CTEC
	@ WOCKHARDT	1%	A 088190	001	Aug 16, 1984	Jun DISC

LINEZOLID

SOLUTION;INTRAVENOUS  
LINEZOLID

AP	AUROBINDO PHARMA LTD	600MG/300ML (2MG/ML)	A 206917	001	Aug 04, 2016	May CDFR
AP	FRESENIUS KABI USA	600MG/300ML (2MG/ML)	A 204764	001	Mar 15, 2016	May CDFR
AP	HOSPIRA INC	600MG/300ML (2MG/ML)	A 205442	001	Jul 07, 2015	May CDFR
AP	HQ SPCLT PHARMA	200MG/100ML (2MG/ML)	A 207001	001	Jul 07, 2017	May CDFR
AP		600MG/300ML (2MG/ML)	A 207001	002	Jul 07, 2017	May CDFR
AP	MYLAN LABS LTD	200MG/100ML (2MG/ML)	A 205154	001	Dec 06, 2017	May CDFR
AP		600MG/300ML (2MG/ML)	A 205154	002	Dec 06, 2017	May CDFR
AP	NANG KUANG PHARM CO	200MG/100ML (2MG/ML)	A 207354	001	Dec 20, 2016	May CDFR
AP		600MG/300ML (2MG/ML)	A 207354	002	Dec 20, 2016	May CDFR
AP	SAGENT PHARMS	200MG/100ML (2MG/ML)	A 204696	001	Mar 02, 2017	May CDFR
AP		600MG/300ML (2MG/ML)	A 204696	002	Mar 02, 2017	May CDFR

SOLUTION; INTRAVENOUS  
LINEZOLID

AP	SANDOZ INC	200MG/100ML (2MG/ML)	A200904	001	Jul 16, 2015	May CDFR
AP		600MG/300ML (2MG/ML)	A200904	002	Jul 16, 2015	May CDFR
AP	TEVA PHARMS	600MG/300ML (2MG/ML)	A200222	001	Jun 27, 2012	May CDFR
LINEZOLID IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER						
+!	HOSPIRA INC	600MG/300ML (2MG/ML)	N206473	001	Jun 18, 2015	May CDFR
ZYVOX						
AP	+ PHARMACIA AND UPJOHN	200MG/100ML (2MG/ML)	N021131	001	Apr 18, 2000	May CDFR
+ @		400MG/200ML (2MG/ML)	N021131	002	Apr 18, 2000	Jul DISC
+		400MG/200ML (2MG/ML)	N021131	002	Apr 18, 2000	May CDFR
AP	+!	600MG/300ML (2MG/ML)	N021131	003	Apr 18, 2000	May CDFR

>D> LITOTRIX (T4;T3)

>D>	TABLET; ORAL					
>D>	THYROLAR-0.25					
>D>	+ ALLERGAN SALES LLC	0.0125MG; 0.0031MG	N016807	001		Sep DISC
>A>	+ @	0.0125MG; 0.0031MG	N016807	001		Sep DISC
	+	0.0125MG; 0.0031MG	N016807	001		Apr CAHN
>D>	THYROLAR-0.5					
>D>	+ ALLERGAN SALES LLC	0.025MG; 0.0063MG	N016807	005		Sep DISC
>A>	+ @	0.025MG; 0.0063MG	N016807	005		Sep DISC
	+	0.025MG; 0.0063MG	N016807	005		Apr CAHN
>D>	THYROLAR-1					
>D>	+ ALLERGAN SALES LLC	0.05MG; 0.0125MG	N016807	004		Sep DISC
>A>	+ @	0.05MG; 0.0125MG	N016807	004		Sep DISC
	+	0.05MG; 0.0125MG	N016807	004		Apr CAHN
>D>	THYROLAR-2					
>D>	+ ALLERGAN SALES LLC	0.1MG; 0.025MG	N016807	002		Sep DISC
>A>	+ @	0.1MG; 0.025MG	N016807	002		Sep DISC
	+	0.1MG; 0.025MG	N016807	002		Apr CAHN
>D>	THYROLAR-3					
>D>	+! ALLERGAN SALES LLC	0.15MG; 0.0375MG	N016807	003		Sep DISC
>A>	+ @	0.15MG; 0.0375MG	N016807	003		Sep DISC
	+!	0.15MG; 0.0375MG	N016807	003		Apr CAHN
THYROLAR-5						
@ ALLERGAN SALES LLC 0.25MG; 0.0625MG N016807 006 Apr CAHN						

LISINOPRIL

TABLET; ORAL  
LISINOPRIL

AB	CASI PHARMS INC	2.5MG	A075994	001	Jul 01, 2002	Mar CAHN
AB		5MG	A075994	002	Jul 01, 2002	Mar CAHN
AB		10MG	A075994	003	Jul 01, 2002	Mar CAHN
AB		20MG	A075994	004	Jul 01, 2002	Mar CAHN
AB		30MG	A075994	005	Jul 01, 2002	Mar CAHN
AB		40MG	A075994	006	Jul 01, 2002	Mar CAHN

LOFEXIDINE HYDROCHLORIDE

TABLET; ORAL  
LUCEMYRA

+!	US WORLDMEDS LLC	EQ 0.18MG BASE	N209229	001	May 16, 2018	May NEWA
----	------------------	----------------	---------	-----	--------------	----------

LOMUSTINE

CAPSULE; ORAL  
GLEOSTINE  
+ @ CORDEN PHARMA

5MG	N017588	004	Dec 19, 2014	Jun DISC
-----	---------	-----	--------------	----------

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL  
IMODIUM  
+ @ J AND J CONSUMER INC 2MG  
LOPERAMIDE HYDROCHLORIDE  
@ YAOPHARMA CO LTD 2MG

N017694	001			Jun CRLD
A072993	001	Aug 28, 1992		Jan CAHN

LORAZEPAM

CONCENTRATE; ORAL  
LORAZEPAM

>A> AA	ANDA REPOSITORY	2MG/ML	A079244	001	Apr 28, 2009	Sep CAHN
>D> AA	SAPTALIS PHARMS	2MG/ML	A079244	001	Apr 28, 2009	Sep CAHN

TABLET;ORAL

## LORAZEPAM

@ ANDA REPOSITORY	0.5MG	A072555	002	Mar 29, 1991	May CMS1
@	1MG	A072555	003	Mar 29, 1991	May CMS1
@ MYLAN	0.5MG	A071591	002	Oct 13, 1987	Jan CMS1
@	1MG	A071591	003	Oct 13, 1987	Jan CMS1
AB OXFORD PHARMS	0.5MG	A077754	001	May 10, 2006	Jul CAHN
AB	1MG	A077754	002	May 10, 2006	Jul CAHN
AB	2MG	A077754	003	May 10, 2006	Jul CAHN
@ SUN PHARM IND LTD	0.5MG	A076045	001	Aug 29, 2001	May DISC
@	1MG	A076045	002	Aug 29, 2001	May DISC
@	2MG	A076045	003	Aug 29, 2001	May DISC

LOSARTAN POTASSIUM

## TABLET;ORAL

## COZAAR

+ @ MERCK SHARP DOHME	25MG	N020386	001	Apr 14, 1995	Apr DISC
+ @	50MG	N020386	002	Apr 14, 1995	Apr DISC
LOSARTAN POTASSIUM					
@ APOTEX CORP	25MG	A090790	001	Oct 06, 2010	Mar DISC
@	50MG	A090790	002	Oct 06, 2010	Mar DISC
@	100MG	A090790	003	Oct 06, 2010	Mar DISC

LOTEPREDNOL ETABONATESUSPENSION/DROPS;OPHTHALMIC  
INVELTYS

+! KALA PHARMS INC	1%	N210565	001	Aug 22, 2018	Aug NEWA
--------------------	----	---------	-----	--------------	----------

LUSUTROMBOPAGTABLET;ORAL  
MULPLETA

+! SHIONOGI INC	3MG	N210923	001	Jul 31, 2018	Jul NEWA
-----------------	-----	---------	-----	--------------	----------

LUTETIUM DOTATATE LU-177

>A>	SOLUTION;INTRAVENOUS				
>A>	LUTATHERA				
>A>	+! AAA USA INC	10mCi/ML			
>D>	SOLUTION;IV (INFUSION)				
>D>	LUTATHERA				
>D>	+! AAA USA INC	10mCi/ML			
	+!	10mCi/ML			
			N208700	001	Jan 26, 2018
			N208700	001	Jan 26, 2018
			N208700	001	Jan 26, 2018
			N208700	001	Jan 26, 2018

MACIMORELIN ACETATEFOR SOLUTION;ORAL  
MACRILEN

+! STRONGBRIDGE IRELAND	EQ 60MG BASE/POUCH	N205598	001	Dec 20, 2017	May CMS1
+!	EQ 60MG BASE/POUCH	N205598	001	Dec 21, 2017	Jan CAHN

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

## INJECTABLE;INJECTION

## PLASMA-LYTE 148 IN WATER IN PLASTIC CONTAINER

+! BAXTER HLTHCARE	30MG/100ML;37MG/100ML;368MG/100ML; 526MG/100ML;502MG/100ML	N017378	001		Apr CRLD
+! BAXTER HLTHCARE	30MG/100ML;37MG/100ML;368MG/100ML; 526MG/100ML;502MG/100ML	N017378	002	Nov 22, 1982	Apr CRLD

MAGNESIUM SULFATE

## INJECTABLE;INJECTION

## MAGNESIUM SULFATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP MYLAN LABS LTD	1GM/100ML	A209932	001	Sep 10, 2018	Aug NEWA
MAGNESIUM SULFATE IN PLASTIC CONTAINER					
>A> AP MYLAN LABS LTD	2GM/50ML (40MG/ML)	A209911	001	Sep 14, 2018	Sep NEWA
>A> AP	4GM/100ML (40MG/ML)	A209911	002	Sep 14, 2018	Sep NEWA

MALATHION

## LOTION;TOPICAL

## OVIDE

AT +! TARO PHARM IND LTD	0.5%	N018613	001	Aug 02, 1982	May CAHN
--------------------------	------	---------	-----	--------------	----------

MANGANESE CHLORIDE

INJECTABLE; INJECTION

MANGANESE CHLORIDE IN PLASTIC CONTAINER

+! HOSPIRA EQ 0.1MG MANGANESE/ML

N018962 001 Jun 26, 1986 Mar CRLD

MANNITOL; SORBITOL

SOLUTION; IRRIGATION

SORBITOL-MANNITOL IN PLASTIC CONTAINER

+! ICU MEDICAL INC 540MG/100ML; 2.7GM/100ML

N018316 001 Mar CRLD

MAZINDOL

TABLET; ORAL

SANOREX

+ @ HEXIM 1MG  
+ @ 2MGN017247 001 Jul CAHN  
N017247 002 Jul CAHNMEBENDAZOLE

TABLET, CHEWABLE; ORAL

VERMOX

+ @ JANSSEN PHARMS 500MG

N208398 001 Oct 19, 2016 Feb DISC

MECHLORETHAMINE HYDROCHLORIDE

GEL; TOPICAL

VALCHLOR

+! HELSINN EQ 0.016% BASE

N202317 001 Aug 23, 2013 Aug CAHN

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HYDROCHLORIDE

>A> @ ANDA REPOSITORY 12.5MG  
>A> @ 25MG  
>D> @ RISING PHARMS 12.5MG  
>D> @ 25MGA040179 001 Jan 30, 1997 Sep CAHN  
A040179 002 Jan 30, 1997 Sep CAHN  
A040179 001 Jan 30, 1997 Sep CAHN  
A040179 002 Jan 30, 1997 Sep CAHNMECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

@ FOSUN PHARMA EQ 50MG BASE  
@ EQ 100MG BASEA072262 001 Nov 29, 1988 Jan CAHN  
A072263 001 Nov 29, 1988 Jan CAHNMEFENAMIC ACID

CAPSULE; ORAL

MEFENAMIC ACID

>D> AB BELCHER PHARMS INC 250MG  
AB 250MG  
>A> AB BELCHER PHARMS LLC 250MG  
AB MICRO LABS 250MGA091608 001 Jun 02, 2014 Sep CAHN  
A091608 001 Jun 02, 2014 Jul CAHN  
A091608 001 Jun 02, 2014 Sep CAHN  
A090562 001 Nov 19, 2010 Feb CAHNMELOXICAM

TABLET; ORAL

MELOXICAM

@ MYLAN 7.5MG  
@ 15MGA077923 001 Jul 19, 2006 Jun DISC  
A077923 002 Jul 19, 2006 Jun DISCMEMANTINE HYDROCHLORIDE

SOLUTION; ORAL

MEMANTINE HYDROCHLORIDE

AA APOTEX INC 2MG/ML  
AA ! BIO-PHARM INC 2MG/ML  
NAMENDA  
+ @ ALLERGAN SALES LLC 2MG/ML  
AA +!  
2MG/MLA209955 001 Feb 09, 2018 Jan NEWA  
A205446 001 Dec 07, 2015 Apr CHRS  
N021627 001 Apr 18, 2005 Apr DISC  
N021627 001 Apr 18, 2005 Jan CAHNTABLET; ORAL  
MEMANTINE HYDROCHLORIDEAB APOTEX INC 5MG  
AB 10MG  
AB CSPC OUYI PHARM CO 5MG  
AB 10MG  
NAMENDA  
AB + ALLERGAN SALES LLC 5MG  
AB +!  
10MGA090244 001 Jul 11, 2018 Jun NEWA  
A090244 002 Jul 11, 2018 Jun NEWA  
A209527 001 May 07, 2018 Apr NEWA  
A209527 002 May 07, 2018 Apr NEWA  
N021487 001 Oct 16, 2003 Jan CAHN  
N021487 002 Oct 16, 2003 Jan CAHN

MEROPENEM

INJECTABLE; INJECTION

MEROPENEM

AP	ACS DOBFAR SPA	500MG/VIAL	A204139	001	Jun 09, 2016	Apr CAHN
AP		1GM/VIAL	A204139	002	Jun 09, 2016	Apr CAHN
>A>	POWDER; INTRAVENOUS					
>A>	MEROPENEM AND SODIUM CHLORIDE IN DUPLEX CONTAINER					
>A>	B BRAUN MEDICAL INC	500MG/VIAL	N202106	001	Apr 30, 2015	Sep CDFR
>A>		1GM/VIAL	N202106	002	Apr 30, 2015	Sep CDFR
>D>	POWDER; IV (INFUSION)					
>D>	MEROPENEM AND SODIUM CHLORIDE IN DUPLEX CONTAINER					
>D>	B BRAUN MEDICAL INC	500MG/VIAL	N202106	001	Apr 30, 2015	Sep CDFR
>D>		1GM/VIAL	N202106	002	Apr 30, 2015	Sep CDFR

MEROPENEM; VABORBACTAM

>A>	POWDER; INTRAVENOUS					
>A>	VABOMERE					
>A>	+! REMPEX PHARMS	1GM/VIAL;1GM/VIAL	N209776	001	Aug 29, 2017	Sep CDFR
>D>	POWDER; IV (INFUSION)					
>D>	VABOMERE					
>D>	+! REMPEX PHARMS	1GM/VIAL;1GM/VIAL	N209776	001	Aug 29, 2017	Sep CDFR
	+!	1GM/VIAL;1GM/VIAL	N209776	001	Aug 29, 2017	Jan CAHN

MESALAMINE

ENEMA; RECTAL

MESALAMINE

@	G AND W LABS INC	4GM/60ML	A076841	001	Sep 30, 2004	Jan DISC
	SUPPOSITORY; RECTAL					
	CANASA					
@	ALLERGAN SALES LLC	500MG	N021252	001	Jan 05, 2001	Jan CAHN
AB	+!	1GM	N021252	002	Nov 05, 2004	Jan CAHN
	TABLET, DELAYED RELEASE; ORAL					
	MESALAMINE					
AB	ACTAVIS LABS FL	1.2GM	A203817	001	Mar 23, 2018	Mar NEWA

MESNA

INJECTABLE; INTRAVENOUS

MESNA

@ MYLAN INSTITUTIONAL 100MG/ML

A076488 001 Mar 08, 2012 Jan DISC

METARAMINOL BITARTRATE

INJECTABLE; INJECTION

METARAMINOL BITARTRATE

@ FRESENIUS KABI USA EQ 10MG BASE/ML

A080722 001 Feb DISC

METAXALONE

TABLET; ORAL

METAXALONE

>A> AB	APPCO PHARMA LLC	800MG	A208774	001	Sep 24, 2018	Sep NEWA
	MOUNTAIN	400MG	A040486	001	Feb 27, 2015	Jan CAHN
>A> AB	RISING PHARMS	800MG	A208774	001	Sep 24, 2018	Sep CAHN

METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HYDROCHLORIDE

AB	LAURUS LABS LTD	500MG	A209882	001	Aug 27, 2018	Aug NEWA
AB		850MG	A209882	002	Aug 27, 2018	Aug NEWA
AB		1GM	A209882	003	Aug 27, 2018	Aug NEWA
	@ PROVIDENT PHARM	500MG	A077853	001	Jul 28, 2006	Jun DISC
	@	850MG	A077853	002	Jul 28, 2006	Jun DISC
	@	1GM	A077853	003	Jul 28, 2006	Jun DISC
	@ SANDOZ	500MG	A075985	001	Jan 25, 2002	Mar DISC
	@	850MG	A075985	002	Jan 25, 2002	Mar DISC
	@	1GM	A075985	003	Jan 25, 2002	Mar DISC
	TABLET, EXTENDED RELEASE; ORAL					
	METFORMIN HYDROCHLORIDE					
AB1	ALIGNSCIENCE PHARMA	500MG	A209303	001	Mar 19, 2018	Mar NEWA
AB1	GRANULES INDIA LTD	500MG	A209313	001	Mar 16, 2018	Mar NEWA
AB		750MG	A209313	002	Mar 16, 2018	Mar NEWA
AB1	PRINSTON INC	500MG	A208880	001	Sep 10, 2018	Aug NEWA

**TABLET, EXTENDED RELEASE;ORAL  
METFORMIN HYDROCHLORIDE**

AB		750MG	A208880	002	Sep 10, 2018	Aug NEWA
>A> AB1	YICHANG HUMANWELL	500MG	A211052	001	Sep 24, 2018	Sep NEWA
>A> AB		750MG	A211052	002	Sep 24, 2018	Sep NEWA

**METFORMIN HYDROCHLORIDE; REPAGLINIDE**

**TABLET;ORAL  
REPAGLINIDE AND METFORMIN HYDROCHLORIDE**

@ LUPIN LTD	500MG;1MG	A200624	001	Jul 15, 2015	May DISC
@	500MG;2MG	A200624	002	Jul 15, 2015	May DISC

**METHADONE HYDROCHLORIDE**

**TABLET;ORAL  
METHADONE HYDROCHLORIDE**

AA	ELITE LABS INC	5MG	A210484	001	Aug 02, 2018	Jul NEWA
AA		10MG	A210484	002	Aug 02, 2018	Jul NEWA
AA	SUN PHARM INDUSTRIES	5MG	A208305	001	Mar 30, 2018	Mar NEWA
AA		10MG	A208305	002	Mar 30, 2018	Mar NEWA

**METHAZOLAMIDE**

**TABLET;ORAL  
METHAZOLAMIDE**

>A> AB	MICRO LABS	25MG	A207438	001	Oct 05, 2018	Sep NEWA
>A> AB		50MG	A207438	002	Oct 05, 2018	Sep NEWA

**METHIMAZOLE**

**TABLET;ORAL  
METHIMAZOLE**

>A> AB	ANDA REPOSITORY	5MG	A202068	001	Mar 07, 2012	Sep CAHN
>A> AB		10MG	A202068	002	Mar 07, 2012	Sep CAHN
AB	CASI PHARMS INC	5MG	A040411	001	Mar 27, 2001	Mar CAHN
AB		10MG	A040411	002	Mar 27, 2001	Mar CAHN
>D> AB	RISING PHARMS	5MG	A202068	001	Mar 07, 2012	Sep CAHN
>D> AB		10MG	A202068	002	Mar 07, 2012	Sep CAHN

**METHOCARBAMOL**

**SOLUTION; IM-IV  
METHOCARBAMOL**

AP	FRESENIUS KABI USA	1GM/10ML (100MG/ML)	A209331	001	Apr 17, 2018	Apr NEWA
TABLET;ORAL						
METHOCARBAMOL						
AA	ALLIED PHARMA INC	500MG	A203550	001	Feb 08, 2017	Feb CAHN
AA		750MG	A203550	002	Feb 08, 2017	Feb CAHN
AA	DBL PHARMS	500MG	A203550	001	Feb 08, 2017	May CAHN
AA		750MG	A203550	002	Feb 08, 2017	May CAHN
	@ FOSUN PHARMA	500MG	A084616	001		Jan CAHN
	@	750MG	A084615	001		Jan CAHN
AA	GRANULES INDIA LTD	500MG	A209312	001	May 07, 2018	Apr NEWA
AA		750MG	A209312	002	May 07, 2018	Apr NEWA
AA	OXFORD PHARMS	500MG	A040489	001	Jan 29, 2003	Jul CAHN
AA		750MG	A040489	002	Jan 29, 2003	Jul CAHN

**METHOTREXATE**

**SOLUTION; SUBCUTANEOUS  
RASUVO**

+!	MEDAC PHARMA INC	7.5MG/0.15ML (7.5MG/0.15ML)	N205776	001	Jul 10, 2014	Apr CHRS
+!		10MG/0.20ML (10MG/0.20ML)	N205776	002	Jul 10, 2014	Apr CHRS
+!		12.5MG/0.25ML (12.5MG/0.25ML)	N205776	003	Jul 10, 2014	Apr CHRS
+!		15MG/0.30ML (15MG/0.30ML)	N205776	004	Jul 10, 2014	Apr CHRS
+!		17.5MG/0.35ML (17.5MG/0.35ML)	N205776	005	Jul 10, 2014	Apr CHRS
+!		20MG/0.4ML (20MG/0.4ML)	N205776	006	Jul 10, 2014	Apr CHRS
+!		22.5MG/0.45ML (22.5MG/0.45ML)	N205776	007	Jul 10, 2014	Apr CHRS
+!		25MG/0.5ML (25MG/0.5ML)	N205776	008	Jul 10, 2014	Apr CHRS
+!		30MG/0.6ML (30MG/0.6ML)	N205776	010	Jul 10, 2014	Apr CHRS

**METHOTREXATE SODIUM**

**INJECTABLE; INJECTION  
METHOTREXATE SODIUM**

@ FRESENIUS KABI USA	EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A040263	002	Feb 26, 1999	Aug DISC
----------------------	--------------------------------------	---------	-----	--------------	----------

INJECTABLE; INJECTION

METHOTREXATE SODIUM PRESERVATIVE FREE

AP	SAGENT PHARMS	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A203407	001	Aug 09, 2018	Jul NEWA
AP		EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A203407	002	Aug 09, 2018	Jul NEWA
AP		EQ 1GM BASE/40ML (EQ 25MG BASE/ML)	A203407	003	Aug 09, 2018	Jul NEWA

METHSUXIMIDE

CAPSULE; ORAL

CELONTIN

+ @ PARKE DAVIS

150MG

N010596

Jun DISC

METHYCLOTHIAZIDE

TABLET; ORAL

METHYCLOTHIAZIDE

@ YAOPHARMA CO LTD

2.5MG

A089835

Jan CAHN

@

5MG

A089837

Jan CAHN

METHYLDOPA

TABLET; ORAL

METHYLDOPA

@ YAOPHARMA CO LTD

125MG

A071700

Jan CAHN

@

250MG

N018934

Jan CAHN

@

500MG

N018934

Jan CAHN

METHYLERGONOVINE MALEATE

TABLET; ORAL

METHYLERGONOVINE MALEATE

AB	AMNEAL PHARMS	0.2MG	A211483	001	Sep 10, 2018	Aug NEWA
AB	GRANULES PHARMS	0.2MG	A210424	001	May 15, 2018	Apr NEWA
AB	! NOVEL LABS INC	0.2MG	A091577	001	May 02, 2011	Apr CTEC

METHYLPHENIDATE HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORAL  
JORNAY PM

+ IRONSHORE PHARMS

20MG

N209311

Aug NEWA

+

40MG

N209311

Aug NEWA

+

60MG

N209311

Aug NEWA

+

80MG

N209311

Aug NEWA

+

100MG

N209311

Aug NEWA

METADATE CD

AB2	+ LANNETT CO INC	10MG	N021259	003	May 27, 2003	Mar CAHN
AB2	+	20MG	N021259	001	Apr 03, 2001	Mar CAHN
AB2	+	30MG	N021259	002	Jun 19, 2003	Mar CAHN
AB2	+	40MG	N021259	004	Feb 19, 2006	Mar CAHN
AB2	+	50MG	N021259	005	Feb 19, 2006	Mar CAHN
AB2	+!	60MG	N021259	006	Feb 19, 2006	Mar CAHN

METHYLPHENIDATE HYDROCHLORIDE

AB1	MAYNE PHARMA	10MG	A200886	001	Feb 26, 2018	Feb NEWA
	FOR SUSPENSION, EXTENDED RELEASE; ORAL					

METHYLPHENIDATE HYDROCHLORIDE

AB	ACTAVIS LABS FL INC	5MG/ML	A206049	001	May 17, 2018	Apr NEWA
	QUILLIVANT XR					

AB	+! NEXTWAVE PHARMS	5MG/ML	N202100	001	Sep 27, 2012	Apr CFTG
	SOLUTION; ORAL					

METHYLPHENIDATE HYDROCHLORIDE

>A AA	WES PHARMA INC	5MG/5ML	A210139	001	Oct 03, 2018	Sep NEWA
>A AA		10MG/5ML	A210139	002	Oct 03, 2018	Sep NEWA

TABLET; ORAL

METHYLPHENIDATE HYDROCHLORIDE

AB	BIONPHARMA INC	5MG	A209753	001	Mar 02, 2018	Feb NEWA
AB		10MG	A209753	002	Mar 02, 2018	Feb NEWA
AB		20MG	A209753	003	Mar 02, 2018	Feb NEWA

AB	LANNETT CO INC	5MG	A086429	001		Mar CAHN
AB		10MG	A085799	001		Mar CAHN
AB		20MG	A086428	001		Mar CAHN

AB	MOUNTAIN	5MG	A091159	001	Mar 12, 2014	Jan CAHN
AB		10MG	A091159	002	Mar 12, 2014	Jan CAHN
AB		20MG	A091159	003	Mar 12, 2014	Jan CAHN

AB	OXFORD PHARMS	5MG	A202892	001	Sep 23, 2014	Jul CAHN
AB		10MG	A202892	002	Sep 23, 2014	Jul CAHN
AB		20MG	A202892	003	Sep 23, 2014	Jul CAHN

TABLET, CHEWABLE;ORALMETHYLPHENIDATE HYDROCHLORIDE

>A> AB	ANDA REPOSITORY	2.5MG	A205756	001	Nov 07, 2016	Sep CAHN
>A> AB		5MG	A205756	002	Nov 07, 2016	Sep CAHN
>A> AB		10MG	A205756	003	Nov 07, 2016	Sep CAHN
>A> AB	RISING PHARMS	2.5MG	A205756	001	Nov 07, 2016	Sep CAHN
>A> AB		5MG	A205756	002	Nov 07, 2016	Sep CAHN
>A> AB		10MG	A205756	003	Nov 07, 2016	Sep CAHN
>D> AB	TEDOR PHARMA INC	2.5MG	A205756	001	Nov 07, 2016	Sep CAHN
>D> AB		5MG	A205756	002	Nov 07, 2016	Sep CAHN
>D> AB		10MG	A205756	003	Nov 07, 2016	Sep CAHN
<u>TABLET, EXTENDED RELEASE;ORAL</u>						
METADATE ER						
AB !	@ LANNETT CO INC	10MG	A040306	001	Oct 20, 1999	Mar CAHN
		20MG	A089601	001	Jun 01, 1988	Mar CAHN
METHYLINE ER						
>D> AB !	SPECGX LLC	20MG	A075629	002	May 09, 2000	Sep CHRS
>A> AB		20MG	A075629	002	May 09, 2000	Sep CHRS
AB !		20MG	A075629	002	May 09, 2000	Aug CHRS
<u>METHYLPHENIDATE HYDROCHLORIDE</u>						
AB	ACTAVIS LABS FL	54MG	A076655	001	Mar 21, 2018	Mar NEWA
AB	AMNEAL PHARMS	18MG	A207515	001	Feb 01, 2018	Jan NEWA
AB		27MG	A207515	002	Feb 01, 2018	Jan NEWA
AB		36MG	A207515	003	Feb 01, 2018	Jan NEWA
AB		54MG	A207515	004	Feb 01, 2018	Jan NEWA
AB	ANJ PHARMS INC	18MG	A208607	001	Jul 14, 2017	May CAHN
AB		27MG	A208607	002	Jul 14, 2017	May CAHN
AB		36MG	A208607	003	Jul 14, 2017	May CAHN
AB		54MG	A208607	004	Jul 14, 2017	May CAHN
AB	MOUNTAIN	18MG	A208607	001	Jul 14, 2017	Jan CAHN
AB		27MG	A208607	002	Jul 14, 2017	Jan CAHN
AB		36MG	A208607	003	Jul 14, 2017	Jan CAHN
AB		54MG	A208607	004	Jul 14, 2017	Jan CAHN
! OSMOTICA		72MG	A205327	005	Jul 28, 2017	Jan CHRS
RITALIN-SR						
+ @ NOVARTIS		20MG	N018029	001	Mar 30, 1982	Aug DISC
<u>TABLET, EXTENDED RELEASE, CHEWABLE;ORAL</u>						
QUILLICHEW ER						
+ NEXTWAVE PHARMS		20MG	N207960	001	Dec 04, 2015	Aug CAHN
+ !		30MG	N207960	002	Dec 04, 2015	Aug CAHN
+ !		40MG	N207960	003	Dec 04, 2015	Aug CAHN

METHYLPREDNISOLONETABLET;ORALMETHYLPREDNISOLONE

AB	TIANJIN TIANYAO	4MG	A204072	001	May 14, 2018	Apr NEWA
AB	ZYDUS PHARMS USA INC	4MG	A206751	001	Apr 23, 2018	Apr NEWA
AB		8MG	A206751	002	Apr 23, 2018	Apr NEWA
AB		16MG	A206751	003	Apr 23, 2018	Apr NEWA
AB		32MG	A206751	004	Apr 23, 2018	Apr NEWA

METHYLPREDNISOLONE ACETATEINJECTABLE; INJECTIONDEPO-MEDROL

AB +!	PHARMACIA AND UPJOHN	20MG/ML	N011757	002		Jun CFTG
METHYLPREDNISOLONE ACETATE						
AB	SAGENT PHARMS	20MG/ML	A201835	001	Jun 27, 2018	Jun NEWA
AB		40MG/ML	A201835	002	Jun 27, 2018	Jun NEWA
AB		80MG/ML	A201835	003	Jun 27, 2018	Jun NEWA

METOCLOPRAMIDE HYDROCHLORIDETABLET;ORALMETOCLOPRAMIDE HYDROCHLORIDE

@ YAOPHARMA CO LTD	EQ 5MG BASE	A074478	001	Oct 05, 1995	Jan CAHN
@	EQ 10MG BASE	A072215	001	Jan 30, 1990	Jan CAHN
@	EQ 10MG BASE	A074478	002	Oct 05, 1995	Jan CAHN

TABLET, ORALLY DISINTEGRATING;ORALMETOCLOPRAMIDE HYDROCHLORIDE

NOVEL LABS INC	EQ 5MG BASE	A202191	001	Aug 15, 2014	Aug CTEC
!	EQ 10MG BASE	A202191	002	Aug 15, 2014	Aug CHRS
METOZOLV ODT					
+ @ SALIX PHARMS	EQ 5MG BASE	N022246	001	Sep 04, 2009	Aug DISC

METOLAZONE

	TABLET;ORAL						
	MYKROX						
	@ LANNETT CO INC	0.5MG		N019532	001	Oct 30, 1987	Apr CAHN
	ZAROXOLYN						
AB	+ LANNETT CO INC	2.5MG		N017386	001		Mar CAHN
AB	+! LANNETT CO INC	5MG		N017386	002		Mar CAHN
AB	+! LANNETT CO INC	10MG		N017386	003		Mar CAHN

METOPROLOL SUCCINATE

	CAPSULE, EXTENDED RELEASE;ORAL						
	KAPSPARGO SPRINKLE						
	+ SPIL	EQ 25MG TARTRATE		N210428	001	Jan 26, 2018	Jun CTNA
	+ SPIL	EQ 25MG TARTRATE		N210428	001	Jan 26, 2018	Jan NEWA
	+ SPIL	EQ 50MG TARTRATE		N210428	002	Jan 26, 2018	Jun CTNA
	+ SPIL	EQ 50MG TARTRATE		N210428	002	Jan 26, 2018	Jan NEWA
	+ SPIL	EQ 100MG TARTRATE		N210428	003	Jan 26, 2018	Jun CTNA
	+ SPIL	EQ 100MG TARTRATE		N210428	003	Jan 26, 2018	Jan NEWA
	+! SPIL	EQ 200MG TARTRATE		N210428	004	Jan 26, 2018	Jun CTNA
	+! SPIL	EQ 200MG TARTRATE		N210428	004	Jan 26, 2018	Jan NEWA
	TABLET, EXTENDED RELEASE;ORAL						
	METOPROLOL SUCCINATE						
AB	ACTAVIS LABS FL INC	EQ 25MG TARTRATE		A076862	002	Aug 03, 2009	Mar CMS1
AB	NOVAST LABS	EQ 25MG TARTRATE		A204106	001	Feb 06, 2018	Jan NEWA
AB		EQ 50MG TARTRATE		A204106	002	Feb 06, 2018	Jan NEWA
AB		EQ 100MG TARTRATE		A204106	003	Feb 06, 2018	Jan NEWA
AB		EQ 200MG TARTRATE		A204106	004	Feb 06, 2018	Jan NEWA
AB	ZYDUS PHARMS USA INC	EQ 25MG TARTRATE		A203894	001	Mar 23, 2018	Mar NEWA
AB		EQ 50MG TARTRATE		A203894	002	Mar 23, 2018	Mar NEWA
AB		EQ 100MG TARTRATE		A203894	003	Mar 23, 2018	Mar NEWA
AB		EQ 200MG TARTRATE		A203894	004	Mar 23, 2018	Mar NEWA

METOPROLOL TARTRATE

	TABLET;ORAL						
	METOPROLOL TARTRATE						
	@ RENATA	50MG		A074453	001	Apr 27, 1995	Jan CAHN
	@ RENATA	100MG		A074453	002	Apr 27, 1995	Jan CAHN
	@ YAOPHARMA CO LTD	50MG		A073288	001	Mar 25, 1994	Jan CAHN
	@ YAOPHARMA CO LTD	100MG		A073289	001	Mar 25, 1994	Jan CAHN

METRONIDAZOLE

	TABLET;ORAL						
	METRONIDAZOLE						
>D> AB	APPCO PHARMA LLC	250MG		A205245	001	Sep 23, 2015	Sep CAHN
>D> AB		500MG		A205245	002	Sep 23, 2015	Sep CAHN
	@ FOSUN PHARMA	250MG		N018620	001	Mar 04, 1982	Jan CAHN
	@ FOSUN PHARMA	250MG		N018740	001	Oct 22, 1982	Jan CAHN
	@ FOSUN PHARMA	500MG		N018620	002	Jun 02, 1983	Jan CAHN
	@ FOSUN PHARMA	500MG		N018740	002	Oct 22, 1982	Jan CAHN
>A> AB	HERITAGE PHARMS INC	250MG		A205245	001	Sep 23, 2015	Sep CAHN
>A> AB		500MG		A205245	002	Sep 23, 2015	Sep CAHN
AB	STRIDES VIVIMED	250MG		A070040	001	Jan 29, 1985	Jul CAHN
	TABLET, EXTENDED RELEASE;ORAL						
	FLAGYL ER						
	+ @ GD SEARLE LLC	750MG		N020868	001	Nov 26, 1997	May DISC
	METRONIDAZOLE						
	@ ALEMBIC PHARMS LTD	750MG		A090222	001	May 05, 2010	May DISC

METYRAPONE

	CAPSULE;ORAL						
	METOPIRONE						
+!	LABORATORIE HRA	250MG		N012911	002	Aug 09, 1996	Jun CAHN
	TABLET;ORAL						
	METOPIRONE						
@	LABORATORIE HRA	250MG		N012911	001		Jun CAHN

MEXILETINE HYDROCHLORIDE

CAPSULE;ORAL

MEXITIL

+ @ BOEHRINGER INGELHEIM	150MG
+ @	200MG
+ @	250MG

N018873	002	Dec 30,	1985	Jul	CRLD
N018873	003	Dec 30,	1985	Jul	CRLD
N018873	004	Dec 30,	1985	Jul	CRLD

MICAFUNGIN SODIUM

INJECTABLE; INTRAVENOUS

MYCAMINE

+! ASTELLAS	EQ 50MG BASE/VIAL
+!	EQ 100MG BASE/VIAL

N021506	002	Mar 16,	2005	May	CDFR
N021506	003	Jun 27,	2006	May	CDFR

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HYDROCHLORIDE

@ AKORN INC	EQ 5MG BASE/ML
-------------	----------------

A075481	001	Jun 30,	2000	Aug	DISC
---------	-----	---------	------	-----	------

SOLUTION; INTRAMUSCULAR

SEIZALAM

>A>	MERIDIAN MEDCL TECHN	EQ 50MG BASE/10ML (EQ 5MG BASE/ML)	N209566	001	Sep 14,	2018	Sep	NEWA
-----	----------------------	------------------------------------	---------	-----	---------	------	-----	------

MIDODRINE HYDROCHLORIDE

TABLET;ORAL

MIDODRINE HYDROCHLORIDE

AB APOTEX INC	2.5MG
AB	5MG
AB	10MG
AB CASI PHARMS INC	2.5MG
AB	5MG
AB	10MG

A077746	001	Sep 12,	2006	Feb	CTEC
A077746	002	Sep 12,	2006	Feb	CTEC
A077746	003	Sep 12,	2006	Feb	CTEC
A076514	001	Sep 11,	2003	Mar	CAHN
A076514	002	Sep 11,	2003	Mar	CAHN
A076514	003	Jul 02,	2004	Mar	CAHN

MIGALASTAT HYDROCHLORIDE

CAPSULE;ORAL

GALAFOLD

+! AMICUS THERAPS US	EQ 123MG BASE
----------------------	---------------

N208623	001	Aug 10,	2018	Aug	NEWA
---------	-----	---------	------	-----	------

MIGLUSTAT

CAPSULE;ORAL

MIGLUSTAT

AB AMERIGEN PHARMS LTD	100MG
AB ZAVESCA	
>A> AB ACTELION PHARMS LTD	100MG

A208342	001	Apr 17,	2018	Apr	NEWA
N021348	001	Jul 31,	2003	Apr	CFTG

MILNACIPRAN HYDROCHLORIDE

TABLET;ORAL

MILNACIPRAN HYDROCHLORIDE

@ USPHARMA WINDLAS	12.5MG
@	25MG
@	50MG
@	100MG

A205071	001	Jan 27,	2016	Mar	CAHN
A205071	002	Jan 27,	2016	Mar	CAHN
A205071	003	Jan 27,	2016	Mar	CAHN
A205071	004	Jan 27,	2016	Mar	CAHN

MINOCYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION

MINOCIN

+! REMPEX PHARMS	EQ 100MG BASE/VIAL
------------------	--------------------

N050444	001				Jan CAHN
---------	-----	--	--	--	----------

TABLET, EXTENDED RELEASE;ORAL

MINOCYCLINE HYDROCHLORIDE

AB ALKEM LABS LTD	EQ 65MG BASE
AB	EQ 115MG BASE
>A> AB AUROBINDO PHARMA LTD	EQ 65MG BASE
>A> AB	EQ 115MG BASE
AB BARR LABS INC	EQ 65MG BASE
AB	EQ 115MG BASE

A204453	006	Mar 16,	2018	Mar	NEWA
A204453	007	Mar 16,	2018	Mar	NEWA
A202261	002	Sep 28,	2018	Sep	NEWA
A202261	004	Sep 28,	2018	Sep	NEWA
A065485	004	May 18,	2012	Jan	CMFD
A065485	005	May 18,	2012	Jan	CMFD

MINOLIRIA

>D> DR REDDYS LABS LTD	EQ 105MG BASE
>D>	EQ 135MG BASE
>A> EPI HLTH	EQ 105MG BASE
>A>	EQ 135MG BASE

N209269	001	May 08,	2017	Sep	CAHN
N209269	002	May 08,	2017	Sep	CAHN
N209269	001	May 08,	2017	Sep	CAHN
N209269	002	May 08,	2017	Sep	CAHN

SOLODYN

AB + MEDICIS	EQ 65MG BASE
AB +!	EQ 115MG BASE

N050808	004	Jul 23,	2009	Mar	CTEC
N050808	005	Jul 23,	2009	Mar	CTEC

MINOXIDIL

TABLET;ORAL

MINOXIDIL

AB SUN PHARM INDUSTRIES 2.5MG A072709 002 Dec 14, 1995 Jun CMS1

MIPOMERSEN SODIUM

SOLUTION;SUBCUTANEOUS

KYNAMRO

+ @ KASTLE THERAPS LLC 200MG/ML (200MG/ML) N203568 001 Jan 29, 2013 Jun DISC

MIRTAZAPINE

TABLET;ORAL

REMERON

+ @ ORGANON USA INC 45MG N020415 003 Mar 17, 1997 Jul DISC

TABLET, ORALLY DISINTEGRATING;ORAL

MIRTAZAPINE

@ ACTAVIS LABS FL INC 15MG A076307 001 Dec 17, 2003 Jun DISC

@ 30MG A076307 002 Dec 17, 2003 Jun DISC

@ 45MG A076307 003 Feb 28, 2006 Jun DISC

MITOMYCIN

INJECTABLE;INJECTION

MITOMYCIN

@ WEST-WARD PHARMS INT 5MG/VIAL A064117 001 Apr 19, 1995 May DISC

@ 20MG/VIAL A064117 002 Apr 19, 1995 May DISC

@ 40MG/VIAL A064117 003 Jun 02, 1999 May CMS1

MITOTANE

TABLET;ORAL

LYSODREN

+! LABORATOIRE HRA 500MG N016885 001 Jul CAHN

MIVACURIUM CHLORIDE

SOLUTION;INTRAVENOUS

MIVACRON

+ @ ABBVIE EQ 10MG BASE/5ML (EQ 2MG BASE/ML) N020098 004 Jan 22, 1992 Jun DISC

+ @ EQ 20MG BASE/10ML (EQ 2MG BASE/ML) N020098 005 Jan 22, 1992 Jun DISC

MODAFINIL

TABLET;ORAL

MODAFINIL

>D> AB APPCO PHARMA LLC 100MG A207196 001 Aug 16, 2017 Sep CAHN  
>D> AB 200MG A207196 002 Aug 16, 2017 Sep CAHN  
>A> AB HERITAGE PHARMS INC 100MG A207196 001 Aug 16, 2017 Sep CAHN  
>A> AB 200MG A207196 002 Aug 16, 2017 Sep CAHNMOMETASONE FUBROATE

CREAM;TOPICAL

MOMETASONE FUBROATE

>A> AB ANDA REPOSITORY 0.1% A076591 001 Apr 18, 2007 Sep CAHN  
>D> AB TOLMAR 0.1% A076591 001 Apr 18, 2007 Sep CAHN

LOTION;TOPICAL

MOMETASONE FUBROATE

>A> AB ANDA REPOSITORY 0.1% A076499 001 Nov 21, 2007 Sep CAHN  
>D> AB TOLMAR 0.1% A076499 001 Nov 21, 2007 Sep CAHN

OINTMENT;TOPICAL

MOMETASONE FUBROATE

>A> AB ANDA REPOSITORY 0.1% A076481 001 Nov 14, 2003 Sep CAHN  
>D> AB TOLMAR 0.1% A076481 001 Nov 14, 2003 Sep CAHN  
AB TORRENT PHARMS LTD 0.1% A207899 001 Jul 13, 2018 Jul NEWAMONTELUKAST SODIUM

GRANULE;ORAL

MONTELUKAST SODIUM

AB TORRENT PHARMS LLC EQ 4MG BASE/PACKET A210431 001 Jul 31, 2018 Jul NEWA

TABLET;ORAL

MONTELUKAST SODIUM

@ APOTEX CORP EQ 10MG BASE A201294 001 Aug 03, 2012 Mar DISC

## TABLET, CHEWABLE;ORAL

MONTELUKAST SODIUM

	@ APOTEX INC	EQ 4MG BASE	A201508	001	Aug 03, 2012	Mar DISC
	@	EQ 5MG BASE	A201508	002	Aug 03, 2012	Mar DISC
AB	UNICHEM LABS LTD	EQ 4MG BASE	A208621	001	Jul 02, 2018	Jun NEWA
AB		EQ 5MG BASE	A208621	002	Jul 02, 2018	Jun NEWA

MORPHINE SULFATE

## INJECTABLE;INJECTION

INFUMORPH

AP	+! WEST-WARD PHARMS INT	10MG/ML	N018565	003	Jul 19, 1991	Jul CFTG
AP	+!	25MG/ML	N018565	004	Jul 19, 1991	Jul CFTG
	MITIGO					
AP	PIRAMAL CRITICAL	10MG/ML	A204393	001	Jul 16, 2018	Jul NEWA
AP		25MG/ML	A204393	002	Jul 16, 2018	Jul NEWA

## SOLUTION;ORAL

MORPHINE SULFATE

AA	ANI PHARMS INC	10MG/5ML	A205509	001	Apr 17, 2018	Apr NEWA
AA		20MG/5ML	A205509	002	Apr 17, 2018	Apr NEWA
AA		100MG/5ML	A205509	003	Apr 17, 2018	Apr NEWA
AA	LANNETT CO INC	10MG/5ML	A202309	001	Nov 25, 2015	May CAHN
AA		20MG/5ML	A202310	001	Oct 30, 2015	May CAHN
>D>	@	100MG/5ML	N201517	001	Jun 23, 2011	Sep CMFD
>A>		100MG/5ML	N201517	001	Jun 23, 2011	Sep CMFD
	@	100MG/5ML	N201517	001	Jun 23, 2011	Aug DISC
AA	NOSTRUM LABS INC	100MG/5ML	A201011	003	Oct 06, 2016	Jul CMS1

## TABLET, EXTENDED RELEASE;ORAL

ARYMO ER

>D>	+ EGALET	15MG	N208603	001	Jan 09, 2017	Sep DISC
>A>	+ @	15MG	N208603	001	Jan 09, 2017	Sep DISC
>D>	+	30MG	N208603	002	Jan 09, 2017	Sep DISC
>A>	+ @	30MG	N208603	002	Jan 09, 2017	Sep DISC
>D>	+	60MG	N208603	003	Jan 09, 2017	Sep DISC
>A>	+ @	60MG	N208603	003	Jan 09, 2017	Sep DISC
	MORPHINE SULFATE					
>D> AB	EPIC PHARMA LLC	15MG	A091357	001	Jun 23, 2016	Sep DISC
>A>	@	15MG	A091357	001	Jun 23, 2016	Sep DISC
>D> AB		30MG	A091357	002	Jun 23, 2016	Sep DISC
>A>	@	30MG	A091357	002	Jun 23, 2016	Sep DISC
>D> AB		60MG	A091357	003	Jun 23, 2016	Sep DISC
>A>	@	60MG	A091357	003	Jun 23, 2016	Sep DISC
>D> AB		100MG	A091357	004	Jun 23, 2016	Sep DISC
>A>	@	100MG	A091357	004	Jun 23, 2016	Sep DISC
>D> AB		200MG	A091357	005	Jun 23, 2016	Sep DISC
>A>	@	200MG	A091357	005	Jun 23, 2016	Sep DISC

MOXIDECTIN

## TABLET;ORAL

MOXIDECTIN

	+! MDGH	2MG	N210867	001	Jun 13, 2018	Jun NEWA
--	---------	-----	---------	-----	--------------	----------

MOXIFLOXACIN HYDROCHLORIDE

>A>	SOLUTION;INTRAVENOUS					
>A>	AVELOX IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER					
>A>	+ @ BAYER HLTHCARE	400MG/250ML (1.6MG/ML)	N021277	001	Nov 30, 2001	Sep CDFR
>A>	MOXIFLOXACIN HYDROCHLORIDE					
>A>	+! FRESENIUS KABI USA	EQ 400MG BASE/250ML (EQ 1.6MG BASE/ML)	N205572	001	Apr 03, 2015	Sep CDFR
>A>	MOXIFLOXACIN HYDROCHLORIDE IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER					
>A>	! MYLAN LABS LTD	400MG/250ML (1.6MG/ML)	A205833	001	May 05, 2017	Sep CDFR
>D>	SOLUTION;IV (INFUSION)					
>D>	AVELOX IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER					
>D>	+ @ BAYER HLTHCARE	400MG/250ML (1.6MG/ML)	N021277	001	Nov 30, 2001	Sep CDFR
>D>	MOXIFLOXACIN HYDROCHLORIDE					
>D>	+! FRESENIUS KABI USA	EQ 400MG BASE/250ML (EQ 1.6MG BASE/ML)	N205572	001	Apr 03, 2015	Sep CDFR
>D>	MOXIFLOXACIN HYDROCHLORIDE IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER					
>D>	! MYLAN LABS LTD	400MG/250ML (1.6MG/ML)	A205833	001	May 05, 2017	Sep CDFR
	TABLET;ORAL					
	MOXIFLOXACIN HYDROCHLORIDE					
>A> AB	SUNSHINE LAKE	EQ 400MG BASE	A206295	001	Sep 28, 2018	Sep NEWA

MUPIROCIN CALCIUM

CREAM;TOPICAL						
BACTROBAN						
+ @ GLAXOSMITHKLINE	EQ 2% BASE		N 050746	001	Dec 11, 1997	Apr DISC
MUPIROCIN						
! GLENMARK PHARMS INC	EQ 2% BASE		A 201587	001	Jan 24, 2013	Apr CHRS
OINTMENT;NASAL						
BACTROBAN						
+ @ GLAXOSMITHKLINE	EQ 2% BASE		N 050703	001	Sep 18, 1995	May DISC

MYCOPHENOLATE MOFETIL

CAPSULE;ORAL						
MYCOPHENOLATE MOFETIL						
@ APOTEX CORP	250MG		A 090419	001	Apr 22, 2009	Mar DISC
TABLET;ORAL						
MYCOPHENOLATE MOFETIL						
@ APOTEX	500MG		A 090499	001	Apr 22, 2009	Mar DISC
AB OXFORD PHARMS	500MG		A 090606	001	Jul 16, 2010	Jul CAHN

NABUMETONE

TABLET;ORAL						
NABUMETONE						
AB CASI PHARMS INC	500MG		A 075280	001	Feb 25, 2002	Mar CAHN
AB	750MG		A 075280	002	Feb 25, 2002	Mar CAHN

NADOLOL

TABLET;ORAL						
NADOLOL						
AB BEXIMCO PHARMS USA	20MG		A 210955	001	Jul 23, 2018	Jul NEWA
AB	40MG		A 210955	002	Jul 23, 2018	Jul NEWA
AB	80MG		A 210955	003	Jul 23, 2018	Jul NEWA
>A> AB NOVAST LABS	20MG		A 210786	001	Jun 01, 2018	Sep CAHN
>A> AB	40MG		A 210786	002	Jun 01, 2018	Sep CAHN
>A> AB	80MG		A 210786	003	Jun 01, 2018	Sep CAHN
>D> AB RICONPHARMA LLC	20MG		A 210786	001	Jun 01, 2018	Sep CAHN
AB	20MG		A 210786	001	Jun 01, 2018	May NEWA
>D> AB	40MG		A 210786	002	Jun 01, 2018	Sep CAHN
AB	40MG		A 210786	002	Jun 01, 2018	May NEWA
>D> AB	80MG		A 210786	003	Jun 01, 2018	Sep CAHN
AB	80MG		A 210786	003	Jun 01, 2018	May NEWA

NAFTIFINE HYDROCHLORIDE

CREAM;TOPICAL						
NAFTIFINE HYDROCHLORIDE						
! TARO	1%		A 205975	001	Sep 08, 2016	Apr CHRS
! TARO PHARMS	1%		A 205975	001	Sep 08, 2016	May CAHN
AB NAFTIN	2%		A 206901	001	Jan 06, 2016	Jun CAHN
+ @ SEBELA IRELAND LTD	1%		N 019599	001	Feb 29, 1988	Apr DISC

NALOXONE HYDROCHLORIDE

SPRAY, METERED;NASAL						
NARCAN						
+ @ ADAPT	2MG/SPRAY		N 208411	002	Jan 24, 2017	Apr DISC

NALTREXONE HYDROCHLORIDE

TABLET;ORAL						
NALTREXONE HYDROCHLORIDE						
@ FOSUN PHARMA	50MG		A 075434	001	Mar 08, 2000	Jan CAHN

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC						
NAPHAZOLINE HYDROCHLORIDE						
@ AKORN INC	0.1%		A 083590	001		Jun DISC

NAPROXEN

## TABLET;ORAL

## NAPROSYN

+ @ ATNAHS PHARMA US	250MG	N 017581	002	Aug	DISC
+ @	375MG	N 017581	003	Aug	DISC
NAPROXEN					
@ FOSUN PHARMA	250MG	A 074140	001	Dec 21,	1993
@	375MG	A 074140	002	Dec 21,	1993
@	500MG	A 074140	003	Dec 21,	1993
TABLET, DELAYED RELEASE;ORAL					
NAPROXEN					
@ FOSUN PHARMA	375MG	A 075061	001	Feb 18,	1998
@	500MG	A 075061	002	Feb 18,	1998

NAPROXEN SODIUM

## TABLET;ORAL

## ANAPROX

+ @ ATNAHS PHARMA US	EQ 250MG BASE	N 018164	001	Aug	DISC
----------------------	---------------	----------	-----	-----	------

NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE

## TABLET;ORAL

## SUMATRIPTAN AND NAPROXEN SODIUM

AB AUROBINDO PHARMA LTD	500MG;EQ 85MG BASE	A 207457	001	Feb 15,	2018	Feb	NEWA
AB MYLAN PHARMS INC	500MG;EQ 85MG BASE	A 090872	001	Sep 04,	2018	Aug	NEWA
AB SUN PHARMA GLOBAL	500MG;EQ 85MG BASE	A 202803	001	Jul 20,	2018	Jul	NEWA
TREXIMET							
+ @ PERNIX IRELAND LTD	60MG;EQ 10MG BASE	N 021926	002	May 14,	2015	Jun	DISC
AB +!	500MG;EQ 85MG BASE	N 021926	001	Apr 15,	2008	Feb	CFTG

NARATRIPTAN HYDROCHLORIDE

## TABLET;ORAL

## NARATRIPTAN

@ APOTEX CORP	EQ 1MG BASE	A 091373	001	Apr 22,	2011	Mar	DISC
@	EQ 2.5MG BASE	A 091373	002	Apr 22,	2011	Mar	DISC
AB CASI PHARMS INC	EQ 1MG BASE	A 090288	001	Jul 07,	2010	Mar	CAHN
AB	EQ 2.5MG BASE	A 090288	002	Jul 07,	2010	Mar	CAHN

NATEGLINIDE

## TABLET;ORAL

## NATEGLINIDE

AB INDICUS PHARMA	60MG	A 205544	001	Jun 18,	2018	Jun	NEWA
AB	120MG	A 205544	002	Jun 18,	2018	Jun	NEWA
AB WILSHIRE PHARMS INC	60MG	A 205544	001	Jun 18,	2018	Jun	CAHN
AB	120MG	A 205544	002	Jun 18,	2018	Jun	CAHN

NEBIVOLOL HYDROCHLORIDE

## TABLET;ORAL

## BYSTOLIC

AB + ALLERGAN SALES LLC	EQ 2.5MG BASE	N 021742	002	Dec 17,	2007	Feb	CFTG
+	EQ 2.5MG BASE	N 021742	002	Dec 17,	2007	Jan	CAHN
AB +	EQ 5MG BASE	N 021742	003	Dec 17,	2007	Feb	CFTG
+	EQ 5MG BASE	N 021742	003	Dec 17,	2007	Jan	CAHN
AB +	EQ 10MG BASE	N 021742	004	Dec 17,	2007	Feb	CFTG
+	EQ 10MG BASE	N 021742	004	Dec 17,	2007	Jan	CAHN
AB +!	EQ 20MG BASE	N 021742	005	Oct 08,	2008	Feb	CFTG
+	EQ 20MG BASE	N 021742	005	Oct 08,	2008	Jan	CAHN
NEBIVOLOL HYDROCHLORIDE							
@ TORRENT PHARMS LTD	EQ 2.5MG BASE	A 203966	001	Mar 02,	2018	Mar	DISC
AB	EQ 2.5MG BASE	A 203966	001	Mar 02,	2018	Feb	NEWA
@	EQ 5MG BASE	A 203966	002	Mar 02,	2018	Mar	DISC
AB	EQ 5MG BASE	A 203966	002	Mar 02,	2018	Feb	NEWA
@	EQ 10MG BASE	A 203966	003	Mar 02,	2018	Mar	DISC
AB	EQ 10MG BASE	A 203966	003	Mar 02,	2018	Feb	NEWA
@	EQ 20MG BASE	A 203966	004	Mar 02,	2018	Mar	DISC
AB	EQ 20MG BASE	A 203966	004	Mar 02,	2018	Feb	NEWA

NEBIVOLOL HYDROCHLORIDE; VALSARTAN

TABLET;ORAL  
BYVALSON  
+! ALLERGAN SALES LLC EQ 5MG BASE;80MG N206302 001 Jun 03, 2016 Jan CAHN

NEFAZODONE HYDROCHLORIDE

TABLET;ORAL  
NEFAZODONE HYDROCHLORIDE  
@ FOSUN PHARMA 50MG A076302 001 Sep 16, 2003 Jan CAHN  
@ 100MG A076302 002 Sep 16, 2003 Jan CAHN  
@ 150MG A076302 003 Sep 16, 2003 Jan CAHN  
@ 200MG A076302 004 Sep 16, 2003 Jan CAHN  
@ 250MG A076302 005 Sep 16, 2003 Jan CAHN

NELARABINE

>A> INJECTABLE;INTRAVENOUS  
>A> ARRANON  
>A> +! NOVARTIS PHARMS CORP 250MG/50ML (5MG/ML) N021877 001 Oct 28, 2005 Sep CDFR  
>D> INJECTABLE;IV (INFUSION)  
>D> ARRANON  
>D> +! NOVARTIS PHARMS CORP 250MG/50ML (5MG/ML) N021877 001 Oct 28, 2005 Sep CDFR

NEOSTIGMINE METHYLSULFATE

SOLUTION;INTRAVENOUS  
BLOXIVERZ  
AP +! AVADEL LEGACY 5MG/10ML (0.5MG/ML) N204078 001 May 31, 2013 Feb CAHN  
AP +! 10MG/10ML (1MG/ML) N204078 002 May 31, 2013 Feb CAHN  
NEOSTIGMINE METHYLSULFATE  
AP AMNEAL PHARMS CO 5MG/10ML (0.5MG/ML) A210051 001 Jun 15, 2018 Jun NEWA  
AP 10MG/10ML (1MG/ML) A210051 002 Jun 15, 2018 Jun NEWA  
AP DR REDDYS LABS LTD 5MG/10ML (0.5MG/ML) A209135 001 Jul 10, 2018 Jun NEWA  
AP 10MG/10ML (1MG/ML) A209135 002 Jul 10, 2018 Jun NEWA  
AP LUITPOLD 5MG/10ML (0.5MG/ML) A209182 001 May 04, 2018 Apr NEWA  
AP 10MG/10ML (1MG/ML) A209182 002 May 04, 2018 Apr NEWA  
AP RENAISSANCE SSA LLC 5MG/10ML (0.5MG/ML) A210989 001 Aug 22, 2018 Aug NEWA  
AP 10MG/10ML (1MG/ML) A210989 002 Aug 22, 2018 Aug NEWA  
>A> NEOSTIGMINE METHYLSULFATE PFS  
>A> FRESENIUS KABI USA 3MG/3ML (1MG/ML) N203629 003 Sep 18, 2018 Sep NEWA

NEVIRAPINE

TABLET;ORAL  
NEVIRAPINE  
@ APOTEX INC 200MG A203021 001 May 22, 2012 Mar DISC  
TABLET, EXTENDED RELEASE;ORAL  
NEVIRAPINE  
@ APOTEX INC 400MG A205258 001 Apr 03, 2014 Jan DISC

NIACIN

TABLET, EXTENDED RELEASE;ORAL  
NIACIN  
AB AUROBINDO PHARMA LTD 500MG A209236 001 Feb 01, 2018 Jan NEWA  
AB 750MG A209236 002 Feb 01, 2018 Jan NEWA  
AB 1GM A209236 003 Feb 01, 2018 Jan NEWA  
AB JUBILANT GENERICS 500MG A209156 001 May 14, 2018 Apr NEWA  
AB 750MG A209156 002 May 14, 2018 Apr NEWA  
AB 1GM A209156 003 May 14, 2018 Apr NEWA

NICARDIPINE HYDROCHLORIDE

INJECTABLE;INJECTION  
CARDENE  
+ @ CHIESI USA INC 25MG/10ML (2.5MG/ML) N019734 001 Jan 30, 1992 May DISC  
NICARDIPINE HYDROCHLORIDE  
EXELA PHARMA SCIENCE 25MG/10ML (2.5MG/ML) N022276 001 Jul 24, 2008 May CTEC  
@ LUITPOLD 25MG/10ML (2.5MG/ML) A090534 001 Nov 17, 2009 May DISC  
@ MYLAN INSTITUTIONAL 25MG/10ML (2.5MG/ML) A090664 001 Nov 17, 2009 May DISC  
@ NAVINTA LLC 25MG/10ML (2.5MG/ML) A090125 001 Nov 17, 2009 May DISC  
@ SUN PHARMA GLOBAL 25MG/10ML (2.5MG/ML) N078405 001 Nov 17, 2009 May DISC  
@ WEST-WARD PHARMS INT 25MG/10ML (2.5MG/ML) A078714 001 Dec 28, 2009 May DISC  
@ WOCKHARDT 25MG/10ML (2.5MG/ML) A090671 001 Nov 17, 2009 May DISC

INJECTABLE; INTRAVENOUS

CARDENE IN 5.0% DEXTROSE IN PLASTIC CONTAINER  
 + @ CHIESI USA INC 40MG/200ML (0.2MG/ML)

N019734 005 Nov 07, 2008 Mar DISC

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

NIFEDIPINE

AB1	ZYDUS PHARMS USA INC	30MG	A210184	001	Jun 29, 2018	Jun NEWA
AB1		60MG	A210184	002	Jun 29, 2018	Jun NEWA
AB1		90MG	A210184	003	Jun 29, 2018	Jun NEWA

NILOTINIB HYDROCHLORIDE

CAPSULE; ORAL

TASIGNA

+ NOVARTIS	EQ 50MG BASE	N022068	003	Mar 22, 2018	Jun CAIN
+ NOVARTIS	EQ 150MG BASE	N022068	002	Jun 17, 2010	Jun CAIN
+! NOVARTIS	EQ 200MG BASE	N022068	001	Oct 29, 2007	Jun CAIN

NILOTINIB HYDROCHLORIDE MONOHYDRATE

CAPSULE; ORAL

TASIGNA

+ NOVARTIS	EQ 50MG BASE	N022068	003	Mar 22, 2018	Mar NEWA
------------	--------------	---------	-----	--------------	----------

NITRIC OXIDE

GAS; INHALATION

INOMAX

>D>	+! MALLINCKRODT HOSP	800PPM	N020845	003	Dec 23, 1999	Sep CFTG
>A> AA	+!	800PPM	N020845	003	Dec 23, 1999	Sep CFTG
>A>	NOXIVENT					
>A>	PRAXAIR DISTRIBUTION	100PPM	A207141	001	Oct 02, 2018	Sep NEWA
>A> AA		800PPM	A207141	002	Oct 02, 2018	Sep NEWA

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN

AB	NOVEL LABS INC	50MG	A203233	001	Jul 09, 2018	Jun NEWA
AB		100MG	A203233	002	Jul 09, 2018	Jun NEWA

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS)

AB	SUNNY PHARMTECH INC	75MG;25MG	A208516	001	May 24, 2018	May NEWA
----	---------------------	-----------	---------	-----	--------------	----------

NITROGLYCERIN

INJECTABLE; INJECTION

NITROGLYCERIN IN DEXTROSE 5%

@ HOSPIRA	10MG/100ML	A071846	001	Aug 31, 1990	Jun DISC
@	20MG/100ML	A071847	001	Aug 31, 1990	Jun DISC
@	40MG/100ML	A071848	001	Aug 31, 1990	Jun DISC

OINTMENT; INTRA-ANAL

RECTIV

+! ALLERGAN SALES LLC	0.4%	N021359	001	Jun 21, 2011	Jan CAHN
-----------------------	------	---------	-----	--------------	----------

TABLET; SUBLINGUAL

NITROGLYCERIN

AB	GLENMARK PHARMS SA	0.3MG	A206391	001	Sep 19, 2017	Jan CAHN
AB		0.4MG	A206391	002	Sep 19, 2017	Jan CAHN
AB		0.6MG	A206391	003	Sep 19, 2017	Jan CAHN
AB	SIGMAPHARM LABS LLC	0.3MG	A207745	001	May 07, 2018	Apr NEWA
AB		0.4MG	A207745	002	May 07, 2018	Apr NEWA
AB		0.6MG	A207745	003	May 07, 2018	Apr NEWA

NOREPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

NOREPINEPHRINE BITARTRATE

>A> AP	MYLAN LABS LTD	EQ 1MG BASE/ML	A211242	001	Oct 04, 2018	Sep NEWA
--------	----------------	----------------	---------	-----	--------------	----------

NORETHINDRONE ACETATE

TABLET;ORAL  
AYGESTIN  
+ @ DURAMED RES 5MG N018405 001 Apr 21, 1982 May DISC  
NORETHINDRONE ACETATE  
AB ! BARR 5MG A075951 001 May 25, 2001 May CHRS

NORGESTREL

TABLET;ORAL  
OPILL  
+ LABORATOIRE HRA 0.075MG N017031 001 Aug CMFD

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE;ORAL  
NORTRIPTYLINE HYDROCHLORIDE  
AB MAYNE PHARMA EQ 10MG BASE A073556 002 Mar 30, 1992 Mar CMS1  
AB EQ 25MG BASE A073556 003 Mar 30, 1992 Mar CMS1  
AB EQ 50MG BASE A073556 004 Mar 30, 1992 Mar CMS1

NYSTATIN

OINTMENT;TOPICAL  
NYSTATIN  
@ G AND W LABS INC 100,000 UNITS/GM A209114 001 Oct 06, 2017 Jan DISC  
AT LYNE 100,000 UNITS/GM A209082 001 May 21, 2018 May NEWA  
AT ZYDUS PHARMS USA INC 100,000 UNITS/GM A207767 001 May 25, 2018 May NEWA  
POWDER;TOPICAL  
NYSTATIN  
AT EPIC PHARMA LLC 100,000 UNITS/GM A210532 001 Apr 30, 2018 Apr NEWA  
SUSPENSION;ORAL  
NYSTATIN  
@ G AND W LABS INC 100,000 UNITS/ML A062349 001 Jul 14, 1982 Jan DISC  
AA LANNETT CO INC 100,000 UNITS/ML A065148 001 Jun 28, 2005 May CAHN  
@ SOCORRO 100,000 UNITS/ML A062832 001 Dec 27, 1991 Jun CAHN  
TABLET;VAGINAL  
NYSTATIN  
@ ODYSSEY PHARMS 100,000 UNITS A062615 001 Oct 17, 1985 Jun DISC

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM;TOPICAL  
NYSTATIN AND TRIAMCINOLONE ACETONIDE  
AT AMNEAL PHARMS LLC 100,000 UNITS/GM;0.1% A209990 001 Feb 15, 2018 Feb NEWA  
AT LUPIN LTD 100,000 UNITS/GM;0.1% A208205 001 May 31, 2018 May NEWA  
OINTMENT;TOPICAL  
NYSTATIN AND TRIAMCINOLONE ACETONIDE  
>D> AT RICONPHARMA LLC 100,000 UNITS/GM;0.1% A206785 001 Dec 29, 2016 Sep CAHN  
>A> AT RISING PHARMS 100,000 UNITS/GM;0.1% A206785 001 Dec 29, 2016 Sep CAHN  
AT STRIDES PHARMA 100,000 UNITS/GM;0.1% A210077 001 Jan 29, 2018 Jan NEWA

OCTREOTIDE ACETATE

INJECTABLE;INJECTION  
OCTREOTIDE ACETATE  
AP USV NORTH AMERICA EQ 0.2MG BASE/ML A203765 001 Sep 07, 2018 Aug NEWA  
AP EQ 1MG BASE/ML A203765 002 Sep 07, 2018 Aug NEWA

OLANZAPINE

TABLET;ORAL  
OLANZAPINE  
>A> AB JIANGSU HANSOH PHARM 2.5MG A209399 001 Sep 24, 2018 Sep NEWA  
>A> AB 5MG A209399 002 Sep 24, 2018 Sep NEWA  
>A> AB 10MG A209399 003 Sep 24, 2018 Sep NEWA  
AB ZYDUS PHARMS USA INC 2.5MG A090459 001 Jul 16, 2018 Jul NEWA  
AB 5MG A090459 002 Jul 16, 2018 Jul NEWA  
AB 7.5MG A090459 003 Jul 16, 2018 Jul NEWA  
AB 10MG A090459 004 Jul 16, 2018 Jul NEWA  
AB 15MG A090459 005 Jul 16, 2018 Jul NEWA  
AB 20MG A090459 006 Jul 16, 2018 Jul NEWA  
TABLET, ORALLY DISINTEGRATING;ORAL  
OLANZAPINE  
AB HEC PHARM 5MG A208146 001 Jul 02, 2018 Jul CAHN  
AB 10MG A208146 002 Jul 02, 2018 Jul CAHN  
AB 15MG A208146 003 Jul 02, 2018 Jul CAHN

**TABLET, ORALLY DISINTEGRATING;ORAL  
OLANZAPINE**

AB		20MG	A208146	004	Jul 02, 2018	Jul CAHN
AB	HEC PHARM CO LTD	5MG	A208146	001	Jul 02, 2018	Jun NEWA
AB		10MG	A208146	002	Jul 02, 2018	Jun NEWA
AB		15MG	A208146	003	Jul 02, 2018	Jun NEWA
AB		20MG	A208146	004	Jul 02, 2018	Jun NEWA

**OLMESARTAN MEDOXOMIL**

TABLET;ORAL  
**OLMESARTAN MEDOXOMIL**

AB	SCIEGEN PHARMS INC	5MG	A208130	001	Jun 29, 2018	Jun NEWA
AB		20MG	A208130	002	Jun 29, 2018	Jun NEWA
AB		40MG	A208130	003	Jun 29, 2018	Jun NEWA

**OLOPATADINE HYDROCHLORIDE**

SOLUTION/DROPS;OPHTHALMIC  
**OLOPATADINE HYDROCHLORIDE**

AT	MICRO LABS LTD INDIA	EQ 0.1% BASE	A204392	001	Mar 21, 2018	Mar NEWA
AT	MYLAN PHARMS INC	EQ 0.1% BASE	A204392	001	Mar 21, 2018	May CAHN

**OMEGA-3-CARBOXYLIC ACIDS**

CAPSULE;ORAL  
EPANOVA

+ @ ASTRAZENECA PHARMS	1GM CONTAINS AT LEAST 850MG OF POLYUNSATURATED FATTY ACIDS	N205060	001	May 05, 2014	Jun DISC
------------------------	--	---------	-----	--------------	----------

**OMEPRAZOLE**

CAPSULE, DELAYED REL PELLETS;ORAL  
**OMEPRAZOLE**

AB	MYLAN PHARMS INC	10MG	A205070	001	Jun 29, 2018	Jun NEWA
AB		20MG	A205070	002	Jun 29, 2018	Jun NEWA
AB		40MG	A205070	003	Jun 29, 2018	Jun NEWA

**OMEPRAZOLE; SODIUM BICARBONATE**

CAPSULE;ORAL  
**OMEPRAZOLE AND SODIUM BICARBONATE**

AB	ZYDUS PHARMS USA INC	20MG;1.1GM	A203290	001	May 25, 2018	May NEWA
AB		40MG;1.1GM	A203290	002	May 25, 2018	May NEWA

**ONDANSETRON**

TABLET, ORALLY DISINTEGRATING;ORAL  
**ONDANSETRON**

@ CHARTWELL MOLECULES	4MG	A077406	003	Dec 26, 2006	Mar CMS1
@	8MG	A077406	004	Dec 26, 2006	Mar CMS1

**ONDANSETRON HYDROCHLORIDE**

TABLET;ORAL  
**ONDANSETRON HYDROCHLORIDE**

AB	CASI PHARMS INC	EQ 4MG BASE	A077517	001	Jun 25, 2007	Mar CAHN
AB		EQ 8MG BASE	A077517	002	Jun 25, 2007	Mar CAHN
AB		EQ 24MG BASE	A077517	003	Jun 25, 2007	Mar CAHN

**ORITAVANCIN DIPHOSPHATE**

>A>	POWDER;INTRAVENOUS					
>A>	ORBACTIV					
>A>	+! MELINTA THERAP	EQ 400MG BASE/VIAL	N206334	001	Aug 06, 2014	Sep CDFR
	POWDER;IV (INFUSION)					
	ORBACTIV					
>D>	+! MELINTA	EQ 400MG BASE/VIAL	N206334	001	Aug 06, 2014	Jan CAHN
>D>	+! MELINTA THERAP	EQ 400MG BASE/VIAL	N206334	001	Aug 06, 2014	Sep CDFR
	+!	EQ 400MG BASE/VIAL	N206334	001	Aug 06, 2014	Mar CAHN

**ORPHENADRINE CITRATE**

TABLET, EXTENDED RELEASE;ORAL  
**ORPHENADRINE CITRATE**

>A> AB	ANDA REPOSITORY	100MG	A040249	001	Jan 29, 1999	Sep CAHN
>D> AB	TEDOR PHARMA INC	100MG	A040249	001	Jan 29, 1999	Sep CAHN

OSELTAMIVIR PHOSPHATE

	CAPSULE;ORAL						
	OSELTAMIVIR PHOSPHATE						
AB	HETERO LABS LTD III	EQ 30MG BASE		A209438	001	Feb 23, 2018	Feb NEWA
AB		EQ 45MG BASE		A209438	002	Feb 23, 2018	Feb NEWA
AB		EQ 75MG BASE		A209438	003	Feb 23, 2018	Feb NEWA
AB	STRIDES PHARMA	EQ 30MG BASE		A209421	001	Jun 08, 2018	May NEWA
AB		EQ 45MG BASE		A209421	002	Jun 08, 2018	May NEWA
AB		EQ 75MG BASE		A209421	003	Jun 08, 2018	May NEWA
	FOR SUSPENSION;ORAL						
	OSELTAMIVIR PHOSPHATE						
AB	AMNEAL PHARMS NY	EQ 6MG BASE/ML		A210186	001	Feb 27, 2018	Aug NEWA
AB	LUPIN ATLANTIS	EQ 6MG BASE/ML		A208347	001	Feb 20, 2018	Feb NEWA

OXACILLIN SODIUM

	INJECTABLE;INJECTION						
	OXACILLIN SODIUM						
AP	! SAGENT PHARMS	EQ 1GM BASE/VIAL		A091246	001	Mar 30, 2012	Jun CHRS
AP	!	EQ 2GM BASE/VIAL		A091246	002	Mar 30, 2012	Jun CHRS
AP	!	EQ 10GM BASE/VIAL		A091245	001	Mar 30, 2012	Jun CHRS
	@ SANDOZ	EQ 1GM BASE/VIAL		A061490	003		May DISC
	@	EQ 2GM BASE/VIAL		A061490	004		May DISC
	@	EQ 10GM BASE/VIAL		A061490	006	May 09, 1991	May DISC
	POWDER;INTRAVENOUS						
	OXACILLIN SODIUM						
	@ SANDOZ	EQ 1GM BASE/VIAL		A062737	001	Dec 23, 1986	May DISC
	@	EQ 2GM BASE/VIAL		A062737	002	Dec 23, 1986	May DISC

OXALIPLATIN

	INJECTABLE;IV (INFUSION)						
	OXALIPLATIN						
AP	ACTAVIS LLC	50MG/10ML (5MG/ML)		A204880	001	Mar 05, 2018	Feb NEWA
AP		100MG/20ML (5MG/ML)		A204880	002	Mar 05, 2018	Feb NEWA
AP	EUGIA PHARMA	50MG/10ML (5MG/ML)		A205529	001	Sep 06, 2017	Apr CAHN
AP		100MG/20ML (5MG/ML)		A205529	002	Sep 06, 2017	Apr CAHN

OXANDROLONE

	TABLET;ORAL						
>D>	OXANDRIN						
>D> AB	+ GEMINI LABS LLC	2.5MG		N013718	001		Sep DISC
>A>	+ @	2.5MG		N013718	001		Sep DISC
>D> AB	+!	10MG		N013718	002	Nov 05, 2001	Sep DISC
>A>	+ @	10MG		N013718	002	Nov 05, 2001	Sep DISC
	OXANDROLONE						
>D> AB	PAR PHARM	10MG		A077827	002	Jun 22, 2007	Sep CHRS
>A> AB	!	10MG		A077827	002	Jun 22, 2007	Sep CHRS

OXICONAZOLE NITRATE

	CREAM;TOPICAL						
	OXICONAZOLE NITRATE						
AB	TARO PHARMS	EQ 1% BASE		A205076	001	Mar 07, 2016	May CAHN

OXTRIPHYLLINE

	TABLET, EXTENDED RELEASE;ORAL						
	CHOLEDYL SA						
	@ WARNER CHILCOTT LLC	400MG		A087863	001	May 24, 1983	Aug DISC

OXYBUTYNIN CHLORIDE

	GEL;TRANSDERMAL						
	GELNIQUE						
AB	+! ALLERGAN SALES LLC	10% (100MG/PACKET)		N022204	001	Jan 27, 2009	May CFTG
	OXYBUTYNIN CHLORIDE						
AB	PAR PHARM INC	10% (100MG/PACKET)		A207329	001	May 31, 2018	May NEWA
	SYRUP;ORAL						
	OXYBUTYNIN CHLORIDE						
AA	LANNETT CO INC	5MG/5ML		A076682	001	Dec 28, 2004	May CAHN
	TABLET;ORAL						
	OXYBUTYNIN CHLORIDE						
AB	TULEX PHARMS INC	5MG		A210125	001	Sep 06, 2018	Aug NEWA

TABLET, EXTENDED RELEASE;ORAL  
DITROPAN XL

AB	+ JANSSEN PHARMS	5MG	N 020897	001	Dec 16, 1998	Jun CMFD
	+ @	5MG	N 020897	001	Dec 16, 1998	Feb DISC
AB	+ @	10MG	N 020897	002	Dec 16, 1998	Jun CMFD
	OXYBUTYNIN CHLORIDE	10MG	N 020897	002	Dec 16, 1998	Feb DISC
AB	! MYLAN PHARMS INC	15MG	A 076644	002	May 10, 2007	Feb CHRS

OXYCODONE HYDROCHLORIDE

## CAPSULE;ORAL

## OXYCODONE HYDROCHLORIDE

AB	+! GENUS LIFESCIENCES	5MG	N 200534	001	Oct 20, 2010	Apr CAHN
----	-----------------------	-----	----------	-----	--------------	----------

## SOLUTION;ORAL

## OXYCODONE HYDROCHLORIDE

AA	+ GENUS LIFESCIENCES	5MG/5ML	N 200535	002	Aug 22, 2013	Apr CAHN
----	----------------------	---------	----------	-----	--------------	----------

AA	+!	100MG/5ML	N 200535	001	Oct 20, 2010	Apr CAHN
----	----	-----------	----------	-----	--------------	----------

AA	SPECGX LLC	5MG/5ML	A 210758	001	Apr 30, 2018	Apr NEWA
----	------------	---------	----------	-----	--------------	----------

AA		100MG/5ML	A 210758	002	Apr 30, 2018	Apr NEWA
----	--	-----------	----------	-----	--------------	----------

## TABLET;ORAL

## OXYCODONE HYDROCHLORIDE

>D> AB	KEN LIFESCIENCE	5MG	A 207119	001	Apr 12, 2016	Sep CAHN
>D> AB		10MG	A 207119	002	Apr 12, 2016	Sep CAHN
>D> AB		15MG	A 207119	003	Apr 12, 2016	Sep CAHN
>D> AB		20MG	A 207119	004	Apr 12, 2016	Sep CAHN
>D> AB		30MG	A 207119	005	Apr 12, 2016	Sep CAHN
>A> AB	NUVO PHARM	5MG	A 207119	001	Apr 12, 2016	Sep CAHN
>A> AB		10MG	A 207119	002	Apr 12, 2016	Sep CAHN
>A> AB		15MG	A 207119	003	Apr 12, 2016	Sep CAHN
>A> AB		20MG	A 207119	004	Apr 12, 2016	Sep CAHN
>A> AB		30MG	A 207119	005	Apr 12, 2016	Sep CAHN

OXYMORPHONE HYDROCHLORIDE

## TABLET;ORAL

## OXYMORPHONE HYDROCHLORIDE

AB	ASCENT PHARMS INC	5MG	A 210175	001	Feb 02, 2018	Jan NEWA
AB		10MG	A 210175	002	Feb 02, 2018	Jan NEWA

## TABLET, EXTENDED RELEASE;ORAL

## OXYMORPHONE HYDROCHLORIDE

! IMPAX LABS	40MG	A 079087	007	Jun 14, 2010	Jun CHRS
--------------	------	----------	-----	--------------	----------

OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE

## OINTMENT;OPHTHALMIC

## TERRAMYCIN W/ POLYMYXIN B SULFATE

@ CASPER PHARMA LLC	EQ 5MG BASE/GM;10,000 UNITS/GM	N 061015	001	Jul DISC
!	EQ 5MG BASE/GM;10,000 UNITS/GM	N 061015	001	Feb CMS2

OXYTOCIN

## INJECTABLE;INJECTION

## OXYTOCIN

AP	SAGENT PHARMS	10USP UNITS/ML (10USP UNITS/ML)	A 091676	001	Jul 13, 2018	Jul NEWA
AP		100USP UNITS/10ML (10USP UNITS/ML)	A 091676	002	Jul 13, 2018	Jul NEWA

PACLITAXEL

## INJECTABLE;INJECTION

## PACLITAXEL

AP	ACCORD HLTHCARE	6MG/ML	A 205720	001	Aug 17, 2018	Aug NEWA
----	-----------------	--------	----------	-----	--------------	----------

PALIPIERIDONE

## TABLET, EXTENDED RELEASE;ORAL

## PALIPIERIDONE

AB	SUN PHARMA GLOBAL	1.5mg	A 205618	001	Apr 06, 2018	Mar NEWA
AB		3MG	A 205618	002	Apr 06, 2018	Mar NEWA
AB		6MG	A 205618	003	Apr 06, 2018	Mar NEWA
AB		9MG	A 205618	004	Apr 06, 2018	Mar NEWA

PALONOSETRON HYDROCHLORIDE

INJECTABLE; INTRAVENOUS

PALONOSETRON HYDROCHLORIDE

>A>	AP	CIPPLA LTD	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A206396	001	Sep 19, 2018	Sep NEWA
>A>	AP	FRESENIUS KABI USA	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A206801	001	Sep 19, 2018	Sep NEWA
>A>	AP		EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A206802	001	Sep 19, 2018	Sep NEWA
>A>	AP	HOSPIRA INC	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A207005	001	Sep 19, 2018	Sep NEWA
>A>	AP		EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)	A207005	002	Sep 19, 2018	Sep NEWA
>A>	AP	MYLAN INSTITUTIONAL	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A206416	001	Sep 19, 2018	Sep NEWA
>A>	AP	QILU PHARM CO LTD	EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)	A205648	002	Sep 19, 2018	Sep NEWA
>A>	AP		EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A205648	001	Sep 19, 2018	Sep NEWA
>A>	AP	SAGENT PHARMS	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A204289	001	Sep 19, 2018	Sep NEWA
>A>	AP		EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A205870	001	Sep 19, 2018	Sep NEWA
AP	TEVA PHARMS USA		EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)	A090713	002	Mar 23, 2018	Mar NEWA
AP			EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A090713	001	Mar 23, 2018	Mar NEWA
>A>	AP	VIRTUS PHARM	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	A209287	001	Sep 19, 2018	Sep NEWA

PANCRELIPIASE (AMYLASE;LIPASE;PROTEASE)

CAPSULE, DELAYED RELEASE; ORAL

PANCREAZE

+	JANSSEN PHARMS	24,600USP UNITS; 4,200USP UNITS; 14,200USP UNITS	N022523	001	Apr 12, 2010	Mar CPOT
+		61,500USP UNITS; 10,500USP UNITS; 35,500USP UNITS	N022523	002	Apr 12, 2010	Mar CPOT
+		83,900USP UNITS; 21,000USP UNITS; 54,700USP UNITS	N022523	004	Apr 12, 2010	Mar CPOT
+!		98,400USP UNITS; 16,800USP UNITS; 56,800USP UNITS	N022523	003	Apr 12, 2010	Mar CPOT
+	VIVUS INC	10,850USP UNITS; 2,600USP UNITS; 6,200USP UNITS	N022523	005	Mar 07, 2014	Jun CAHN
+		24,600USP UNITS; 4,200USP UNITS; 14,200USP UNITS	N022523	001	Apr 12, 2010	Jun CAHN
+		61,500USP UNITS; 10,500USP UNITS; 35,500USP UNITS	N022523	002	Apr 12, 2010	Jun CAHN
+		83,900USP UNITS; 21,000USP UNITS; 54,700USP UNITS	N022523	004	Apr 12, 2010	Jun CAHN
+!		98,400USP UNITS; 16,800USP UNITS; 56,800USP UNITS	N022523	003	Apr 12, 2010	Jun CAHN

PANTOPRAZOLE SODIUM

FOR SUSPENSION, DELAYED RELEASE; ORAL

PROTONIX

+!	WYETH PHARMS	EQ 40MG BASE	N022020	001	Nov 14, 2007	Jul CAHN
<u>INJECTABLE; IV (INFUSION)</u>						
PANTOPRAZOLE SODIUM						
AP	MYLAN LABS LTD	EQ 40MG BASE/VIAL	A208580	001	May 04, 2018	Apr NEWA
AP	PROTONIX IV					
AP	+! WYETH PHARMS	EQ 40MG BASE/VIAL	N020988	001	Mar 22, 2001	Jul CAHN
<u>TABLET, DELAYED RELEASE; ORAL</u>						
PANTOPRAZOLE SODIUM						
@	SUN PHARM INDs LTD	EQ 20MG BASE	A200794	001	May 02, 2012	Apr DISC
@		EQ 40MG BASE	A200794	002	May 02, 2012	Apr DISC
PROTONIX						
AB	+ WYETH PHARMS	EQ 20MG BASE	N020987	002	Jun 12, 2001	Jul CAHN
AB	+!	EQ 40MG BASE	N020987	001	Feb 02, 2000	Jul CAHN

PARICALCITOL

CAPSULE; ORAL

PARICALCITOL

AB	LOTUS PHARM CO LTD	1MCG	A206710	001	Feb 24, 2016	Jun CAHN
AB		2MCG	A206710	002	Feb 24, 2016	Jun CAHN
AB		4MCG	A206710	003	Feb 24, 2016	Jun CAHN

**SOLUTION; INTRAVENOUS  
PARICALCITOL**

>A> AP	AUROBINDO PHARMA LTD	0.002MG/ML (0.002MG/ML)	A205982	001	Oct 09, 2018	Sep NEWA
>A> AP		0.005MG/ML (0.005MG/ML)	A205982	002	Oct 09, 2018	Sep NEWA
>A> AP		0.01MG/2ML (0.005MG/ML)	A205982	003	Oct 09, 2018	Sep NEWA

**PAROXETINE HYDROCHLORIDE**

TABLET, EXTENDED RELEASE; ORAL  
PAROXETINE HYDROCHLORIDE

AB	SCIECURE PHARMA INC	EQ 12.5MG BASE	A209293	001	Jun 12, 2018	May NEWA
AB		EQ 25MG BASE	A209293	002	Jun 12, 2018	May NEWA
AB		EQ 37.5MG BASE	A209293	003	Jun 12, 2018	May NEWA

**PASIREOTIDE FAMOATE**

FOR SUSPENSION; INTRAMUSCULAR  
SIGNIFOR LAR KIT

+ NOVARTIS PHARMS CORP	EQ 10MG BASE/VIAL	N203255	004	Jun 29, 2018	Jun NEWA
+ NOVARTIS PHARMS CORP	EQ 20MG BASE/VIAL	N203255	001	Dec 15, 2014	Jun CDFR
+ NOVARTIS PHARMS CORP	EQ 30MG BASE/VIAL	N203255	005	Jun 29, 2018	Jun NEWA
+ NOVARTIS PHARMS CORP	EQ 40MG BASE/VIAL	N203255	002	Dec 15, 2014	Jun CDFR
+ NOVARTIS PHARMS CORP	EQ 60MG BASE/VIAL	N203255	003	Dec 15, 2014	Jun CDFR

POWDER; INTRAMUSCULAR  
SIGNIFOR LAR KIT

+ NOVARTIS PHARMS CORP	EQ 20MG BASE/VIAL	N203255	001	Dec 15, 2014	Jun CTNA
+ NOVARTIS PHARMS CORP	EQ 40MG BASE/VIAL	N203255	002	Dec 15, 2014	Jun CTNA
+ NOVARTIS PHARMS CORP	EQ 60MG BASE/VIAL	N203255	003	Dec 15, 2014	Jun CTNA

**PATISIRAN SODIUM**

SOLUTION; INTRAVENOUS  
ONPATRO

+! ALNYLAM PHARMS INC	EQ 10MG BASE/5ML (EQ 2MG BASE/ML)	N210922	001	Aug 10, 2018	Aug NEWA
-----------------------	-----------------------------------	---------	-----	--------------	----------

**PEGADEMASE BOVINE**

INJECTABLE; INJECTION  
ADAGEN

+! LEADANT BIOSCI INC	250 UNITS/ML	N019818	001	Mar 21, 1990	Jun CAHN
-----------------------	--------------	---------	-----	--------------	----------

**PEMETREXED DISODIUM**

POWDER; INTRAVENOUS  
ALIMTA

+! LILLY	EQ 100MG BASE/VIAL	N021462	002	Sep 07, 2007	Jun CDFR
+! LILLY	EQ 500MG BASE/VIAL	N021462	001	Feb 04, 2004	Jun CDFR

**PEMOLINE**

TABLET; ORAL  
PEMOLINE

@ FOSUN PHARMA	18.75MG	A075286	001	Dec 27, 1999	Jan CAHN
@ FOSUN PHARMA	37.5MG	A075286	002	Jun 30, 1999	Jan CAHN
@ FOSUN PHARMA	75MG	A075286	003	Jun 30, 1999	Jan CAHN

**PENICILLIN G BENZATHINE**

INJECTABLE; INJECTION  
BICILLIN L-A

+ @ KING PHARMS LLC	300,000 UNITS/ML	N050141	003		Jun DISC
@ CASPER PHARMA LLC	600,000 UNITS/ML	N060014	001		Jul DISC
@ CASPER PHARMA LLC	600,000 UNITS/ML	N060014	001		Feb CMS2

BC

**PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE**

INJECTABLE; INJECTION  
BICILLIN C-R

+ @ KING PHARMS LLC	150,000 UNITS/ML; 150,000 UNITS/ML	N050138	002		Jun DISC
---------------------	------------------------------------	---------	-----	--	----------

**PENTAZOCINE LACTATE**

INJECTABLE; INJECTION  
TALWIN

+ @ HOSPIRA	EQ 30MG BASE/ML	N016194	001		Jun DISC
-------------	-----------------	---------	-----	--	----------

PERAMIVIR

SOLUTION; INTRAVENOUS  
RAPIVAB  
+! BIOCRYST 200MG/20ML (10MG/ML) N206426 001 Dec 19, 2014 Jun CDFR

PERINDOPRIL ERBUMINE

TABLET; ORAL  
PERINDOPRIL ERBUMINE  
@ APOTEX 2MG A090463 001 Aug 30, 2010 Jan DISC  
@ 4MG A090463 002 Aug 30, 2010 Jan DISC  
@ 8MG A090463 003 Aug 30, 2010 Jan DISC  
AB AUROBINDO PHARMA 2MG A079070 001 Nov 10, 2009 Mar CHRS  
AB 4MG A079070 002 Nov 10, 2009 Mar CHRS

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL  
PHENDIMETRAZINE TARTRATE  
@ VIRTUS PHARMS 35MG A085695 001 May CAHN  
CAPSULE, EXTENDED RELEASE; ORAL  
PHENDIMETRAZINE TARTRATE  
@ VIRTUS PHARMS 105MG A087378 001 May CAHN  
+! 105MG N018074 001 Mar CAHN  
TABLET; ORAL  
PHENDIMETRAZINE TARTRATE  
@ VIRTUS PHARMS 35MG A085497 001 May CAHN  
AA 35MG A085588 001 Mar CAHN  
@ 35MG A086365 001 May CAHN

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL  
PHENTERMINE HYDROCHLORIDE  
@ ELITE LABS INC 15MG A040460 001 Jan 14, 2003 Jan CAHN  
>D> AA KEN LIFESCIENCE 15MG A205019 001 Dec 05, 2014 Sep CAHN  
>D> AA 30MG A205019 002 Dec 05, 2014 Sep CAHN  
>D> AA 37.5MG A205017 001 Sep 25, 2014 Sep CAHN  
>A> AA NUVO PHARM 15MG A205019 001 Dec 05, 2014 Sep CAHN  
>A> AA 30MG A205019 002 Dec 05, 2014 Sep CAHN  
>A> AA 37.5MG A205017 001 Sep 25, 2014 Sep CAHN  
TABLET; ORAL  
PHENTERMINE HYDROCHLORIDE  
>D> AA INGENUS PHARMS NJ 37.5MG A091451 001 Sep 21, 2012 Sep CAHN  
>D> AA KEN LIFESCIENCE 37.5MG A205008 001 Sep 25, 2014 Sep CAHN  
>A> AA NOVAST LABS 37.5MG A091451 001 Sep 21, 2012 Sep CAHN  
>A> AA NUVO PHARM 37.5MG A205008 001 Sep 25, 2014 Sep CAHN

PHENYLBUTAZONE

CAPSULE; ORAL  
PHENYLBUTAZONE  
@ FOSUN PHARMA 100MG A087774 001 Jun 16, 1982 Jan CAHN  
TABLET; ORAL  
PHENYLBUTAZONE  
@ FOSUN PHARMA 100MG A084339 001 Jan CAHN

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION; INTRAVENOUS  
PHENYLEPHRINE HYDROCHLORIDE  
AP AMNEAL PHARMS CO 10MG/ML (10MG/ML) A211079 001 Jul 05, 2018 Jun NEWA  
AP 50MG/5ML (10MG/ML) A211078 001 Jul 19, 2018 Jul NEWA  
AP 100MG/10ML (10MG/ML) A211078 002 Jul 19, 2018 Jul NEWA  
AP CIPLA LTD 10MG/ML (10MG/ML) A210334 001 Apr 27, 2018 Jun CDFR  
AP 100MG/10ML (10MG/ML) A210333 002 Apr 27, 2018 Jun CDFR  
AP +! WEST WARD PHARM CORP 10MG/ML (10MG/ML) N203826 001 Dec 20, 2012 Jun CDFR  
PHENYLEPHRINE HYDROCHLORIDE  
AP CIPLA LTD 50MG/5ML (10MG/ML) A210333 001 Apr 27, 2018 Jun CDFR  
VAZCULEP  
AP + AVADEL LEGACY 10MG/ML (10MG/ML) N204300 001 Jun 27, 2014 Jun CTEC  
+ 10MG/ML (10MG/ML) N204300 001 Jun 27, 2014 Jun CDFR  
AP + 50MG/5ML (10MG/ML) N204300 002 Jun 27, 2014 Jun CDFR  
AP +! 100MG/10ML (10MG/ML) N204300 003 Jun 27, 2014 Jun CDFR

SOLUTION;IV (INFUSION)

## PHENYLEPHRINE HYDROCHLORIDE

AP	CIPPLA LTD	10MG/ML (10MG/ML)	A210334	001	Apr 27, 2018	Apr NEWA
AP		100MG/10ML (10MG/ML)	A210333	002	Apr 27, 2018	Apr NEWA
AP	+! WEST WARD PHARM CORP	10MG/ML (10MG/ML)	N203826	001	Dec 20, 2012	Apr CFTG
	PHENYLEPHRINE HYDROCHLORIDE					
AP	CIPPLA LTD	50MG/5ML (10MG/ML)	A210333	001	Apr 27, 2018	Apr NEWA
	VAZCULEP					
AP	+ AVADEL LEGACY	50MG/5ML (10MG/ML)	N204300	002	Jun 27, 2014	Apr CFTG
AP	+!	100MG/10ML (10MG/ML)	N204300	003	Jun 27, 2014	Apr CFTG

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

## SYRUP;ORAL

## PHENYLEPHRINE HYDROCHLORIDE AND PROMETHAZINE HYDROCHLORIDE

AA	! VINTAGE	5MG/5ML; 6.25MG/5ML	A040654	001	Dec 07, 2006	Jan CHRS
	PROMETH VC PLAIN		A088761	001	Nov 08, 1984	Jan DISC

PHENYTOIN

## SUSPENSION;ORAL

## PHENYTOIN

AB	WOCKHARDT BIO AG	125MG/5ML	A040420	001	Apr 19, 2002	Jan CAHN
----	------------------	-----------	---------	-----	--------------	----------

PHYTONADIONE

## TABLET;ORAL

## MEPHYTON

AB	+! VALEANT PHARMS	5MG	N010104	003		Apr CFTG
AB	AMNEAL PHARMS CO	5MG	A209373	001	May 11, 2018	Apr NEWA

PIMAVANSERIN TARTRATE

## CAPSULE;ORAL

## NUPLAZID

+! ACADIA PHARMS INC

EQ 34MG BASE

N210793

001 Jun 28, 2018 Jun NEWA

## TABLET;ORAL

## NUPLAZID

+! ACADIA PHARMS INC

EQ 10MG BASE

N207318

002 Jun 28, 2018 Jun NEWA

PIOGLITAZONE HYDROCHLORIDE

## TABLET;ORAL

## PIOGLITAZONE HYDROCHLORIDE

AB	NEOPHARMA	EQ 15MG BASE	A078383	001	Mar 12, 2013	Aug CAHN
AB		EQ 30MG BASE	A078383	002	Mar 12, 2013	Aug CAHN
AB		EQ 45MG BASE	A078383	003	Mar 12, 2013	Aug CAHN
AB	PRINSTON INC	EQ 15MG BASE	A207806	001	Apr 17, 2018	Apr NEWA
AB		EQ 30MG BASE	A207806	002	Apr 17, 2018	Apr NEWA
AB		EQ 45MG BASE	A207806	003	Apr 17, 2018	Apr NEWA

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

## INJECTABLE;INJECTION

## PIPERACILLIN AND TAZOBACTAM

AP	APOLLO PHARMS INC	EQ 12GM BASE/VIAL; EQ 1.5GM BASE/VIAL	A207848	001	May 11, 2018	Aug NEWA
AP	FRESENIUS KABI	EQ 2GM BASE/VIAL; EQ 250MG BASE/VIAL	A203719	001	May 18, 2018	May NEWA
AP		EQ 3GM BASE/VIAL; EQ 375MG BASE/VIAL	A203719	002	May 18, 2018	May NEWA
AP		EQ 4GM BASE/VIAL; EQ 500MG BASE/VIAL	A203719	003	May 18, 2018	May NEWA
AP		EQ 36GM BASE/VIAL; EQ 4.5GM BASE/VIAL	A203720	001	May 11, 2018	Apr NEWA
AP	FRESENIUS KABI USA	EQ 12GM BASE/VIAL; EQ 1.5GM BASE/VIAL	A206204	001	May 11, 2018	Apr NEWA
AP	QILU TIANHE	EQ 2GM BASE/VIAL; EQ 250MG BASE/VIAL	A204959	001	Aug 10, 2018	Jul NEWA
AP		EQ 3GM BASE/VIAL; EQ 375MG BASE/VIAL	A204959	002	Aug 10, 2018	Jul NEWA
AP		EQ 4GM BASE/VIAL; EQ 500MG BASE/VIAL	A204959	003	Aug 10, 2018	Jul NEWA
AP	SANDOZ INC	EQ 12GM BASE/VIAL; EQ 1.5GM BASE/VIAL	A203557	001	Oct 29, 2014	Apr CDFR
AP	WOCKHARDT BIO AG	EQ 36GM BASE/VIAL; EQ 4.5GM BASE/VIAL	A207146	001	Mar 17, 2017	Jan CPOT

INJECTABLE; INJECTION  
ZOSYN

AP	+!	WYETH PHARMS	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	N 050684	001	Oct 22, 1993	Aug CAHN
AP	+!		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	N 050684	002	Oct 22, 1993	Aug CAHN
AP	+!		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	N 050684	003	Oct 22, 1993	Aug CAHN
AP	+!		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	N 050684	004	Oct 22, 1993	Aug CAHN
		ZOSYN IN PLASTIC CONTAINER					
	+!	WYETH PHARMS	EQ 40MG BASE/ML;EQ 5MG BASE/ML	N 050750	001	Feb 24, 1998	Aug CAHN
	+!		EQ 60MG BASE/ML;EQ 7.5MG BASE/ML	N 050750	002	Feb 24, 1998	Aug CAHN
	+!		EQ 4GM BASE/100ML;EQ 500MG BASE/100ML	N 050750	003	Feb 24, 1998	Aug CAHN

PIROXICAM

CAPSULE; ORAL  
PIROXICAM

>A>	AB	BRECKENRIDGE PHARM	10MG	A 208991	001	Feb 21, 2018	Sep CAHN
>A>	AB		20MG	A 208991	002	Feb 21, 2018	Sep CAHN
>D>	AB	LABORATORIOS CINFA	10MG	A 208991	001	Feb 21, 2018	Sep CAHN
	AB		10MG	A 208991	001	Feb 21, 2018	Feb NEWA
>D>	AB		20MG	A 208991	002	Feb 21, 2018	Sep CAHN
	AB		20MG	A 208991	002	Feb 21, 2018	Feb NEWA
	AB	MICRO LABS	10MG	A 206152	001	Dec 29, 2017	Feb CRLD
	AB		20MG	A 206152	002	Dec 29, 2017	Feb CRLD
	AB	STRIDES PHARMA	10MG	A 210347	001	Jan 26, 2018	Jan NEWA
	AB		20MG	A 210347	002	Jan 26, 2018	Jan NEWA
	AB	ZYDUS PHARMS USA INC	10MG	A 205585	001	Jul 17, 2018	Jul NEWA
	AB		20MG	A 205585	002	Jul 17, 2018	Jul NEWA

PLAZOMICIN SULFATE

SOLUTION; INTRAVENOUS  
ZEMDRI

+!	ACHAOGEN INC	EQ 500MG BASE/10ML (EQ 50MG BASE/ML)	N 210303	001	Jun 25, 2018	Jun NEWA
----	--------------	---	----------	-----	--------------	----------

POLIDOCANOL

SOLUTION; INTRAVENOUS  
VARITHENA

+!	PROVENSI	77.5MG/7.75ML (10MG/ML)	N 205098	002	Dec 21, 2017	Jan CDFR
----	----------	-------------------------	----------	-----	--------------	----------

POSACONAZOLE

SOLUTION; INTRAVENOUS  
NOXAFILE

+!	MERCK SHARP DOHME	300MG/16.7ML (18MG/ML)	N 205596	001	Mar 13, 2014	Aug CDFR
----	-------------------	------------------------	----------	-----	--------------	----------

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

MICRO-K

+ @	NESHER PHARMS	8MEQ	N 018238	001		Apr DISC
		MICRO-K 10				
+ @	NESHER PHARMS	10MEQ	N 018238	002	May 14, 1984	Apr DISC

SOLUTION; ORAL

POTASSIUM CHLORIDE

AA	AMNEAL PHARMS LLC	20MEQ/15ML	A 210041	001	Jul 19, 2018	Jul NEWA
AA		40MEQ/15ML	A 210041	002	Jul 19, 2018	Jul NEWA
AA	APOTEX INC	20MEQ/15ML	A 211067	001	Aug 08, 2018	Jul NEWA
AA		40MEQ/15ML	A 211067	002	Aug 08, 2018	Jul NEWA
AA	+ GENUS LIFESCIENCES	20MEQ/15ML	N 206814	001	Dec 22, 2014	Jul CFTG
AA	+!	40MEQ/15ML	N 206814	002	Dec 22, 2014	Jul CFTG
AA	NOVEL LABS INC	20MEQ/15ML	A 209786	001	Aug 29, 2018	Aug NEWA
AA		40MEQ/15ML	A 209786	002	Aug 29, 2018	Aug NEWA

TABLET, EXTENDED RELEASE; ORAL

K-TAB

AB3	+ ABBVIE	10MEQ	N 018279	001		Jan CTEC
AB2	+!	20MEQ	N 018279	003	Nov 25, 2013	Jan CTEC
		POTASSIUM CHLORIDE				
AB3	PADDICK LLC	10MEQ	A 209688	001	Jan 12, 2018	Jan NEWA
AB2		20MEQ	A 209688	002	Jan 12, 2018	Jan NEWA
AB2	STRIDES PHARMA	8MEQ	A 210733	001	Aug 31, 2018	Aug NEWA
AB2		10MEQ	A 210733	002	Aug 31, 2018	Aug NEWA

## TABLET, EXTENDED RELEASE;ORAL

POTASSIUM CHLORIDE

AB2	YICHANG HUMANWELL	8MEQ	A209314	001	Jun 22, 2018	Jun NEWA
AB2		10MEQ	A209314	002	Jun 22, 2018	Jun NEWA

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.224% IN SODIUM CHLORIDE 0.9%

+ @ BAXTER HLTHCARE	224MG/100ML; 900MG/100ML	N017648	003	Jun DISC
---------------------	--------------------------	---------	-----	----------

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE;ORAL

POTASSIUM CITRATE

AB	MOUNTAIN	5MEQ	A077440	001	Jun 09, 2006	Jan CAHN
AB		10MEQ	A077440	002	Jun 09, 2006	Jan CAHN
AB	TEVA PHARMS USA INC	5MEQ	A209758	001	Mar 05, 2018	Feb NEWA
AB		10MEQ	A209758	002	Mar 05, 2018	Feb NEWA
AB		15MEQ	A209758	003	Mar 05, 2018	Feb NEWA

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET;ORAL

PRAMIPEXOLE DIHYDROCHLORIDE

>A> AB	CSPC OUYI PHARM CO	0.25MG	A211088	001	Oct 03, 2018	Sep NEWA
>A> AB		0.5MG	A211088	002	Oct 03, 2018	Sep NEWA
>A> AB		0.75MG	A211088	003	Oct 03, 2018	Sep NEWA
>A> AB		1MG	A211088	004	Oct 03, 2018	Sep NEWA
>A> AB		1.5MG	A211088	005	Oct 03, 2018	Sep NEWA

PRASUGREL HYDROCHLORIDE

TABLET;ORAL

PRASUGREL

AB	ACCORD HLTHCARE	EQ 5MG BASE	A205987	001	Feb 02, 2018	Jan NEWA
AB		EQ 10MG BASE	A205987	002	Feb 02, 2018	Jan NEWA
AB	AMNEAL PHARMS	EQ 5MG BASE	A205913	001	Jun 19, 2018	Jun NEWA
AB		EQ 10MG BASE	A205913	002	Jun 19, 2018	Jun NEWA
AB	USPHARMA WINDLAS	EQ 5MG BASE	A205790	001	Oct 16, 2017	Jan CAHN
AB		EQ 10MG BASE	A205790	002	Oct 16, 2017	Jan CAHN

PRAVASTATIN SODIUM

TABLET;ORAL

PRAVASTATIN SODIUM

>D> AB	APPCO PHARMA LLC	10MG	A209869	001	Apr 13, 2018	Sep CAHN
		10MG	A209869	001	Apr 13, 2018	Apr NEWA
>D> AB		20MG	A209869	002	Apr 13, 2018	Sep CAHN
		20MG	A209869	002	Apr 13, 2018	Apr NEWA
>D> AB		40MG	A209869	003	Apr 13, 2018	Sep CAHN
		40MG	A209869	003	Apr 13, 2018	Apr NEWA
>D> AB		80MG	A209869	004	Apr 13, 2018	Sep CAHN
		80MG	A209869	004	Apr 13, 2018	Apr NEWA
>A> AB	UPSHER-SMITH LABS	10MG	A209869	001	Apr 13, 2018	Sep CAHN
>A> AB		20MG	A209869	002	Apr 13, 2018	Sep CAHN
>A> AB		40MG	A209869	003	Apr 13, 2018	Sep CAHN
>A> AB		80MG	A209869	004	Apr 13, 2018	Sep CAHN

PRAZOSIN HYDROCHLORIDE

CAPSULE;ORAL

PRAZOSIN HYDROCHLORIDE

>A> AB	NOVITIUM PHARMA	EQ 1MG BASE	A210971	001	Oct 03, 2018	Sep NEWA
>A> AB		EQ 2MG BASE	A210971	002	Oct 03, 2018	Sep NEWA
>A> AB		EQ 5MG BASE	A210971	003	Oct 03, 2018	Sep NEWA

PREDNISOLONE

SYRUP;ORAL

PREDNISOLONE

AA	LANNETT CO INC	15MG/5ML	A040775	001	Sep 21, 2007	May CAHN
	TABLET;ORAL					
	PREDNISOLONE					
	@ FOSUN PHARMA	5MG	A080339	001		Jan CAHN

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION;ORAL

PREDNISOLONE SODIUM PHOSPHATE

AA	! WOCKHARDT BIO AG	EQ 15MG BASE/5ML	A076895	001	Oct 04, 2004	Jan CAHN
	SOLUTION/DROPS;OPHTHALMIC	PREDNISOLONE SODIUM PHOSPHATE				

@ BAUSCH AND LOMB

EQ 0.11% PHOSPHATE

A040065 001 Jul 29, 1994 Apr CAHN

PREDNISONE

TABLET;ORAL

PREDNISONE

@ HIKMA PHARMS

2.5MG

A040538 001 Jan 08, 2004 May DISC

PREGABALIN

TABLET, EXTENDED RELEASE;ORAL

LYRICA CR

+ PF PRISM CV

82.5MG

N209501 001 Oct 11, 2017 Aug CAHN

+ !

165MG

N209501 002 Oct 11, 2017 Aug CAHN

+ !

330MG

N209501 003 Oct 11, 2017 Aug CAHN

PRILOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

CITANESE PLAIN DENTAL

+ @ DENTSPLY PHARM

4%

N021382 001

May CRLD

PRIMAQUINE PHOSPHATE

TABLET;ORAL

PRIMAQUINE PHOSPHATE

>D> AB	INGENUS PHARMS NJ	EQ 15MG BASE	A206043	001	Jun 23, 2016	Sep CAHN
>A> AB	NOVAST LABS	EQ 15MG BASE	A206043	001	Jun 23, 2016	Sep CAHN

PRIMIDONE

TABLET;ORAL

PRIMIDONE

AB	OXFORD PHARMS	50MG	A040586	001	Feb 24, 2005	Jul CAHN
AB		250MG	A040586	002	Feb 24, 2005	Jul CAHN

PROPAFENONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

PROPAFENONE HYDROCHLORIDE

AB	INDICUS PHARMA	225MG	A205956	001	Jul 02, 2018	Jun NEWA
AB		325MG	A205956	002	Jul 02, 2018	Jun NEWA
AB		425MG	A205956	003	Jul 02, 2018	Jun NEWA
AB	WILSHIRE PHARMS INC	225MG	A205956	001	Jul 02, 2018	Jul CAHN
AB		325MG	A205956	002	Jul 02, 2018	Jul CAHN
AB		425MG	A205956	003	Jul 02, 2018	Jul CAHN

TABLET;ORAL

PROPAFENONE HYDROCHLORIDE

AB	! VINTAGE PHARMS	300MG	A075938	003	Oct 17, 2002	Jul CHRS
	RYTHMOL					
+ @	GLAXOSMITHKLINE LLC	150MG	N019151	001	Nov 27, 1989	Jul DISC
+ @		225MG	N019151	003	Nov 20, 1992	Jul DISC
+ @		300MG	N019151	002	Nov 27, 1989	Jul DISC

PROPARACAINe HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

ALCAINE

@ ALCON LABS INC

0.5%

A080027 001

May DISC

AT	!	0.5%	A080027	001		Feb CAHN
	PROPARACAINe HYDROCHLORIDE					

AT	!	AKORN INC	0.5%	A040277	001	Mar 16, 2000	May CHRS
----	---	-----------	------	---------	-----	--------------	----------

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

PROPRANOLOL HYDROCHLORIDE

@ MYLAN

60MG

A078022 001 Feb 15, 2007 Jun DISC

@

80MG

A078022 002 Feb 15, 2007 Jun DISC

@

120MG

A078022 003 Feb 15, 2007 Jun DISC

@

160MG

A078022 004 Feb 15, 2007 Jun DISC

INJECTABLE; INJECTION

## PROPRANOLOL HYDROCHLORIDE

+ @ BAXTER HLTHCARE CORP 1MG/ML  
 @ FOSUN PHARMA 1MG/ML  
 ! HIKMA FARMACEUTICA 1MG/ML

N016419 001 Jul DISC  
 A076400 001 Feb 26, 2003 Jan CAHN  
 A077760 001 Jan 31, 2008 Jul CHRS

TABLET; ORAL

## INDERAL

>A> + @ WYETH PHARMS 10MG  
 >A> + @ 20MG  
 >A> + @ 40MG  
 >A> + @ 60MG  
 >A> + @ 80MG  
 >A> + @ 90MG  
 >D> + @ WYETH PHARMS INC 10MG  
 >D> + @ 20MG  
 >D> + @ 40MG  
 >D> + @ 60MG  
 >D> + @ 80MG  
 >D> + @ 90MG

N016418 001 Sep CAHN  
 N016418 003 Sep CAHN  
 N016418 002 Sep CAHN  
 N016418 009 Oct 18, 1982 Sep CAHN  
 N016418 004 Sep CAHN  
 N016418 010 Oct 18, 1982 Sep CAHN  
 N016418 001 Sep CAHN  
 N016418 003 Sep CAHN  
 N016418 002 Sep CAHN  
 N016418 009 Oct 18, 1982 Sep CAHN  
 N016418 004 Sep CAHN  
 N016418 010 Oct 18, 1982 Sep CAHN

## PROPRANOLOL HYDROCHLORIDE

AB IMPAX LABS INC 20MG  
 AB 40MG  
 AB 60MG  
 AB WATSON LABS 60MG  
 @ YAOPHARMA CO LTD 10MG  
 @ 20MG  
 @ 40MG  
 @ 60MG  
 @ 80MG

A071972 002 Apr 06, 1988 May CMS1  
 A071972 003 Apr 06, 1988 May CMS1  
 A071976 002 May 13, 1986 May CMS1  
 A070178 002 Apr 23, 2018 Jul NEWA  
 A070663 001 Jun 13, 1986 Jan CAHN  
 A070664 001 Jun 13, 1986 Jan CAHN  
 A070665 001 Jun 13, 1986 Jan CAHN  
 A070666 001 Oct 10, 1986 Jan CAHN  
 A070667 001 Jun 13, 1986 Jan CAHN

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDETABLET; ORAL

## CORPHED

@ FOSUN PHARMA 60MG;2.5MG

A088602 001 Apr 11, 1985 Jan CAHN

PYRIDOSTIGMINE BROMIDETABLET; ORAL

## PYRIDOSTIGMINE BROMIDE

>A> AB APNAR PHARMA LP 60MG  
 >D> AB INVATECH PHARMA 60MG  
 AB 60MG

A211181 001 Jul 20, 2018 Sep CAHN  
 A211181 001 Jul 20, 2018 Sep CAHN  
 A211181 001 Jul 20, 2018 Jul NEWA

TABLET, EXTENDED RELEASE; ORAL  
PYRIDOSTIGMINE BROMIDE

>A> AB ANDA REPOSITORY 180MG  
 >D> AB KINEDEXE UK 180MG  
 >A> AB RISING PHARMS 180MG

A205464 001 Aug 15, 2017 Sep CAHN  
 A205464 001 Aug 15, 2017 Sep CAHN  
 A205464 001 Aug 15, 2017 Sep CAHN

PYRIMETHAMINETABLET; ORAL

## DARAPRIM

+! VYERA PHARMS LLC 25MG

N008578 001 Jan CAHN

QUAZEPAMTABLET; ORAL

## DORAL

@ GALT PHARMS 7.5MG  
 +! 15MG

N018708 003 Feb 26, 1987 Feb CAHN  
 N018708 001 Dec 27, 1985 Feb CAHN

QUETIAPINE FUMARATETABLET, EXTENDED RELEASE; ORAL

## QUETIAPINE FUMARATE

>A> AB ALIGNSCIENCE PHARMA EQ 150MG BASE  
 >A> AB EQ 200MG BASE

A209497 001 Sep 28, 2018 Sep NEWA  
 A209497 002 Sep 28, 2018 Sep NEWA

QUINAPRIL HYDROCHLORIDETABLET; ORAL

## QUINAPRIL HYDROCHLORIDE

@ SUN PHARM INDs LTD EQ 5MG BASE  
 @ EQ 10MG BASE  
 @ EQ 20MG BASE  
 @ EQ 40MG BASE  
 @ YAOPHARMA CO LTD EQ 5MG BASE

A076607 001 Dec 15, 2004 Apr DISC  
 A076607 002 Dec 15, 2004 Apr DISC  
 A076607 003 Dec 15, 2004 Apr DISC  
 A076607 004 Dec 15, 2004 Apr DISC  
 A076803 001 Mar 02, 2005 Jan CAHN

TABLET;ORAL

## QUINAPRIL HYDROCHLORIDE

@	EQ 10MG BASE	A076803	002	Mar 02, 2005	Jan CAHN
@	EQ 20MG BASE	A076803	003	Mar 02, 2005	Jan CAHN
@	EQ 40MG BASE	A076803	004	Mar 02, 2005	Jan CAHN

QUINIDINE SULFATE

## TABLET, EXTENDED RELEASE;ORAL

## QUINIDINE SULFATE

@ G AND W LABS INC	300MG	A040045	001	Jun 30, 1994	Jan DISC
--------------------	-------	---------	-----	--------------	----------

QUININE SULFATE

## CAPSULE;ORAL

## QUININE SULFATE

>A> AB	NOVAST LABS	324MG	A204372	001	Jul 22, 2015	Sep CAHN
>D> AB	RICONPHARMA LLC	324MG	A204372	001	Jul 22, 2015	Sep CAHN

RABEPRAZOLE SODIUM

## CAPSULE, DELAYED RELEASE;ORAL

## ACIPHEX SPRINKLE

+ CERECOR INC	5MG	N204736	001	Mar 26, 2013	Feb CAHN
+! MERCK SHARP DOHME	10MG	N204736	002	Mar 26, 2013	Feb CAHN

## TABLET, DELAYED RELEASE;ORAL

## RABEPRAZOLE SODIUM

AB	ALKEM LABS LTD	20MG	A208644	001	Apr 24, 2018	Apr NEWA
----	----------------	------	---------	-----	--------------	----------

RALTEGRAVIR POTASSIUM

## TABLET;ORAL

## ISENTRESS HD

+! MERCK SHARP DOHME	EQ 600MG BASE	N022145	002	May 26, 2017	May CHRS
----------------------	---------------	---------	-----	--------------	----------

RAMELTEON

## TABLET;ORAL

## RAMELTEON

AB	DR REDDYS LABS SA	8MG	A091693	001	Jul 26, 2013	Mar CAHN
----	-------------------	-----	---------	-----	--------------	----------

RAMIPRIL

## CAPSULE;ORAL

## RAMIPRIL

AB	CHARTWELL MOLECULAR	1.25MG	A078745	001	Jun 18, 2008	Jun CAHN
AB		2.5MG	A078745	002	Jun 18, 2008	Jun CAHN
AB		5MG	A078745	003	Jun 18, 2008	Jun CAHN
AB		10MG	A078745	004	Jun 18, 2008	Jun CAHN

@ WATSON LABS	5MG	A076549	003	Oct 24, 2005	Mar DISC
@ YAOPHARMA CO LTD	1.25MG	A077514	001	Jun 18, 2008	Jan CAHN
@	2.5MG	A077514	002	Jun 18, 2008	Jan CAHN
@	5MG	A077514	003	Jun 18, 2008	Jan CAHN
@	10MG	A077514	004	Jun 18, 2008	Jan CAHN

## TABLET;ORAL

## RAMIPRIL

@ APOTEX INC	1.25MG	A091069	001	Dec 02, 2015	May DISC
@	2.5MG	A091069	002	Dec 02, 2015	May DISC
@	5MG	A091069	003	Dec 02, 2015	May DISC
@	10MG	A091069	004	Dec 02, 2015	May DISC

RANITIDINE HYDROCHLORIDE

## CAPSULE;ORAL

## RANITIDINE HYDROCHLORIDE

>A> AB	AJANTA PHARMA LTD	EQ 150MG BASE	A209859	001	Sep 27, 2018	Sep NEWA
>A> AB		EQ 300MG BASE	A209859	002	Sep 27, 2018	Sep NEWA
AB	AUROBINDO PHARMA LTD	EQ 150MG BASE	A211058	001	Jul 16, 2018	Jul NEWA
AB		EQ 300MG BASE	A211058	002	Jul 16, 2018	Jul NEWA

## SYRUP;ORAL

## RANITIDINE HYDROCHLORIDE

>A> AA	ANDA REPOSITORY	EQ 15MG BASE/ML	A090054	001	Nov 15, 2010	Sep CAHN
AA	LANNETT CO INC	EQ 15MG BASE/ML	A078890	001	Jul 01, 2010	May CAHN
AA	! PHARM ASSOC	EQ 15MG BASE/ML	A077405	001	Sep 21, 2007	Jul CHRS
>D> AA	TOLMAR	EQ 15MG BASE/ML	A090054	001	Nov 15, 2010	Sep CAHN
	ZANTAC					
+ @ GLAXO GRP LTD		EQ 15MG BASE/ML	N019675	001	Dec 30, 1988	Jul DISC

TABLET;ORALRANITIDINE HYDROCHLORIDE

AB	! AMNEAL PHARMS NY	EQ 300MG BASE	A077824	002	Oct 13, 2006	Jul CHRS
AB	VIVIMED GLOBAL	EQ 150MG BASE	A210010	001	Aug 01, 2018	Jul NEWA
AB		EQ 300MG BASE	A210010	002	Aug 01, 2018	Jul NEWA
	ZANTAC 150					
+ @ GLAXO GRP LTD	EQ 150MG BASE	N018703	001	Jun 09, 1983	Apr DISC	
ZANTAC 300						
+ @ GLAXO GRP LTD	EQ 300MG BASE	N018703	002	Dec 09, 1985	Jul DISC	

RASAGILINE MESYLATETABLET;ORALRASAGILINE MESYLATE

@ APOTEX INC	EQ 0.5MG BASE	A201950	001	Sep 12, 2013	Mar DISC
@	EQ 1MG BASE	A201950	002	Sep 12, 2013	Mar DISC
AB SANDOZ INC	EQ 0.5MG BASE	A201892	001	Jul 27, 2018	Jul NEWA
	EQ 1MG BASE	A201892	002	Jul 27, 2018	Jul NEWA

REMIFENTANIL HYDROCHLORIDEINJECTABLE;INJECTIONREMIFENTANIL HYDROCHLORIDE

AP FRESENIUS KABI USA	EQ 1MG BASE/VIAL	A206223	001	Jan 16, 2018	Jan NEWA
AP	EQ 2MG BASE/VIAL	A206223	002	Jan 16, 2018	Jan NEWA
AP	EQ 5MG BASE/VIAL	A206223	003	Jan 16, 2018	Jan NEWA
	ULTIVA				
AP + MYLAN INSTITUTIONAL	EQ 1MG BASE/VIAL	N020630	001	Jul 12, 1996	Jan CFTG
AP +	EQ 2MG BASE/VIAL	N020630	002	Jul 12, 1996	Jan CFTG
AP +!	EQ 5MG BASE/VIAL	N020630	003	Jul 12, 1996	Jan CFTG

REPAGLINIDETABLET;ORALREPAGLINIDE

AB CASI PHARMS INC	0.5MG	A078555	001	Nov 22, 2013	Mar CAHN
AB	1MG	A078555	002	Jan 22, 2014	Mar CAHN
AB	2MG	A078555	003	Jan 22, 2014	Mar CAHN

RIBAVIRINCAPSULE;ORALRIBAVIRIN

AB CASI PHARMS INC	200MG	A076192	001	Apr 06, 2004	Mar CAHN
TABLET;ORAL COPEGUS @ ROCHE	200MG	N021511	001	Dec 03, 2002	Apr DISC

RILUZOLE

>A> SUSPENSION;ORAL >A> TIGLUTIK KIT >A> +! ITALFARMACO SPA	50MG/10ML	N209080	001	Sep 05, 2018	Sep NEWA
---	-----------	---------	-----	--------------	----------

RISEDRONATE SODIUMTABLET, DELAYED RELEASE;ORALRISEDRONATE SODIUM

AB IMPAX LABS INC	35MG	A205066	001	Jun 29, 2018	Jun NEWA
AB ZYDUS PHARMS USA INC	35MG	A203822	001	Sep 11, 2018	Aug NEWA

RISPERIDONEFOR SUSPENSION, EXTENDED RELEASE;SUBCUTANEOUSPERSERIS KIT

+ INDIVIOR INC	90MG	N210655	001	Jul 27, 2018	Jul NEWA
+!	120MG	N210655	002	Jul 27, 2018	Jul NEWA

SOLUTION;ORALRISPERIDONE

>A> AA AUROBINDO PHARMA LTD	1MG/ML	A078452	001	Sep 04, 2009	Sep CAHN
AA LANNETT CO INC	1MG/ML	A079158	001	Dec 03, 2010	May CAHN
>D> AA LIFESTAR PHARMA	1MG/ML	A078452	001	Sep 04, 2009	Sep CAHN

TABLET;ORALRISPERIDONE

AB CHARTWELL MOLECULAR	0.25MG	A077543	001	May 18, 2011	Mar CAHN
AB	0.5MG	A077543	002	May 18, 2011	Mar CAHN
AB	1MG	A077543	003	May 18, 2011	Mar CAHN
AB	2MG	A077543	004	May 18, 2011	Mar CAHN
AB	3MG	A077543	005	May 18, 2011	Mar CAHN

**TABLET;ORAL**  
**RISPERIDONE**

AB		4MG	A077543	006	May 18, 2011	Mar CAHN
AB	RENATA	0.25MG	A078707	001	Dec 29, 2008	Jan CAHN
AB		0.5MG	A078707	002	Dec 29, 2008	Jan CAHN
AB		1MG	A078707	003	Dec 29, 2008	Jan CAHN
AB		2MG	A078707	004	Dec 29, 2008	Jan CAHN
AB		3MG	A078707	005	Dec 29, 2008	Jan CAHN
AB		4MG	A078707	006	Dec 29, 2008	Jan CAHN

**RITONAVIR****CAPSULE;ORAL**

NORVIR

+ @ ABBVIE 100MG

N020945 001 Jun 29, 1999 Apr DISC

**TABLET;ORAL**

RITONAVIR

>A> AB AMNEAL PHARMS LLC 100MG  
 >A> AB AUROBINDO PHARMA LTD 100MG  
 >A> AB HETERO LABS LTD III 100MG

A208890 001 Sep 17, 2018 Sep NEWA  
 A206614 001 Sep 17, 2018 Sep NEWA  
 A204587 001 Sep 17, 2018 Sep NEWA

**RIVASTIGMINE****FILM, EXTENDED RELEASE;TRANSDERMAL**  
**RIVASTIGMINE**

AB MYLAN TECHNOLOGIES 4.6MG/24HR  
 AB 9.5MG/24HR  
 AB 13.3MG/24HR

A205622 001 Jun 20, 2018 Jun NEWA  
 A205622 002 Jun 20, 2018 Jun NEWA  
 A205622 003 Jun 20, 2018 Jun NEWA

**RIZATRIPTAN BENZOATE****TABLET;ORAL**  
**MAXALT**

+ @ MERCK EQ 5MG BASE  
 RIZATRIPTAN BENZOATE  
 @ APOTEX INC EQ 5MG BASE  
 @ EQ 10MG BASE

N020864 001 Jun 29, 1998 Apr DISC  
 A202244 001 Dec 31, 2012 Mar DISC  
 A202244 002 Dec 31, 2012 Mar DISC

**TABLET, ORALLY DISINTEGRATING;ORAL**

MAXALT-MLT  
 + @ MERCK EQ 5MG BASE  
 RIZATRIPTAN BENZOATE  
 @ APOTEX INC EQ 5MG BASE  
 @ EQ 10MG BASE

N020865 001 Jun 29, 1998 Apr DISC  
 A202477 001 Jul 01, 2013 Mar DISC  
 A202477 002 Jul 01, 2013 Mar DISC

**ROCURONIUM BROMIDE****INJECTABLE;INJECTION**  
**ROCURONIUM BROMIDE**

AP GLAND CHEMS PVT 50MG/5ML (10MG/ML)  
 AP 100MG/10ML (10MG/ML)  
 AP GLAND PHARMA LTD 50MG/5ML (10MG/ML)  
 AP 100MG/10ML (10MG/ML)

A205656 001 Apr 04, 2018 Mar NEWA  
 A205656 002 Apr 04, 2018 Mar NEWA  
 A205656 001 Apr 04, 2018 Apr CAHN  
 A205656 002 Apr 04, 2018 Apr CAHN

**ROFLUMILAST****TABLET;ORAL**  
**DALIRESP**

>D> +! ASTRAZENECA PHARMS 250MCG  
 >A> AB +! 500MCG  
 +! 500MCG  
 AB +! 500MCG

N022522 002 Jan 23, 2018 Jan NEWA  
 N022522 001 Feb 28, 2011 Sep CTEC  
 N022522 001 Feb 28, 2011 Sep CTEC  
 N022522 001 Feb 28, 2011 Aug CTEC  
 N022522 001 Feb 28, 2011 Jul CFTG

>A> AB BRECKENRIDGE PHARM 500MCG  
 @ MYLAN PHARMS INC 500MCG  
 AB 500MCG  
 AB TORRENT PHARMS LTD 500MCG

A208236 001 Oct 03, 2018 Sep NEWA  
 A208257 001 Jul 13, 2018 Aug DISC  
 A208257 001 Jul 13, 2018 Jul NEWA  
 A208272 001 Aug 06, 2018 Jul NEWA

**ROLAPITANT HYDROCHLORIDE****EMULSION;INTRAVENOUS**  
**VARUBI**

+ @ TERSERA THERAPS LLC EQ 166.5MG BASE/92.5ML (EQ 1.8MG BASE/ML)

N208399 001 Oct 25, 2017 Aug CDFR

**EMULSION;IV (INFUSION)**  
**VARUBI**

+ @ TERSERA THERAPS LLC EQ 166.5MG BASE/92.5ML (EQ 1.8MG BASE/ML)

N208399 001 Oct 25, 2017 Jul CAHN

EMULSION;IV (INFUSION)

VARUBI

+ @ TESARO INC EQ 166.5MG BASE/92.5ML (EQ 1.8MG  
BASE/ML) N208399 001 Oct 25, 2017 Jun DISC

TABLET;ORAL

VARUBI

+! TERSERA THERAPS LLC EQ 90MG BASE N206500 001 Sep 01, 2015 Jul CAHN

ROMIDEPSINPOWDER;INTRAVENOUS

ISTODAX

+! CELGENE 10MG/VIAL N022393 001 Nov 05, 2009 Aug CDFR

ROPINIROLE HYDROCHLORIDETABLET;ORAL

ROPINIROLE HYDROCHLORIDE

@ G AND W LABS INC	EQ 0.25MG BASE	A077460	001	May 05, 2008	Jan DISC
@	EQ 0.5MG BASE	A077460	002	May 05, 2008	Jan DISC
@	EQ 1MG BASE	A077460	003	May 05, 2008	Jan DISC
@	EQ 2MG BASE	A077460	004	May 05, 2008	Jan DISC
@	EQ 3MG BASE	A077460	005	May 05, 2008	Jan DISC
@	EQ 4MG BASE	A077460	006	May 05, 2008	Jan DISC
@	EQ 5MG BASE	A077460	007	May 19, 2008	Jan DISC

TABLET, EXTENDED RELEASE;ORAL

ROPINIROLE HYDROCHLORIDE

>D> AB	MYLAN PHARMS INC	EQ 2MG BASE	A200462	001	Oct 15, 2012	Sep DISC
>A>	@	EQ 2MG BASE	A200462	001	Oct 15, 2012	Sep DISC
>D> AB		EQ 4MG BASE	A200462	003	Oct 15, 2012	Sep DISC
>A>	@	EQ 4MG BASE	A200462	003	Oct 15, 2012	Sep DISC
>D> AB		EQ 6MG BASE	A200462	004	Oct 15, 2012	Sep DISC
>A>	@	EQ 6MG BASE	A200462	004	Oct 15, 2012	Sep DISC
>D> AB		EQ 8MG BASE	A200462	005	Oct 15, 2012	Sep DISC
>A>	@	EQ 8MG BASE	A200462	005	Oct 15, 2012	Sep DISC
>D> AB		EQ 12MG BASE	A200462	006	Oct 15, 2012	Sep DISC
>A>	@	EQ 12MG BASE	A200462	006	Oct 15, 2012	Sep DISC

ROPIVACAINE HYDROCHLORIDESOLUTION;INJECTION

NAROPIN

AP	+ FRESENIUS KABI USA	400MG/200ML (2MG/ML)	N020533	007	Sep 24, 1996	Mar CTEC
AP	+	500MG/100ML (5MG/ML)	N020533	009	Jan 04, 2011	May CTEC
AP	+	1GM/200ML (5MG/ML)	N020533	010	Jan 04, 2011	May CTEC

ROPIVACAINE HYDROCHLORIDE

AP	AKORN	200MG/100ML (2MG/ML)	A204636	001	Mar 16, 2018	Mar NEWA
AP		400MG/200ML (2MG/ML)	A204636	002	Mar 16, 2018	Mar NEWA
AP	INFORLIFE	200MG/100ML (2MG/ML)	A206166	001	Jun 11, 2018	May NEWA
AP		400MG/200ML (2MG/ML)	A206166	002	Jun 11, 2018	May NEWA
AP		500MG/100ML (5MG/ML)	A206166	003	Jun 11, 2018	May NEWA
AP		1GM/200ML (5MG/ML)	A206166	004	Jun 11, 2018	May NEWA
AP	SOMERSET THERAPS LLC	20MG/10ML (2MG/ML)	A207636	001	Jun 15, 2018	Jun NEWA
AP		40MG/20ML (2MG/ML)	A207636	002	Jun 15, 2018	Jun NEWA
AP		100MG/20ML (5MG/ML)	A207636	003	Jun 15, 2018	Jun NEWA
AP		100MG/10ML (10MG/ML)	A207636	006	Jun 15, 2018	Jun NEWA
AP		150MG/30ML (5MG/ML)	A207636	004	Jun 15, 2018	Jun NEWA
AP		150MG/20ML (7.5MG/ML)	A207636	005	Jun 15, 2018	Jun NEWA
AP		200MG/20ML (10MG/ML)	A207636	007	Jun 15, 2018	Jun NEWA

ROSIGLITAZONE MALEATETABLET;ORAL

AVANDIA

+ SB PHARMCO	EQ 2MG BASE	N021071	002	May 25, 1999	Jul CTEC
+	EQ 4MG BASE	N021071	003	May 25, 1999	Jul CTEC
+ @	EQ 8MG BASE	N021071	004	May 25, 1999	Jul DISC

ROSIGLITAZONE MALEATE

@ TEVA	EQ 2MG BASE	A076747	001	Jan 25, 2013	Jul DISC
@	EQ 4MG BASE	A076747	002	Jan 25, 2013	Jul DISC
@	EQ 8MG BASE	A076747	003	Jan 25, 2013	Jul DISC

ROSVUSTATIN CALCIUM

TABLET;ORAL

ROSVUSTATIN CALCIUM

AB	ALLIED	5MG	A079168	001	Jul 19, 2016	Aug CAHN
AB		10MG	A079168	002	Jul 19, 2016	Aug CAHN
AB		20MG	A079168	003	Jul 19, 2016	Aug CAHN
AB		40MG	A079168	004	Jul 19, 2016	Aug CAHN

SELEGILINE HYDROCHLORIDE

CAPSULE;ORAL

>D>	ELDEPRYL					
>D> AB	+! SOMERSET	5MG	N020647	001	May 15, 1996	Sep DISC
>A>	+ @	5MG	N020647	001	May 15, 1996	Sep DISC
	SELEGILINE HYDROCHLORIDE					
>D> AB	APOTEX	5MG	A075321	001	Dec 04, 1998	Sep CHRS
>A> AB	!	5MG	A075321	001	Dec 04, 1998	Sep CHRS

SELENIUM SULFIDE

LOTION/SHAMPOO;TOPICAL

SELENIUM SULFIDE

AT	! PERRIGO NEW YORK	2.5%	A089996	001	Jan 10, 1991	Jul CHRS
	+ @ CHATTEM	2.5%	N007936	001		Jul DISC

SERTRALINE HYDROCHLORIDE

CONCENTRATE;ORAL

SERTRALINE HYDROCHLORIDE

@ ACI HEALTHCARE LTD EQ 20MG BASE/ML

A076934 001 Jun 30, 2006 May CAHN

TABLET;ORAL

SERTRALINE HYDROCHLORIDE

@ CHARTWELL MOLECULAR EQ 25MG BASE  
@ EQ 50MG BASE  
@ EQ 100MG BASE  
@ FOSUN PHARMA EQ 25MG BASE  
@ EQ 50MG BASE  
@ EQ 100MG BASEA077162 001 Feb 06, 2007 Mar CAHN  
A077162 002 Feb 06, 2007 Mar CAHN  
A077162 003 Feb 06, 2007 Mar CAHN  
A077713 001 Feb 06, 2007 Jan CAHN  
A077713 002 Feb 06, 2007 Jan CAHN  
A077713 003 Feb 06, 2007 Jan CAHNSEVELAMER CARBONATE

TABLET;ORAL

RENELA

AB	+! SANOFI	800MG	N022127	001	Oct 19, 2007	Aug CAHN
AB	SANDOZ INC	800MG	A200959	001	Mar 20, 2018	Mar NEWA

SILDENAFIL CITRATE

TABLET;ORAL

SILDENAFIL CITRATE

AB	AJANTA PHARMA LTD	EQ 20MG BASE	A210394	001	May 04, 2018	Apr NEWA
AB	AMNEAL PHARMS NY	EQ 25MG BASE	A202023	001	Jun 27, 2018	Jun NEWA
AB		EQ 50MG BASE	A202023	002	Jun 27, 2018	Jun NEWA
AB		EQ 100MG BASE	A202023	003	Jun 27, 2018	Jun NEWA
	@ APOTEX CORP	EQ 20MG BASE	A091379	001	Nov 06, 2012	Mar DISC
AB	AUROBINDO PHARMA LTD	EQ 25MG BASE	A203962	001	Jun 11, 2018	May NEWA
AB		EQ 50MG BASE	A203962	002	Jun 11, 2018	May NEWA
AB		EQ 100MG BASE	A203962	003	Jun 11, 2018	May NEWA
AB	HETERO LABS LTD V	EQ 25MG BASE	A202659	001	Jun 11, 2018	May NEWA
AB		EQ 50MG BASE	A202659	002	Jun 11, 2018	May NEWA
AB		EQ 100MG BASE	A202659	003	Jun 11, 2018	May NEWA
AB	RUBICON RES PVT LTD	EQ 25MG BASE	A204882	001	Jun 11, 2018	May NEWA
AB		EQ 50MG BASE	A204882	002	Jun 11, 2018	May NEWA
AB		EQ 100MG BASE	A204882	003	Jun 11, 2018	May NEWA
AB	TORRENT PHARMS LTD	EQ 25MG BASE	A091448	001	Jun 11, 2018	May NEWA
AB		EQ 50MG BASE	A091448	002	Jun 11, 2018	May NEWA
AB		EQ 100MG BASE	A091448	003	Jun 11, 2018	May NEWA

SILVER SULFADIAZINE

CREAM;TOPICAL

SSD AF

@ DR REDDYS LA

1%

N018578 003 Jul 11, 1990 Jun DISC

SIMEPREVIR SODIUM

CAPSULE;ORAL  
OLYSIO  
+ @ JANSSEN PRODS EQ 150MG BASE

N205123 001 Nov 22, 2013 May DISC

SIMVASTATIN

TABLET;ORAL  
SIMVASTATIN

@ HISUN PHARM	10MG	A206557	001	Nov 13, 2017	May DISC
@	20MG	A206557	002	Nov 13, 2017	May DISC
@	40MG	A206557	003	Nov 13, 2017	May DISC
@	80MG	A206557	004	Nov 13, 2017	May DISC
@ HISUN PHARM HANGZHOU	10MG	A206557	001	Nov 13, 2017	Aug CAHN
@	20MG	A206557	002	Nov 13, 2017	Aug CAHN
@	40MG	A206557	003	Nov 13, 2017	Aug CAHN
@	80MG	A206557	004	Nov 13, 2017	Aug CAHN
@ YAOPHARMA CO LTD	5MG	A077766	001	Dec 20, 2006	Jan CAHN
@	10MG	A077766	002	Dec 20, 2006	Jan CAHN
@	20MG	A077766	003	Dec 20, 2006	Jan CAHN
@	40MG	A077766	004	Dec 20, 2006	Jan CAHN
@	80MG	A077766	005	Dec 20, 2006	Jan CAHN

SINECATECHINS

OINTMENT;TOPICAL  
VEREGEN

+! FOUGERA PHARMS INC 15%

N021902 001 Oct 31, 2006 Jan CAHN

SODIUM BENZOATE; SODIUM PHENYLACETATE

SOLUTION;INTRAVENOUS  
AMMONUL

AP +! MEDICIS	10%;10% (5GM/50ML;5GM/50ML)	N020645	001	Feb 17, 2005	May CDFR
AP AILEX PHARMS LLC	10%;10% (5GM/50ML;5GM/50ML)	A207096	001	Feb 24, 2016	May CDFR
AP MAIA PHARMS INC	10%;10% (5GM/50ML;5GM/50ML)	A208521	001	May 08, 2017	May CDFR
AP NAVINTA LLC	10%;10% (5GM/50ML;5GM/50ML)	A205880	001	Aug 04, 2016	May CDFR

SODIUM BICARBONATE

INJECTABLE;INJECTION  
SODIUM BICARBONATE

@ HOSPIRA INC 0.5MEQ/ML  
@ 0.5MEQ/MLA202679 001 Mar 07, 2017 Mar DISC  
A202981 001 Mar 04, 2016 Mar DISCSODIUM CHLORIDE

INJECTABLE;INJECTION

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP FRESENIUS KABI USA	450MG/100ML	A208122	001	Jul 23, 2018	Jul NEWA
SODIUM CHLORIDE 0.9%					
+ @ MEDEFIL INC	18MG/2ML (9MG/ML)	N202832	002	Jan 06, 2012	Jun CRLD
+ @	22.5MG/2.5ML (9MG/ML)	N202832	003	Jan 06, 2012	Jun CRLD
+ @	27MG/3ML (9MG/ML)	N202832	004	Jan 06, 2012	Jun CRLD
+ @	45MG/5ML (9MG/ML)	N202832	005	Jan 06, 2012	Jun CRLD
+	90MG/10ML (9MG/ML)	N202832	006	Jan 06, 2012	Jun CRLD
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER					

+ @ ICU MEDICAL INC 9MG/ML  
+ ! 9MG/MLN019217 001 Jul 13, 1984 Apr DISC  
N019217 001 Jul 13, 1984 Feb CAHN  
N202832 001 Jan 06, 2012 Jun CRLD

+ @ MEDEFIL INC 9MG/ML (9MG/ML)

SOLUTION;IRRIGATION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AT +! B BRAUN	900MG/100ML	N016733	001		Mar CRLD
---------------	-------------	---------	-----	--	----------

SODIUM FLUORIDE F-18

INJECTABLE;INTRAVENOUS  
SODIUM FLUORIDE F-18

AP SOFIE	10-200mCi/ML	A203592	001	Aug 18, 2015	Feb CAHN
@ UNIV TX MD ANDERSON	10-200mCi/ML	A203247	001	Dec 23, 2013	Jun DISC

SODIUM IODIDE I-131

CAPSULE;ORAL

SODIUM IODIDE I 131

+ @ MALLINKRODT NUCLEAR

0.8-100mCi

N016517 001

Jun DISC

SOLUTION;ORAL

SODIUM IODIDE I 131

+ @ MALLINKRODT NUCLEAR

3.5-150mCi/VIAL

N016515 001

Jun DISC

SODIUM NITROPRUSSIDE

INJECTABLE;INJECTION

SODIUM NITROPRUSSIDE

AP	APICORE US	25MG/ML	A209584	001	Aug 10, 2018	Jul NEWA
AP	CIPILA LTD	25MG/ML	A210855	001	Jul 16, 2018	Jul NEWA
AP	MEDICURE	25MG/ML	A209584	001	Aug 10, 2018	Aug CAHN
AP	MYLAN LABS LTD	25MG/ML	A210763	001	Apr 17, 2018	Apr NEWA
AP	RENAISSANCE SSA LLC	25MG/ML	A209834	001	Jun 26, 2018	Jun NEWA
AP	SOMERSET THERAPS LLC	25MG/ML	A210882	001	Aug 17, 2018	Aug NEWA
SOLUTION;INTRAVENOUS						
NIPRIDE RTU IN SODIUM CHLORIDE 0.9%						
+!	EXELA PHARMA SCS LLC	10MG/50ML (0.2MG/ML)	N209387	002	Dec 07, 2017	Aug CDFR
+!		20MG/100ML (0.2MG/ML)	N209387	003	Jul 13, 2018	Jul NEWA
+!		50MG/100ML (0.5MG/ML)	N209387	001	Mar 08, 2017	Aug CDFR

SODIUM POLYSTYRENE SULFONATE

POWDER;ORAL, RECTAL

SODIUM POLYSTYRENE SULFONATE

AA	APNAR PHARMA LP	454GM/BOT	A206815	001	Feb 18, 2016	Mar CAHN
----	-----------------	-----------	---------	-----	--------------	----------

SODIUM ZIRCONIUM CYCLOSILICATE

FOR SUSPENSION;ORAL

LOKEIMMA

+ ASTRAZENECA PHARMS

5GM/PACKET

N207078 001

May NEWA

+!

10GM/PACKET

N207078 002

May NEWA

SOMATROPIN

INJECTABLE;INJECTION

BIO-TROPIN

@ FERRING

4.8MG/VIAL

N019774 001

May 1995

ZOMACTON

BX	+! FERRING	5MG/VIAL	N019774	002	Jan 04, 2002	Feb CAIN
	+	10MG/VIAL	N019774	003	Mar 07, 2012	Feb CAIN

SOMATROPIN RECOMBINANT

INJECTABLE;INJECTION

GENOTROPIN PRESERVATIVE FREE

+ @ PHARMACIA AND UPJOHN 1.5MG/VIAL

NUTROPIN AQ PEN

N020280 004

Aug 1995

+ @ GENENTECH

10MG/2ML (5MG/ML)

N020522 002

Jun DISC

+ @

20MG/2ML (10MG/ML)

N020522 006

Jan 2008

VALTROPIN

@ LG CHEM LTD

5MG/VIAL

N021905 001

Apr 2007

+ LG CHEM LTD

SOTALOL HYDROCHLORIDE

TABLET;ORAL

SOTALOL HYDROCHLORIDE

AB1	OXFORD PHARMS	80MG	A075563	001	Nov 07, 2003	Jul CAHN
AB1		120MG	A075563	002	Nov 07, 2003	Jul CAHN
AB1		160MG	A075563	003	Nov 07, 2003	Jul CAHN
AB1		240MG	A075563	004	Nov 07, 2003	Jul CAHN

SPIRONOLACTONE

TABLET;ORAL

SPIRONOLACTONE

AB	CASI PHARMS INC	25MG	A086809	001		Mar CAHN
AB	OXFORD PHARMS	25MG	A040750	001	Aug 29, 2006	Jul CAHN
AB		50MG	A040750	002	Aug 29, 2006	Jul CAHN
AB		100MG	A040750	003	Aug 29, 2006	Jul CAHN
AB	ZYDUS PHARMS USA INC	25MG	A205936	001	Jul 18, 2018	Jul NEWA
AB		50MG	A205936	002	Jul 18, 2018	Jul NEWA
AB		100MG	A205936	003	Jul 18, 2018	Jul NEWA

STANOZOLOL

TABLET;ORAL  
WINSTROL  
+ @ LUNDBECK INC 2MG N012885 001 May 14, 1984 Aug CRLD

STERILE WATER FOR IRRIGATION

LIQUID;IRRIGATION  
STERILE WATER IN PLASTIC CONTAINER  
AT + B BRAUN 100% N016734 001 Mar CRLD

STIRIPENTOL

CAPSULE;ORAL  
DIACOMIT  
+ BIOCODEX SA 250MG N206709 001 Aug 20, 2018 Aug NEWA  
+! 500MG N206709 002 Aug 20, 2018 Aug NEWA  
FOR SUSPENSION;ORAL  
DIACOMIT  
+ BIOCODEX SA 250MG/PACKET N207223 001 Aug 20, 2018 Aug NEWA  
+! 500MG/PACKET N207223 002 Aug 20, 2018 Aug NEWA

SUCCINYLCHOLINE CHLORIDE

INJECTABLE;INJECTION  
SUCCINYLCHOLINE CHLORIDE  
AP RENAISSANCE SSA LLC 20MG/ML A210231 001 Jun 04, 2018 May NEWA  
AP ZYDUS PHARMS USA INC 20MG/ML A209467 001 May 04, 2018 Apr NEWA

SUCRALFATE

SUSPENSION;ORAL  
CARAFATE  
+! ALLERGAN SALES LLC 1GM/10ML N019183 001 Dec 16, 1993 Jan CAHN  
TABLET;ORAL  
CARAFATE  
AB +! ALLERGAN SALES LLC 1GM N018333 001 Jan CAHN  
SUCRALFATE  
@ MYLAN IRELAND LTD 1GM A074415 001 Jun 08, 1998 Jul DISC

SULFADIAZINE

TABLET;ORAL  
SULFADIAZINE  
+ @ LILLY 500MG N004122 002 Aug CRLD

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION;ORAL  
BACTRIM  
+ @ SUN PHARM INDUSTRIES 200MG/5ML;40MG/5ML N017560 001 Jul CRLD  
SULFAMETHOXAZOLE AND TRIMETHOPRIM  
AB LANNETT CO INC 200MG/5ML;40MG/5ML A077785 001 Jan 24, 2007 May CAHN  
TABLET;ORAL  
SULFAMETHOXAZOLE AND TRIMETHOPRIM  
@ FOSUN PHARMA 400MG;80MG A070889 001 Nov 13, 1986 Jan CAHN  
@ 400MG;80MG N018598 003 May 19, 1982 Jan CAHN  
@ 800MG;160MG A070890 001 Nov 13, 1986 Jan CAHN  
@ SUN PHARM INDUSTRIES 400MG;80MG A071017 002 Aug 25, 1986 Apr CMS1  
SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH  
@ FOSUN PHARMA 800MG;160MG N018598 004 May 19, 1982 Jan CAHN

SULINDAC

TABLET;ORAL  
SULINDAC  
@ FOSUN PHARMA 150MG A072712 001 Aug 30, 1991 Jan CAHN  
@ 200MG A072713 001 Aug 30, 1991 Jan CAHN

SUMATRIPTAN SUCCINATE

INJECTABLE;SUBCUTANEOUS  
SUMAVENT DOSEPRO  
+ @ ENDO VENTURES LTD EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) N022239 002 Nov 26, 2013 Mar DISC  
+ @ EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) N022239 001 Jul 15, 2009 Mar DISC

SOLUTION;SUBCUTANEOUS ZEMBRACE SYMTOUCH							
>D>	DR REDDYS LABS LTD	EQ 3MG BASE/0.5ML (EQ 3MG BASE/0.5ML)	N208223	001	Jan 28, 2016	Sep	CRLD
>A>	+	EQ 3MG BASE/0.5ML (EQ 3MG BASE/0.5ML)	N208223	001	Jan 28, 2016	Sep	CRLD
	TABLET;ORAL SUMATRIPTAN SUCCINATE						
	@ FOSUN PHARMA	EQ 25MG BASE	A076976	001	Aug 10, 2009	Jan	CAHN
	@	EQ 50MG BASE	A076976	002	Aug 10, 2009	Jan	CAHN
	@	EQ 100MG BASE	A076976	003	Aug 10, 2009	Jan	CAHN
<u>TACROLIMUS</u>							
FOR SUSPENSION;ORAL PROGRAF							
+!	ASTELLAS	EQ 0.2MG BASE/PACKET	N210115	001	May 24, 2018	May	NEWA
+!		EQ 1MG BASE/PACKET	N210115	002	May 24, 2018	May	NEWA
OINTMENT;TOPICAL TACROLIMUS							
AB	GLENMARK PHARMS LTD	0.1%	A210393	001	Apr 16, 2018	Apr	NEWA
<u>Tadalafil</u>							
TABLET;ORAL ADCIRCA							
AB2	+! ELI LILLY CO	20MG	N022332	001	May 22, 2009	Aug	CTEC
AB	+!	20MG	N022332	001	May 22, 2009	Jul	CFTG
	CIALIS						
AB	+! LILLY	2.5MG	N021368	004	Jan 07, 2008	May	CFTG
AB	+	5MG	N021368	001	Nov 21, 2003	May	CFTG
AB	+	10MG	N021368	002	Nov 21, 2003	May	CFTG
AB1	+!	20MG	N021368	003	Nov 21, 2003	Aug	CTEC
AB	+!	20MG	N021368	003	Nov 21, 2003	May	CFTG
	Tadalafil						
AB2	MYLAN PHARMS INC	20MG	A200630	001	Aug 03, 2018	Aug	CTEC
AB		20MG	A200630	001	Aug 03, 2018	Jul	NEWA
AB	TEVA PHARMS USA	2.5MG	A090141	001	May 22, 2018	May	NEWA
AB		5MG	A090141	002	May 22, 2018	May	NEWA
AB		10MG	A090141	003	May 22, 2018	May	NEWA
AB1		20MG	A090141	004	May 22, 2018	Aug	CTEC
AB		20MG	A090141	004	May 22, 2018	May	NEWA
<u>Tafenoxquine Succinate</u>							
TABLET;ORAL ARAKODA							
+!	60 DEGREES PHARMS	EQ 100MG BASE	N210607	001	Aug 08, 2018	Aug	NEWA
	KRINTAFEL						
+!	GLAXOSMITHKLINE	EQ 150MG BASE	N210795	001	Jul 20, 2018	Jul	NEWA
<u>Talc</u>							
AEROSOL;INTRAPLEURAL SCLEROSOL							
+!	LYMOL MEDCL	4GM/SPRAY	N020587	001	Dec 24, 1997	Mar	CPOT
<u>Taliglucerase Alfa</u>							
POWDER;INTRAVENOUS ELELYSO							
+!	PFIZER	200 UNITS/VIAL	N022458	001	May 01, 2012	Aug	CDFR
<u>Tamoxifen Citrate</u>							
SOLUTION;ORAL SOLTAMOX							
	MIDATECH PHARMA US	EQ 20MG BASE/10ML	N021807	001	Oct 29, 2005	Mar	CPOT
<u>Tapentadol Hydrochloride</u>							
SOLUTION;ORAL NUCYNTA							
+!	DEPOMED INC	EQ 20MG BASE/ML	N203794	001	Oct 15, 2012	May	DISC
TABLET;ORAL NUCYNTA							
>A>	+! DEPO NF	EQ 50MG BASE	N022304	001	Nov 20, 2008	Sep	CAHN
>A>	+	EQ 75MG BASE	N022304	002	Nov 20, 2008	Sep	CAHN
>A>	+!	EQ 100MG BASE	N022304	003	Nov 20, 2008	Sep	CAHN

	TABLET;ORAL NUCYNTA					
>D>	+ DEPOMED INC	EQ 50MG BASE	N 022304	001	Nov 20, 2008	Sep CAHN
>D>	+ !	EQ 75MG BASE	N 022304	002	Nov 20, 2008	Sep CAHN
>D>	+ !	EQ 100MG BASE	N 022304	003	Nov 20, 2008	Sep CAHN
	TABLET, EXTENDED RELEASE;ORAL NUCYNTA ER					
>A>	+ DEPO NF	EQ 50MG BASE	N 200533	001	Aug 25, 2011	Sep CAHN
>A>	+ !	EQ 100MG BASE	N 200533	002	Aug 25, 2011	Sep CAHN
>A>	+ !	EQ 150MG BASE	N 200533	003	Aug 25, 2011	Sep CAHN
>A>	+ !	EQ 200MG BASE	N 200533	004	Aug 25, 2011	Sep CAHN
>A>	+ !	EQ 250MG BASE	N 200533	005	Aug 25, 2011	Sep CAHN
>D>	+ DEPOMED INC	EQ 50MG BASE	N 200533	001	Aug 25, 2011	Sep CAHN
>D>	+ !	EQ 100MG BASE	N 200533	002	Aug 25, 2011	Sep CAHN
>D>	+ !	EQ 150MG BASE	N 200533	003	Aug 25, 2011	Sep CAHN
>D>	+ !	EQ 200MG BASE	N 200533	004	Aug 25, 2011	Sep CAHN
>D>	+ !	EQ 250MG BASE	N 200533	005	Aug 25, 2011	Sep CAHN
	<u>TAZAROTENE</u>					
	CREAM;TOPICAL TAZAROTENE					
AB	TARO PHARMS	0.1%	A 208258	001	Apr 03, 2017	May CAHN
	<u>TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT</u>					
	INJECTABLE;INJECTION PULMOLITE					
	+ @ JUBILANT DRAXIMAGE	N/A	N 017776	001		Feb DISC
	<u>TECHNETIUM TC-99M MEDRONATE KIT</u>					
	INJECTABLE;INJECTION CIS-MDP					
	PHARMALUCENCE	N/A	N 018124	001		Jan CTEC
	MDP-BRACCO					
	@ CARDINAL HEALTH 414	N/A	N 018107	001		Jan DISC
	<u>TECHNETIUM TC-99M PENTETATE KIT</u>					
	INJECTABLE;INJECTION DTPA					
	+! JUBILANT DRAXIMAGE	N/A	N 018511	001	Dec 29, 1989	Jan CAHN
	<u>TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR</u>					
	SOLUTION;INTRAVENOUS, INTRAVESICULAR, OPHTHALMIC RADIOGENIX SYSTEM					
	+ NORTHSTAR MEDICAL	30-1153mCi/GENERATOR	N 202158	001	Feb 08, 2018	Feb NEWA
	<u>TECOVIRIMAT</u>					
	CAPSULE;ORAL TPOXX					
	+! SIGA TECHNOLOGIES	200MG	N 208627	001	Jul 13, 2018	Jul NEWA
	<u>TEDIZOLID PHOSPHATE</u>					
	POWDER;INTRAVENOUS SIVEXTRO					
	+! CUBIST PHARMS LLC	200MG/VIAL	N 205436	001	Jun 20, 2014	Aug CDFR
	<u>TELAVANCIN HYDROCHLORIDE</u>					
	POWDER;INTRAVENOUS VIBATIV					
	+ @ THERAVANCE BIOPHARMA	EQ 250MG BASE/VIAL	N 022110	001	Sep 11, 2009	Aug CDFR
	+!	EQ 750MG BASE/VIAL	N 022110	002	Sep 11, 2009	Aug CDFR
	<u>TELMISARTAN</u>					
	TABLET;ORAL TELMISARTAN					
	@ WATSON LABS	40MG	A 078710	002	Jan 08, 2014	Jul DISC

TEMOZOLOMIDE

	CAPSULE;ORAL						
	TEMOZOLOMIDE						
AB	APOTEX INC	5MG	A204159	001	Jul 05, 2018	Jun NEWA	
AB		20MG	A204159	002	Jul 05, 2018	Jun NEWA	
AB		100MG	A204159	003	Jul 05, 2018	Jun NEWA	
AB		140MG	A204159	004	Jul 05, 2018	Jun NEWA	
AB		180MG	A204159	005	Jul 05, 2018	Jun NEWA	
AB		250MG	A204159	006	Jul 05, 2018	Jun NEWA	
	@ MYLAN PHARMS INC	5MG	A205227	001	Jun 29, 2016	Apr DISC	
	@	20MG	A205227	002	Jun 29, 2016	Apr DISC	
	@	100MG	A205227	003	Jun 29, 2016	Mar DISC	
	@	140MG	A205227	004	Jun 29, 2016	Mar DISC	
	@	180MG	A205227	005	Jun 29, 2016	Mar DISC	
	@	250MG	A205227	006	Jun 29, 2016	Mar DISC	

TEMISIROLIMUS

	SOLUTION;INTRAVENOUS						
	TEMISIROLIMUS						
AP	ACCORD HLTHCARE	25MG/ML (25MG/ML)	A203153	001	Jul 30, 2018	Jul NEWA	
AP	TORISEL		N022088	001	May 30, 2007	Jul CFTG	

TENOFOVIR DISOPROXIL FUMARATE

	TABLET;ORAL						
	TENOFOVIR DISOPROXIL FUMARATE						
AB	APOTEX INC	300MG	A206481	001	Jul 26, 2018	Jul NEWA	
AB	AUROBINDO PHARMA LTD	150MG	A090647	001	Jan 26, 2018	Jan NEWA	
AB		200MG	A090647	002	Jan 26, 2018	Jan NEWA	
AB		250MG	A090647	003	Jan 26, 2018	Jan NEWA	
AB		300MG	A090647	004	Jan 26, 2018	Jan NEWA	
AB	CIPLA LTD	300MG	A078800	001	Jan 26, 2018	Jan NEWA	
AB	HETERO LABS LTD III	300MG	A090636	001	Jan 26, 2018	Jan NEWA	
AB	LAURUS LABS PVT	300MG	A209550	001	Feb 26, 2018	Feb NEWA	
AB	MACLEODS PHARMS LTD	300MG	A203232	001	Jan 26, 2018	Jan NEWA	
AB	STRIDES PHARMA	300MG	A090742	001	Jan 26, 2018	Jan NEWA	
AB	TEVA PHARMS USA	150MG	A091612	002	Jan 26, 2018	Jan NEWA	
AB		200MG	A091612	003	Jan 26, 2018	Jan NEWA	
AB		250MG	A091612	004	Jan 26, 2018	Jan NEWA	
	VIREAD						
AB	+ GILEAD SCIENCES INC	150MG	N021356	002	Jan 18, 2012	Jan CFTG	
AB	+	200MG	N021356	003	Jan 18, 2012	Jan CFTG	
AB	+	250MG	N021356	004	Jan 18, 2012	Jan CFTG	

TERCONAZOLE

	CREAM;VAGINAL						
	TERAZOL 7						
	+ @ JANSSEN PHARMS	0.4%	N019579	001	Dec 31, 1987	Feb DISC	
AB	! TARO	0.4%	A076043	001	Jan 19, 2005	Feb CHRS	
	SUPPOSITORY;VAGINAL						
	TERAZOL 3						
	+ @ JANSSEN PHARMS	80MG	N019641	001	May 24, 1988	Feb DISC	
AB	! PERRIGO NEW YORK	80MG	A077149	001	Mar 17, 2006	Feb CHRS	

TERIFLUNOMIDE

	TABLET;ORAL						
	AUBAGIO						
AB	+ SANOFI AVENTIS US	7MG	N202992	001	Sep 12, 2012	Jul CFTG	
AB	+!	14MG	N202992	002	Sep 12, 2012	Jul CFTG	
	TERIFLUNOMIDE						
>A>	AB AMNEAL PHARMS CO	7MG	A209613	001	Sep 28, 2018	Sep NEWA	
>A>	AB TEVA PHARMS USA	14MG	A209613	002	Sep 28, 2018	Sep NEWA	
AB		7MG	A209700	001	Sep 04, 2018	Aug NEWA	
AB		14MG	A209700	002	Sep 04, 2018	Aug NEWA	
AB	WATSON LABS TEVA	7MG	A209549	001	Jul 27, 2018	Jul NEWA	
AB		14MG	A209549	002	Jul 27, 2018	Jul NEWA	

TESTOSTERONE

SOLUTION, METERED; TRANSDERMAL

TESTOSTERONE

AT CIPLA LTD 30MG/1.5ML ACTUATION A209533 001 Jan 29, 2018 Jan NEWA

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION

TESTOSTERONE CYPIONATE

AO CIPLA LTD 100MG/ML A210362 001 Jun 19, 2018 Jun NEWA  
AO 200MG/ML A210362 002 Jun 19, 2018 Jun NEWATESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

DELATESTRYL

+ @ ENDO PHARMS 200MG/ML N009165 003 Jun DISC

TESTOSTERONE ENANTHATE

@ MYLAN INSTITUTIONAL 200MG/ML A040647 001 Oct 05, 2009 Jun DISC

AO NEXUS PHARMS 200MG/ML A040575 001 Jun 14, 2006 Aug CMFD

@ 200MG/ML A040575 001 Jun 14, 2006 Jul DISC

AO 200MG/ML A040575 001 Jun 14, 2006 Jun CAHN

AO ! WATSON PHARMS INC 200MG/ML A085598 001 Jun CHRS  
SOLUTION; SUBCUTANEOUS  
>A> XYOSTED (AUTOINJECTOR)

&gt;A&gt; + @ ANTARES PHARMA INC 50MG/0.5ML (50MG/0.5ML) N209863 001 Sep 28, 2018 Sep NEWA

&gt;A&gt; + @ 75MG/0.5ML (75MG/0.5ML) N209863 002 Sep 28, 2018 Sep NEWA

&gt;A&gt; + @ 100MG/0.5ML (100MG/0.5ML) N209863 003 Sep 28, 2018 Sep NEWA

TETRABENAZINE

TABLET; ORAL

TETRABENAZINE

AB LUPIN LTD 12.5MG A210544 001 Apr 20, 2018 Apr NEWA  
AB 25MG A210544 002 Apr 20, 2018 Apr NEWATETRACAIN HYDROCHLORIDE

SOLUTION; OPHTHALMIC

TETRACAIN HYDROCHLORIDE

+! ALCON LABS 0.5% N208135 001 Feb 29, 2016 Mar CAHN

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

ACHROMYCIN V

>D> AB + HERITAGE PHARMA 250MG N050278 003 Sep CAHN  
>D> AB +! 500MG N050278 001 Sep CAHN  
>A> AB + HERITAGE PHARMS INC 250MG N050278 003 Sep CAHN  
>A> AB +! 500MG N050278 001 Sep CAHN  
TETRACYCLINE HYDROCHLORIDE  
>A> AB AMNEAL PHARMS NY 250MG A210674 001 Sep 18, 2018 Sep NEWA  
>A> AB 500MG A210674 002 Sep 18, 2018 Sep NEWATHEOPHYLLINE

INJECTABLE; INJECTION

THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER

+! B BRAUN 40MG/100ML N019826 001 Aug 14, 1992 Jun CTEC

THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER

+! B BRAUN 160MG/100ML N019826 003 Aug 14, 1992 Jun CTEC

THEOPHYLLINE 0.32% AND DEXTROSE 5% IN PLASTIC CONTAINER

+! B BRAUN 320MG/100ML N019826 006 Aug 14, 1992 Jun CTEC

THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER

+ @ HOSPIRA INC 4MG/ML N019211 007 Dec 14, 1984 Jun DISC

+ @ 40MG/100ML N019211 001 Dec 14, 1984 Jun DISC

+ @ 160MG/100ML N019211 003 Dec 14, 1984 Jun DISC

+ @ 320MG/100ML N019211 006 Jan 20, 1988 Jun DISC

TABLET, EXTENDED RELEASE; ORAL

THEOCHRON

AB NOSTRUM PHARMS LLC 100MG A087400 003 Feb 21, 1985 Jan CTEC  
AB 200MG A087400 004 Feb 21, 1985 Jan CTEC

THIORIDAZINE HYDROCHLORIDE

TABLET;ORAL

THIORIDAZINE HYDROCHLORIDE

@ FOSUN PHARMA	10MG	A088131	001	Aug 30, 1983	Jan CAHN
@	15MG	A088132	001	Aug 30, 1983	Jan CAHN
@	25MG	A088133	001	Aug 30, 1983	Jan CAHN
@	50MG	A088134	001	Aug 30, 1983	Jan CAHN
@	100MG	A088135	001	Nov 20, 1984	Jan CAHN
@	150MG	A088136	001	Sep 17, 1986	Jan CAHN
@	200MG	A088137	001	Sep 17, 1986	Jan CAHN

THIOTEP A

INJECTABLE;INJECTION

THIOTEP A

AP	DR REDDYS LABS LTD	15MG/VIAL	A210337	001	May 04, 2018	Apr NEWA
AP	JIANGSU HENGRUI MED	15MG/VIAL	A209150	001	May 04, 2018	Apr NEWA
AP	! WEST-WARD PHARMS INT	15MG/VIAL	A075547	001	Apr 02, 2001	Apr CTEC
	POWDER;INTRAVENOUS					
	TEPADINA					
+!	ADIENNE SA	15MG/VIAL	N208264	001	Jan 26, 2017	Aug CDFR
+!		100MG/VIAL	N208264	002	Jan 26, 2017	Aug CDFR

THIOTHIXENE

CAPSULE;ORAL

NAVANE

+ @ PFIZER	1MG	N016584	001		Jan CRLD
+ @	2MG	N016584	002		Jan CRLD
+ @	5MG	N016584	003		Jan CRLD
+ @	10MG	N016584	004		Jan CRLD
+ @	20MG	N016584	005		Jan CRLD

TICAGRELOR

TABLET;ORAL

BRILINTA

AB	+ ASTRAZENECA PHARMS	60MG	N022433	002	Sep 03, 2015	Aug CFTG
AB	+!	90MG	N022433	001	Jul 20, 2011	Aug CFTG
	TICAGRELOR					
AB	WATSON LABS INC	60MG	A208390	001	Sep 04, 2018	Aug NEWA
AB		90MG	A208390	002	Sep 04, 2018	Aug NEWA

TICLOPIDINE HYDROCHLORIDE

TABLET;ORAL

TICLOPIDINE HYDROCHLORIDE

@ YAOPHARMA CO LTD	250MG	A075318	001	Aug 20, 1999	Jan CAHN
@	250MG	A075326	001	Aug 20, 1999	Jan CAHN

TIGECYCLINE

POWDER;INTRAVENOUS

TIGECYCLINE

AP	ACCORD HLTHCARE INC	50MG/VIAL	N208744	001	Jan 18, 2018	Jun CDFR
AP	AMNEAL PHARMS LLC	50MG/VIAL	N211158	001	Aug 02, 2018	Aug NEWA
AP	FRESENIUS KABI USA	50MG/VIAL	N205645	001	Dec 01, 2016	Jun CDFR
AP	SANDOZ INC	50MG/VIAL	A091620	001	May 27, 2015	Jun CDFR
	TYGACIL					
AP	+! PF PRISM CV	50MG/VIAL	N021821	001	Jun 15, 2005	Jun CDFR
	POWDER;IV (INFUSION)					
	TIGECYCLINE					
	ACCORD HLTHCARE INC	50MG/VIAL	N208744	001	Jan 18, 2018	Jan NEWA

TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC

TIMOPTIC

AT	+ ATON	EQ 0.25% BASE	N018086	001		Jan CMFD
AT1	+	EQ 0.5% BASE	N018086	002		Jan CMFD
	TABLET;ORAL					
	TIMOLOL MALEATE					
	@ YAOPHARMA CO LTD	5MG	A072550	001	Apr 13, 1989	Jan CAHN
	@	10MG	A072551	001	Apr 13, 1989	Jan CAHN
	@	20MG	A072552	001	Apr 13, 1989	Jan CAHN

TIZANIDINE HYDROCHLORIDE

TABLET;ORAL

TIZANIDINE HYDROCHLORIDE

AB	CASI PHARMS INC	EQ 2MG BASE	A076280	001	Nov 26, 2002	Mar CAHN
AB		EQ 4MG BASE	A076280	002	Jun 27, 2002	Mar CAHN
AB	ZYDUS PHARMS USA INC	EQ 2MG BASE	A208187	001	Mar 09, 2018	Feb NEWA
AB		EQ 4MG BASE	A208187	002	Mar 09, 2018	Feb NEWA

TOBRAMYCIN

SOLUTION;INHALATION

TOBRAMYCIN

AN	DR REDDYS LABS INTL	300MG/5ML	A207080	001	Jul 09, 2018	Jun NEWA
AN	DR REDDYS LABS SA	300MG/5ML	A207080	001	Jul 09, 2018	Jul CAHN

TOFACITINIB CITRATE

TABLET;ORAL

XELJANZ

+! PF PRISM CV

EQ 10MG BASE

N203214 002 May 30, 2018 May NEWA

TOLAZAMIDE

TABLET;ORAL

TOLAZAMIDE

@ YAOPHARMA CO LTD

100MG

A071633 001 Dec 09, 1987

Jan CAHN

@

250MG

A070289 001 Mar 13, 1986

Jan CAHN

@

500MG

A070290 001 Mar 13, 1986

Jan CAHN

TOLBUTAMIDE

TABLET;ORAL

TOLBUTAMIDE

@ YAOPHARMA CO LTD

500MG

A086574 001

Jan CAHN

TOLCAPONE

TABLET;ORAL

TOLCAPONE

AB	INGENUS PHARMS LLC	100MG	A208937	001	Aug 07, 2018	Jul NEWA
----	--------------------	-------	---------	-----	--------------	----------

TOLMETIN SODIUM

CAPSULE;ORAL

TOLMETIN SODIUM

@ FOSUN PHARMA

EQ 400MG BASE

A073462 001 Apr 30, 1992

Jan CAHN

TABLET;ORAL

TOLMETIN SODIUM

@ FOSUN PHARMA

EQ 200MG BASE

A073588 001 Jul 31, 1992

Jan CAHN

@

EQ 600MG BASE

A074002 001 Sep 27, 1993

Jan CAHN

TOLTERODINE TARTRATE

TABLET;ORAL

TOLTERODINE TARTRATE

@ APOTEX CORP

1MG

A200164 001 Sep 25, 2012

Mar DISC

@

2MG

A200164 002 Sep 25, 2012

Mar DISC

TOLVAPtan

TABLET;ORAL

JYNARQUE

+ OTSUKA PHARM CO LTD

15MG

N204441 001 Apr 23, 2018

Apr NEWA

+

30MG

N204441 002 Apr 23, 2018

Apr NEWA

+

45MG

N204441 003 Apr 23, 2018

Apr NEWA

+

60MG

N204441 004 Apr 23, 2018

Apr NEWA

+!

90MG

N204441 005 Apr 23, 2018

Apr NEWA

TOPIRAMATE

CAPSULE;ORAL

TOPIRAMATE

@ FOSUN PHARMA

15MG

A079206 001 Oct 14, 2009

Jan CAHN

@

25MG

A079206 002 Oct 14, 2009

Jan CAHN

TRABECTEDIN

POWDER; INTRAVENOUS  
YONDELIS  
+! JANSSEN PRODS 1MG/VIAL N207953 001 Oct 23, 2015 Aug CDFR

TRAMADOL HYDROCHLORIDE

TABLET; ORAL  
TRAMADOL HYDROCHLORIDE  
@ FOSUN PHARMA 50MG A075968 001 Jun 25, 2002 Jan CAHN

TRANDOLAPRIL

TABLET; ORAL  
MAVIK  
+ @ ABBVIE 1MG N020528 001 Apr 26, 1996 Mar DISC  
+ @ 2MG N020528 002 Apr 26, 1996 Mar DISC  
+ @ 4MG N020528 003 Apr 26, 1996 Mar DISC  
TRANDOLAPRIL  
AB ! LUPIN 4MG A077522 003 Jun 12, 2007 Mar CHRS  
@ WATSON LABS 1MG A077805 001 Jun 12, 2007 May DISC  
@ 2MG A077805 002 Jun 12, 2007 May DISC  
@ 4MG A077805 003 Jun 12, 2007 May DISC

TRANEXAMIC ACID

INJECTABLE; INJECTION  
TRANEXAMIC ACID  
AP ACIC PHARMS 100MG/ML A202436 001 Feb 11, 2014 May CAHN

TRANYLCYPROMINE SULFATE

TABLET; ORAL  
TRANYLCYPROMINE SULFATE  
>A> AB CNTY LINE PHARMS EQ 10MG BASE A206856 001 Apr 17, 2018 Sep CAHN  
>D> AB KINEDEXE UK EQ 10MG BASE A206856 001 Apr 17, 2018 Sep CAHN  
AB EQ 10MG BASE A206856 001 Apr 17, 2018 Apr NEWA

TRAZODONE HYDROCHLORIDE

TABLET; ORAL  
TRAZODONE HYDROCHLORIDE  
@ FOSUN PHARMA 100MG A072483 001 Apr 30, 1990 Jan CAHN  
AB OXFORD PHARMS 50MG A072192 001 Feb 02, 1989 Jul CAHN  
AB 100MG A072193 001 Feb 02, 1989 Jul CAHN

TREPROSTINIL

SOLUTION; INTRAVENOUS, SUBCUTANEOUS  
REMODULIN  
UNITED THERAP 20MG/20ML (1MG/ML) N208276 001 Jul 30, 2018 Jul NEWA  
50MG/20ML (2.5MG/ML) N208276 002 Jul 30, 2018 Jul NEWA  
100MG/20ML (5MG/ML) N208276 003 Jul 30, 2018 Jul NEWA  
200MG/20ML (10MG/ML) N208276 004 Jul 30, 2018 Jul NEWA

TRETINOIN

LOTION; TOPICAL  
ALTRENO  
+! DOW PHARM 0.05% N209353 001 Aug 23, 2018 Aug NEWA

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL  
TRIAMCINOLONE ACETONIDE  
AT LANNETT CO INC 0.025% A040671 001 Jun 09, 2006 May CAHN  
AT 0.1% A040671 002 Jun 09, 2006 May CAHN  
AT MACLEODS PHARMS LTD 0.025% A209535 001 May 18, 2018 May NEWA  
AT 0.1% A209535 002 May 18, 2018 May NEWA  
AT 0.5% A209535 003 May 18, 2018 May NEWA  
AT PERRIGO NEW YORK 0.025% A086413 002 Mar CMS1  
AT 0.1% A086413 003 Mar CMS1  
AT TARO PHARM IND LTD 0.1% A040039 001 Nov 26, 1997 May CAHN

INJECTABLE; INJECTION  
KENALOG-40

>D> AP +! APOTHECON 40MG/ML N014901 001 Sep CTEC  
>A> AB +! 40MG/ML N014901 001 Sep CTEC

<u>INJECTABLE; INJECTION</u>					
TRIAMCINOLONE ACETONIDE					
>D> AP	AMNEAL PHARMS CO	40MG/ML	A207550	001	Dec 11, 2017
>A> AB		40MG/ML	A207550	001	Dec 11, 2017
<u>LOTION; TOPICAL</u>					
TRIAMCINOLONE ACETONIDE					
AT	LANNETT CO INC	0.1%	A040672	002	Dec 13, 2006
<u>OINTMENT; TOPICAL</u>					
TRIAMCINOLONE ACETONIDE					
AT	! PERRIGO NEW YORK	0.025%	A087385	002	Jun CMS1
AT	!	0.1%	A087385	003	Jun CMS1
AT	TARO PHARM INDUS LTD	0.1%	A040037	001	Sep 30, 1994
<u>SPRAY; TOPICAL</u>					
KENALOG					
AT	+! SUN PHARM INDUS INC	0.147MG/GM	N012104	001	Feb CAHN
TRIAMCINOLONE ACETONIDE					
>D> AT	RICONPHARMA LLC	0.147MG/GM	A206786	001	Sep 08, 2017
>A> AT	RISING PHARMS	0.147MG/GM	A206786	001	Sep 08, 2017
<u><b>TRIENTINE HYDROCHLORIDE</b></u>					
CAPSULE; ORAL					
SYPRINE					
AB	+! ATON	250MG	N019194	001	Nov 08, 1985
TRIENTINE HYDROCHLORIDE					
AB	WATSON LABS TEVA	250MG	A207567	001	Feb 07, 2018
<u><b>TRIFLUOPERAZINE HYDROCHLORIDE</b></u>					
CONCENTRATE; ORAL					
TRIFLUOPERAZINE HYDROCHLORIDE					
@ FOSUN PHARMA		EQ 10MG BASE/ML	A085787	001	Apr 15, 1982
<u><b>TROPICAMIDE</b></u>					
SOLUTION/DROPS; OPHTHALMIC					
TROPICAMIDE					
AT	BAUSCH AND LOMB	0.5%	A040067	001	Jul 27, 1994
<u><b>UROFOLLITROPIN</b></u>					
INJECTABLE; INTRAMUSCULAR, SUBCUTANEOUS					
BRAVELLE					
+ @ FERRING		75 IU/VIAL	N021289	001	May 06, 2002
<u><b>URSODIOL</b></u>					
CAPSULE; ORAL					
URSODIOL					
AB	ABHAI LLC	300MG	A210707	001	May 17, 2018
TABLET; ORAL					
URSO 250					
AB	+ ALLERGAN SALES LLC	250MG	N020675	001	Dec 10, 1997
URSO FORTE					
AB	+! ALLERGAN SALES LLC	500MG	N020675	002	Jul 21, 2004
<u><b>VALACYCLOVIR HYDROCHLORIDE</b></u>					
TABLET; ORAL					
VALACYCLOVIR HYDROCHLORIDE					
AB	TIME-CAP LABS INC	EQ 500MG BASE	A079012	001	May 24, 2010
AB		EQ 1GM BASE	A079012	002	May 24, 2010
<u><b>VALBENAZINE TOSYLATE</b></u>					
CAPSULE; ORAL					
INGREZZA					
+! NEUROCRINE		EQ 40MG BASE	N209241	001	Apr 11, 2017
+		EQ 80MG BASE	N209241	002	Oct 04, 2017
<u><b>VALPROIC ACID</b></u>					
SYRUP; ORAL					
VALPROIC ACID					
AA	LANNETT CO INC	250MG/5ML	A077960	001	Oct 13, 2006
					May CAHN

VALSARTAN

SOLUTION;ORAL

PREXXARTAN

+ @	CARMEL BIOSCIENCES	20MG/5ML	N209139	001	Dec 19, 2017	Jun DISC
+ @		80MG/20ML	N209139	002	Dec 19, 2017	Jun DISC

TABLET;ORAL

VALSARTAN

AB	SQUARE PHARMS LTD	40MG	A205347	001	Apr 09, 2018	Mar NEWA
AB		80MG	A205347	002	Apr 09, 2018	Mar NEWA
AB		160MG	A205347	003	Apr 09, 2018	Mar NEWA
AB		320MG	A205347	004	Apr 09, 2018	Mar NEWA
AB	UNICHEM LABS LTD	40MG	A209261	001	May 04, 2018	Apr NEWA
AB		80MG	A209261	002	May 04, 2018	Apr NEWA
AB		160MG	A209261	003	May 04, 2018	Apr NEWA
AB		320MG	A209261	004	May 04, 2018	Apr NEWA
@	WATSON LABS INC	40MG	A090642	001	Jan 05, 2015	Aug DISC
@		80MG	A090642	002	Jan 05, 2015	Aug DISC
@		160MG	A090642	003	Jan 05, 2015	Aug DISC
@		320MG	A090642	004	Jan 05, 2015	Aug DISC

VANCOMYCIN HYDROCHLORIDE

CAPSULE;ORAL

VANCOMYCIN HYDROCHLORIDE

@	FRESENIUS KABI USA	EQ 125MG BASE	A065453	001	Jun 18, 2012	Feb DISC
@		EQ 250MG BASE	A065453	002	Jun 18, 2012	Feb DISC

FOR SOLUTION;ORAL

FIRVANQ KIT

+!	RXMTM THERAPS LLC	EQ 25MG BASE/ML	N208910	001	Jan 26, 2018	Jan NEWA
+!		EQ 50MG BASE/ML	N208910	002	Jan 26, 2018	Jan NEWA

INJECTABLE;INJECTION

VANCOCIN HYDROCHLORIDE IN PLASTIC CONTAINER

+!	BAXTER HLTHCARE	EQ 1GM BASE/200ML	N050671	003	Mar 01, 1999	Apr NEWA
	VANCOMYCIN HYDROCHLORIDE					

>A> AP	HIKMA PHARMS	EQ 750MG BASE/VIAL	A206616	001	Oct 03, 2018	Sep NEWA
>A> AP		EQ 750MG BASE/VIAL	A206616	001	Oct 03, 2018	Sep CAHN

POWDER;INTRAVENOUS

VANCOMYCIN HYDROCHLORIDE

+!	MYLAN LABS LTD	EQ 250MG BASE/VIAL	N209481	001	Jul 10, 2018	Jul NEWA
+!		EQ 750MG BASE/VIAL	N209481	002	Jul 10, 2018	Jul NEWA
+!		EQ 1.25GM BASE/VIAL	N209481	003	Jul 10, 2018	Jul NEWA
+!		EQ 1.5GM BASE/VIAL	N209481	004	Jul 10, 2018	Jul NEWA

VARDENAFIL HYDROCHLORIDE

TABLET;ORAL

LEVITRA

+ @	BAYER HLTHCARE	2.5MG	N021400	003	Aug 19, 2003	Apr DISC
	TABLET, ORALLY DISINTEGRATING;ORAL					

STAXYN

+!	BAYER HLTHCARE	10MG	N200179	001	Jun 17, 2010	Jul CMFD
+ @		10MG	N200179	001	Jun 17, 2010	Apr DISC

VARENICLINE TARTRATE

TABLET;ORAL

CHANTIX

+ PF PRISM CV	EQ 0.5MG BASE	N021928	001	May 10, 2006	Feb CAHN
+ !	EQ 1MG BASE	N021928	002	May 10, 2006	Feb CAHN

VELAGLUCEASE ALFA

INJECTABLE;INTRAVENOUS

VPRIV

SHIRE HUMAN GENETIC	400 UNITS/VIAL	N022575	001	Feb 26, 2010	Jul CDFR
POWDER;INTRAVENOUS					

VPRIV

@ SHIRE HUMAN GENETIC	200 UNITS/VIAL	N022575	002	Feb 26, 2010	Jul CDFR

VENLAFAKINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL  
EFFEXOR XR

AB	+	WYETH PHARMS	EQ 37.5MG BASE	N020699	001	Oct 20, 1997	Jul CAHN
AB	+		EQ 75MG BASE	N020699	002	Oct 20, 1997	Jul CAHN
	@		EQ 100MG BASE	N020699	003	Oct 20, 1997	Jul CAHN
AB	+!		EQ 150MG BASE	N020699	004	Oct 20, 1997	Jul CAHN
		TABLET;ORAL					
		VENLAFAKINE HYDROCHLORIDE					
	@	FOSUN PHARMA	EQ 25MG BASE	A077515	001	Jun 13, 2008	Jan CAHN
	@		EQ 37.5MG BASE	A077515	002	Jun 13, 2008	Jan CAHN
	@		EQ 50MG BASE	A077515	003	Jun 13, 2008	Jan CAHN
	@		EQ 75MG BASE	A077515	004	Jun 13, 2008	Jan CAHN
	@		EQ 100MG BASE	A077515	005	Jun 13, 2008	Jan CAHN

VERAPAMIL HYDROCHLORIDE

SOLUTION;INTRAVENOUS  
VERAPAMIL HYDROCHLORIDE

AP		AMNEAL PHARMS CO	5MG/2ML (2.5MG/ML)	A210994	001	Jul 13, 2018	Jul NEWA
AP			10MG/4ML (2.5MG/ML)	A210994	002	Jul 13, 2018	Jul NEWA
AP		EXELA PHARMA SCS LLC	10MG/4ML (2.5MG/ML)	N018925	002	Apr 05, 2018	May NEWA
AP	!	HOSPIRA	5MG/2ML (2.5MG/ML)	A070738	001	May 06, 1987	Jan CPOT
AP		SOMERSET THERAPS LLC	5MG/2ML (2.5MG/ML)	A211015	001	Jun 18, 2018	Jun NEWA
AP			5MG/2ML (2.5MG/ML)	A211035	001	Jun 18, 2018	Jun NEWA
AP			10MG/4ML (2.5MG/ML)	A211015	002	Jun 18, 2018	Jun NEWA
AP			10MG/4ML (2.5MG/ML)	A211035	002	Jun 18, 2018	Jun NEWA

TABLET;ORAL  
ISOPTIN

+ @	MT ADAMS	40MG	N018593	003	Nov 23, 1987	Apr CRLD
+ @		80MG	N018593	001	Mar 08, 1982	Apr CRLD
+ @		120MG	N018593	002	Mar 08, 1982	Apr CRLD
		VERAPAMIL HYDROCHLORIDE				
@	YAOPHARMA CO LTD	40MG	A073168	001	Jul 31, 1992	Jan CAHN
@		80MG	A071423	001	May 24, 1988	Jan CAHN
@		120MG	A071424	001	May 25, 1988	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL  
VERAPAMIL HYDROCHLORIDE

@	APOTEX CORP	120MG	A200878	001	Apr 20, 2012	Mar DISC
@		180MG	A200878	002	Apr 20, 2012	Mar DISC
@		240MG	A200878	003	Apr 20, 2012	Mar DISC

VIGABATRIN

FOR SOLUTION;ORAL  
VIGABATRIN

AA		AMNEAL PHARMS	500MG/PACKET	A210155	001	Mar 13, 2018	Feb NEWA
AA		TEVA PHARMS USA	500MG/PACKET	A209824	001	Apr 23, 2018	Apr NEWA
AA		VIGADROME					
AA		AUCTA PHARMS	500MG/PACKET	A210196	001	Jun 21, 2018	Jun NEWA

VILAZODONE HYDROCHLORIDE

TABLET;ORAL  
VIIBRYD

+	ALLERGAN SALES LLC	10MG	N022567	001	Jan 21, 2011	Jan CAHN
+		20MG	N022567	002	Jan 21, 2011	Jan CAHN
+		40MG	N022567	003	Jan 21, 2011	Jan CAHN

VINBLASTINE SULFATE

INJECTABLE;INJECTION

VELBAN

+ @	LILLY	10MG/VIAL	N012665	001		Apr CRLD
-----	-------	-----------	---------	-----	--	----------

VITAMIN A PALMITATE

INJECTABLE;INJECTION

AQUASOL A

+!	CASPER PHARMA LLC	EQ 50,000 UNITS BASE/ML	N006823	001		Jul CAHN
----	-------------------	-------------------------	---------	-----	--	----------

VORICONAZOLE

INJECTABLE;IV (INFUSION)

VORICONAZOLE

AP	ZYDUS PHARMS USA INC	200MG/VIAL	A208983	001	Jul 16, 2018	Jul NEWA
AB	TABLET;ORAL					
AB	VORICONAZOLE					

AB	RISING PHARMS	50MG	A206762	001	May 24, 2016	Aug CAHN
AB		200MG	A206762	002	May 24, 2016	Aug CAHN

WARFARIN SODIUM

TABLET;ORAL

WARFARIN SODIUM

@ YAOPHARMA CO LTD	1MG	A040196	001	Sep 30, 1997	Jan CAHN
@	2MG	A040196	002	Sep 30, 1997	Jan CAHN
@	2.5MG	A040196	003	Sep 30, 1997	Jan CAHN
@	3MG	A040196	008	Jul 26, 2000	Jan CAHN
@	4MG	A040196	004	Sep 30, 1997	Jan CAHN
@	5MG	A040196	005	Sep 30, 1997	Jan CAHN
@	6MG	A040196	009	Jul 26, 2000	Jan CAHN
@	7.5MG	A040196	006	Sep 30, 1997	Jan CAHN
@	10MG	A040196	007	Sep 30, 1997	Jan CAHN

ZICONOTIDE ACETATE

INJECTABLE;INTRATHECAL

PRIALT

>D>	+! JAZZ PHARMS INTL	100MCG/1ML (100MCG/ML)	N021060	002	Dec 28, 2004	Sep CAHN
>D>	@	200MCG/2ML (100MCG/ML)	N021060	003	Dec 28, 2004	Sep CAHN
>D>	+!	500MCG/20ML (25MCG/ML)	N021060	001	Dec 28, 2004	Sep CAHN
>D>	+!	500MCG/5ML (100MCG/ML)	N021060	004	Dec 28, 2004	Sep CAHN
>A>	+! TERSERA THERAPS LLC	100MCG/1ML (100MCG/ML)	N021060	002	Dec 28, 2004	Sep CAHN
>A>	@	200MCG/2ML (100MCG/ML)	N021060	003	Dec 28, 2004	Sep CAHN
>A>	+!	500MCG/20ML (25MCG/ML)	N021060	001	Dec 28, 2004	Sep CAHN
>A>	+!	500MCG/5ML (100MCG/ML)	N021060	004	Dec 28, 2004	Sep CAHN

ZIPRASIDONE HYDROCHLORIDE

CAPSULE;ORAL

ZIPRASIDONE HYDROCHLORIDE

@ MYLAN PHARMS INC	EQ 20MG BASE	A202395	001	Oct 10, 2013	Mar DISC
@	EQ 40MG BASE	A202395	002	Oct 10, 2013	Mar DISC
@	EQ 60MG BASE	A202395	003	Oct 10, 2013	Mar DISC
@	EQ 80MG BASE	A202395	004	Oct 10, 2013	Jul DISC

ZOLEDRONIC ACID

INJECTABLE;IV (INFUSION)

ZOLEDRONIC

AP	GLAND PHARMA LTD	EQ 4MG BASE/100ML	A205749	001	Jun 29, 2018	Jun NEWA
AP	ZOLEDRONIC ACID					
AP	INFORLIFE	EQ 4MG BASE/100ML	N203231	001	Aug 02, 2013	Jan CAHN

AP		EQ 5MG BASE/100ML	A202828	001	Sep 23, 2013	Jan CAHN
----	--	-------------------	---------	-----	--------------	----------

ZOLMITRIPTAN

TABLET;ORAL

ZOLMITRIPTAN

@ APOTEX INC	2.5MG	A202078	001	May 14, 2013	Mar DISC	
@	5MG	A202078	002	May 14, 2013	Mar DISC	
>D> AB	APPCO PHARMA LLC	2.5MG	A206973	001	Jun 30, 2017	Sep CAHN
>D> AB		5MG	A206973	002	Jun 30, 2017	Sep CAHN
@ MYLAN PHARMS INC	2.5MG	A203186	001	May 14, 2013	Jul DISC	
@	5MG	A203186	002	May 14, 2013	Jul DISC	
>A> AB	TWI PHARMS	2.5MG	A206973	001	Jun 30, 2017	Sep CAHN
>A> AB		5MG	A206973	002	Jun 30, 2017	Sep CAHN
AB	ZYDUS PHARMS USA INC	2.5MG	A203019	001	Jul 11, 2018	Jun NEWA
AB		5MG	A203019	002	Jul 11, 2018	Jun NEWA

TABLET, ORALLY DISINTEGRATING;ORAL

ZOLMITRIPTAN

@ APOTEX INC	2.5MG	A202476	001	May 14, 2013	Mar DISC
@	5MG	A202476	002	May 14, 2013	Mar DISC

ZOLPIDEM TARTRATE

TABLET;ORAL

ZOLPIDEM TARTRATE

@ SUN PHARM INDS LTD	5MG	A078055	001	Apr 23, 2007	Apr DISC
@	10MG	A078055	002	Apr 23, 2007	Apr DISC

ZONISAMIDE

CAPSULE;ORAL

ZONEGRAN

+ @ SUNOVION PHARMS INC	50MG	N020789	002	Aug 22, 2003	Jul DISC	
ZONISAMIDE						
@ AUROBINDO PHARMA LTD	25MG	A077645	002	Sep 29, 2006	Feb CAHN	
@	50MG	A077645	003	Sep 29, 2006	Feb CAHN	
@	100MG	A077645	001	Dec 22, 2005	Feb CAHN	
>D> AB	BIONPHARMA INC	25MG	A077813	001	Aug 16, 2006	Sep CAHN
>D> AB		50MG	A077813	002	Aug 16, 2006	Sep CAHN
>D> AB		100MG	A077813	003	Aug 16, 2006	Sep CAHN
>A> AB	BLUEPHARMA	25MG	A077813	001	Aug 16, 2006	Sep CAHN
>A> AB		50MG	A077813	002	Aug 16, 2006	Sep CAHN
>A> AB		100MG	A077813	003	Aug 16, 2006	Sep CAHN

**ACETAMINOPHEN**

SUPPOSITORY;RECTAL					
ACEPHEN					
@ G AND W LABS	325MG	N 018060	003	Dec 18, 1986	Jan DISC
@	650MG	N 018060	002		Jan DISC
ACETAMINOPHEN					
+ TARO PHARM IND LTD	120MG	N 018337	003	Sep 12, 1983	May CAHN
+	325MG	N 018337	002		May CAHN
+!	650MG	N 018337	001		May CAHN
INFANTS' FEVERALL					
+ TARO PHARM IND LTD	80MG	N 018337	004	Aug 26, 1992	May CAHN
TABLET, EXTENDED RELEASE;ORAL					
ACETAMINOPHEN					
HERITAGE PHARMA	650MG	A 207035	001	May 31, 2018	May NEWA

**ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE**

TABLET, CHEWABLE;ORAL					
GAVISCON					
+ @ SANOFI AVENTIS US	160MG;40MG	N 018685	002	Dec 09, 1983	May DISC

**ASPIRIN**

CAPSULE;ORAL					
VAZALORE					
+! PLX PHARMA	325MG	N 203697	001	Jan 14, 2013	Aug CTNA

**BUTENAFINE HYDROCHLORIDE**

CREAM;TOPICAL					
BUTENAFINE HYDROCHLORIDE					
TARO PHARMS	1%	A 205181	001	Nov 16, 2017	May CAHN

**CETIRIZINE HYDROCHLORIDE**

CAPSULE;ORAL					
CETIRIZINE HYDROCHLORIDE ALLERGY					
AUROBINDO PHARMA LTD	10MG	A 209107	001	Jul 20, 2018	Jul NEWA
CETIRIZINE HYDROCHLORIDE HIVES RELIEF					
AUROBINDO PHARMA LTD	10MG	A 209107	002	Jul 20, 2018	Jul NEWA

SYRUP;ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY					
ALLIED	5MG/5ML	A 091327	001	Oct 17, 2011	Sep CAHN
APNAR PHARMA LP	5MG/5ML	A 091327	001	Oct 17, 2011	Sep CAHN
CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF					
ALLIED	5MG/5ML	A 091327	002	Oct 17, 2011	Sep CAHN
APNAR PHARMA LP	5MG/5ML	A 091327	002	Oct 17, 2011	Sep CAHN

TABLET;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY					
JUBILANT CADISTA	5MG	A 078933	001	Jun 15, 2010	Sep CAHN
	10MG	A 078933	002	Jun 15, 2010	Sep CAHN
MARKSANS PHARMA	5MG	A 078933	001	Jun 15, 2010	Sep CAHN
	10MG	A 078933	002	Jun 15, 2010	Sep CAHN
PLD ACQUISITIONS	5MG	A 077946	001	Dec 27, 2007	Feb CAHN
	10MG	A 077946	002	Dec 27, 2007	Feb CAHN
CETIRIZINE HYDROCHLORIDE HIVES					

JUBILANT CADISTA	5MG	A 078933	003	Jun 15, 2010	Sep CAHN
	10MG	A 078933	004	Jun 15, 2010	Sep CAHN
MARKSANS PHARMA	5MG	A 078933	003	Jun 15, 2010	Sep CAHN
	10MG	A 078933	004	Jun 15, 2010	Sep CAHN
! UNIQUE PHARM LABS	10MG	A 077829	002	Aug 26, 2009	Aug CHRS
ZYRTEC ALLERGY					
+ @ J AND J CONSUMER INC	5MG	N 019835	003	Nov 16, 2007	Aug DISC
ZYRTEC HIVES RELIEF					
+ @ J AND J CONSUMER INC	5MG	N 019835	005	Nov 16, 2007	Aug DISC
	10MG	N 019835	006	Nov 16, 2007	Aug DISC

**CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE**

TABLET, EXTENDED RELEASE;ORAL					
CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE					
PLD ACQUISITIONS	5MG;120MG	A 077991	001	Mar 05, 2008	Feb CAHN

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SOLUTION;TOPICAL

SOLUPREP

+! 3M HEALTH CARE 2%;70%

N208288 001 Aug 08, 2018 Aug NEWA

SPONGE;TOPICAL

CHLORAPREP ONE-STEP

+! BECTON DICKINSON CO 2%;70% (1ML)

N020832 008 Oct 23, 2008 Feb NEWA

CLEMASTINE FUMARATE

TABLET;ORAL

CLEMASTINE FUMARATE

! L PERRIGO CO 1.34MG  
@ PLD ACQUISITIONS LLC 1.34MG  
1.34MGA074512 001 Nov 22, 1995 Jul CHRS  
A073458 001 Oct 31, 1993 Jul DISC  
A073458 001 Oct 31, 1993 Jan CAHN

TAVIST-1

+ @ GLAXOSMITHKLINE CONS 1.34MG

N020925 001 Aug 21, 1992 Jul DISC

CLOTRIMAZOLE

CREAM;VAGINAL

MYCELEX-7

@ BAYER HEALTHCARE LLC 1%

N018230 002 Dec 26, 1991 Mar DISC

CREAM, TABLET;TOPICAL, VAGINAL

MYCELEX-7 COMBINATION PACK

@ BAYER HEALTHCARE LLC 1%,100MG

N020389 002 Jun 23, 1994 Feb DISC

TABLET;VAGINAL

MYCELEX-7

@ BAYER HEALTHCARE LLC 100MG

N018182 002 Dec 26, 1991 Mar DISC

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE

@ AVANTHI INC 6MG;120MG

A078648 001 Feb 27, 2013 Jun DISC

DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN

TABLET, EXTENDED RELEASE;ORAL

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

PERRIGO R AND D 30MG;600MG  
60MG;1.2GMA207602 002 Mar 05, 2018 Apr NEWA  
A207602 001 Mar 05, 2018 Apr NEWAESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED RELEASE;ORAL

ESOMEPRAZOLE MAGNESIUM

DR REDDYS LABS LTD EQ 20MG BASE

A207673 001 May 15, 2018 Apr NEWA

FEXOFENADINE HYDROCHLORIDE

SUSPENSION;ORAL

CHILDREN'S ALLEGRA ALLERGY

>D> + @ SANOFI AVENTIS US 30MG/5ML  
>A> + 30MG/5ML  
+ @ 30MG/5MLN201373 001 Jan 24, 2011 Sep CMFD  
N201373 001 Jan 24, 2011 Sep CMFD  
N201373 001 Jan 24, 2011 Jul DISC

CHILDREN'S ALLEGRA HIVES

+ @ SANOFI AVENTIS US 30MG/5ML  
CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY  
! ACTAVIS MID ATLANTIC 30MG/5ML  
@ TARO PHARM 30MG/5ML  
CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES  
! ACTAVIS MID ATLANTIC 30MG/5ML  
@ TARO PHARM 30MG/5MLN201373 002 Jan 24, 2011 Jul DISC  
A203330 001 Nov 18, 2014 Jul CHRS  
A208123 001 Nov 09, 2017 Jul DISC  
A203330 002 Nov 18, 2014 Jul CHRS  
A208123 002 Nov 09, 2017 Jul DISC

TABLET;ORAL

ALLEGRA HIVES

+ @ SANOFI AVENTIS US 60MG  
+ @ 180MG  
CHILDREN'S ALLEGRA ALLERGY  
+ @ SANOFI AVENTIS US 30MG  
CHILDREN'S ALLEGRA HIVES  
+ @ SANOFI AVENTIS US 30MG  
FEXOFENADINE HYDROCHLORIDE ALLERGY  
UNIQUE PHARM LABS 180MGN020872 008 Jan 24, 2011 Jun DISC  
N020872 009 Jan 24, 2011 Jun DISC  
N020872 005 Jan 24, 2011 Jun DISC  
N020872 006 Jan 24, 2011 Jun DISC  
A210137 001 Aug 13, 2018 Jul NEWA

TABLET, ORALLY DISINTEGRATING;ORAL  
CHILDREN'S ALLEGRA ALLERGY

+ @ SANOFI AVENTIS US	30MG	N 021909	002	Jan 24, 2011	Jul DISC
CHILDREN'S ALLEGRA HIVES					
+ @ SANOFI AVENTIS US	30MG	N 021909	003	Jan 24, 2011	Jul DISC
CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY					
@ DR REDDYS LABS LTD	30MG	A 202978	001	Jan 18, 2013	Jul DISC
CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES					
@ DR REDDYS LABS LTD	30MG	A 202978	002	Jan 18, 2013	Jul DISC

GUAIFENESIN

TABLET, EXTENDED RELEASE;ORAL  
GUAIFENESIN

AMNEAL PHARMS	600MG	A 207342	001	Jul 11, 2018	Jun NEWA
	1.2GM	A 207342	002	Jul 11, 2018	Jun NEWA
GUARDIAN DRUG	600MG	A 209215	001	Sep 06, 2017	Aug CAHN
	1.2GM	A 209215	002	Sep 06, 2017	Aug CAHN
OHM LABS INC	600MG	A 209254	001	Jul 16, 2018	Jul NEWA
	1.2GM	A 209254	002	Jul 16, 2018	Jul NEWA

IBUPROFEN

CAPSULE;ORAL  
IBUPROFEN

AUROBINDO PHARMA LTD	EQ 200MG FREE ACID AND POTASSIUM SALT	A 207753	001	Jun 29, 2018	Jun NEWA
STRIDES PHARMA	EQ 200MG FREE ACID AND POTASSIUM SALT	A 204469	001	Mar 28, 2018	Mar NEWA

SUSPENSION;ORAL  
IBUPROFEN

AUROBINDO PHARMA LTD	100MG/5ML	A 209179	001	Apr 17, 2018	Apr NEWA
GUARDIAN DRUG	100MG/5ML	A 210149	001	Aug 17, 2018	Aug NEWA

SUSPENSION/DROPS;ORAL  
IBUPROFEN

GUARDIAN DRUG	40MG/ML	A 210755	001	Sep 26, 2018	Sep NEWA
---------------	---------	----------	-----	--------------	----------

>A>

TABLET;ORAL IBUPROFEN					
--------------------------	--	--	--	--	--

>D>

AIPING PHARM INC	200MG	A 206990	001	Aug 21, 2018	Sep CAHN
	200MG	A 206990	001	Aug 21, 2018	Aug NEWA

>D>

DR REDDYS LABS INC	200MG	A 207095	001	May 05, 2017	Sep CAHN
--------------------	-------	----------	-----	--------------	----------

>D>

LNK	100MG	A 076117	001	Nov 20, 2001	Jul CPOT
-----	-------	----------	-----	--------------	----------

>A>

@	100MG	A 076741	001	Jun 17, 2004	Sep DISC
---	-------	----------	-----	--------------	----------

>A>

@ P AND L DEV LLC	200MG	A 070733	001	Sep 19, 1986	Jan CAHN
-------------------	-------	----------	-----	--------------	----------

>A>

SHANDONG XINHUA	200MG	A 206990	001	Aug 21, 2018	Sep CAHN
-----------------	-------	----------	-----	--------------	----------

>A>

STRIDES PHARMA	200MG	A 207095	001	May 05, 2017	Sep CAHN
----------------	-------	----------	-----	--------------	----------

TABLET, CHEWABLE;ORAL  
CHILDREN'S MOTRIN

+ @ J AND J CONSUMER INC	50MG	N 020601	001	Nov 15, 1996	Jul DISC
IBUPROFEN					
@ PERRIGO	50MG	A 076359	001	Jan 16, 2004	Jul DISC
!	100MG	A 076359	002	Jan 16, 2004	Jul CHRS
JUNIOR STRENGTH MOTRIN					
+ @ J AND J CONSUMER INC	100MG	N 020601	003	Nov 15, 1996	Jul DISC

LEVOCEFTIRIZINE DIHYDROCHLORIDE

TABLET;ORAL  
LEVOCEFTIRIZINE DIHYDROCHLORIDE  
DR REDDYS LABS LTD 5MG

A 210375	001	Jan 19, 2018	Jan NEWA
----------	-----	--------------	----------

LEVONORGESTREL

TABLET;ORAL  
LEVONORGESTREL

>A>	AMNEAL PHARMS	1.5MG	A 204044	001	Jul 03, 2018	Sep CAHN
>A>	APOTEX INC	1.5MG	A 205329	001	Sep 18, 2018	Sep NEWA
>D>	HAUPT PHARMA	1.5MG	A 204044	001	Jul 03, 2018	Sep CAHN
		1.5MG	A 204044	001	Jul 03, 2018	Jun NEWA

LOPERAMIDE HYDROCHLORIDE

SOLUTION;ORAL

LOPERAMIDE HYDROCHLORIDE

>D>	ALLIED	1MG/5ML	A073079	001	Apr 30, 1992	Sep DISC
>A>	@	1MG/5ML	A073079	001	Apr 30, 1992	Sep DISC

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET;ORAL

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

PERRIGO R AND D 2MG;125MG

A209837 001 Sep 05, 2018 Aug NEWA

LORATADINE

SYRUP;ORAL

LORATADINE

AUROBINDO PHARMA LTD 1MG/ML

A208931 001 Jun 29, 2018 Jun NEWA

TABLET;ORAL

LORATADINE

AUROBINDO PHARMA LTD 10MG

A208314 001 Apr 16, 2018 Apr NEWA

PLD ACQUISITIONS LLC 10MG

A075209 001 Jan 21, 2003 Jan CAHN

TABLET, CHEWABLE;ORAL

LORATADINE

SUN PHARMA GLOBAL 5MG

A210088 001 Apr 16, 2018 Apr NEWA

TABLET, ORALLY DISINTEGRATING;ORAL

LORATADINE

AUROBINDO PHARMA LTD 10MG

A208477 001 Apr 11, 2018 Mar NEWA

MICONAZOLE NITRATE

CREAM;VAGINAL

MICONAZOLE NITRATE

TARO PHARMS 2%

A074444 001 Jan 13, 1997 May CAHN

CREAM, SUPPOSITORY;TOPICAL, VAGINAL

MICONAZOLE 7 COMBINATION PACK

@ G AND W LABS 2%,100MG

A076585 001 Mar 26, 2004 Jan DISC

NAPROXEN SODIUM

CAPSULE;ORAL

NAPROXEN SODIUM

PURACAP PHARM LLC EQ 200MG BASE

A208363 001 Mar 15, 2018 Jun NEWA

TABLET;ORAL

NAPROXEN SODIUM

@ PLD ACQUISITIONS LLC EQ 200MG BASE

A074646 001 Jan 13, 1997 Jan CAHN

NICOTINE POLACRILEX

GUM, CHEWING;BUCCAL

THRIVE

@ GLAXOSMITHKLINE CONS EQ 4MG BASE

A077656 001 Jun 19, 2007 Aug DISC

EQ 4MG BASE

A077656 001 Jun 19, 2007 Feb CAHN

TROCHE/LOZENGE;ORAL

NICORETTE

+ GLAXOSMITHKLINE CONS EQ 2MG BASE

N021330 001 Oct 31, 2002 Feb CTNA

EQ 4MG BASE

N021330 002 Oct 31, 2002 Feb CTNA

NICOTINE POLACRILEX

WATSON LABS INC EQ 2MG BASE

A209206 001 Jun 26, 2018 Jun NEWA

EQ 4MG BASE

A209206 002 Jun 26, 2018 Jun NEWA

WATSON LABS TEVA EQ 2MG BASE

A209519 001 Jul 02, 2018 Jun NEWA

EQ 4MG BASE

A209519 002 Jul 02, 2018 Jun NEWA

OMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED RELEASE;ORAL

OMEPRAZOLE MAGNESIUM

SPLI EQ 20MG BASE

A210593 001 Jul 20, 2018 Jul NEWA

TABLET, DELAYED RELEASE;ORAL

OMEPRAZOLE MAGNESIUM

AUROBINDO PHARMA LTD EQ 20MG BASE

A206877 001 Jun 06, 2018 May NEWA

OMEPRAZOLE; SODIUM BICARBONATE

CAPSULE;ORAL

OMEPRAZOLE AND SODIUM BICARBONATE  
ZYDUS PHARMS USA INC 20MG;1.1GM

A203345 001 Mar 16, 2018 Mar NEWA

POLYETHYLENE GLYCOL 3350

FOR SOLUTION;ORAL

POLYETHYLENE GLYCOL 3350

APNAR PHARMA LP 17GM/SCOOPFUL  
AUROBINDO PHARMA LTD 17GM/SCOOPFULA202071 001 Dec 28, 2012 Mar CAHN  
A209017 001 Apr 09, 2018 Mar NEWAPSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

AFRINOL

+ @ SCHERING PLOUGH 120MG

N018191 001 Jul DISC

RANITIDINE HYDROCHLORIDE

TABLET;ORAL

RANITIDINE HYDROCHLORIDE

GRANULES INDIA LTD EQ 150MG BASE  
EQ 150MG BASE  
VIVIMED GLOBAL EQ 75MG BASE  
EQ 150MG BASEA210243 001 Aug 20, 2018 Aug NEWA  
A210243 002 Aug 20, 2018 Aug NEWA  
A209160 001 Mar 05, 2018 Feb NEWA  
A209161 001 Feb 22, 2018 Feb NEWATERBINAFINE

GEL;TOPICAL

LAMISIL AT

+! GLAXOSMITHKLINE CONS 1%

N021958 001 Jul 24, 2006 Feb CAHN

TERBINAFINE HYDROCHLORIDE

SOLUTION;TOPICAL

LAMISIL AT

+! GLAXOSMITHKLINE CONS 1%

N021124 001 Mar 17, 2000 Feb CAHN

SPRAY;TOPICAL

LAMISIL AT

+! GLAXOSMITHKLINE CONS 1%

N021124 002 Mar 17, 2000 Feb CAHN

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

**CUMULATIVE SUPPLEMENT NUMBER 9 SEPTEMBER 2018**

NO SEPTEMBER 2018 APPROVALS

## ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The 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 SEPTEMBER 2018 ADDITIONS

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b><u>ABEMACICLIB - VERZENIO</u></b>						
N 208716 001	7855211	Dec 15, 2029	DS DP U-2132		I-768	Feb 26, 2021
	7855211	Dec 15, 2029	DS DP U-2135			
	7855211	Dec 15, 2029	DS DP U-2251			
<b><u>ABEMACICLIB - VERZENIO</u></b>						
N 208716 002	7855211	Dec 15, 2029	DS DP U-2132		I-768	Feb 26, 2021
	7855211	Dec 15, 2029	DS DP U-2135			
	7855211	Dec 15, 2029	DS DP U-2251			
<b><u>ABEMACICLIB - VERZENIO</u></b>						
N 208716 003	7855211	Dec 15, 2029	DS DP U-2132		I-768	Feb 26, 2021
	7855211	Dec 15, 2029	DS DP U-2135			
	7855211	Dec 15, 2029	DS DP U-2251			
<b><u>ABEMACICLIB - VERZENIO</u></b>						
N 208716 004	7855211	Dec 15, 2029	DS DP U-1981		I-768	Feb 26, 2021
	7855211	Dec 15, 2029	DS DP U-2132			
	7855211	Dec 15, 2029	DS DP U-2135			
	7855211	Dec 15, 2029	DS DP U-2251			
<b><u>ABIRATERONE ACETATE - ZYTIGA</u></b>						
N 202379 001	8822438	Aug 24, 2027	U-1579		I-765	Feb 07, 2021
	8822438	Aug 24, 2027	U-1580			
	8822438	Aug 24, 2027	U-2235			
<b><u>ABIRATERONE ACETATE - ZYTIGA</u></b>						
N 202379 002	8822438	Aug 24, 2027	U-1579		I-765	Feb 07, 2021
	8822438	Aug 24, 2027	U-1580			
	8822438	Aug 24, 2027	U-2235			
<b><u>ABIRATERONE ACETATE - YONSA</u></b>						
N 210308 001	9889144	Mar 17, 2034	DP			
<b><u>ACALABRUTINIB - CALQUENCE</u></b>						
N 210259 001	7459554	Nov 24, 2026	DS		ODE-175	Oct 31, 2024
<b><u>ACETAMINOPHEN - OFIRMEV</u></b>						
N 022450 001	9399012	Sep 11, 2031	U-2261			
	9399012	Sep 11, 2031	U-2262			
	9399012*PED	Mar 11, 2032				
	9610265	Nov 13, 2028	U-2263			
	9610265*PED	May 13, 2029				
	9987238	Nov 13, 2028	U-2261			
	9987238*PED	May 13, 2029				
<b><u>ACETAMINOPHEN; BENZHYDROCODONE HYDROCHLORIDE - APADAZ</u></b>						
N 208653 001	8461137	Feb 22, 2031	DS DP			
	8748413	Jul 01, 2030	DS DP			
	8828978	Jul 01, 2030	DP			
	9132125	Jul 01, 2030	DS DP U-2249			
	9549923	Jul 01, 2030	DS DP			
<b><u>ACLIDINIUM BROMIDE - TUDORZA PRESSAIR</u></b>						
N 202450 001	RE46417	Feb 10, 2025	DS DP U-1263			
<b><u>AFATINIB DIMALEATE - GILOTRIE</u></b>						
N 201292 001	10004743	Jul 05, 2030	DP		I-763	Jan 12, 2021

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>AFATINIB DIMALEATE - GILOTRIE</u> N 201292 002	10004743	Jul 05, 2030	DP		I-763	Jan 12, 2021
<u>AFATINIB DIMALEATE - GILOTRIE</u> N 201292 003	10004743	Jul 05, 2030	DP		I-763	Jan 12, 2021
<u>ALBUTEROL SULFATE - VENTOLIN HFA</u> N 020983 001	9861771	Oct 11, 2020	DP			
<u>ALBUTEROL SULFATE - PROAIR HFA</u> N 021457 001	10022509 10022510	May 18, 2031 May 18, 2031	DP DP			
<u>ALBUTEROL SULFATE - PROAIR RESPICLICK</u> N 205636 001	10022510	May 18, 2031	DP			
<u>ALCOHOL - ABLYSINOL</u> N 207987 001					ODE-192	Jun 21, 2025
<u>ALCOHOL - ABLYSINOL</u> N 207987 002					ODE-192	Jun 21, 2025
<u>ALLOPURINOL; LESINURAD - DUZALLO</u> N 209203 001	9956205	Dec 28, 2031	U-2104			
<u>ALLOPURINOL; LESINURAD - DUZALLO</u> N 209203 002	9956205	Dec 28, 2031	U-2104			
<u>AMANTADINE HYDROCHLORIDE - GOCOVRI</u> N 208944 001	9867791 9867792 9867793 9877933	Dec 02, 2030 Dec 02, 2030 Dec 02, 2030 Dec 02, 2030	U-2106 U-2106 U-2106 U-2224		I-769	Aug 24, 2020
<u>AMANTADINE HYDROCHLORIDE - GOCOVRI</u> N 208944 002	9867791 9867792 9867793 9877933	Dec 02, 2030 Dec 02, 2030 Dec 02, 2030 Dec 02, 2030	U-2106 U-2106 U-2106 U-2224		I-769	Aug 24, 2020
<u>AMANTADINE HYDROCHLORIDE - OSMOLEX ER</u> N 209410 001	8252331 8574626 RE39069	Mar 13, 2030 Nov 28, 2025 May 29, 2018	DP DP U-20 DP			
<u>AMANTADINE HYDROCHLORIDE - OSMOLEX ER</u> N 209410 002	8252331 8574626 RE39069	Mar 13, 2030 Nov 28, 2025 May 29, 2018	DP DP U-20 DP			
<u>AMANTADINE HYDROCHLORIDE - OSMOLEX ER</u> N 209410 003	8252331 8574626 RE39069	Mar 13, 2030 Nov 28, 2025 May 29, 2018	DP DP U-20 DP			
<u>AMINOLEVULINIC ACID HYDROCHLORIDE - LEVULAN</u> N 020965 001					I-766	Mar 09, 2021
<u>AMLODIPINE BESYLATE; CELECOXIB - CONSENSI</u> N 210045 001					NC	May 31, 2021

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>AMLODIPINE BESYLATE; CELECOXIB - CONSENSI</u>						
N 210045 002					NC	May 31, 2021
<u>AMLODIPINE BESYLATE; CELECOXIB - CONSENSI</u>						
N 210045 003					NC	May 31, 2021
<u>AMPHETAMINE - DYANAVEL XR</u>						
N 208147 001 >A> 10086087		Mar 15, 2027	DP			
<u>AMPHETAMINE SULFATE - AMPHETAMINE SULFATE</u>						
A 211139 001				>A> CGT		Mar 26, 2019
<u>AMPHETAMINE SULFATE - AMPHETAMINE SULFATE</u>						
A 211139 002				>A> CGT		Mar 30, 2019
<u>ANGIOTENSIN II ACETATE - GIAPREZA</u>						
N 209360 001	10028995	Dec 18, 2034	U-2338		NCE	Dec 21, 2022
	9220745	Dec 18, 2034	U-2217			
	9220745	Dec 18, 2034	U-2218			
	9572856	Sep 20, 2030	U-2221			
	9867863	Dec 16, 2029	U-2231			
<u>ANGIOTENSIN II ACETATE - GIAPREZA</u>						
N 209360 002	10028995	Dec 18, 2034	U-2338		NCE	Dec 21, 2022
	9220745	Dec 18, 2034	U-2217			
	9220745	Dec 18, 2034	U-2218			
	9572856	Sep 20, 2030	U-2221			
	9867863	Dec 16, 2029	U-2231			
<u>APALUTAMIDE - ERLEADA</u>						
N 210951 001 >A> 10052314		Sep 23, 2033	U-2381		NCE	Feb 14, 2023
>A> 10052314		Sep 23, 2033	U-2382			
	8445507	Sep 15, 2030	DS DP U-2237			
	8802689	Mar 27, 2027	U-2237			
	9388159	Mar 27, 2027	DS DP			
	9481663	Jun 04, 2033	DS DP U-2237			
	9884054	Sep 23, 2033	U-2237			
<u>APREMILAST - OTEZLA</u>						
N 205437 001 >A> 10092541		May 29, 2034	U-2403			
	7427638	Feb 16, 2028	DS DP			
	9724330	Mar 19, 2023	U-1561			
	9724330	Mar 19, 2023	U-1595			
	9872854	May 29, 2034	U-2232			
	9872854	May 29, 2034	U-2233			
<u>APREMILAST - OTEZLA</u>						
N 205437 002 >A> 10092541		May 29, 2034	U-2403			
	7427638	Feb 16, 2028	DS DP			
	9724330	Mar 19, 2023	U-1561			
	9724330	Mar 19, 2023	U-1595			
	9872854	May 29, 2034	U-2232			
	9872854	May 29, 2034	U-2233			
<u>APREMILAST - OTEZLA</u>						
N 205437 003 >A> 10092541		May 29, 2034	U-2403			
	7427638	Feb 16, 2028	DS DP			
	9724330	Mar 19, 2023	U-1561			
	9724330	Mar 19, 2023	U-1595			
	9872854	May 29, 2034	U-2232			
	9872854	May 29, 2034	U-2233			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>APREPITANT - CINVANTI</b></u>						
N 209296 001	9974742	Sep 18, 2035	DP			
	9974793	Sep 18, 2035	DP			
	9974794	Sep 18, 2035	DP U-2161			
<u><b>ARIPIPRAZOLE - ABILIFY MYCITE KIT</b></u>						
N 207202 001	9941931	Nov 04, 2030	DP			
<u><b>ARIPIPRAZOLE - ABILIFY MYCITE KIT</b></u>						
N 207202 002	9941931	Nov 04, 2030	DP			
<u><b>ARIPIPRAZOLE - ABILIFY MYCITE KIT</b></u>						
N 207202 003	9941931	Nov 04, 2030	DP			
<u><b>ARIPIPRAZOLE - ABILIFY MYCITE KIT</b></u>						
N 207202 004	9941931	Nov 04, 2030	DP			
<u><b>ARIPIPRAZOLE - ABILIFY MYCITE KIT</b></u>						
N 207202 005	9941931	Nov 04, 2030	DP			
<u><b>ARIPIPRAZOLE - ABILIFY MYCITE KIT</b></u>						
N 207202 006	9941931	Nov 04, 2030	DP			
<u><b>ARIPIPRAZOLE LAUROXIL - ARISTADA</b></u>						
N 207533 001 >A> 9452131		Mar 19, 2035	U-2402			
<u><b>ARIPIPRAZOLE LAUROXIL - ARISTADA</b></u>						
N 207533 002 >A> 9452131		Mar 19, 2035	U-2402			
<u><b>ARIPIPRAZOLE LAUROXIL - ARISTADA</b></u>						
N 207533 003 >A> 9452131		Mar 19, 2035	U-2402			
<u><b>ARIPIPRAZOLE LAUROXIL - ARISTADA</b></u>						
N 207533 004 >A> 9452131		Mar 19, 2035	U-2402			
<u><b>ARIPIPRAZOLE LAUROXIL - ARISTADA INITIO KIT</b></u>						
N 209830 001	10016415	Sep 08, 2035	DP		NCE	Oct 05, 2020
	8431576	Oct 26, 2030	DS			
	8796276	Jun 24, 2030		U-543		
<u><b>ARSENIC TRIOXIDE - TRISENOX</b></u>						
N 021248 001	6723351	Nov 10, 2018	U-2204		ODE-167	Jan 12, 2025
	6723351	Nov 10, 2018	U-2229			
	6723351	Nov 10, 2018	U-573			
	6855339	Nov 10, 2018	U-2204			
	6855339	Nov 10, 2018	U-2229			
	6855339	Nov 10, 2018	U-617			
	6861076	Nov 10, 2018	U-2204			
	6861076	Nov 10, 2018	U-2229			
	6861076	Nov 10, 2018	U-617			
	6884439	Nov 10, 2018	U-2204			
	6884439	Nov 10, 2018	U-2229			
	6884439	Nov 10, 2018	U-651			
	6982096	Nov 10, 2018	U-2204			
	6982096	Nov 10, 2018	U-2229			
	6982096	Nov 10, 2018	U-651			
	8273379	Nov 10, 2018	U-1291			
	8273379	Nov 10, 2018	U-2204			
	8273379	Nov 10, 2018	U-2229			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>ARSENIC TRIOXIDE - TRISENOX</b></u>						
N 021248 002	6723351	Nov 10, 2018	U-2204		ODE-167	Jan 12, 2025
	6723351	Nov 10, 2018	U-2229			
	6855339	Nov 10, 2018	U-2204			
	6855339	Nov 10, 2018	U-2229			
	6861076	Nov 10, 2018	U-2204			
	6861076	Nov 10, 2018	U-2229			
	6884439	Nov 10, 2018	U-2204			
	6884439	Nov 10, 2018	U-2229			
	6982096	Nov 10, 2018	U-2204			
	6982096	Nov 10, 2018	U-2229			
	8273379	Nov 10, 2018	U-2204			
	8273379	Nov 10, 2018	U-2229			
<u><b>ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - PLENNU</b></u>						
N 209381 001	10016504	Sep 10, 2033	DP		NP	May 04, 2021
	8999313	Sep 10, 2033	DP			
	9326969	Sep 10, 2033	U-2310			
	9592252	Aug 11, 2032	DP U-2310			
	9707297	Sep 10, 2033	DP			
<u><b>ASENAPINE MALEATE - SAPHRIS</b></u>						
N 022117 001				M-158	Mar 12, 2018	
				NPP	Mar 12, 2018	
				PED	Sep 12, 2018	
				PED	Sep 12, 2018	
<u><b>ASENAPINE MALEATE - SAPHRIS</b></u>						
N 022117 002				M-158	Mar 12, 2018	
				NPP	Mar 12, 2018	
				PED	Sep 12, 2018	
				PED	Sep 12, 2018	
<u><b>ASPIRIN; OMEPRAZOLE - YOSPRALA</b></u>						
N 205103 001	9987231	Jan 02, 2033	U-2324			
<u><b>ASPIRIN; OMEPRAZOLE - YOSPRALA</b></u>						
N 205103 002	9987231	Jan 02, 2033	U-2324			
<u><b>ATAZANAVIR SULFATE; COBICISTAT - EVOTAZ</b></u>						
N 206353 001	10039718	Oct 04, 2032	DP			
<u><b>AVATROMBOPAG MALEATE - DOPTELET</b></u>						
N 210238 001	7638536	May 05, 2025	DS DP		NCE	May 21, 2023
	8765764	Jan 15, 2023	U-2314			
<u><b>AVIBACTAM SODIUM; CEFTAZIDIME - AVYCAZ</b></u>						
N 206494 001	7112592	Feb 24, 2022	DS DP U-2244			
	7112592	Feb 24, 2022	DS DP U-282			
	8178554	Jul 24, 2021	DS DP U-2245			
	8178554	Jul 24, 2021	DS DP U-282			
<u><b>AZELAIC ACID - FINACEA</b></u>						
N 207071 001	9211259	Feb 28, 2029	U-1796			
<u><b>AZELASTINE HYDROCHLORIDE - ASTEPRO</b></u>						
N 022203 002	9919050	Nov 22, 2025	DP			
<u><b>AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE - DYMISTA</b></u>						
N 202236 001	9901585	Jun 13, 2023	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>BARICITINIB - OLUMIANT</b></u>						
N 207924 001	8158616	Jun 08, 2030	DS DP		NCE	May 31, 2023
	8420629	Mar 10, 2029	U-247			
<u><b>BAZEDOXIFENE ACETATE; ESTROGENS, CONJUGATED - DUAVEE</b></u>						
N 022247 001	5998402	Apr 04, 2019	DS DP U-594			
<u><b>BECLOMETHASONE DIPROPIONATE - QVAR 80</b></u>						
N 020911 001	10022509	May 18, 2031	DP			
	10022510	May 18, 2031	DP			
<u><b>BECLOMETHASONE DIPROPIONATE - QVAR 40</b></u>						
N 020911 002	10022509	May 18, 2031	DP			
	10022510	May 18, 2031	DP			
<u><b>BECLOMETHASONE DIPROPIONATE - QVAR REDIHALER</b></u>						
N 207921 001	10022509	May 18, 2031	DP			
	10022510	May 18, 2031	DP			
<u><b>BENDAMUSTINE HYDROCHLORIDE - BENDAMUSTINE HYDROCHLORIDE</b></u>						
N 205580 001	10010533	Jan 28, 2031	DP			
	8609707	Aug 11, 2031	DP U-1971			
	8609707	Aug 11, 2031	DP U-1972			
	8791270	Jan 12, 2026	DP U-1971			
	8791270	Jan 12, 2026	DP U-1972			
	9265831	Jan 28, 2031	DP			
	9572796	Jan 28, 2031	DP U-1971			
	9572796	Jan 28, 2031	DP U-1972			
	9572797	Jan 28, 2031	U-1971			
	9572797	Jan 28, 2031	U-1972			
<u><b>BENDAMUSTINE HYDROCHLORIDE - BENDEKA</b></u>						
N 208194 001	10010533	Jan 28, 2031	DP		ODE-179	Dec 07, 2022
	10052385	Mar 15, 2033	U-1971			
	10052385	Mar 15, 2033	U-1972			
	8791270	Jan 12, 2026	DP U-1790			
<u><b>BETAMETHASONE DIPROPIONATE - SERNIVO</b></u>						
N 208079 001	9877974	Aug 31, 2030	DP U-1858			
<u><b>BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - BIKTARVY</b></u>						
N 210251 001	6642245	Nov 04, 2020	U-257		NCE	Feb 07, 2023
	6703396	Mar 09, 2021	DS DP			
	7390791	May 07, 2022	DS DP			
	7803788	Feb 02, 2022	U-257			
	8754065	Aug 15, 2032	DS DP U-257			
	9216996	Dec 19, 2033	DS DP			
	9296769	Aug 15, 2032	DS DP U-257			
	9708342	Jun 19, 2035	DS DP			
	9732092	Dec 19, 2033	DS DP			
<u><b>BINIMETINIB - MEKTOVI</b></u>						
N 210498 001	>A> 10005761	Aug 27, 2030	U-2331		NCE	Jun 27, 2023
	>A> 7777050	Mar 13, 2023	DS DP		ODE-194	Jun 27, 2025
	>A> 8178693	Mar 13, 2023	DS DP			
	>A> 8193229	Mar 13, 2023	U-2330			
	>A> 8513293	Mar 13, 2023	U-2331			
	>A> 9314464	Jul 04, 2031	U-2332			
	>A> 9562016	Oct 18, 2033	DS DP			
	>A> 9593100	Aug 27, 2030	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>BINIMETINIB - MEKTOVI</b></u>						
N 210498 001	>A> 9598376	Oct 18, 2033	U-2330			
	>A> 9850229	Aug 27, 2030	U-2333			
	>A> 9980944	Oct 18, 2033	U-2334			
<u><b>BOSUTINIB MONOHYDRATE - BOSULIF</b></u>						
N 203341 001				ODE-163		Dec 19, 2024
<u><b>BOSUTINIB MONOHYDRATE - BOSULIF</b></u>						
N 203341 002				ODE-163		Dec 19, 2024
<u><b>BOSUTINIB MONOHYDRATE - BOSULIF</b></u>						
N 203341 003				ODE-163		Dec 19, 2024
<u><b>BRIMONIDINE TARTRATE - ALPHAGAN P</b></u>						
N 021770 001	9687443	Jul 10, 2021	DP			
	9687443*PED	Jan 10, 2022				
<u><b>BRIMONIDINE TARTRATE - MIRVASO</b></u>						
N 204708 001	9861631	Mar 25, 2031	U-1428			
	9861632	Mar 25, 2031	U-1428			
<u><b>BRIMONIDINE TARTRATE - LUMIFY</b></u>						
N 208144 001	8293742	Jul 14, 2030	U-2222			
<u><b>BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN</b></u>						
N 021398 001	9907801	Apr 19, 2022	DP U-2239			
	9907802	Apr 19, 2022	DP U-2240			
<u><b>BRIVARACETAM - BRIVIACT</b></u>						
N 205836 001	6784197	Feb 21, 2021	DS DP U-2295			
	6911461	Feb 21, 2021	DS DP U-2295			
	8492416	Feb 21, 2021	U-2295			
<u><b>BRIVARACETAM - BRIVIACT</b></u>						
N 205836 002	6784197	Feb 21, 2021	DS DP U-2295			
	6911461	Feb 21, 2021	DS DP U-2295			
	8492416	Feb 21, 2021	U-2295			
<u><b>BRIVARACETAM - BRIVIACT</b></u>						
N 205836 003	6784197	Feb 21, 2021	DS DP U-2295			
	6911461	Feb 21, 2021	DS DP U-2295			
	8492416	Feb 21, 2021	U-2295			
<u><b>BRIVARACETAM - BRIVIACT</b></u>						
N 205836 004	6784197	Feb 21, 2021	DS DP U-2295			
	6911461	Feb 21, 2021	DS DP U-2295			
	8492416	Feb 21, 2021	U-2295			
<u><b>BRIVARACETAM - BRIVIACT</b></u>						
N 205836 005	6784197	Feb 21, 2021	DS DP U-2295			
	6911461	Feb 21, 2021	DS DP U-2295			
	8492416	Feb 21, 2021	U-2295			
<u><b>BRIVARACETAM - BRIVIACT</b></u>						
N 205838 001	6784197	Feb 21, 2021	DS DP U-2295			
	6911461	Feb 21, 2021	DS DP U-2295			
	8492416	Feb 21, 2021	U-2295			
<u><b>BROMOCRIPTINE MESYLATE - CYCLOSET</b></u>						
N 020866 001	9895422	Jun 07, 2030	U-2114			
	9895422	Jun 07, 2030	U-2116			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>BROMOCRIPTINE MESYLATE - CYCLOSET</u>						
N 020866 001	9895422	Jun 07, 2030	U-2281			
	9895422	Jun 07, 2030	U-2282			
	9895422	Jun 07, 2030	U-2283			
	9895422	Jun 07, 2030	U-2284			
	9895422	Jun 07, 2030	U-2285			
	9895422	Jun 07, 2030	U-2286			
	9895422	Jun 07, 2030	U-2287			
>A>	9993474	Apr 30, 2032	U-2384			
>A>	9993474	Apr 30, 2032	U-2385			
>A>	9993474	Apr 30, 2032	U-2386			
>A>	9993474	Apr 30, 2032	U-2387			
>A>	9993474	Apr 30, 2032	U-2388			
>A>	9993474	Apr 30, 2032	U-2389			
>A>	9993474	Apr 30, 2032	U-2390			
>A>	9993474	Apr 30, 2032	U-2391			
>A>	9993474	Apr 30, 2032	U-2392			
>A>	9993474	Apr 30, 2032	U-2393			
<u>BUDESONIDE - UCERIS</u>						
N 203634 001	>A> 10064878	Jun 09, 2020	DP	U-1325		
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 001	8387615	Mar 26, 2027	DP			
	8387615*PED	Sep 26, 2027				
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>						
N 021929 002	8387615	Mar 26, 2027	DP			
	8387615*PED	Sep 26, 2027				
<u>BUPIVACAINE - EXPAREL</u>						
N 022496 001				I-771		Apr 06, 2021
<u>BUPIVACAINE - EXPAREL</u>						
N 022496 002				I-771		Apr 06, 2021
<u>BUPRENORPHINE - SUBLOCADE</u>						
N 209819 001				NP		Nov 30, 2020
<u>BUPRENORPHINE - SUBLOCADE</u>						
N 209819 002				NP		Nov 30, 2020
<u>BUPRENORPHINE HYDROCHLORIDE - BELBUCA</u>						
N 207932 001	9901539	Dec 21, 2032	U-1556			
<u>BUPRENORPHINE HYDROCHLORIDE - BELBUCA</u>						
N 207932 002	9901539	Dec 21, 2032	U-1556			
<u>BUPRENORPHINE HYDROCHLORIDE - BELBUCA</u>						
N 207932 003	9901539	Dec 21, 2032	U-1556			
<u>BUPRENORPHINE HYDROCHLORIDE - BELBUCA</u>						
N 207932 004	9901539	Dec 21, 2032	U-1556			
<u>BUPRENORPHINE HYDROCHLORIDE - BELBUCA</u>						
N 207932 005	9901539	Dec 21, 2032	U-1556			
<u>BUPRENORPHINE HYDROCHLORIDE - BELBUCA</u>						
N 207932 006	9901539	Dec 21, 2032	U-1556			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>BUPRENORPHINE HYDROCHLORIDE - BELBUCA</u>						
N 207932 007	9901539	Dec 21, 2032		U-1556		
<u>BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - SUBOXONE</u>						
N 022410 001	9931305	Feb 14, 2022	DP			
<u>BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - SUBOXONE</u>						
N 022410 002	9931305	Feb 14, 2022	DP			
<u>BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - SUBOXONE</u>						
N 022410 003	9931305	Feb 14, 2022	DP			
<u>BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - SUBOXONE</u>						
N 022410 004	9931305	Feb 14, 2022	DP			
<u>CABOZANTINIB S-MALATE - CABOMETYX</u>						
N 208692 001	10039757	Jul 18, 2031		U-1480		
<u>CABOZANTINIB S-MALATE - CABOMETYX</u>						
N 208692 002	10039757	Jul 18, 2031		U-1480		
<u>CABOZANTINIB S-MALATE - CABOMETYX</u>						
N 208692 003	10039757	Jul 18, 2031		U-1480		
<u>CALCIFEDIOL - RAYALDEE</u>						
N 208010 001	8426391	Aug 27, 2028	U-1872			
	9861644	Mar 14, 2034	DP			
	9925147	Apr 25, 2028	DP U-2255			
	9925147	Apr 25, 2028	DP U-2256			
	9925147	Apr 25, 2028	DP U-2257			
	9925147	Apr 25, 2028	DP U-2258			
	9925147	Apr 25, 2028	DP U-2259			
	9943530	Feb 02, 2027	U-2274			
<u>CANAGLIFLOZIN - INVOKANA</u>						
N 204042 001	8222219	Apr 11, 2025		U-493		
<u>CANAGLIFLOZIN - INVOKANA</u>						
N 204042 002	8222219	Apr 11, 2025		U-493		
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u>						
N 204353 001	8222219	Apr 11, 2025		U-493		
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u>						
N 204353 002	8222219	Apr 11, 2025		U-493		
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u>						
N 204353 003	8222219	Apr 11, 2025		U-493		
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u>						
N 204353 004	8222219	Apr 11, 2025		U-493		
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u>						
N 205879 001	8222219	Apr 11, 2025		U-493		
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u>						
N 205879 002	8222219	Apr 11, 2025		U-493		

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u>						
N 205879 003	8222219	Apr 11, 2025	U-493			
<u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u>						
N 205879 004	8222219	Apr 11, 2025	U-493			
<u>CANGRELOR - KENGREAL</u>						
N 204958 001	10039780	Jul 10, 2035	U-2260			
	6114313	Dec 11, 2018	DP U-1715			
	6130208	Jun 29, 2019	DP U-1715			
	9925265	May 13, 2029	U-2260			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 001	7094427	May 29, 2022	DP U-1645	Y		
	9901640	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 002	7094427	May 29, 2022	DP U-1645	Y		
	9901640	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 003	7094427	May 29, 2022	DP U-1645	Y		
	9901640	Dec 26, 2028	DP U-219			
<u>CARBIDOPA; LEVODOPA - RYTARY</u>						
N 203312 004	7094427	May 29, 2022	DP U-1645	Y		
	9901640	Dec 26, 2028	DP U-219			
<u>CARFILZOMIB - KYPROLIS</u>						
N 202714 003	7232818	Apr 14, 2025	DS DP			
	7417042	Jul 20, 2026	DS DP			
	7491704	Apr 14, 2025	U-2319			
	7491704	Apr 14, 2025	U-2320			
	7737112	Dec 07, 2027	DP			
	8129346	Apr 14, 2025	U-2319			
	8129346	Apr 14, 2025	U-2320			
	8207125	Apr 14, 2025	DS DP			
	8207126	Apr 14, 2025	DP			
	8207127	Apr 14, 2025	U-2319			
	8207127	Apr 14, 2025	U-2320			
	8207297	Apr 14, 2025	DS DP			
	9493582	Feb 27, 2033	DP			
	9511109	Oct 21, 2029	U-1924			
<u>CEFTOLOZANE SULFATE; TAZOBACTAM SODIUM - ZERBAXA</u>						
N 206829 001	9872906	Mar 14, 2034	DP			
<u>CETIRIZINE HYDROCHLORIDE - ZERVIASTE</u>						
N 208694 001	9993471	Mar 15, 2030	U-1680			
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - PREVANTICS SWAB</u>						
N 021524 001				M-221	Feb 14, 2021	
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - PREVANTICS SWABSTICK</u>						
N 021524 002				M-221	Feb 14, 2021	
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - PREVANTICS MAXI SWABSTICK</u>						
N 021524 003				M-221	Feb 14, 2021	
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - SOLUPREP</u>						
N 208288 001 >A> 8623935		Jul 26, 2029	DP U-1022	NP	Aug 08, 2021	

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>CIPROFLOXACIN - OTIPRIO</u>						
N 207986 001	9603796	Apr 21, 2029	DS DP U-2252		I-770	Mar 02, 2021
<u>CITRIC ACID; MAGNESIUM OXIDE; SODIUM PICOSULFATE - PREPOPIK</u>						
N 202535 001					NPP	Aug 15, 2021
<u>CLEVIDIPINE - CLEVIPREX</u>						
N 022156 001	10010537	Oct 10, 2031	DP			
<u>CLEVIDIPINE - CLEVIPREX</u>						
N 022156 002	10010537	Oct 10, 2031	DP			
<u>CLEVIDIPINE - CLEVIPREX</u>						
N 022156 003	10010537	Oct 10, 2031	DP			
<u>CLOBETASOL PROPIONATE - IMPOYZ</u>						
N 209483 001	10064875	Aug 31, 2030	DP U-1408			
	10064875	Aug 31, 2030	DP U-1858			
	10064875	Aug 31, 2030	DP U-193			
	10064875	Aug 31, 2030	DP U-742			
	10064875	Aug 31, 2030	DP U-88			
	9956231	Aug 31, 2030	DP U-1408			
	9956231	Aug 31, 2030	DP U-1761			
	9956231	Aug 31, 2030	DP U-1858			
	9956231	Aug 31, 2030	DP U-193			
	9956231	Aug 31, 2030	DP U-742			
	9956231	Aug 31, 2030	DP U-88			
<u>COBICISTAT - TYBOST</u>						
N 203094 001	10039718	Oct 04, 2032	DP			
<u>COBICISTAT; DARUNAVIR ETHANOLATE - PREZCOBIX</u>						
N 205395 001	10039718	Oct 04, 2032	DP			
	8148374	Sep 03, 2029	DS DP U-1279			
	9889115	Jun 23, 2019	U-1660			
<u>COBICISTAT; DARUNAVIR ETHANOLATE; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - SYMTUZA</u>						
N 210455 001	10039718	Oct 04, 2032	DP		NC	Jul 17, 2020
	6642245	Nov 04, 2020	U-2352		NCE	Nov 05, 2020
	6703396	Mar 09, 2021	DS DP			
	7390791	May 07, 2022	DS DP			
	7470506	Jun 23, 2019	U-2352			
	7700645	Dec 26, 2026	DS DP			
	7803788	Feb 02, 2022	U-2352			
	8148374	Sep 03, 2029	DS DP U-2353			
	8148374	Sep 03, 2029	DS DP U-2364			
	8148374	Sep 03, 2029	DS DP U-2365			
	8518987	Feb 16, 2024	DS DP			
	8597876	Jun 23, 2019	U-2352			
	8754065	Aug 15, 2032	DS DP U-2352			
	9296769	Aug 15, 2032	DS DP U-2352			
	9889115	Jun 23, 2019	U-2352			
<u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - GENVOYA</u>						
N 207561 001	10039718	Oct 04, 2032	DP			
	9891239	Sep 03, 2029	DP U-257			
<u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - STRIBILD</u>						
N 203100 001	10039718	Oct 04, 2032	DP			
	9891239	Sep 03, 2029	DP U-257			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>COCAINE HYDROCHLORIDE - GOPRELTO</u>						
N 209963 001	10016407	Feb 07, 2037	U-2329		NCE	Dec 14, 2022
	9867815	Feb 07, 2037	U-2225			
	9867815	Feb 07, 2037	U-2226			
	9867815	Feb 07, 2037	U-2227			
<u>COPANLISIB DIHYDROCHLORIDE - ALIOOPA</u>						
N 209936 001	RE46856	Oct 22, 2029	DS DP U-2124			
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>						
N 021777 001	8877245	Nov 14, 2023		U-979		
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>						
N 021777 002	8877245	Nov 14, 2023		U-979		
<u>CYCLOSPORINE - CEQUA</u>						
N 210913 001	8980839	Aug 23, 2033	DP U-1483			
	9937225	Aug 23, 2033	DP U-1483			
<u>CYSTEAMINE BITARTRATE - PROCYSB1</u>						
N 203389 001	9925156	Jan 26, 2027	DS DP U-1399		ODE-162	Dec 22, 2024
	9925157	Jan 26, 2027	DS DP U-1399			
	9925158	Jan 26, 2027	DS DP U-1399			
<u>CYSTEAMINE BITARTRATE - PROCYSB1</u>						
N 203389 002	9925156	Jan 26, 2027	DS DP U-1399		ODE-162	Dec 22, 2024
	9925157	Jan 26, 2027	DS DP U-1399			
	9925158	Jan 26, 2027	DS DP U-1399			
<u>CYTARABINE; DAUNORUBICIN - VYXEOS</u>						
N 209401 001	10028912	Sep 29, 2034	DP U-2341			
	10028912	Sep 29, 2034	DP U-2342			
<u>DABIGATRAN ETEXILATE MESYLATE - PRADAXA</u>						
N 022512 001	9925174	Jun 14, 2023	DP			
<u>DABIGATRAN ETEXILATE MESYLATE - PRADAXA</u>						
N 022512 002	9925174	Jun 14, 2023	DP			
<u>DABIGATRAN ETEXILATE MESYLATE - PRADAXA</u>						
N 022512 003	9925174	Jun 14, 2023	DP			
<u>DABRAFENIB MESYLATE - TAFINLAR</u>						
N 202806 001	7994185	Jan 20, 2030	DS DP U-1406		I-778	Apr 30, 2021
	7994185	Jan 20, 2030	DS DP U-2031		I-781	May 04, 2021
	7994185	Jan 20, 2030	DS DP U-2032		ODE-182	Apr 30, 2025
	7994185	Jan 20, 2030	DS DP U-2296		ODE-183	May 04, 2025
	8415345	Jan 20, 2030	DS DP U-1406			
	8415345	Jan 20, 2030	DS DP U-2031			
	8415345	Jan 20, 2030	DS DP U-2032			
	8415345	Jan 20, 2030	DS DP U-2296			
	8703781	Oct 15, 2030	DS DP U-1713			
	8703781	Oct 15, 2030	DS DP U-2032			
	8703781	Oct 15, 2030	DS DP U-2296			
	8703781	Oct 15, 2030	DS DP U-2297			
	8703781	Oct 15, 2030	DS DP U-2298			
	8835443	Jun 10, 2025	U-2026			
	8835443	Jun 10, 2025	U-2027			
	8835443	Jun 10, 2025	U-2296			
	8835443	Jun 10, 2025	U-2298			
	9233956	May 04, 2029	U-1811			
	9233956	May 04, 2029	U-2031			
	9233956	May 04, 2029	U-2032			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b><u>DABRAFENIB MESYLATE - TAFINLAR</u></b>						
N 202806 001	9233956	May 04, 2029	U-2296			
	9233956	May 04, 2029	U-2297			
<b><u>DABRAFENIB MESYLATE - TAFINLAR</u></b>						
N 202806 002	7994185	Jan 20, 2030	DS DP U-1406	I-778	Apr 30, 2021	
	7994185	Jan 20, 2030	DS DP U-2031	I-781	May 04, 2021	
	7994185	Jan 20, 2030	DS DP U-2032	ODE-182	Apr 30, 2025	
	7994185	Jan 20, 2030	DS DP U-2296	ODE-183	May 04, 2025	
	8415345	Jan 20, 2030	DS DP U-1406			
	8415345	Jan 20, 2030	DS DP U-2031			
	8415345	Jan 20, 2030	DS DP U-2032			
	8415345	Jan 20, 2030	DS DP U-2296			
	8703781	Oct 15, 2030	DS DP U-1713			
	8703781	Oct 15, 2030	DS DP U-2032			
	8703781	Oct 15, 2030	DS DP U-2296			
	8703781	Oct 15, 2030	DS DP U-2297			
	8703781	Oct 15, 2030	DS DP U-2298			
	8835443	Jun 10, 2025	U-2026			
	8835443	Jun 10, 2025	U-2027			
	8835443	Jun 10, 2025	U-2296			
	8835443	Jun 10, 2025	U-2298			
	9233956	May 04, 2029	U-1811			
	9233956	May 04, 2029	U-2031			
	9233956	May 04, 2029	U-2032			
	9233956	May 04, 2029	U-2296			
	9233956	May 04, 2029	U-2297			
<b><u>DALFAMPRIDINE - AMPYRA</u></b>						
N 022250 001	9918973	Dec 13, 2024	U-1030			
<b><u>DANTROLENE SODIUM - RYANODEX</u></b>						
N 205579 001	9884044	Jun 13, 2022	DP U-1546			
<b><u>DAPAGLIFLOZIN - FARXIGA</u></b>						
N 202293 001	7456254	Jun 30, 2025	DP U-2139			
	8329648	Aug 18, 2026	U-2139			
	8329648	Aug 18, 2026	U-2212			
	8329648	Aug 18, 2026	U-2213			
	8431685	Apr 13, 2025	DP U-2139			
	8461105	Apr 13, 2025	DP U-2139			
	8721615	Jan 18, 2030	DP	Y		
	8906851	Aug 18, 2026	U-2139			
	9238076	Apr 15, 2024	DP U-2139			
<b><u>DAPAGLIFLOZIN - FARXIGA</u></b>						
N 202293 002	7456254	Jun 30, 2025	DP U-2139			
	8329648	Aug 18, 2026	U-2139			
	8329648	Aug 18, 2026	U-2212			
	8329648	Aug 18, 2026	U-2213			
	8431685	Apr 13, 2025	DP U-2139			
	8461105	Apr 13, 2025	DP U-2139			
	8721615	Jan 18, 2030	DP	Y		
	8906851	Aug 18, 2026	U-2139			
	9238076	Apr 15, 2024	DP U-2139			
<b><u>DARUNAVIR ETHANOLATE - PREZISTA</u></b>						
N 021976 002	9889115	Jun 23, 2019	U-1305			
<b><u>DARUNAVIR ETHANOLATE - PREZISTA</u></b>						
N 021976 004	9889115	Jun 23, 2019	U-1305			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 005	9889115	Jun 23, 2019	U-1305			
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 021976 006	9889115	Jun 23, 2019	U-1305			
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N 202895 001	9889115	Jun 23, 2019	U-1305			
<u>DASATINIB - SPRYCEL</u>						
N 021986 001	>A> 6596746 >A> 6596746 >A> 6596746*PED >A> 7125875 >A> 7125875 >A> 7125875*PED >A> 7153856 >A> 7153856*PED >A> 7491725 >A> 7491725*PED >A> 8680103 >A> 8680103*PED	Jun 28, 2020 Jun 28, 2020 Dec 28, 2020 Apr 13, 2020 Apr 13, 2020 Oct 13, 2020 Apr 28, 2020 Oct 28, 2020 Mar 28, 2026 Sep 28, 2026 Feb 04, 2025 Aug 04, 2025	DS DP U-748 DS DP U-780 DS DP U-780 U-779 U-780 U-780 U-780 DS DP DS DP DP		ODE-164	Nov 09, 2024
N 021986 002	>A> 6596746 >A> 6596746 >A> 6596746*PED >A> 7125875 >A> 7125875 >A> 7125875*PED >A> 7153856 >A> 7153856*PED >A> 7491725 >A> 7491725*PED >A> 8680103 >A> 8680103*PED	Jun 28, 2020 Jun 28, 2020 Dec 28, 2020 Apr 13, 2020 Apr 13, 2020 Oct 13, 2020 Apr 28, 2020 Oct 28, 2020 Mar 28, 2026 Sep 28, 2026 Feb 04, 2025 Aug 04, 2025	DS DP U-748 DS DP U-780 DS DP U-780 U-779 U-780 U-780 U-780 DS DP DS DP DP		ODE-164	Nov 09, 2024
N 021986 003	>A> 6596746 >A> 6596746 >A> 6596746*PED >A> 7125875 >A> 7125875 >A> 7125875*PED >A> 7153856 >A> 7153856*PED >A> 7491725 >A> 7491725*PED >A> 8680103 >A> 8680103*PED	Jun 28, 2020 Jun 28, 2020 Dec 28, 2020 Apr 13, 2020 Apr 13, 2020 Oct 13, 2020 Apr 28, 2020 Oct 28, 2020 Mar 28, 2026 Sep 28, 2026 Feb 04, 2025 Aug 04, 2025	DS DP U-748 DS DP U-780 DS DP U-780 U-779 U-780 U-780 U-780 DS DP DS DP DP		ODE-164	Nov 09, 2024
N 021986 004	>A> 6596746 >A> 6596746 >A> 6596746*PED >A> 7125875 >A> 7125875 >A> 7125875*PED >A> 7153856 >A> 7153856*PED >A> 7491725 >A> 7491725*PED >A> 8680103 >A> 8680103*PED	Jun 28, 2020 Jun 28, 2020 Dec 28, 2020 Apr 13, 2020 Apr 13, 2020 Oct 13, 2020 Apr 28, 2020 Oct 28, 2020 Mar 28, 2026 Sep 28, 2026 Feb 04, 2025 Aug 04, 2025	DS DP U-748 DS DP U-780 DS DP U-780 U-779 U-780 U-780 U-780 DS DP DS DP DP		ODE-164	Nov 09, 2024

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>DASATINIB - SPRYCEL</u>						
N 021986 005	>A> 6596746	Jun 28, 2020	DS DP U-748		ODE-164	Nov 09, 2024
	>A> 6596746	Jun 28, 2020	DS DP U-780			
	>A> 6596746*PED	Dec 28, 2020				
	>A> 7125875	Apr 13, 2020	U-779			
	>A> 7125875	Apr 13, 2020	U-780			
	>A> 7125875*PED	Oct 13, 2020				
	>A> 7153856	Apr 28, 2020	U-780			
	>A> 7153856*PED	Oct 28, 2020				
	>A> 7491725	Mar 28, 2026	DS DP			
	>A> 7491725*PED	Sep 28, 2026				
	>A> 8680103	Feb 04, 2025	DP			
	>A> 8680103*PED	Aug 04, 2025				
<u>DASATINIB - SPRYCEL</u>						
N 021986 006	>A> 6596746	Jun 28, 2020	DS DP U-748		ODE-164	Nov 09, 2024
	>A> 6596746	Jun 28, 2020	DS DP U-780			
	>A> 6596746*PED	Dec 28, 2020				
	>A> 7125875	Apr 13, 2020	U-779			
	>A> 7125875	Apr 13, 2020	U-780			
	>A> 7125875*PED	Oct 13, 2020				
	>A> 7153856	Apr 28, 2020	U-780			
	>A> 7153856*PED	Oct 28, 2020				
	>A> 7491725	Mar 28, 2026	DS DP			
	>A> 7491725*PED	Sep 28, 2026				
	>A> 8680103	Feb 04, 2025	DP			
	>A> 8680103*PED	Aug 04, 2025				
<u>DEOXYCHOLIC ACID - KYBELLA</u>						
N 206333 001	9949986	Feb 21, 2028	U-1940			
<u>DESMOPRESSIN ACETATE - NOCDURNA</u>						
N 022517 001	7560429	Feb 02, 2024	DP U-2326		NP	Jun 21, 2021
	7947654	Dec 29, 2023	DP			
	8802624	Dec 29, 2023	U-2326			
	9220747	May 07, 2023	U-2326			
	9504647	May 07, 2023	DP U-2326			
	9919025	May 07, 2023	U-2326			
	9974826	Apr 13, 2030	U-2326			
<u>DESMOPRESSIN ACETATE - NOCDURNA</u>						
N 022517 002	7560429	Feb 02, 2024	DP U-2326		NP	Jun 21, 2021
	7947654	Dec 29, 2023	DP			
	8802624	Dec 29, 2023	U-2326			
	9220747	May 07, 2023	U-2326			
	9504647	May 07, 2023	DP U-2326			
	9919025	May 07, 2023	U-2326			
	9974826	Apr 13, 2030	U-2327			
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
N 021992 001				M-222		Feb 06, 2021
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
N 021992 002				M-222		Feb 06, 2021
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
N 021992 003				M-222		Feb 06, 2021
<u>DEXAMETHASONE - DEXYCU KIT</u>						
N 208912 001	10022502	Sep 12, 2020	U-2340		NP	Feb 09, 2021
	10028965	May 23, 2034	U-2340			
	6960346	Jul 03, 2023	DP			
	7560120	Sep 05, 2022	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</b></u>						
N 021038 002	10016396	Jan 04, 2032	DP			
<u><b>DEXMEDETOMIDINE HYDROCHLORIDE - PRECEDEX</b></u>						
N 021038 003	10016396	Jan 04, 2032	DP			
<u><b>DEXMEDETOMIDINE HYDROCHLORIDE - DEXMEDETOMIDINE HYDROCHLORIDE</b></u>						
N 206628 003	9649296	Apr 20, 2036	DP			
	9717796	Apr 20, 2036	DP			
<u><b>DEXMEDETOMIDINE HYDROCHLORIDE - DEXMEDETOMIDINE HYDROCHLORIDE</b></u>						
N 206628 004	9649296	Apr 20, 2036	DP			
	9717796	Apr 20, 2036	DP			
<u><b>DIMETHYL FUMARATE - TECFIDERA</b></u>						
N 204063 001	6509376	Apr 01, 2019	DP			
	7320999	Oct 20, 2019	U-1384			
	7619001	Apr 01, 2019	U-1384			
	7803840	Apr 01, 2019	U-1385			
	8399514	Feb 07, 2028	U-1384			
	8759393	Jul 04, 2018	DP			
<u><b>DIMETHYL FUMARATE - TECFIDERA</b></u>						
N 204063 002	6509376	Apr 01, 2019	DP			
	7320999	Oct 20, 2019	U-1384			
	7619001	Apr 01, 2019	U-1384			
	7803840	Apr 01, 2019	U-1385			
	8399514	Feb 07, 2028	U-1384			
	8759393	Jul 04, 2018	DP			
<u><b>DORAVIRINE - PIFELTRO</b></u>						
N 210806 001 >A> 8486975		Oct 07, 2031	DS DP U-2394		NCE	Aug 30, 2023
<u><b>DORAVIRINE; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE - DELSTRIGO</b></u>						
N 210807 001 >A> 8486975		Oct 07, 2031	DS DP U-2395		NCE	Aug 30, 2023
<u><b>DOXEPIN HYDROCHLORIDE - SILENOR</b></u>						
N 022036 001	9861607	May 18, 2027	U-620			
	9907780	Apr 11, 2028	DP			
<u><b>DOXEPIN HYDROCHLORIDE - SILENOR</b></u>						
N 022036 002	9861607	May 18, 2027	U-620			
	9907780	Apr 11, 2028	DP			
<u><b>DOXYCYCLINE - ORACEA</b></u>						
N 050805 001 >A> 10058564		Apr 05, 2022	DS DP U-1063			
<u><b>DOXYLAMINE SUCCINATE; PYRIDOXINE HYDROCHLORIDE - BONJESTA</b></u>						
N 209661 001	9937132	Feb 18, 2033	DP U-1382			
<u><b>DUVELISIB - COPIKTRA</b></u>						
N 211155 001				>A> NCE		Sep 24, 2023
<u><b>DUVELISIB - COPIKTRA</b></u>						
N 211155 002				>A> NCE		Sep 24, 2023
<u><b>ECONAZOLE NITRATE - ECOZA</b></u>						
N 205175 001 >A> 10071054		Aug 08, 2031	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>EFAVIRENZ - EFAVIRENZ</b></u>						
A 078064 001					PC	Jun 19, 2018
<u><b>EFAVIRENZ - EFAVIRENZ</b></u>						
A 078064 002					PC	Jun 19, 2018
<u><b>EFAVIRENZ - EFAVIRENZ</b></u>						
A 078064 003					PC	Jun 19, 2018
<u><b>EFAVIRENZ - EFAVIRENZ</b></u>						
A 091471 001					PC	Feb 14, 2018
<u><b>EFINACONAZOLE - JUBLIA</b></u>						
N 203567 001	9877955	Jan 03, 2028		U-1969		
<u><b>ELAGOLIX SODIUM - ORILISSA</b></u>						
N 210450 001	6872728	Jan 25, 2021	DS DP		NCE	Jul 23, 2023
	7056927	Sep 10, 2024	DS DP			
	7176211	Jul 06, 2024		U-2360		
	7179815	Mar 07, 2021		U-2360		
	7419983	Jul 06, 2024	DS DP	U-2360		
	7462625	Jan 25, 2021	DS DP	U-2360		
<u><b>ELAGOLIX SODIUM - ORILISSA</b></u>						
N 210450 002	6872728	Jan 25, 2021	DS DP		NCE	Jul 23, 2023
	7056927	Sep 10, 2024	DS DP			
	7176211	Jul 06, 2024		U-2360		
	7179815	Mar 07, 2021		U-2360		
	7419983	Jul 06, 2024	DS DP	U-2360		
	7462625	Jan 25, 2021	DS DP	U-2360		
<u><b>ELIGLUSTAT TARTRATE - CERDELGA</b></u>						
N 205494 001	6916802	Apr 29, 2022	DS	U-1571		
>A>	7196205	Jun 26, 2026	DS			
	7253185	Apr 29, 2022	DP			
<u><b>EMPAGLIFLOZIN - JARDIANCE</b></u>						
N 204629 001	9949997	May 17, 2034		U-2292		
	9949998	Jun 11, 2034		U-2290		
<u><b>EMPAGLIFLOZIN - JARDIANCE</b></u>						
N 204629 002	9949997	May 17, 2034		U-2292		
	9949998	Jun 11, 2034		U-2290		
<u><b>EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI</b></u>						
N 206073 001	9949998	Jun 11, 2034		U-2290		
<u><b>EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI</b></u>						
N 206073 002	9949998	Jun 11, 2034		U-2290		
<u><b>EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE - SYNJARDY XR</b></u>						
N 208658 001	9949998	Jun 11, 2034		U-2290		
<u><b>EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE - SYNJARDY XR</b></u>						
N 208658 002	9949998	Jun 11, 2034		U-2290		
<u><b>EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE - SYNJARDY XR</b></u>						
N 208658 003	9949998	Jun 11, 2034		U-2290		

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE - SYNJARDY XR</b></u>						
N 208658 004	9949998	Jun 11, 2034		U-2290		
<u><b>ENALAPRIL MALEATE - EPANED KIT</b></u>						
N 204308 001	9968553	Nov 06, 2032		U-1723		
	9968553	Nov 06, 2032		U-185		
	9968553	Nov 06, 2032		U-1892		
	9968553	Nov 06, 2032		U-3		
	9968553	Nov 06, 2032		U-71		
<u><b>ENALAPRIL MALEATE - EPANED</b></u>						
N 208686 001	10039745	Mar 25, 2036	DP			
<u><b>ENCORAFENIB - BRAFTOVI</b></u>						
N 210496 001	10005761	Aug 27, 2030		U-2335		
	8501758	Mar 04, 2031	DS DP		NCE	Jun 27, 2023
	8541575	Feb 26, 2030	DS DP	U-2335	ODE-194	Jun 27, 2025
	8946250	Jul 23, 2029	DS DP			
	9314464	Jul 04, 2031		U-2336		
	9387208	Nov 21, 2032	DP			
	9593099	Aug 27, 2030	DS			
	9593100	Aug 27, 2030		DP		
	9763941	Nov 21, 2032		U-2335		
	9850229	Aug 27, 2030		U-2337		
	9850230	Aug 27, 2030		U-2334		
<u><b>ENCORAFENIB - BRAFTOVI</b></u>						
N 210496 002	10005761	Aug 27, 2030		U-2335		
	8501758	Mar 04, 2031	DS DP		NCE	Jun 27, 2023
	8541575	Feb 26, 2030	DS DP	U-2335	ODE-194	Jun 27, 2025
	8946250	Jul 23, 2029	DS DP			
	9314464	Jul 04, 2031		U-2336		
	9387208	Nov 21, 2032	DP			
	9593099	Aug 27, 2030	DS			
	9593100	Aug 27, 2030		DP		
	9763941	Nov 21, 2032		U-2335		
	9850229	Aug 27, 2030		U-2337		
	9850230	Aug 27, 2030		U-2334		
<u><b>ENZALUTAMIDE - XTANDI</b></u>						
N 203415 001	8183274	Aug 24, 2026		U-1281	I-786	Jul 13, 2021
	8183274	Aug 24, 2026		U-1588		
	8183274	Aug 24, 2026		U-2345		
	9126941	May 15, 2026		U-1588		
	9126941	May 15, 2026		U-2345		
<u><b>EPINEPHRINE - EPINEPHRINE</b></u>						
N 205029 001	10004700	Aug 14, 2034	DP	U-2325		
	10039728	Aug 14, 2034		U-1828		
<u><b>ERAVACYCLINE DIHYDROCHLORIDE - XERAVA</b></u>						
N 211109 001					NCE	Aug 27, 2023
					GAIN	Aug 27, 2028
<u><b>ERIBULIN MESYLATE - HALAVEN</b></u>						
N 201532 001	RE46965	Jan 08, 2027	DP			
<u><b>ERTUGLIFLOZIN - STEGLATRO</b></u>						
N 209803 001	8080580	Jul 13, 2030	DS DP	U-2214		
<u><b>ERTUGLIFLOZIN - STEGLATRO</b></u>						
N 209803 002	8080580	Jul 13, 2030	DS DP	U-2214		

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 001	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 002	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 003	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; METFORMIN HYDROCHLORIDE - SEGLUROMET</u>						
N 209806 004	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439902	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE - STEGLUJAN</u>						
N 209805 001	6699871	Jul 26, 2022	DS DP U-2214			
	6890898	Feb 02, 2019	U-2215			
	7078381	Feb 02, 2019	U-2216			
	7326708	Nov 24, 2026	DS DP U-2214			
	7459428	Feb 02, 2019	U-2215			
	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439901	Oct 21, 2030	U-2214			
<u>ERTUGLIFLOZIN; SITAGLIPTIN PHOSPHATE - STEGLUJAN</u>						
N 209805 002	6699871	Jul 26, 2022	DS DP U-2214			
	6890898	Feb 02, 2019	U-2215			
	7078381	Feb 02, 2019	U-2216			
	7326708	Nov 24, 2026	DS DP U-2214			
	7459428	Feb 02, 2019	U-2215			
	8080580	Jul 13, 2030	DS DP U-2214			
	9308204	Oct 21, 2030	DP			
	9439901	Oct 21, 2030	U-2214			
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM 24HR</u>						
N 207920 001	7411070	May 25, 2018	DS			
	7411070*PED	Nov 25, 2018				
<u>ESTRADIOL - IMVEXXY</u>						
N 208564 001	9180091	Dec 20, 2033	DP U-2316		NP	May 29, 2021
	9180091	Dec 20, 2033	DP U-2317			
	9289382	Nov 21, 2032	DP			
<u>ESTRADIOL - IMVEXXY</u>						
N 208564 002	9180091	Dec 20, 2033	DP U-2316		NP	May 29, 2021
	9180091	Dec 20, 2033	DP U-2317			
	9289382	Nov 21, 2032	DP			
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - BALCOLTRA</u>						
N 208612 001	6716814	Aug 16, 2021	DS DP			
<u>ETHINYL ESTRADIOL; SEGESTERONE ACETATE - ANNOVERA</u>						
N 209627 001					NCE	Aug 10, 2023
<u>ETRAVIRINE - INTELENCE</u>						
N 022187 001	6878717	Nov 05, 2019	U-1016		>A> NPP	Jul 16, 2021
	6878717	Nov 05, 2019	U-1237		>A> PED	Jan 16, 2022

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b><u>ETRAVIRINE - INTELENCE</u></b>						
N 022187 001	6878717	Nov 05, 2019	U-2354			
	6878717	Nov 05, 2019	U-256			
	6878717*PED	May 05, 2020				
	7037917	Dec 13, 2020	DS DP U-1016			
	7037917	Dec 13, 2020	DS DP U-1237			
	7037917	Dec 13, 2020	DS DP U-2354			
	7037917	Dec 13, 2020	DS DP U-256			
	7037917*PED	Jun 13, 2021				
	7887845	Mar 25, 2019	DP			
	7887845*PED	Sep 25, 2019				
	8003789	Nov 01, 2019	DS DP			
	8003789*PED	May 01, 2020				
<b><u>ETRAVIRINE - INTELENCE</u></b>						
N 022187 002	6878717	Nov 05, 2019	U-1016		>A> NPP	Jul 16, 2021
	6878717	Nov 05, 2019	U-1237		>A> PED	Jan 16, 2022
	6878717	Nov 05, 2019	U-2354			
	6878717	Nov 05, 2019	U-256			
	6878717*PED	May 05, 2020				
	7037917	Dec 13, 2020	DS DP U-1016			
	7037917	Dec 13, 2020	DS DP U-1237			
	7037917	Dec 13, 2020	DS DP U-2354			
	7037917	Dec 13, 2020	DS DP U-256			
	7037917*PED	Jun 13, 2021				
	7887845	Mar 25, 2019	DP			
	7887845*PED	Sep 25, 2019				
	8003789	Nov 01, 2019	DS DP			
	8003789*PED	May 01, 2020				
<b><u>ETRAVIRINE - INTELENCE</u></b>						
N 022187 003	6878717	Nov 05, 2019	U-1016		>A> NPP	Jul 16, 2021
	6878717	Nov 05, 2019	U-1237		>A> PED	Jan 16, 2022
	6878717	Nov 05, 2019	U-2354			
	6878717	Nov 05, 2019	U-256			
	6878717*PED	May 05, 2020				
	7037917	Dec 13, 2020	DS DP U-1237			
	7037917	Dec 13, 2020	DS DP U-2354			
	7037917*PED	Jun 13, 2021				
	7887845	Mar 25, 2019	DP			
	7887845*PED	Sep 25, 2019				
	8003789	Nov 01, 2019	DS DP			
	8003789*PED	May 01, 2020				
<b><u>EVEROLIMUS - AFINITOR DISPERZ</u></b>						
N 203985 001	8778962	Feb 18, 2022	U-1541		I-773	Apr 10, 2021
	8778962	Feb 18, 2022	U-2280		ODE-169	Apr 10, 2025
	8778962*PED	Aug 18, 2022				
<b><u>EVEROLIMUS - AFINITOR DISPERZ</u></b>						
N 203985 002	8778962	Feb 18, 2022	U-1541		I-773	Apr 10, 2021
	8778962	Feb 18, 2022	U-2280		ODE-169	Apr 10, 2025
	8778962*PED	Aug 18, 2022				
<b><u>EVEROLIMUS - AFINITOR DISPERZ</u></b>						
N 203985 003	8778962	Feb 18, 2022	U-1541		I-773	Apr 10, 2021
	8778962	Feb 18, 2022	U-2280		ODE-169	Apr 10, 2025
	8778962*PED	Aug 18, 2022				
<b><u>EXENATIDE - BYDUREON BCISE</u></b>						
N 209210 001	9884092	Aug 18, 2026	U-1313			
	9884092	Aug 18, 2026	U-2154			
	9884092	Aug 18, 2026	U-2155			
	9884092	Aug 18, 2026	U-2156			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>EXENATIDE SYNTHETIC - BYDUREON</b></u>						
N 022200 001	6872700	Jan 14, 2020	U-2288	M-224		Apr 02, 2021
	6872700	Jan 14, 2020	U-654			
	9884092	Aug 18, 2026	U-1313			
	9884092	Aug 18, 2026	U-2154			
	9884092	Aug 18, 2026	U-2155			
	9884092	Aug 18, 2026	U-2156			
<u><b>EXENATIDE SYNTHETIC - BYDUREON PEN</b></u>						
N 022200 002	6872700	Jan 14, 2020	U-2288	M-224		Apr 02, 2021
	6872700	Jan 14, 2020	U-654			
	9884092	Aug 18, 2026	U-1313			
	9884092	Aug 18, 2026	U-2154			
	9884092	Aug 18, 2026	U-2155			
	9884092	Aug 18, 2026	U-2156			
<u><b>FENTANYL - SUBSYS</b></u>						
N 202788 001	10016403	Jan 25, 2027	DP			
<u><b>FENTANYL - SUBSYS</b></u>						
N 202788 002	10016403	Jan 25, 2027	DP			
<u><b>FENTANYL - SUBSYS</b></u>						
N 202788 003	10016403	Jan 25, 2027	DP			
<u><b>FENTANYL - SUBSYS</b></u>						
N 202788 004	10016403	Jan 25, 2027	DP			
<u><b>FENTANYL - SUBSYS</b></u>						
N 202788 005	10016403	Jan 25, 2027	DP			
<u><b>FENTANYL - SUBSYS</b></u>						
N 202788 006	10016403	Jan 25, 2027	DP			
<u><b>FENTANYL - SUBSYS</b></u>						
N 202788 007	10016403	Jan 25, 2027	DP			
<u><b>FENTANYL CITRATE - LAZANDA</b></u>						
N 022569 001	9814705	Jan 08, 2024	DP			
<u><b>FENTANYL CITRATE - LAZANDA</b></u>						
N 022569 002	9814705	Jan 08, 2024	DP			
<u><b>FENTANYL CITRATE - LAZANDA</b></u>						
N 022569 003	9814705	Jan 08, 2024	DP			
<u><b>FERRIC CITRATE - AURYXIA</b></u>						
N 205874 001	5753706	Feb 03, 2019	DP U-1577			
<u><b>FERUMOXYTOL - FERAHEME</b></u>						
N 022180 001				I-767		Feb 02, 2021
<u><b>FINGOLIMOD HYDROCHLORIDE - GILENYA</b></u>						
N 022527 001	5604229	Feb 18, 2019	DS U-1086		NPP	May 11, 2021
	5604229*PED	Aug 18, 2019			PED	Nov 11, 2021
	8324283	Mar 29, 2026	DP			
	8324283*PED	Sep 29, 2026				
	9187405	Jun 25, 2027	U-1086			
	9187405*PED	Dec 25, 2027				

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>FINGOLIMOD HYDROCHLORIDE - GILENYA</u>						
N 022527 002	5604229	Feb 18, 2019	DS U-1086		NS	May 11, 2021
	5604229*PED	Aug 18, 2019			PED	Nov 11, 2021
	9592208	Mar 30, 2032	DP U-2315			
	9592208*PED	Sep 30, 2032				
<u>FISH OIL TRIGLYCERIDES - OMEGAVEN</u>						
N 210589 001 >A>	9566260	Nov 12, 2023	DP U-2366		NCE	Jul 27, 2023
>A>	9629821	Nov 12, 2023	DP U-2367		ODE-202	Jul 27, 2025
<u>FISH OIL TRIGLYCERIDES - OMEGAVEN</u>						
N 210589 002	9566260	Nov 12, 2023	DP U-2366		NCE	Jul 27, 2023
	9629821	Nov 12, 2023	DP U-2367		ODE-202	Jul 27, 2025
<u>FLUCICLOVINE F-18 - AXUMIN</u>						
N 208054 001	10010632	Nov 28, 2026	DP			
<u>FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN - TRI-LUMA</u>						
N 021112 001	7915243	Sep 08, 2023	DP			
	7939516	Sep 08, 2023	DP			
	8247395	Oct 25, 2022	DP			
<u>FLUTICASONE FUROATE - ARNUITY ELLIPTA</u>						
N 205625 001	8534281	Mar 08, 2030	DP		NPP	May 17, 2021
<u>FLUTICASONE FUROATE - ARNUITY ELLIPTA</u>						
N 205625 002	8534281	Mar 08, 2030	DP			
<u>FLUTICASONE FUROATE - ARNUITY ELLIPTA</u>						
N 205625 003	7101866	Aug 03, 2021	DS DP U-2349		NS	May 17, 2021
	7629335	Aug 03, 2021	DP			
	8113199	Oct 23, 2027	DP			
	8161968	Feb 05, 2028	DP			
	8201556	Feb 05, 2029	DP			
	8534281	Mar 08, 2030	DP			
	8746242	Oct 11, 2030	DP			
	9333310	Oct 02, 2027	DP			
<u>FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE - TRELEGY ELLIPTA</u>						
N 209482 001	8534281	Mar 08, 2030	DP		I-775	Apr 24, 2021
	9750726	Nov 29, 2030	DP			
<u>FLUTICASONE FUROATE; VILANTEROL TRIFENATATE - BREO ELLIPTA</u>						
N 204275 001	8534281	Mar 08, 2030	DP			
<u>FLUTICASONE FUROATE; VILANTEROL TRIFENATATE - BREO ELLIPTA</u>						
N 204275 002	8534281	Mar 08, 2030	DP			
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
N 021433 001	9861771	Oct 11, 2020	DP			
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
N 021433 002	9861771	Oct 11, 2020	DP			
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
N 021433 003	9861771	Oct 11, 2020	DP			
<u>FLUTICASONE PROPIONATE - ARMONAIR RESPICLICK</u>						
N 208798 001	10022510	May 18, 2031	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>FLUTICASONE PROPIONATE - ARMONAIR RESPICLICK</u>						
N 208798 002	10022510	May 18, 2031	DP			
<u>FLUTICASONE PROPIONATE - ARMONAIR RESPICLICK</u>						
N 208798 003	10022510	May 18, 2031	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
N 021254 001	9861771	Oct 11, 2020	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
N 021254 002	9861771	Oct 11, 2020	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
N 021254 003	9861771	Oct 11, 2020	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - AIRDUO RESPICLICK</u>						
N 208799 001	10022510	May 18, 2031	DP			
	9987229	Sep 01, 2024	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - AIRDUO RESPICLICK</u>						
N 208799 002	10022510	May 18, 2031	DP			
	9987229	Sep 01, 2024	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - AIRDUO RESPICLICK</u>						
N 208799 003	10022510	May 18, 2031	DP			
	9987229	Sep 01, 2024	DP			
<u>FORMOTEROL FUMARATE - PERFOROMIST</u>						
N 022007 001	9730890	Jun 22, 2021	DP			
<u>FOSAPREPITANT DIMEGLUMINE - EMEND</u>						
N 022023 001	5691336	Mar 04, 2019	DS DP		NPP	Apr 03, 2021
	5691336*PED	Sep 04, 2019			PED	Oct 03, 2021
<u>FOSAPREPITANT DIMEGLUMINE - EMEND</u>						
N 022023 002	5691336	Mar 04, 2019	DS DP U-2265		NPP	Apr 03, 2021
	5691336*PED	Sep 04, 2019			PED	Oct 03, 2021
<u>FOSNETUPITANT CHLORIDE HYDROCHLORIDE; PALONOSETRON HYDROCHLORIDE - AKYNZEO</u>						
N 210493 001	8426450	May 23, 2032	DS DP		NCE	Apr 19, 2023
	8895586	May 23, 2032		U-2301		
	9186357	Nov 18, 2030		U-2301		
	9403772	May 23, 2032	DS	U-2301		
	9908907	May 23, 2032	DS DP			
<u>FOSTAMATINIB DISODIUM - TAVALISSE</u>						
N 209299 001	7449458	Sep 04, 2026	DS		NCE	Apr 17, 2023
	7538108	Mar 28, 2026	DS	U-2294	ODE-174	Apr 17, 2025
	7989448	Jun 12, 2026	DS	U-2294		
	8163902	Jun 17, 2026	DS	U-2294		
	8211889	Jan 19, 2026	DS			
	8263122	Nov 24, 2030	DP			
	8445485	Jun 17, 2026	DP			
	8652492	Nov 06, 2028	DP			
	8771648	Jul 27, 2032	DP			
	8912170	Jun 17, 2026		U-2294		
	8951504	Jul 27, 2032		U-2294		
	9266912	Jan 19, 2026		U-2294		
	9283238	Jun 17, 2026		U-2294		
	9737554	Jan 19, 2026	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>FOSTAMATINIB DISODIUM - TAVALISSE</b></u>						
N 209299 002	7449458	Sep 04, 2026	DS		NCE	Apr 17, 2023
	7538108	Mar 28, 2026	DS	U-2294	ODE-174	Apr 17, 2025
	7989448	Jun 12, 2026	DS	U-2294		
	8163902	Jun 17, 2026	DS	U-2294		
	8211889	Jan 19, 2026	DS			
	8263122	Nov 24, 2030	DP			
	8445485	Jun 17, 2026	DP			
	8652492	Nov 06, 2028	DP			
	8771648	Jul 27, 2032	DP			
	8912170	Jun 17, 2026		U-2294		
	8951504	Jul 27, 2032		U-2294		
	9266912	Jan 19, 2026		U-2294		
	9283238	Jun 17, 2026		U-2294		
	9737554	Jan 19, 2026	DP			
<u><b>GADOXETATE DISODIUM - EOVI</b></u>						
N 022090 002	6039931	Nov 13, 2021		U-1239		
<u><b>GALLIUM DOTATATE GA-68 - NETSPOT</b></u>						
N 208547 001	9375498	Aug 10, 2032		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 001	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 002	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 003	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 004	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 005	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 006	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 007	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 008	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 009	9241948	Jul 01, 2033		DP		
<u><b>GEMCITABINE HYDROCHLORIDE - INFUGEM</b></u>						
N 208313 010	9241948	Jul 01, 2033		DP		
<u><b>GLECAPREVIR; PIBRENTASVIR - MAVYRET</b></u>						
N 209394 001 >A> 10028937		Jun 10, 2030		U-2141		M-230
	10039754	Jun 10, 2030		U-2141		Aug 06, 2021
<u><b>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</b></u>						
N 021700 001	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
N 021700 002	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
N 021700 003	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
N 021700 004	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
N 021700 005	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				
<u>GLYCEROL PHENYLBUTYRATE - RAVICTI</u>						
N 203284 001	10045958	Sep 22, 2030	U-1816			
	10045959	Sep 22, 2030	U-1816			
	9962359	Sep 22, 2030	U-1816			
	9999608	Sep 22, 2030	U-1816			
<u>GLYCOPYRROLATE - SEEBRI</u>						
N 207923 001	9931304	Jun 27, 2021	DP			
	9962338	Jun 27, 2021	DP			
<u>GLYCOPYRROLATE ; INDACATEROL MALEATE - UTIBRON</u>						
N 207930 001	9931304	Jun 27, 2021	DP			
	9962338	Jun 27, 2021	DP			
<u>GLYCOPYRRONIUM TOSYLATE - OBREXZA</u>						
N 210361 001	>A> 10004717	Feb 28, 2033	DP U-2398			
	>A> 10052267	Oct 17, 2028	DP U-2398			
	>A> 6433003	Apr 10, 2020	U-2398			
	>A> 8618160	Dec 10, 2029	DP U-2398			
	>A> 8859610	Feb 28, 2033	DP U-2398			
	>A> 9006462	Feb 28, 2033	DP			
	>A> 9259414	Feb 28, 2033	U-2398			
	>A> 9744105	Jul 18, 2030	DP U-2398			
<u>GRANISETRON - SUSTOL</u>						
N 022445 001	9913910	Sep 28, 2024	U-2253			
<u>HALOBETASOL PROPIONATE - HALOBETASOL PROPIONATE</u>						
N 210566 001				NDF		May 24, 2021
<u>HEXAMINOLEVULINATE HYDROCHLORIDE - CYSVIEW KIT</u>						
N 022555 001	7348361	Nov 06, 2020	DP U-1087	M-220		Feb 15, 2021
	7348361	Nov 06, 2020	DP U-2250			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 001	10028946	Jul 25, 2033	U-1810			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 002	10028946	Jul 25, 2033	U-1810			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 003	10028946	Jul 25, 2033	U-1810			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 004	10028946	Jul 25, 2033	U-1810			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 005	10028946	Jul 25, 2033	U-1810			
<u>HYDROCODONE BITARTRATE - ZOHYDRO ER</u>						
N 202880 006	10028946	Jul 25, 2033	U-1810			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 001	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 002	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 003	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 004	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 005	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 006	9872837	Dec 21, 2031	DP			
<u>HYDROCODONE BITARTRATE - HYSINGLA</u>						
N 206627 007	9872837	Dec 21, 2031	DP			
<u>HYDROCORTISONE BUTYRATE - HYDROCORTISONE BUTYRATE</u>						
A 209556 001				PC		Aug 11, 2018
<u>HYDROGEN PEROXIDE - ESKATA</u>						
N 209305 001	9980983	Apr 21, 2035	U-2205			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID-HP</u>						
N 019034 001	9248229	Mar 12, 2034	DP			
	9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID-HP</u>						
N 019034 002	9248229	Mar 12, 2034	DP			
	9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u>						
N 019034 003	9248229	Mar 12, 2034	DP			
	9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u>						
N 019034 004	9248229	Mar 12, 2034	DP			
	9731082	Apr 23, 2032	DP			
<u>HYDROMORPHONE HYDROCHLORIDE - DILAUDID</u>						
N 019034 005	9248229	Mar 12, 2034	DP			
	9731082	Apr 23, 2032	DP			
<u>HYDROXYPROGESTERONE CAPROATE - MAKENA (AUTOINJECTOR)</u>						
N 021945 004	8021335	Oct 04, 2026	DP			
	8562564	Jan 24, 2026	DP			
	9180259	Jan 24, 2026	DP			
	9533102	Jan 24, 2026	DP			
	9629959	Jan 24, 2026	DP			
	9789257	Feb 11, 2034	DP			
	9844558	May 02, 2036	U-2236			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>HYDROXYPROGESTERONE CAPROATE - MAKENA (AUTOINJECTOR)</b></u>						
N 021945 004	RE44846	Aug 10, 2019	DP			
<u><b>HYDROXYUREA - SIKLOS</b></u>						
N 208843 001					ODE-177	Dec 21, 2024
<u><b>HYDROXYUREA - SIKLOS</b></u>						
N 208843 002					ODE-177	Dec 21, 2024
<u><b>IBRUTINIB - IMBRUVICA</b></u>						
N 205552 001	10004746	Jun 03, 2031	U-1684			
	10004746	Jun 03, 2031	U-1946			
	10004746	Jun 03, 2031	U-2241			
	10004746	Jun 03, 2031	U-2242			
	10016435	Jun 03, 2031	U-1650			
>A>	8563563	Apr 26, 2027	U-1491			
>A>	8563563	Apr 26, 2027	U-1650			
>A>	8563563	Apr 26, 2027	U-1946			
>A>	8563563	Apr 26, 2027	U-2219			
<u><b>IBRUTINIB - IMBRUVICA</b></u>						
N 205552 002	10004746	Jun 03, 2031	U-1684		NCE	Nov 13, 2018
	10004746	Jun 03, 2031	U-1946			
	10004746	Jun 03, 2031	U-2241			
	10004746	Jun 03, 2031	U-2242			
	10016435	Jun 03, 2031	U-1650			
	7514444	Dec 28, 2026	DS DP			
	8008309	Dec 28, 2026	DS DP			
	8476284	Dec 28, 2026	U-1456			
	8476284	Dec 28, 2026	U-1650			
	8476284	Dec 28, 2026	U-1946			
	8476284	Dec 28, 2026	U-1947			
	8497277	Dec 28, 2026	U-1456			
	8497277	Dec 28, 2026	U-1491			
	8497277	Dec 28, 2026	U-1650			
	8497277	Dec 28, 2026	U-1946			
	8497277	Dec 28, 2026	U-1947			
>A>	8563563	Apr 26, 2027	U-1491			
>A>	8563563	Apr 26, 2027	U-1650			
>A>	8563563	Apr 26, 2027	U-1946			
>A>	8563563	Apr 26, 2027	U-2219			
	8697711	Dec 28, 2026	DS DP			
	8703780	Dec 28, 2026	U-1491			
	8735403	Dec 28, 2026	DS DP			
	8754090	Jun 03, 2031	U-1456			
	8754091	Dec 28, 2026	DP			
	8952015	Dec 28, 2026	U-1456			
	8952015	Dec 28, 2026	U-1491			
	8952015	Dec 28, 2026	U-1650			
	8952015	Dec 28, 2026	U-1946			
	8952015	Dec 28, 2026	U-1947			
	8957079	Dec 28, 2026	DS DP			
	8999999	Jun 03, 2031	U-1491			
	8999999	Jun 03, 2031	U-1946			
	8999999	Jun 03, 2031	U-2228			
	9125889	Jun 03, 2031	U-1650			
	9181257	Dec 28, 2026	DS			
	9296753	Oct 30, 2033	DS			
	9540382	Aug 18, 2033	U-1456			
	9540382	Aug 18, 2033	U-1491			
	9540382	Aug 18, 2033	U-1650			
	9540382	Aug 18, 2033	U-1946			
	9540382	Aug 18, 2033	U-1947			
	9713617	Jun 03, 2033	DP			
	9725455	Jun 03, 2033	DS			
	9795604	Oct 24, 2034	U-2150			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b><u>IBRUTINIB - IMBRUVICA</u></b>						
N 205552 002	9801881	Jun 03, 2031	U-1491			
	9801883	Jun 03, 2031	U-2159			
	9814721	Jun 03, 2031	U-1947			
<b><u>IBRUTINIB - IMBRUVICA</u></b>						
N 210563 001	10004746	Jun 03, 2031	U-1684		NCE	Nov 13, 2018
	10004746	Jun 03, 2031	U-1946			
	10004746	Jun 03, 2031	U-2241			
	10004746	Jun 03, 2031	U-2242			
	10010507	Mar 03, 2036	DP			
	10016435	Jun 03, 2031	U-1650			
	7514444	Dec 28, 2026	DS DP			
	8008309	Dec 28, 2026	DS DP			
	8476284	Dec 28, 2026	U-1456			
	8476284	Dec 28, 2026	U-1650			
	8476284	Dec 28, 2026	U-1946			
	8476284	Dec 28, 2026	U-1947			
	8476284	Dec 28, 2026	U-2241			
	8497277	Dec 28, 2026	U-1456			
	8497277	Dec 28, 2026	U-1491			
	8497277	Dec 28, 2026	U-1650			
	8497277	Dec 28, 2026	U-1946			
	8497277	Dec 28, 2026	U-1947			
	8497277	Dec 28, 2026	U-2241			
	8497277	Dec 28, 2026	U-2242			
>A>	8563563	Apr 26, 2027	U-1491			
>A>	8563563	Apr 26, 2027	U-1650			
>A>	8563563	Apr 26, 2027	U-1946			
>A>	8563563	Apr 26, 2027	U-2241			
>A>	8563563	Apr 26, 2027	U-2242			
	8697711	Dec 28, 2026	DS DP			
	8703780	Dec 28, 2026	U-1491			
	8703780	Dec 28, 2026	U-2242			
	8735403	Dec 28, 2026	DS DP			
	8754090	Jun 03, 2031	U-1456			
	8754091	Dec 28, 2026	DP			
	8952015	Dec 28, 2026	U-1456			
	8952015	Dec 28, 2026	U-1491			
	8952015	Dec 28, 2026	U-1650			
	8952015	Dec 28, 2026	U-1946			
	8952015	Dec 28, 2026	U-1947			
	8952015	Dec 28, 2026	U-2241			
	8952015	Dec 28, 2026	U-2242			
	8957079	Dec 28, 2026	DS DP			
	8999999	Jun 03, 2031	U-1491			
	8999999	Jun 03, 2031	U-1946			
	8999999	Jun 03, 2031	U-2241			
	8999999	Jun 03, 2031	U-2242			
	9125889	Jun 03, 2031	U-1650			
	9181257	Dec 28, 2026	DS			
	9296753	Oct 30, 2033	DS			
	9655857	Mar 03, 2036	DP			
	9725455	Jun 03, 2033	DS			
	9795604	Oct 24, 2034	U-2150			
	9801881	Jun 03, 2031	U-1491			
	9801881	Jun 03, 2031	U-2242			
	9801883	Jun 03, 2031	U-2159			
	9801883	Jun 03, 2031	U-2243			
	9814721	Jun 03, 2031	U-1947			
<b><u>IBRUTINIB - IMBRUVICA</u></b>						
N 210563 002	10004746	Jun 03, 2031	U-1684		NCE	Nov 13, 2018
	10004746	Jun 03, 2031	U-1946			
	10004746	Jun 03, 2031	U-2241			
	10004746	Jun 03, 2031	U-2242			
	10010507	Mar 03, 2036	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b><u>IBRUTINIB - IMBRUVICA</u></b>						
N 210563 002	10016435	Jun 03, 2031	U-1650			
	7514444	Dec 28, 2026	DS DP			
	8008309	Dec 28, 2026	DS DP			
	8476284	Dec 28, 2026	U-1456			
	8476284	Dec 28, 2026	U-1650			
	8476284	Dec 28, 2026	U-1946			
	8476284	Dec 28, 2026	U-1947			
	8476284	Dec 28, 2026	U-2241			
	8497277	Dec 28, 2026	U-1456			
	8497277	Dec 28, 2026	U-1491			
	8497277	Dec 28, 2026	U-1650			
	8497277	Dec 28, 2026	U-1946			
	8497277	Dec 28, 2026	U-1947			
	8497277	Dec 28, 2026	U-2241			
	>A> 8563563	Apr 26, 2027	U-1491			
	>A> 8563563	Apr 26, 2027	U-1650			
	>A> 8563563	Apr 26, 2027	U-1946			
	>A> 8563563	Apr 26, 2027	U-2241			
	>A> 8563563	Apr 26, 2027	U-2242			
	8697711	Dec 28, 2026	DS DP			
	8703780	Dec 28, 2026	U-1491			
	8703780	Dec 28, 2026	U-2242			
	8735403	Dec 28, 2026	DS DP			
	8754090	Jun 03, 2031	U-1456			
	8754091	Dec 28, 2026	DP			
	8952015	Dec 28, 2026	U-1456			
	8952015	Dec 28, 2026	U-1491			
	8952015	Dec 28, 2026	U-1650			
	8952015	Dec 28, 2026	U-1946			
	8952015	Dec 28, 2026	U-1947			
	8952015	Dec 28, 2026	U-2241			
	8952015	Dec 28, 2026	U-2242			
	8957079	Dec 28, 2026	DS DP			
	89999999	Jun 03, 2031	U-1491			
	89999999	Jun 03, 2031	U-1946			
	89999999	Jun 03, 2031	U-2241			
	89999999	Jun 03, 2031	U-2242			
	9125889	Jun 03, 2031	U-1650			
	9181257	Dec 28, 2026	DS			
	9296753	Oct 30, 2033	DS			
	9655857	Mar 03, 2036	DP			
	9725455	Jun 03, 2033	DS			
	9795604	Oct 24, 2034	U-2150			
	9801881	Jun 03, 2031	U-1491			
	9801881	Jun 03, 2031	U-2242			
	9801883	Jun 03, 2031	U-2159			
	9801883	Jun 03, 2031	U-2243			
	9814721	Jun 03, 2031	U-1947			
<b><u>IBRUTINIB - IMBRUVICA</u></b>						
N 210563 003	10004746	Jun 03, 2031	U-1684		NCE	Nov 13, 2018
	10004746	Jun 03, 2031	U-1946			
	10004746	Jun 03, 2031	U-2241			
	10004746	Jun 03, 2031	U-2242			
	10010507	Mar 03, 2036	DP			
	10016435	Jun 03, 2031	U-1650			
	7514444	Dec 28, 2026	DS DP			
	8008309	Dec 28, 2026	DS DP			
	8476284	Dec 28, 2026	U-1456			
	8476284	Dec 28, 2026	U-1650			
	8476284	Dec 28, 2026	U-1946			
	8476284	Dec 28, 2026	U-1947			
	8476284	Dec 28, 2026	U-2241			
	8497277	Dec 28, 2026	U-1456			
	8497277	Dec 28, 2026	U-1491			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>IBRUTINIB - IMBRUVICA</u>						
N 210563 003	8497277	Dec 28, 2026	U-1650			
	8497277	Dec 28, 2026	U-1946			
	8497277	Dec 28, 2026	U-1947			
	8497277	Dec 28, 2026	U-2241			
	8497277	Dec 28, 2026	U-2242			
>A>	8563563	Apr 26, 2027	U-1491			
>A>	8563563	Apr 26, 2027	U-1650			
>A>	8563563	Apr 26, 2027	U-1946			
>A>	8563563	Apr 26, 2027	U-2241			
>A>	8563563	Apr 26, 2027	U-2242			
	8697711	Dec 28, 2026	DS DP			
	8703780	Dec 28, 2026	U-1491			
	8703780	Dec 28, 2026	U-2242			
	8735403	Dec 28, 2026	DS DP			
	8754090	Jun 03, 2031	U-1456			
	8754091	Dec 28, 2026	DP			
	8952015	Dec 28, 2026	U-1456			
	8952015	Dec 28, 2026	U-1491			
	8952015	Dec 28, 2026	U-1650			
	8952015	Dec 28, 2026	U-1946			
	8952015	Dec 28, 2026	U-1947			
	8952015	Dec 28, 2026	U-2241			
	8952015	Dec 28, 2026	U-2242			
	8957079	Dec 28, 2026	DS DP			
	8999999	Jun 03, 2031	U-1491			
	8999999	Jun 03, 2031	U-1946			
	8999999	Jun 03, 2031	U-2241			
	8999999	Jun 03, 2031	U-2242			
	9125889	Jun 03, 2031	U-1650			
	9181257	Dec 28, 2026	DS			
	9296753	Oct 30, 2033	DS			
	9655857	Mar 03, 2036	DP			
	9725455	Jun 03, 2033	DS			
	9795604	Oct 24, 2034	U-2150			
	9801881	Jun 03, 2031	U-1491			
	9801881	Jun 03, 2031	U-2242			
	9801883	Jun 03, 2031	U-2159			
	9801883	Jun 03, 2031	U-2243			
	9814721	Jun 03, 2031	U-1947			
<u>IBRUTINIB - IMBRUVICA</u>						
N 210563 004	10004746	Jun 03, 2031	U-1684		NCE	Nov 13, 2018
	10004746	Jun 03, 2031	U-1946			
	10004746	Jun 03, 2031	U-2241			
	10004746	Jun 03, 2031	U-2242			
	10010507	Mar 03, 2036	DP			
	10016435	Jun 03, 2031	U-1650			
	7514444	Dec 28, 2026	DS DP			
	8008309	Dec 28, 2026	DS DP			
	8476284	Dec 28, 2026	U-1456			
	8476284	Dec 28, 2026	U-1650			
	8476284	Dec 28, 2026	U-1946			
	8476284	Dec 28, 2026	U-1947			
	8476284	Dec 28, 2026	U-2241			
	8497277	Dec 28, 2026	U-1456			
	8497277	Dec 28, 2026	U-1491			
	8497277	Dec 28, 2026	U-1650			
	8497277	Dec 28, 2026	U-1946			
	8497277	Dec 28, 2026	U-1947			
	8497277	Dec 28, 2026	U-2241			
	8497277	Dec 28, 2026	U-2242			
>A>	8563563	Apr 26, 2027	U-1491			
>A>	8563563	Apr 26, 2027	U-1650			
>A>	8563563	Apr 26, 2027	U-1946			
>A>	8563563	Apr 26, 2027	U-2241			
>A>	8563563	Apr 26, 2027	U-2242			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>IBRUTINIB - IMBRUVICA</u>						
N 210563 004	8697711	Dec 28, 2026	DS DP			
	8703780	Dec 28, 2026		U-1491		
	8703780	Dec 28, 2026		U-2242		
	8735403	Dec 28, 2026	DS DP			
	8754090	Jun 03, 2031		U-1456		
	8754091	Dec 28, 2026	DP			
	8952015	Dec 28, 2026		U-1456		
	8952015	Dec 28, 2026		U-1491		
	8952015	Dec 28, 2026		U-1650		
	8952015	Dec 28, 2026		U-1946		
	8952015	Dec 28, 2026		U-1947		
	8952015	Dec 28, 2026		U-2241		
	8952015	Dec 28, 2026		U-2242		
	8957079	Dec 28, 2026	DS DP			
	8999999	Jun 03, 2031		U-1491		
	8999999	Jun 03, 2031		U-1946		
	8999999	Jun 03, 2031		U-2241		
	8999999	Jun 03, 2031		U-2242		
	9125889	Jun 03, 2031		U-1650		
	9181257	Dec 28, 2026	DS			
	9296753	Oct 30, 2033	DS			
	9655857	Mar 03, 2036	DP			
	9725455	Jun 03, 2033	DS			
	9795604	Oct 24, 2034		U-2150		
	9801881	Jun 03, 2031		U-1491		
	9801881	Jun 03, 2031		U-2242		
	9801883	Jun 03, 2031		U-2159		
	9801883	Jun 03, 2031		U-2243		
	9814721	Jun 03, 2031		U-1947		
<u>IBUPROFEN - CALDOLOR</u>						
N 022348 002	9072661	Mar 16, 2032		U-2264		
	9072710	Mar 16, 2032		U-2266		
<u>INGENOL MEBUTATE - PICATO</u>						
N 202833 001	9861603	Dec 18, 2026		U-1440		
<u>INGENOL MEBUTATE - PICATO</u>						
N 202833 002	9861603	Dec 18, 2026		U-1440		
<u>INSULIN ASPART - FIASP FLEXTOUCH</u>						
N 208751 002	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>INSULIN ASPART RECOMBINANT - NOVOLOG FLEXTOUCH</u>						
N 020986 005	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>INSULIN ASPART; INSULIN DEGLUDEC - RYZODEG 70/30</u>						
N 203313 001 >A>	7615532	Jun 28, 2029	DS DP			
	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
	9884094	May 01, 2033		U-2238		
<u>INSULIN DEGLUDEC - TRESIBA</u>						
N 203314 001 >A>	7615532	Jun 28, 2029	DS DP			
	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>INSULIN DEGLUDEC - TRESIBA</u>						
N 203314 002 >A>	7615532	Jun 28, 2029	DS DP			
	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>INSULIN DEGLUDEC - TRESIBA</u>						
N 203314 002 >A>	7615532	Jun 28, 2029	DS DP			
	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>INSULIN DEGLUDEC; LIRAGLUTIDE - XULTOPHY 100/3.6</u>						
N 208583 001 >A>	7615532	Jun 28, 2029	DS DP			
	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>INSULIN DETEMIR RECOMBINANT - LEVEMIR FLEXTOUCH</u>						
N 021536 005	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>INSULIN GLARGINE RECOMBINANT - TOUJEO MAX SOLOSTAR</u>						
N 206538 002	7918833	Sep 23, 2027	DP			
	8512297	Sep 15, 2024	DP			
	8556864	Mar 03, 2024	DP			
	8603044	Mar 02, 2024	DP			
	8679069	Apr 12, 2025	DP			
	8992486	Jun 05, 2024	DP			
	9011391	Mar 26, 2024	DP U-1832			
	9233211	Mar 02, 2024	DP			
	9345750	May 18, 2031	DP U-1855			
	9408979	Mar 02, 2024	DP			
	9526844	Mar 02, 2024	DP			
	9533105	Aug 17, 2024	DP			
	9561331	Aug 28, 2024	DP			
	9604008	Mar 02, 2024	DP			
	9604009	Aug 16, 2024	DP			
	9610409	Mar 02, 2024	DP			
	9623189	Aug 19, 2024	DP			
	9775954	Mar 02, 2024	DP			
	9827379	Mar 02, 2024	DP U-2146			
<u>INSULIN GLARGINE; LIXISENATIDE - SOLIQUA 100/33</u>						
N 208673 001	10029011	Aug 02, 2032	DP			
	9717852	Apr 08, 2033	DP			
	9950039	Dec 10, 2035	U-2277			
	9950039	Dec 10, 2035	U-2278			
	9950039	Dec 10, 2035	U-2279			
<u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u>						
N 021629 003	9717852	Apr 08, 2033	DP			
<u>INSULIN LISPRO - ADMELOG SOLOSTAR</u>						
N 209196 002	7918833	Sep 23, 2027	DP			
	8512297	Sep 15, 2024	DP			
	8556864	Mar 03, 2024	DP			
	8603044	Mar 02, 2024	DP			
	8679069	Apr 12, 2025	DP			
	8992486	Jun 05, 2024	DP			
	9011391	Mar 26, 2024	DP U-1832			
	9233211	Mar 02, 2024	DP			
	9408979	Mar 02, 2024	DP			
	9526844	Mar 02, 2024	DP			
	9533105	Aug 17, 2024	DP			
	9561331	Aug 28, 2024	DP			
	9604008	Mar 02, 2024	DP			
	9604009	Aug 16, 2024	DP			
	9610409	Mar 02, 2024	DP			
	9623189	Aug 19, 2024	DP			
	9717852	Apr 08, 2033	DP			
	9775954	Mar 02, 2024	DP			
	9827379	Mar 04, 2024	DP U-2146			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>INSULIN LISPRO - ADMELOG SOLOSTAR</u>						
N 209196 002	7918833	Sep 23, 2027	DP			
	8512297	Sep 15, 2024	DP			
	8556864	Mar 03, 2024	DP			
	8603044	Mar 02, 2024	DP			
	8679069	Apr 12, 2025	DP			
	8992486	Jun 05, 2024	DP			
	9011391	Mar 26, 2024	DP U-1832			
	9233211	Mar 02, 2024	DP			
	9408979	Mar 02, 2024	DP			
	9526844	Mar 02, 2024	DP			
	9533105	Aug 17, 2024	DP			
	9561331	Aug 28, 2024	DP			
	9604008	Mar 02, 2024	DP			
	9604009	Aug 16, 2024	DP			
	9610409	Mar 02, 2024	DP			
	9623189	Aug 19, 2024	DP			
	9717852	Apr 08, 2033	DP			
	9775954	Mar 02, 2024	DP			
	9827379	Mar 04, 2024	DP U-2146			
<u>INSULIN RECOMBINANT HUMAN - AFREZZA</u>						
N 022472 001 >A> 10046031		Aug 11, 2029	U-2383			
	9943571	Aug 11, 2029	U-1537			
<u>INSULIN RECOMBINANT HUMAN - AFREZZA</u>						
N 022472 002 >A> 10046031		Aug 11, 2029	U-2383			
	9943571	Aug 11, 2029	U-1537			
<u>INSULIN RECOMBINANT HUMAN - AFREZZA</u>						
N 022472 003 >A> 10046031		Aug 11, 2029	U-2383			
	9943571	Aug 11, 2029	U-1537			
<u>TOBENGUANE I-131 - AZEDRA</u>						
N 209607 001				NP	Jul 30, 2021	
				ODE-204	Jul 30, 2025	
<u>ITRACONAZOLE - ITRACONAZOLE</u>						
A 205573 001				>A> PC	Mar 17, 2019	
<u>IVACAFTOR - KALYDECO</u>						
N 203188 001 8629162		Jun 24, 2025	U-2234		ODE-186	Feb 21, 2021
					ODE-187	Dec 29, 2021
					ODE-189	Jul 31, 2024
					ODE-190	May 17, 2024
					ODE-199	Aug 15, 2025
<u>IVACAFTOR - KALYDECO</u>						
N 207925 001 8629162		Jun 24, 2025	U-2234		ODE-188	Mar 17, 2022
					ODE-189	Jul 31, 2024
					ODE-190	May 17, 2024
					ODE-199	Aug 15, 2025
<u>IVACAFTOR - KALYDECO</u>						
N 207925 002 8629162		Jun 24, 2025	U-2234		ODE-188	Mar 17, 2022
					ODE-189	Jul 31, 2024
					ODE-190	May 17, 2024
					ODE-199	Aug 15, 2025
<u>IVACAFTOR; IVACAFTOR, TEZACAFTOR - SYMDEKO (COPACKAGED)</u>						
N 210491 001 10022352		Apr 09, 2027	DP U-2343		NCE	Feb 12, 2023
>A> 10058546		Jul 15, 2033	U-2399		ODE-173	Feb 12, 2025
7495103		May 20, 2027	DS DP			
7645789		May 01, 2027	DS DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>IVACAFTOR; IVACAFTOR, TEZACAFTOR - SYMDEKO (COPACKAGED)</u>						
N 210491 001	7776905	Jun 03, 2027	DS DP			
	8324242	Aug 05, 2027		U-2246		
	8410274	Dec 28, 2026		DP		
	8415387	Nov 12, 2027		U-2246		
	8598181	May 01, 2027		U-2246		
	8623905	May 01, 2027	DS DP			
	8629162	Jun 24, 2025		U-2247		
	8754224	Dec 28, 2026	DS DP			
	9012496	Jul 15, 2033		U-2248		
	9670163	Dec 28, 2026	DP	U-2246		
	9931334	Dec 28, 2026	DP	U-2275		
	9974781	Apr 09, 2027	DP	U-2318		
<u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u>						
N 206038 001	9931334	Dec 28, 2026	DP	U-2276	M-218	Jan 25, 2021
<u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u>						
N 206038 002	9931334	Dec 28, 2026	DP	U-2276	M-218	Jan 25, 2021
<u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u>						
N 211358 001	7495103	May 20, 2027	DS DP		NCE	Jul 02, 2020
	7973038	Nov 08, 2026		U-2374	NP	Aug 07, 2021
	8324242	Aug 05, 2027		U-2374	ODE-195	Aug 07, 2025
	8410274	Dec 28, 2026		DP		
	8507534	Sep 20, 2030	DS DP			
	8653103	Dec 04, 2028		DP		
>A>	8716338	Sep 20, 2030	DP	U-2396		
	8741933	Nov 08, 2026		U-2374		
	8754224	Dec 28, 2026	DS DP			
	8846718	Dec 04, 2028		U-2375		
	8993600	Dec 11, 2030		DP		
	9150552	Dec 04, 2028		U-2375		
>A>	9192606	Sep 29, 2029	DP	U-2397		
	9216969	Nov 08, 2026		DP		
	9670163	Dec 28, 2026	DP	U-2376		
	9931334	Dec 28, 2026	DP	U-2376		
<u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u>						
N 211358 002	7495103	May 20, 2027	DS DP		NCE	Jul 02, 2020
	7973038	Nov 08, 2026		U-2374	NP	Aug 07, 2021
	8324242	Aug 05, 2027		U-2374	ODE-195	Aug 07, 2025
	8410274	Dec 28, 2026		DP		
	8507534	Sep 20, 2030	DS DP			
	8653103	Dec 04, 2028		DP		
>A>	8716338	Sep 20, 2030	DP	U-2396		
	8741933	Nov 08, 2026		U-2374		
	8754224	Dec 28, 2026	DS DP			
	8846718	Dec 04, 2028		U-2375		
	8993600	Dec 11, 2030		DP		
	9150552	Dec 04, 2028		U-2375		
>A>	9192606	Sep 29, 2029	DP	U-2397		
	9216969	Nov 08, 2026		DP		
	9670163	Dec 28, 2026	DP	U-2376		
	9931334	Dec 28, 2026	DP	U-2376		
<u>IVOSIDENIB - TIBSOVO</u>						
N 211192 001	9474779	Aug 19, 2033	DS DP	U-2350	NCE	Jul 20, 2023
	9850277	Jan 18, 2033	DS DP	U-2350	ODE-203	Jul 20, 2025
	9968595	Mar 13, 2035	DP	U-2351		
<u>LACOSAMIDE - VIMPAT</u>						
N 022253 001	RE38551	Mar 17, 2022	DS DP	U-1567		
	RE38551	Mar 17, 2022	DS DP	U-2140		

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b>LACOSAMIDE - VIMPAT</b>						
N 022253 002	RE38551	Mar 17, 2022	DS DP U-1567			
	RE38551	Mar 17, 2022	DS DP U-2140			
<b>LACOSAMIDE - VIMPAT</b>						
N 022253 003	RE38551	Mar 17, 2022	DS DP U-1567			
	RE38551	Mar 17, 2022	DS DP U-2140			
<b>LACOSAMIDE - VIMPAT</b>						
N 022253 004	RE38551	Mar 17, 2022	DS DP U-1567			
	RE38551	Mar 17, 2022	DS DP U-2140			
<b>LACOSAMIDE - VIMPAT</b>						
N 022255 001	RE38551	Mar 17, 2022	DS DP U-1567			
	RE38551	Mar 17, 2022	DS DP U-2140			
<b>LANSOPRAZOLE - PREVACID</b>						
N 021428 001	9901546	May 17, 2019	DP			
	9901546*PED	Nov 17, 2019				
<b>LANSOPRAZOLE - PREVACID</b>						
N 021428 002	9901546	May 17, 2019	DP			
	9901546*PED	Nov 17, 2019				
<b>LATANOPROST - XELPROS</b>						
N 206185 001	>A> 9539262	Apr 20, 2035	DP U-2400			
	>A> 9629852	Sep 12, 2029	DP			
<b>LEDIPASVIR; SOFOBUVIR - HARVONI</b>						
N 205834 001	10039779	Jan 30, 2034	DS DP U-2369			
	10039779	Jan 30, 2034	DS DP U-2370			
<b>LENVATINIB MESYLATE - LENVIMA</b>						
N 206947 001				I-787	Aug 15, 2021	
				ODE-196	Aug 15, 2025	
<b>LENVATINIB MESYLATE - LENVIMA</b>						
N 206947 002				I-787	Aug 15, 2021	
				ODE-196	Aug 15, 2025	
<b>LEGINURAD - ZURAMPIC</b>						
N 207988 001	9956205	Dec 28, 2031	U-2311			
<b>LETHERMOVIR - PREVYMIS</b>						
N 209939 001				ODE-165	Nov 08, 2024	
<b>LETHERMOVIR - PREVYMIS</b>						
N 209939 002				ODE-165	Nov 08, 2024	
<b>LETHERMOVIR - PREVYMIS</b>						
N 209940 001				ODE-165	Nov 08, 2024	
<b>LETHERMOVIR - PREVYMIS</b>						
N 209940 002				ODE-165	Nov 08, 2024	
<b>LETROZOLE; RIBOCICLIB SUCCINATE - KISQALI FEMARA CO-PACK (COPACKAGED)</b>						
N 209935 001	9868739	Nov 09, 2031	U-1981			
<b>LEUPROLIDE ACETATE - ELIGARD</b>						
N 021731 001	9914802	Nov 13, 2020	DS DP U-1666			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>LEUPROLIDE ACETATE - LUTRATE DEPOT KIT</u> N 205054 001 >A> 9789064		Dec 15, 2020	DP			
<u>LEVONORGESTREL - LILETTA</u> N 206229 001 10028858		Mar 22, 2034	DP U-2348			
<u>LEVOHYROXINE SODIUM - LEVOTHYROXINE SODIUM</u> A 206163 001				PC		Sep 29, 2018
<u>LEVOHYROXINE SODIUM - LEVOTHYROXINE SODIUM</u> A 206163 002	7723390	Mar 14, 2024	DP	PC		Sep 29, 2018
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 003 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 004 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 005 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 006 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 007 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 008 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 009 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 010 7723390		Mar 14, 2024	DP			
<u>LEVOHYROXINE SODIUM - TIROSINT</u> N 021924 013 7691411 7723390		Mar 14, 2024 Mar 14, 2024	DP DP			
<u>LIDOCAINE - ZTLIDO</u> N 207962 001 9283174 9925264 9931403		May 10, 2031 May 10, 2031 May 10, 2031	DP DP U-2267 DP	NP		Feb 28, 2021
<u>LIFITEGRAST - XIIDRA</u> N 208073 001 9890141		Oct 21, 2030	DS			
<u>LINAGLIPTIN - TRADJENTA</u> N 201280 001 10034877		Aug 05, 2029	U-2347			
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u> N 201281 001 10022379		Apr 02, 2029	U-2339			
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u> N 201281 002 10022379		Apr 02, 2029	U-2339			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>LINAGLITPIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u>						
N 201281 003	10022379	Apr 02, 2029		U-2339		
<u>LINAGLITPIN; METFORMIN HYDROCHLORIDE - JENTADUETO XR</u>						
N 208026 001	10022379	Apr 02, 2029		U-2339		
<u>LINAGLITPIN; METFORMIN HYDROCHLORIDE - JENTADUETO XR</u>						
N 208026 002	10022379	Apr 02, 2029		U-2339		
<u>LIRAGLUTIDE RECOMBINANT - VICTOZA</u>						
N 022341 001	9968659	Jan 09, 2037		U-2313		
<u>LIRAGLUTIDE RECOMBINANT - SAXENDA</u>						
N 206321 001	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>LISINOPRIL - OBRELIS</u>						
N 208401 001	10039800	Nov 06, 2035	U-1723			
	10039800	Nov 06, 2035	U-185			
	10039800	Nov 06, 2035	U-1864			
	10039800	Nov 06, 2035	U-1991			
	10039800	Nov 06, 2035	U-3			
	10039800	Nov 06, 2035	U-71			
	10039800	Nov 06, 2035	U-8			
<u>LIXISENATIDE - ADLYXIN</u>						
N 208471 001	10028910	Nov 11, 2030	DP			
	9440029	Jan 30, 2032	DP			
	9855388	Apr 24, 2029	DP	U-1881		
	9981013	Aug 30, 2030		U-2297		
<u>LIXISENATIDE - ADLYXIN</u>						
N 208471 002	10028910	Nov 11, 2030	DP			
	9440029	Jan 30, 2032	DP			
	9855388	Apr 24, 2029	DP	U-1881		
	9981013	Aug 30, 2030		U-2297		
<u>LOFEXIDINE HYDROCHLORIDE - LUCEMYRA</u>						
N 209229 001					NCE	May 16, 2023
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 001	10016404	Mar 07, 2025	U-1316			
	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 002	10016404	Mar 07, 2025	U-1316			
	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 003	10016404	Mar 07, 2025	U-1316			
	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 004	10016404	Mar 07, 2025	U-1316			
	9861622	Mar 07, 2025	U-1316			
<u>LOMITAPIDE MESYLATE - JUXTAPID</u>						
N 203858 005	10016404	Mar 07, 2025	U-1316			
	9861622	Mar 07, 2025	U-1316			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>LOMITAPIDE MESYLATE - JUXTAPID</b></u>						
N 203858 006	10016404	Mar 07, 2025	U-1316			
	9861622	Mar 07, 2025	U-1316			
<u><b>LOTEPREDNOL ETABONATE - LOTELEX</b></u>						
N 202872 001				M-229		Jul 20, 2021
<u><b>LOTEPREDNOL ETABONATE - INVELTYS</b></u>						
N 210565 001				NP		Aug 22, 2021
<u><b>LUBIPROSTONE - AMITIZA</b></u>						
N 021908 001				M-225		Apr 26, 2021
<u><b>LUBIPROSTONE - AMITIZA</b></u>						
N 021908 002				M-225		Apr 26, 2021
<u><b>LULICONAZOLE - LUZU</b></u>						
N 204153 001				NPP		Feb 20, 2021
<u><b>LURASIDONE HYDROCHLORIDE - LATUDA</b></u>						
N 200603 001	9174975	Feb 20, 2024	U-1770		NPP	Mar 05, 2021
	9174975*PED	Aug 20, 2024				
	9907794	May 26, 2026	DP			
<u><b>LURASIDONE HYDROCHLORIDE - LATUDA</b></u>						
N 200603 002	9174975	Feb 20, 2024	U-1770		NPP	Mar 05, 2021
	9174975*PED	Aug 20, 2024				
	9907794	May 26, 2026	DP			
<u><b>LURASIDONE HYDROCHLORIDE - LATUDA</b></u>						
N 200603 003	9174975	Feb 20, 2024	U-1770		NPP	Mar 05, 2021
	9174975*PED	Aug 20, 2024				
	9907794	May 26, 2026	DP			
<u><b>LURASIDONE HYDROCHLORIDE - LATUDA</b></u>						
N 200603 004	9174975	Feb 20, 2024	U-1770		NPP	Mar 05, 2021
	9174975*PED	Aug 20, 2024				
	9907794	May 26, 2026	DP			
<u><b>LURASIDONE HYDROCHLORIDE - LATUDA</b></u>						
N 200603 005	9174975	Feb 20, 2024	U-1770		NPP	Mar 05, 2021
	9174975*PED	Aug 20, 2024				
	9907794	May 26, 2026	DP			
<u><b>LUSUTROMBOPAG - MULPLETA</b></u>						
N 210923 001	7601746	Sep 05, 2024	DS DP U-2344		NCE	Jul 31, 2023
	8530668	Jan 21, 2030	DS DP			
	8889722	Jul 29, 2028	DS DP			
	9427402	Sep 29, 2031	DP			
<u><b>LUTETIUM DOTATATE LU-177 - LUTATHERA</b></u>						
N 208700 001					NCE	Jan 26, 2023
					ODE-166	Jan 26, 2025
<u><b>MACIMORELIN ACETATE - MACRILEN</b></u>						
N 205598 001	6861409	Aug 01, 2022	DS DP U-2220		ODE-170	Dec 20, 2024
	8192719	Oct 12, 2027	U-2220			
<u><b>MACITENTAN - OPSUMIT</b></u>						
N 204410 001	7094781	Dec 05, 2025	DS DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>MELPHALAN HYDROCHLORIDE - EVOMELA</u> N 207155 001	10040872	Jan 30, 2034	DP			
<u>METFORMIN HYDROCHLORIDE - GLUMETZA</u> N 021748 002	8323692	Mar 30, 2023	DP			
<u>METHOTREXATE SODIUM - XATMER</u> N 208400 001	9855215	Jan 02, 2033	DP			
<u>METHYLERGONOVINE MALEATE - METHYLERGONOVINE MALEATE</u> A 211483 001				>A> CGT		Mar 20, 2019
<u>METHYLPHENIDATE HYDROCHLORIDE - APTENSIO XR</u> N 205831 001	10039719	Dec 16, 2019	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - APTENSIO XR</u> N 205831 002	10039719	Dec 16, 2019	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - APTENSIO XR</u> N 205831 003	10039719	Dec 16, 2019	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - APTENSIO XR</u> N 205831 004	10039719	Dec 16, 2019	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - APTENSIO XR</u> N 205831 005	10039719	Dec 16, 2019	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - APTENSIO XR</u> N 205831 006	10039719	Dec 16, 2019	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - APTENSIO XR</u> N 205831 007	10039719	Dec 16, 2019	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM</u> N 209311 001	>A> 8916588 8927010 9023389 >A> 9028868 >A> 9034902 9283214 9498447 >A> 9603809	Mar 23, 2032 Mar 23, 2032	U-2357 DP DP U-2357 U-2357 DP DP U-2357		NP	Aug 08, 2021
<u>METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM</u> N 209311 002	>A> 8916588 8927010 9023389 >A> 9028868 >A> 9034902 9283214 9498447 >A> 9603809	Mar 23, 2032 Mar 23, 2032	U-2357 DP DP U-2357 U-2357 DP DP U-2357		NP	Aug 08, 2021
<u>METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM</u> N 209311 003	>A> 8916588 8927010 9023389 >A> 9028868 >A> 9034902 9283214 9498447 >A> 9603809	Mar 23, 2032 Mar 23, 2032	U-2357 DP DP U-2357 U-2357 DP DP U-2357		NP	Aug 08, 2021

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM</u>						
N 209311 003	>A> 8916588	Mar 23, 2032	U-2357		NP	Aug 08, 2021
	8927010	Mar 23, 2032	DP			
	9023389	Mar 23, 2032	DP			
	>A> 9028868	Mar 23, 2032	U-2357			
	>A> 9034902	Mar 23, 2032	U-2357			
	9283214	Mar 23, 2032	DP			
	9498447	Mar 23, 2032	DP			
	>A> 9603809	Mar 23, 2032	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM</u>						
N 209311 004	>A> 8916588	Mar 23, 2032	U-2357		NP	Aug 08, 2021
	8927010	Mar 23, 2032	DP			
	9023389	Mar 23, 2032	DP			
	>A> 9028868	Mar 23, 2032	U-2357			
	>A> 9034902	Mar 23, 2032	U-2357			
	9283214	Mar 23, 2032	DP			
	9498447	Mar 23, 2032	DP			
	>A> 9603809	Mar 23, 2032	U-2357			
<u>METHYLPHENIDATE HYDROCHLORIDE - JORNAY PM</u>						
N 209311 005	>A> 8916588	Mar 23, 2032	U-2357		NP	Aug 08, 2021
	8927010	Mar 23, 2032	DP			
	9023389	Mar 23, 2032	DP			
	>A> 9028868	Mar 23, 2032	U-2357			
	>A> 9034902	Mar 23, 2032	U-2357			
	9283214	Mar 23, 2032	DP			
	9498447	Mar 23, 2032	DP			
	>A> 9603809	Mar 23, 2032	U-2357			
<u>METOPROLOL SUCCINATE - KAPSPARGO SPRINKLE</u>						
N 210428 001	9504655	Jul 09, 2035	DP			
	9700530	Jul 09, 2035	DP			
<u>METOPROLOL SUCCINATE - KAPSPARGO SPRINKLE</u>						
N 210428 002	9504655	Jul 09, 2035	DP			
	9700530	Jul 09, 2035	DP			
<u>METOPROLOL SUCCINATE - KAPSPARGO SPRINKLE</u>						
N 210428 003	9504655	Jul 09, 2035	DP			
	9700530	Jul 09, 2035	DP			
<u>METOPROLOL SUCCINATE - KAPSPARGO SPRINKLE</u>						
N 210428 004	9504655	Jul 09, 2035	DP			
	9700530	Jul 09, 2035	DP			
<u>MIFEPRISTONE - KORLYM</u>						
N 202107 001	10006924	Aug 12, 2036	U-1643			
	9943526	Apr 20, 2036	U-1643			
<u>MIGALASTAT HYDROCHLORIDE - GALAFOLD</u>						
N 208623 001	>A> 8592362	Feb 12, 2029	U-2371		NCE	Aug 10, 2023
	>A> 9000011	May 16, 2027	U-2371		ODE-205	Aug 10, 2025
	>A> 9095584	Feb 12, 2029	U-2371			
	>A> 9480682	May 16, 2027	U-2371			
	>A> 9987263	May 16, 2027	U-2371			
	>A> 9999618	Apr 28, 2028	U-2372			
	>A> 9999618	Apr 28, 2028	U-2373			
<u>MIRABEGRON - MYRBETRIQ</u>						
N 202611 001	8772315	Oct 30, 2028	U-2300		I-777	Apr 27, 2021

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b>MIRABEGRON - MYRBETRIO</b>						
N 202611 002	8772315	Oct 30, 2028	U-2300		I-777	Apr 27, 2021
<b>MOMETASONE FUROATE - SINUVA</b>						
N 209310 001	7544192	Nov 29, 2026	U-2272			
	7662141	Mar 12, 2024	U-2272			
	7713255	Mar 12, 2024	U-2272			
	7951130	Mar 12, 2024	U-2272			
	7951131	Mar 12, 2024	U-2272			
	7951133	Mar 12, 2024	U-2272			
	8025635	Jun 12, 2027	DP U-2272			
	8109918	Mar 12, 2024	U-2272			
	8763222	Feb 08, 2032	DP			
	9585681	Apr 04, 2026	U-2272			
<b>MOXIDECTIN - MOXIDECTIN</b>						
N 210867 001					NCE	Jun 13, 2023
					ODE-193	Jun 13, 2025
<b>NALOXONE HYDROCHLORIDE - NARCAN</b>						
N 208411 001 >A> 10085937		Mar 16, 2035	U-1903			
<b>NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIQ</b>						
N 205777 001 9907793		Apr 04, 2023	DP U-1556			
<b>NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE - TARGINIQ</b>						
N 205777 002 9907793		Apr 04, 2023	DP U-1556			
<b>NAPROXEN SODIUM - NAPROXEN SODIUM</b>						
N 021920 001 10022344		Mar 03, 2026	DP U-1731			
	10022344	Mar 03, 2026	DP U-1732			
	10028925	Mar 03, 2026	DP U-1731			
	10028925	Mar 03, 2026	DP U-1732			
<b>NERATINIB MALEATE - NERLYNX</b>						
N 208051 001 10035788		Oct 15, 2028	U-2043			
<b>NETARSUDIL DIMESYLATE - RHOPRESSA</b>						
N 208254 001 9931336		Mar 14, 2034	DS DP U-1524			
<b>NETUPITANT; PALONOSETRON HYDROCHLORIDE - AKYNZEO</b>						
N 205718 001 8623826		Nov 18, 2030	U-2293			
	9186357	Nov 18, 2030	U-2293			
	9271975	Sep 09, 2031	U-2293			
	9943515	Nov 18, 2030	U-2293			
	9951016	Sep 25, 2035	DS DP			
<b>NILOTINIB HYDROCHLORIDE - TASIGNA</b>						
N 022068 001 7169791		Jul 04, 2023	DS DP U-836		D-170	Dec 22, 2020
	7169791*PED	Jan 04, 2024			NPP	Mar 22, 2021
	8163904	Aug 23, 2028	DS DP		ODE-171	Mar 22, 2025
	8163904*PED	Feb 23, 2029			ODE-172	Mar 22, 2025
	8293756	Sep 25, 2027	DP		PED	Jun 22, 2021
	8293756*PED	Mar 25, 2028			PED	Sep 22, 2021
	8389537	Jul 18, 2026	DS DP U-1374		PED	Sep 22, 2025
	8389537*PED	Jan 18, 2027			PED	Sep 22, 2025
	8415363	Jul 18, 2026	DS DP U-1407			
	8415363*PED	Jan 18, 2027				
	8501760	Jul 18, 2026	DS DP			
	8501760*PED	Jan 18, 2027				
	9061029	Apr 07, 2032	DP U-1374			
	9061029*PED	Oct 07, 2032				

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>NILOTINIB HYDROCHLORIDE - TASIGNA</u>						
N 022068 002	7169791	Jul 04, 2023	DS DP U-836	D-170	Dec 22, 2020	
	7169791*PED	Jan 04, 2024		NPP	Mar 22, 2021	
	8163904	Aug 23, 2028	DS DP	ODE-171	Mar 22, 2025	
	8163904*PED	Feb 23, 2029		ODE-172	Mar 22, 2025	
	8293756	Sep 25, 2027	DP	PED	Jun 22, 2021	
	8293756*PED	Mar 25, 2028		PED	Sep 22, 2021	
	8389537	Jul 18, 2026	DS DP U-1374	PED	Sep 22, 2025	
	8389537*PED	Jan 18, 2027		PED	Sep 22, 2025	
	8415363	Jul 18, 2026	DS DP U-1407			
	8415363*PED	Jan 18, 2027				
	8501760	Jul 18, 2026	DS DP			
	8501760*PED	Jan 18, 2027				
	9061029	Apr 07, 2032	DP U-1374			
	9061029*PED	Oct 07, 2032				
<u>NILOTINIB HYDROCHLORIDE - TASIGNA</u>						
N 022068 003	7169791	Jul 04, 2023	DS DP U-836	NPP	Mar 22, 2021	
	7169791*PED	Jan 04, 2024		ODE-171	Mar 22, 2025	
	8163904	Aug 23, 2028	DS DP	ODE-172	Mar 22, 2025	
	8163904*PED	Feb 23, 2029		PED	Sep 22, 2021	
	8293756	Sep 25, 2027	DP	PED	Sep 22, 2025	
	8293756*PED	Mar 25, 2028		PED	Sep 22, 2025	
	8389537	Jul 18, 2026	DS DP U-1374			
	8389537*PED	Jan 18, 2027				
	8415363	Jul 18, 2026	DS DP U-1407			
	8415363*PED	Jan 18, 2027				
	8501760	Jul 18, 2026	DS DP			
	8501760*PED	Jan 18, 2027				
	9061029	Apr 07, 2032	DS DP U-1374			
	9061029*PED	Oct 07, 2032				
<u>NINTEDANIB ESYLATE - OFEV</u>						
N 205832 001	9907756	Jun 07, 2029	DP			
<u>NINTEDANIB ESYLATE - OFEV</u>						
N 205832 002	9907756	Jun 07, 2029	DP			
<u>NITRIC OXIDE - INOMAX</u>						
N 020845 003				M-167	Oct 09, 2018	
<u>NUSINERSEN SODIUM - SPINRAZA</u>						
N 209531 001	9926559	Jan 09, 2034	U-1943	M-226	May 14, 2021	
<u>OLAPARIB - LYNPARZA</u>						
N 208558 001	8143241	Aug 12, 2027	U-2101	I-762	Jan 12, 2021	
	8143241	Aug 12, 2027	U-2102	ODE-180	Aug 17, 2024	
	8143241	Aug 12, 2027	U-2103	ODE-181	Aug 17, 2024	
	8143241	Aug 12, 2027	U-2358			
	8143241	Aug 12, 2027	U-2359			
	8859562	Aug 04, 2031	U-2101			
	8859562	Aug 04, 2031	U-2102			
	8859562	Aug 04, 2031	U-2358			
	8859562	Aug 04, 2031	U-2359			
	8912187	Mar 12, 2024	U-2101			
	8912187	Mar 12, 2024	U-2102			
	8912187	Mar 12, 2024	U-2358			
	8912187	Mar 12, 2024	U-2359			
<u>OLAPARIB - LYNPARZA</u>						
N 208558 002	8143241	Aug 12, 2027	U-2101	I-762	Jan 12, 2021	
	8143241	Aug 12, 2027	U-2102	ODE-180	Aug 17, 2024	
	8143241	Aug 12, 2027	U-2103	ODE-181	Aug 17, 2024	
	8143241	Aug 12, 2027	U-2358			
	8143241	Aug 12, 2027	U-2359			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>OLAPARIB - LYNPARZA</b></u>						
N 208558 002	8859562	Aug 04, 2031	U-2101			
	8859562	Aug 04, 2031	U-2102			
	8859562	Aug 04, 2031	U-2358			
	8859562	Aug 04, 2031	U-2359			
	8912187	Mar 12, 2024	U-2101			
	8912187	Mar 12, 2024	U-2102			
	8912187	Mar 12, 2024	U-2358			
	8912187	Mar 12, 2024	U-2359			
<u><b>OMEGA-3-CARBOXYLIC ACIDS - EPANOVA</b></u>						
N 205060 001	5792795	May 13, 2019	DP			
	5948818	May 13, 2019	DP			
<u><b>OMEPRAZOLE - OMEPRAZOLE</b></u>						
N 209400 001 >A> 10076494		Dec 08, 2036	DP			
<u><b>ORITAVANCIN DIPHOSPHATE - ORBACTIV</b></u>						
N 206334 001	5840684	Nov 24, 2020	DS DP U-1569			
<u><b>OSIMERTINIB MESYLATE - TAGRISSO</b></u>						
N 208065 001	8946235	Aug 08, 2032	DS DP U-1777	I-774	Apr 18, 2021	
	8946235	Aug 08, 2032	DS DP U-2289	ODE-176	Apr 18, 2025	
	9732058	Jul 25, 2032	DS DP U-1777			
	9732058	Jul 25, 2032	DS DP U-2289			
<u><b>OSIMERTINIB MESYLATE - TAGRISSO</b></u>						
N 208065 002	8946235	Aug 08, 2032	DS DP U-1777	I-774	Apr 18, 2021	
	8946235	Aug 08, 2032	DS DP U-2289	ODE-176	Apr 18, 2025	
	9732058	Jul 25, 2032	DS DP U-1777			
	9732058	Jul 25, 2032	DS DP U-2289			
<u><b>OSPEMIFENE - OSPHENIA</b></u>						
N 203505 001	9855224	Feb 13, 2024	U-1369			
	9855224	Feb 13, 2024	U-1370			
<u><b>OXYCODONE - XTAMPZA ER</b></u>						
N 208090 001	10004729	Dec 10, 2030	DP U-1556			
	9968598	Sep 02, 2036	DP U-1556			
<u><b>OXYCODONE - XTAMPZA ER</b></u>						
N 208090 002	10004729	Dec 10, 2030	DP U-1556			
	9968598	Sep 02, 2036	DP U-1556			
<u><b>OXYCODONE - XTAMPZA ER</b></u>						
N 208090 003	10004729	Dec 10, 2030	DP U-1556			
	9968598	Sep 02, 2036	DP U-1556			
<u><b>OXYCODONE - XTAMPZA ER</b></u>						
N 208090 004	10004729	Dec 10, 2030	DP U-1556			
	9968598	Sep 02, 2036	DP U-1556			
<u><b>OXYCODONE - XTAMPZA ER</b></u>						
N 208090 005	10004729	Dec 10, 2030	DP U-1556			
	9968598	Sep 02, 2036	DP U-1556			
<u><b>OXYMETAZOLINE HYDROCHLORIDE - RHOFADE</b></u>						
N 208552 001	8815929	Jan 22, 2024	U-1959			
	9974773	Jun 11, 2035	U-2306			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>OZENOXACIN - XEPI</u>						
N 208945 001	6335447	Apr 06, 2019	DS			
	9180200	Jan 29, 2032	DP U-805			
	9399014	Dec 15, 2029	U-805			
<u>PALONOSETRON HYDROCHLORIDE - PALONOSETRON HYDROCHLORIDE</u>						
A 090713 002				PC		Sep 19, 2018
<u>PALONOSETRON HYDROCHLORIDE - PALONOSETRON HYDROCHLORIDE</u>						
A 201533 001				PC		Sep 19, 2018
<u>PALONOSETRON HYDROCHLORIDE - PALONOSETRON HYDROCHLORIDE</u>						
A 201533 002				PC		Sep 19, 2018
<u>PASIREOTIDE PAMOATE - SIGNIFOR LAR KIT</u>						
N 203255 001				I-785		Jun 29, 2021
<u>PASIREOTIDE PAMOATE - SIGNIFOR LAR KIT</u>						
N 203255 002				I-785		Jun 29, 2021
<u>PASIREOTIDE PAMOATE - SIGNIFOR LAR KIT</u>						
N 203255 003				I-785		Jun 29, 2021
<u>PASIREOTIDE PAMOATE - SIGNIFOR LAR KIT</u>						
N 203255 004				I-785		Jun 29, 2021
<u>PASIREOTIDE PAMOATE - SIGNIFOR LAR KIT</u>						
N 203255 005				I-785		Jun 29, 2021
<u>PATIROMER SORBITEX CALCIUM - VELTASSA</u>						
N 205739 001	9925212	Oct 08, 2033	U-1766			
<u>PATIROMER SORBITEX CALCIUM - VELTASSA</u>						
N 205739 002	9925212	Oct 08, 2033	U-1766			
<u>PATIROMER SORBITEX CALCIUM - VELTASSA</u>						
N 205739 003	9925212	Oct 08, 2033	U-1766			
<u>PATISIRAN SODIUM - ONPATTRO</u>						
N 210922 001	8058069	Apr 15, 2029	DP		NCE	Aug 10, 2023
	8158601	Nov 10, 2030	DP U-2378		ODE-197	Aug 10, 2025
	8168775	Oct 20, 2029	DS DP U-2378			
	8334373	May 27, 2025	DS DP			
	8362231	Mar 30, 2021	DS DP			
	8372968	Mar 30, 2021	DS DP			
	8492359	Apr 15, 2029	DP			
	8552171	Mar 30, 2021	DS DP			
	8642076	Oct 03, 2027	DP			
	8741866	Oct 20, 2029	U-2378			
	8778902	Mar 30, 2021	U-2378			
	8802644	Oct 21, 2030	DP U-2378			
	8822668	Apr 15, 2029	DP U-2378			
	8895718	Mar 30, 2021	DS DP			
	8895721	Mar 30, 2021	DS DP			
	9193753	Mar 30, 2021	U-2378			
	9234196	Oct 20, 2029	DP U-2378			
	9364435	Apr 15, 2029	DP U-2378			
	9567582	Mar 30, 2021	DS DP			
	9943538	Nov 04, 2023	DP			
	9943539	Nov 04, 2023	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>PIMAVANSERIN TARTRATE - NUPLAZID</u>						
N 207318 002	10028944	Jan 15, 2024		U-1974		
	6756393	Mar 06, 2021	DS DP			
	6815458	Mar 06, 2021	DS DP	U-1843		
	7115634	Oct 06, 2021	DS DP			
	7601740	Jun 17, 2027	DS DP			
	7659285	Aug 24, 2026		U-1844		
	7732615	Jun 03, 2028	DS DP			
	7858789	Dec 13, 2020	DS DP			
	7923564	Sep 26, 2025	DS DP			
	8110574	Dec 13, 2020	DS DP			
	8618130	Jan 15, 2024		U-1845		
	8921393	Jan 15, 2024		U-1846		
	9296694	Mar 06, 2021	DS DP			
	9566271	Jan 15, 2024		U-1974		
	9765053	Jul 27, 2022		U-1974		
<u>PIMAVANSERIN TARTRATE - NUPLAZID</u>						
N 210793 001	10028944	Jan 15, 2024			NCE	Apr 29, 2021
	6756393	Mar 06, 2021	DS DP			
	6815458	Mar 06, 2021	DS DP	U-1843		
	7115634	Oct 06, 2021	DS DP			
	7601740	Jun 17, 2027	DS DP			
	7659285	Aug 24, 2026		U-1844		
	7732615	Jun 03, 2028	DS DP			
	7858789	Dec 13, 2020	DS DP			
	7923564	Sep 26, 2025	DS DP			
	8110574	Dec 13, 2020	DS DP			
	8618130	Jan 15, 2024		U-1845		
	8921393	Jan 15, 2024		U-1846		
	9296694	Mar 06, 2021	DS DP			
	9566271	Jan 15, 2024		U-1974		
	9765053	Jul 27, 2022		U-1974		
<u>PIRFENIDONE - ESBRIET</u>						
N 022535 001	8383150	Sep 22, 2026	DP	U-1607		
	8383150	Sep 22, 2026	DP	U-2361		
<u>PIRFENIDONE - ESBRIET</u>						
N 208780 001 >A>	8383150	Sep 22, 2026	DP	U-2361		
	8420674	Dec 18, 2027		U-2079		
<u>PIRFENIDONE - ESBRIET</u>						
N 208780 002	7566729	Apr 22, 2029		U-2269		
	7566729	Apr 22, 2029		U-2270		
	7635707	Apr 22, 2029		U-2072		
	7635707	Apr 22, 2029		U-2073		
	7635707	Apr 22, 2029		U-2074		
	7635707	Apr 22, 2029		U-2075		
	7635707	Apr 22, 2029		U-2076		
	7635707	Apr 22, 2029		U-2083		
	7767700	Dec 18, 2027		U-2080		
	7816383	Jan 08, 2030		U-2042		
	7816383	Jan 08, 2030		U-2050		
	7910610	Jan 08, 2030		U-2048		
	7910610	Jan 08, 2030		U-2049		
	8013002	Jan 08, 2030		U-2047		
	8013002	Jan 08, 2030		U-2082		
	8084475	Jan 08, 2030		U-2054		
	8084475	Jan 08, 2030		U-2268		
	8318780	Jan 08, 2030		U-2046		
	8318780	Jan 08, 2030		U-2081		
>A>	8383150	Sep 22, 2026	DP	U-2361		
	8420674	Dec 18, 2027		U-2079		
	8592462	Apr 22, 2029		U-2055		
	8592462	Apr 22, 2029		U-2056		

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b><u>PIRFENIDONE - ESBRIET</u></b>						
N 208780 002	8592462	Apr 22, 2029	U-2057			
	8592462	Apr 22, 2029	U-2058			
	8592462	Apr 22, 2029	U-2059			
	8592462	Apr 22, 2029	U-2060			
	8592462	Apr 22, 2029	U-2061			
	8592462	Apr 22, 2029	U-2062			
	8592462	Apr 22, 2029	U-2063			
	8609701	Apr 22, 2029	U-2064			
	8609701	Apr 22, 2029	U-2065			
	8609701	Apr 22, 2029	U-2066			
	8609701	Apr 22, 2029	U-2067			
	8609701	Apr 22, 2029	U-2068			
	8609701	Apr 22, 2029	U-2069			
	8609701	Apr 22, 2029	U-2070			
	8648098	Jan 08, 2030	U-2051			
	8648098	Jan 08, 2030	U-2052			
	8754109	Jan 08, 2030	U-2053			
	8778947	Aug 30, 2033	U-2044			
	8778947	Aug 30, 2033	U-2045			
	9561217	Jan 25, 2022	DP			
<b><u>PIRFENIDONE - ESBRIET</u></b>						
N 208780 003 >A>	8383150	Sep 22, 2026	DP U-2361			
	8420674	Dec 18, 2027	U-2079			
<b><u>PLAZOMICIN SULFATE - ZEMDRI</u></b>						
N 210303 001	8383596	Jun 02, 2031	DS U-2328		NCE	Jun 25, 2023
	8822424	Nov 21, 2028	DP		GAIN	Jun 25, 2028
	9266919	Nov 21, 2028	U-2328			
	9688711	Nov 21, 2028	DS U-2328			
<b><u>PLECANATIDE - TRULANCE</u></b>						
N 208745 001	10011637	Jun 05, 2034	DS		I-764	Jan 24, 2021
	9610321	Sep 15, 2031	U-1999			
	9610321	Sep 15, 2031	U-2230			
	9919024	Sep 15, 2031	U-1999			
	9919024	Sep 15, 2031	U-2230			
	9925231	Sep 15, 2031	DP			
<b><u>POMALIDOMIDE - POMALYST</u></b>						
N 204026 001	8198262	Jun 17, 2025	U-1360			
	8198262	Jun 17, 2025	U-2254			
	8673939	May 15, 2023	U-1360			
	8673939	May 15, 2023	U-2254			
	8735428	May 15, 2023	U-1360			
	8735428	May 15, 2023	U-2254			
	9993467	May 19, 2030	DP			
<b><u>POMALIDOMIDE - POMALYST</u></b>						
N 204026 002	8198262	Jun 17, 2025	U-1360			
	8198262	Jun 17, 2025	U-2254			
	8673939	May 15, 2023	U-1360			
	8673939	May 15, 2023	U-2254			
	8735428	May 15, 2023	U-1360			
	8735428	May 15, 2023	U-2254			
	9993467	May 19, 2030	DP			
<b><u>POMALIDOMIDE - POMALYST</u></b>						
N 204026 003	8198262	Jun 17, 2025	U-1360			
	8198262	Jun 17, 2025	U-2254			
	8673939	May 15, 2023	U-1360			
	8673939	May 15, 2023	U-2254			
	8735428	May 15, 2023	U-1360			
	8735428	May 15, 2023	U-2254			
	8735428	May 15, 2023	U-2254			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 003	9993467	May 19, 2030	DP			
<u>POMALIDOMIDE - POMALYST</u>						
N 204026 004	8198262	Jun 17, 2025	U-1360			
	8198262	Jun 17, 2025	U-2254			
	8673939	May 15, 2023	U-1360			
	8673939	May 15, 2023	U-2254			
	8735428	May 15, 2023	U-1360			
	8735428	May 15, 2023	U-2254			
	9993467	May 19, 2030	DP			
<u>POTASSIUM CHLORIDE - POTASSIUM CHLORIDE</u>						
A 211067 001				CGT		Feb 25, 2019
<u>POTASSIUM CHLORIDE - POTASSIUM CHLORIDE</u>						
A 211067 002				CGT		Mar 06, 2019
<u>PREGABALIN - LYRICA</u>						
N 021446 001				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 021446 002				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 021446 003				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 021446 004				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 021446 005				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 021446 006				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 021446 007				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 021446 008				NPP		May 03, 2021
<u>PREGABALIN - LYRICA</u>						
N 022488 001				NPP		May 03, 2021
<u>PREGABALIN - LYRICA CR</u>						
N 209501 001	10022447	Nov 02, 2026	U-2136			
	10022447	Nov 02, 2026	U-2137			
<u>PREGABALIN - LYRICA CR</u>						
N 209501 002	10022447	Nov 02, 2026	U-2136			
	10022447	Nov 02, 2026	U-2137			
<u>PREGABALIN - LYRICA CR</u>						
N 209501 003	10022447	Nov 02, 2026	U-2136			
	10022447	Nov 02, 2026	U-2137			
<u>RADIUM RA-223 DICHLORIDE - XOFIGO</u>						
N 203971 001	6635234	Nov 17, 2022	U-2271			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>REGORAFENIB - STIVARGA</b></u>						
N 203085 001	9957232	Jul 09, 2032	DS			
<u><b>RIBOCICLIB SUCCINATE - KISOQALI</b></u>						
N 209092 001	8962630	Dec 09, 2029	U-1981	I-783	Jul 18, 2021	
	8962630	Dec 09, 2029	U-2355	I-784	Jul 18, 2021	
	8962630	Dec 09, 2029	U-2356			
	9416136	Aug 20, 2029	U-1981			
	9416136	Aug 20, 2029	U-2355			
	9416136	Aug 20, 2029	U-2356			
	9868739	Nov 09, 2031	U-1981			
	9868739	Nov 09, 2031	U-2355			
	9868739	Nov 09, 2031	U-2356			
<u><b>RILPIVIRINE HYDROCHLORIDE - EDURANT</b></u>						
N 202022 001				M-223		Feb 01, 2021
<u><b>RILUZOLE - TIGLUTIK KIT</b></u>						
N 209080 001 >A> 8765150		Mar 12, 2029	DP U-2401			
<u><b>RIOCIGUAT - ADEMPAS</b></u>						
N 204819 001	7173037	Dec 04, 2026	DS DP			
<u><b>RIOCIGUAT - ADEMPAS</b></u>						
N 204819 002	7173037	Dec 04, 2026	DS DP			
<u><b>RIOCIGUAT - ADEMPAS</b></u>						
N 204819 003	7173037	Dec 04, 2026	DS DP			
<u><b>RIOCIGUAT - ADEMPAS</b></u>						
N 204819 004	7173037	Dec 04, 2026	DS DP			
<u><b>RIOCIGUAT - ADEMPAS</b></u>						
N 204819 005	7173037	Dec 04, 2026	DS DP			
<u><b>RISPERIDONE - PERSERIS KIT</b></u>						
N 210655 001	10010612	Feb 13, 2028	DP		NP	Jul 27, 2021
	10058554	Sep 26, 2026	U-2363			
	9180197	Feb 13, 2028	DP			
	9186413	Feb 13, 2028	U-543			
	9597402	Sep 26, 2026	DP			
<u><b>RISPERIDONE - PERSERIS KIT</b></u>						
N 210655 002	10010612	Feb 13, 2028	DP		NP	Jul 27, 2021
	10058554	Sep 26, 2026	U-2363			
	9180197	Feb 13, 2028	DP			
	9186413	Feb 13, 2028	U-543			
	9597402	Sep 26, 2026	DP			
<u><b>RITONAVIR - RITONAVIR</b></u>						
A 202573 001					PC	Sep 16, 2018
<u><b>RITONAVIR - NORVIR</b></u>						
N 209512 001				ODE-184		Jun 07, 2024
<u><b>RIVAROXABAN - XARELTO</b></u>						
N 022406 001	9415053	Nov 13, 2024	DP U-1167			
	9415053	Nov 13, 2024	DP U-1200			
	9415053	Nov 13, 2024	DP U-1301			
	9415053	Nov 13, 2024	DP U-1302			
	9415053	Nov 13, 2024	DP U-2142			
	9539218	Feb 17, 2034	U-1953			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b>RIVAROXABAN - XARELTO</b>						
N 022406 001	9539218	Feb 17, 2034	U-1954			
	9539218	Feb 17, 2034	U-1955			
	9539218	Feb 17, 2034	U-1957			
	9539218	Feb 17, 2034	U-2143			
<b>RIVAROXABAN - XARELTO</b>						
N 022406 002	7157456	Aug 28, 2024	DS DP U-1301			
	7157456	Aug 28, 2024	DS DP U-1302			
<b>RIVAROXABAN - XARELTO</b>						
N 022406 003	7157456	Aug 28, 2024	DS DP U-1301			
	7157456	Aug 28, 2024	DS DP U-1302			
	7592339	Dec 11, 2020	U-1167			
	7592339	Dec 11, 2020	U-1200			
	7592339	Dec 11, 2020	U-1301			
	7592339	Dec 11, 2020	U-1302			
	7592339	Dec 11, 2020	U-1303			
	9415053	Nov 13, 2024	DP U-1167			
	9415053	Nov 13, 2024	DP U-1200			
	9415053	Nov 13, 2024	DP U-1301			
	9415053	Nov 13, 2024	DP U-1302			
<b>ROFLUMILAST - DALIRESP</b>						
N 022522 001					D-171	Jan 23, 2021
<b>ROFLUMILAST - DALIRESP</b>						
N 022522 002	5712298	Jan 27, 2020	DS DP U-1115		NS	Jan 23, 2021
	8431154	Feb 19, 2023	DP			
	8536206	Mar 08, 2024	U-1115			
	8604064	Mar 08, 2024	U-1115			
	8618142	Mar 08, 2024	DP			
	9468598	Feb 19, 2023	DP			
<b>ROPIVACAINE HYDROCHLORIDE - NAROPIN</b>						
N 020533 006	7828787	Oct 18, 2025	DP			
	7857802	Nov 28, 2026	DP			
	8118802	May 18, 2023	DP			
	8162915	May 23, 2024	DP			
<b>ROPIVACAINE HYDROCHLORIDE - NAROPIN</b>						
N 020533 007	7828787	Oct 18, 2025	DP			
	7857802	Nov 28, 2026	DP			
	8118802	May 18, 2023	DP			
	8162915	May 23, 2024	DP			
<b>ROSIGLITAZONE MALEATE - AVANDIA</b>						
N 021071 002	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				
<b>ROSIGLITAZONE MALEATE - AVANDIA</b>						
N 021071 003	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				
<b>ROSIGLITAZONE MALEATE - AVANDIA</b>						
N 021071 004	7358366	Apr 19, 2020	DS		Y	
	7358366*PED	Oct 19, 2020				
<b>ROTIGOTINE - NEUPRO</b>						
N 021829 001	9925150	Mar 01, 2032	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>ROTIGOTINE - NEUPRO</b></u>						
N 021829 002	9925150	Mar 01, 2032	DP			
<u><b>ROTIGOTINE - NEUPRO</b></u>						
N 021829 003	9925150	Mar 01, 2032	DP			
<u><b>ROTIGOTINE - NEUPRO</b></u>						
N 021829 004	9925150	Mar 01, 2032	DP			
<u><b>ROTIGOTINE - NEUPRO</b></u>						
N 021829 005	9925150	Mar 01, 2032	DP			
<u><b>ROTIGOTINE - NEUPRO</b></u>						
N 021829 006	9925150	Mar 01, 2032	DP			
<u><b>RUCAPARIB CAMSYLATE - RUBRACA</b></u>						
N 209115 001	7351701	Jul 23, 2024	U-2012	I-772	Apr 06, 2021	
	7351701	Jul 23, 2024	U-2101	ODE-168	Apr 06, 2025	
	7351701	Jul 23, 2024	U-2273			
	7531530	Jul 23, 2024	U-2012			
	7531530	Jul 23, 2024	U-2101			
	7531530	Jul 23, 2024	U-2273			
	8071579	Aug 12, 2027	U-2012			
	8071579	Aug 12, 2027	U-2101			
	8071579	Aug 12, 2027	U-2273			
	8143241	Aug 12, 2027	U-2012			
	8143241	Aug 12, 2027	U-2101			
	8143241	Aug 12, 2027	U-2273			
	8859562	Aug 04, 2031	U-2012			
	8859562	Aug 04, 2031	U-2101			
	8859562	Aug 04, 2031	U-2273			
	9861638	Feb 10, 2031	U-2012			
	9861638	Feb 10, 2031	U-2101			
	9861638	Feb 10, 2031	U-2273			
	9987285	Aug 17, 2035	DP			
<u><b>RUCAPARIB CAMSYLATE - RUBRACA</b></u>						
N 209115 002	7351701	Jul 23, 2024	U-2012	I-772	Apr 06, 2021	
	7351701	Jul 23, 2024	U-2101	ODE-168	Apr 06, 2025	
	7351701	Jul 23, 2024	U-2273			
	7531530	Jul 23, 2024	U-2012			
	7531530	Jul 23, 2024	U-2101			
	7531530	Jul 23, 2024	U-2273			
	8071579	Aug 12, 2027	U-2012			
	8071579	Aug 12, 2027	U-2101			
	8071579	Aug 12, 2027	U-2273			
	8143241	Aug 12, 2027	U-2012			
	8143241	Aug 12, 2027	U-2101			
	8143241	Aug 12, 2027	U-2273			
	8859562	Aug 04, 2031	U-2012			
	8859562	Aug 04, 2031	U-2101			
	8859562	Aug 04, 2031	U-2273			
	9861638	Feb 10, 2031	U-2012			
	9861638	Feb 10, 2031	U-2101			
	9861638	Feb 10, 2031	U-2273			
	9987285	Aug 17, 2035	DP			
<u><b>RUCAPARIB CAMSYLATE - RUBRACA</b></u>						
N 209115 003	7351701	Jul 23, 2024	U-2012	I-772	Apr 06, 2021	
	7351701	Jul 23, 2024	U-2101	ODE-168	Apr 06, 2025	
	7351701	Jul 23, 2024	U-2273			
	7531530	Jul 23, 2024	U-2012			
	7531530	Jul 23, 2024	U-2101			
	7531530	Jul 23, 2024	U-2273			
	8071579	Aug 12, 2027	U-2012			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>RUCAPARIB CAMSYLATE - RUBRACA</u>						
N 209115 003	8071579	Aug 12, 2027	U-2101			
	8071579	Aug 12, 2027	U-2273			
	8143241	Aug 12, 2027	U-2012			
	8143241	Aug 12, 2027	U-2101			
	8143241	Aug 12, 2027	U-2273			
	8859562	Aug 04, 2031	U-2012			
	8859562	Aug 04, 2031	U-2101			
	8859562	Aug 04, 2031	U-2273			
	9861638	Feb 10, 2031	U-2012			
	9861638	Feb 10, 2031	U-2101			
	9861638	Feb 10, 2031	U-2273			
	9987285	Aug 17, 2035	DP			
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 001	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>SIMEPREVIR SODIUM - OLYSTIO</u>						
N 205123 001	9856265	Jul 28, 2026	DS DP U-1467			
<u>SODIUM ZIRCONIUM CYCLOSILICATE - LOKEELMA</u>						
N 207078 001	6332985	Mar 29, 2019	U-2312		NCE	May 18, 2023
	8802152	Apr 19, 2032	DS			
	8808750	Feb 10, 2032	U-2312			
	8877255	Oct 22, 2033	DS			
	9592253	Oct 14, 2035	DS	U-2312		
	9844567	Feb 10, 2032	U-2312			
	9861658	Feb 10, 2032	U-2312			
<u>SODIUM ZIRCONIUM CYCLOSILICATE - LOKEELMA</u>						
N 207078 002	6332985	Mar 29, 2019	U-2312		NCE	May 18, 2023
	8802152	Apr 19, 2032	DS			
	8808750	Feb 10, 2032	U-2312			
	8877255	Oct 22, 2033	DS			
	9592253	Oct 14, 2035	DS	U-2312		
	9844567	Feb 10, 2032	U-2312			
	9861658	Feb 10, 2032	U-2312			
<u>SOFOSBUVIR; VELPATASVIR; VOXILAPREVIR - VOSEVI</u>						
N 209195 001	9868745	Nov 16, 2032	DS DP			
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N 021148 008	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N 021148 009	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N 021148 010	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N 021148 011	9616180	Jan 20, 2026	DP			
	9861757	Jan 20, 2026	DP			
<u>SOYBEAN OIL - LIPOSYN III 30%</u>						
N 020181 001	9717852	Apr 08, 2033	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<b><u>STIRIPENTOL - DIACOMIT</u></b>						
N 206709 001					NCE ODE-198	Aug 20, 2023 Aug 20, 2025
<b><u>STIRIPENTOL - DIACOMIT</u></b>						
N 206709 002					NCE ODE-198	Aug 20, 2023 Aug 20, 2025
<b><u>STIRIPENTOL - DIACOMIT</u></b>						
N 207223 001					NCE ODE-198	Aug 20, 2023 Aug 20, 2025
<b><u>STIRIPENTOL - DIACOMIT</u></b>						
N 207223 002					NCE ODE-198	Aug 20, 2023 Aug 20, 2025
<b><u>TADALAFIL - CIALIS</u></b>						
N 021368 001	6821975	Nov 19, 2020	DS DP U-1184	Y	M-219	Feb 15, 2021
	6821975	Nov 19, 2020	DS DP U-533	Y	PED	Aug 15, 2021
	6821975	Nov 19, 2020	DS DP U-614	Y		
	6821975*PED	May 19, 2021				
	7182958	Apr 26, 2020	DP U-1184	Y		
	7182958	Apr 26, 2020	DP U-155	Y		
	7182958*PED	Oct 26, 2020				
<b><u>TADALAFIL - CIALIS</u></b>						
N 021368 002	6821975	Nov 19, 2020	DS DP U-533	Y	M-219	Feb 15, 2021
	6821975	Nov 19, 2020	DS DP U-614	Y	PED	Aug 15, 2021
	6821975*PED	May 19, 2021				
	7182958	Apr 26, 2020	DP U-155	Y		
	7182958*PED	Oct 26, 2020				
<b><u>TADALAFIL - CIALIS</u></b>						
N 021368 003	6821975	Nov 19, 2020	DS DP U-533	Y	M-219	Feb 15, 2021
	6821975	Nov 19, 2020	DS DP U-614	Y	PED	Aug 15, 2021
	6821975*PED	May 19, 2021				
	7182958	Apr 26, 2020	DP U-155	Y		
	7182958*PED	Oct 26, 2020				
<b><u>TADALAFIL - CIALIS</u></b>						
N 021368 004	6821975	Nov 19, 2020	DS DP U-533	Y	M-219	Feb 15, 2021
	6821975	Nov 19, 2020	DS DP U-614	Y	PED	Aug 15, 2021
	6821975*PED	May 19, 2021				
	7182958	Apr 26, 2020	DP U-155	Y		
	7182958*PED	Oct 26, 2020				
<b><u>TADALAFIL - ADCIRCA</u></b>						
N 022332 001	6821975	Nov 19, 2020	DS DP	Y		
	6821975*PED	May 19, 2021				
	7182958	Apr 26, 2020	DP	Y		
	7182958*PED	Oct 26, 2020				
<b><u>TAFENOQUINE SUCCINATE - ARAKODA</u></b>						
N 210607 001					NCE NP	Jul 20, 2023 Aug 08, 2021
<b><u>TAFENOQUINE SUCCINATE - KRINTAFEL</u></b>						
N 210795 001					NCE ODE-201	Jul 20, 2023 Jul 20, 2025
<b><u>TAFLUPROST - ZIOPTAN</u></b>						
N 202514 001	9999593	May 28, 2029	DP			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>TALC - STERITALC</u> N 205555 001				ODE-191		May 01, 2024
<u>TALC - STERITALC</u> N 205555 002				ODE-191		May 01, 2024
<u>TALC - STERITALC</u> N 205555 003				ODE-191		May 01, 2024
<u>TASIMELTEON - HETLIOZ</u> N 205677 001 >A> 10071977 >A> 5856529 9855241		Feb 12, 2035 Dec 09, 2022 Jan 25, 2033	DS DP DS DP U-2149 U-2149			
<u>TAVABOROLE - KERYDIN</u> N 204427 001	7582621 7582621*PED 9549938 9549938*PED 9566289 9566289*PED 9566290 9566290*PED 9572823 9572823*PED	May 26, 2027 Nov 26, 2027 Feb 16, 2026 Aug 16, 2026 Feb 16, 2026 Aug 16, 2026 Feb 16, 2026 Aug 16, 2026 Feb 16, 2026 Aug 16, 2026		U-2016 U-1951 DP U-1970 U-1970	Y	
<u>TECOVIRIMAT - TPOXX</u> N 208627 001	7737168 8039504 8124643 8530509 8802714 9339466	May 03, 2027 Jul 23, 2027 Jun 18, 2024 Jun 18, 2024 Jun 18, 2024 Mar 23, 2031		U-2346 DP DS DP DP U-2346 DS DP	NCE ODE-200	Jul 13, 2023 Jul 13, 2025
<u>TEDUGLUTIDE RECOMBINANT - GATTEX KIT</u> N 203441 001	9968655 9968656 9968658 9974835 9974837 9981014 9981016 9987334 9987335 9993528	Nov 01, 2025 Nov 01, 2025		U-2308 U-2308 U-1320 U-1320 U-1320 U-1320 U-1320 U-1320 U-1320 U-1320		
<u>TIGECYCLINE - TIGECYCLINE</u> N 211158 001 >A> 9855335		Apr 07, 2033		DP		
<u>TOBRAMYCIN - BETHKIS</u> N 201820 001	7696178	Sep 22, 2022		DP		
<u>TOFACITINIB CITRATE - XELJANZ</u> N 203214 001	7842699	Dec 08, 2020		U-2322	I-780	May 30, 2021
<u>TOFACITINIB CITRATE - XELJANZ</u> N 203214 002	6956041 6965027 7265221 7301023 7842699 RE41783	Dec 08, 2020 Mar 25, 2023 Dec 08, 2020 May 23, 2022 Dec 08, 2020 Dec 08, 2025	DP DS DS DS U-2322 DS		I-780	May 30, 2021

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>TOFACITINIB CITRATE - XELJANZ XR</b></u>						
N 208246 001	9937181	Mar 14, 2034	DP			
<u><b>TOLVAPTAN - JYNARQUE</b></u>						
N 204441 001	5753677	May 19, 2020	U-2307	I-779	Apr 23, 2021	
	5972882	Dec 14, 2018	U-2307	ODE-178	Apr 23, 2025	
	8501730	Sep 01, 2026	DS			
<u><b>TOLVAPTAN - JYNARQUE</b></u>						
N 204441 002	5753677	May 19, 2020	U-2307	I-779	Apr 23, 2021	
	5972882	Dec 14, 2018	U-2307	ODE-178	Apr 23, 2025	
	8501730	Sep 01, 2026	DS			
<u><b>TOLVAPTAN - JYNARQUE</b></u>						
N 204441 003	5753677	May 19, 2020	U-2307	I-779	Apr 23, 2021	
	5972882	Dec 14, 2018	U-2307	ODE-178	Apr 23, 2025	
	8501730	Sep 01, 2026	DS			
<u><b>TOLVAPTAN - JYNARQUE</b></u>						
N 204441 004	5753677	May 19, 2020	U-2307	I-779	Apr 23, 2021	
	5972882	Dec 14, 2018	U-2307	ODE-178	Apr 23, 2025	
	8501730	Sep 01, 2026	DS			
<u><b>TOLVAPTAN - JYNARQUE</b></u>						
N 204441 005	5753677	May 19, 2020	U-2307	I-779	Apr 23, 2021	
	5972882	Dec 14, 2018	U-2307	ODE-178	Apr 23, 2025	
	8501730	Sep 01, 2026	DS			
<u><b>TRABECTEDIN - YONDELIS</b></u>						
N 207953 001	8895557	Jan 07, 2028	DP	>A> M-232	Jun 29, 2021	
	8895557*PED	Jul 07, 2028		NCE	Oct 23, 2020	
				ODE-100	Oct 23, 2022	
				PED	Apr 23, 2021	
				>A> PED	Dec 29, 2021	
				PED	Apr 23, 2023	
<u><b>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</b></u>						
N 204114 001	7378423	May 29, 2027	DS DP	I-778	Apr 30, 2021	
	8835443	Jun 10, 2025	U-1581	I-781	May 04, 2021	
	8835443	Jun 10, 2025	U-1582	ODE-182	Apr 30, 2025	
	8835443	Jun 10, 2025	U-2020	ODE-183	May 04, 2025	
	8835443	Jun 10, 2025	U-2037			
	8835443	Jun 10, 2025	U-2302			
	8835443	Jun 10, 2025	U-2305			
<u><b>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</b></u>						
N 204114 002	7378423	May 29, 2027	DS DP	I-778	Apr 30, 2021	
	8835443	Jun 10, 2025	U-1581	I-781	May 04, 2021	
	8835443	Jun 10, 2025	U-1582	ODE-182	Apr 30, 2025	
	8835443	Jun 10, 2025	U-2020	ODE-183	May 04, 2025	
	8835443	Jun 10, 2025	U-2037			
	8835443	Jun 10, 2025	U-2302			
	8835443	Jun 10, 2025	U-2305			
<u><b>TRAMETINIB DIMETHYL SULFOXIDE - MEKINIST</b></u>						
N 204114 003	7378423	May 29, 2027	DS DP	I-778	Apr 30, 2021	
	8835443	Jun 10, 2025	U-1581	I-781	May 04, 2021	
	8835443	Jun 10, 2025	U-1582	ODE-182	Apr 30, 2025	
	8835443	Jun 10, 2025	U-2020	ODE-183	May 04, 2025	
	8835443	Jun 10, 2025	U-2037			
	8835443	Jun 10, 2025	U-2302			
	8835443	Jun 10, 2025	U-2305			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u>TREPROSTINIL - REMODULIN</u>						
N 021272 001 >A> 10076505		Dec 16, 2024	DP			
<u>TREPROSTINIL - REMODULIN</u>						
N 021272 002 >A> 10076505		Dec 16, 2024	DP			
<u>TREPROSTINIL - REMODULIN</u>						
N 021272 003 >A> 10076505		Dec 16, 2024	DP			
<u>TREPROSTINIL - REMODULIN</u>						
N 021272 004 >A> 10076505		Dec 16, 2024	DP			
<u>TREPROSTINIL - TYVASO</u>						
N 022387 001 8497393		Dec 15, 2028	DS		Y	
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 002 8497393		Dec 15, 2028	DS		Y	
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 003 8497393		Dec 15, 2028	DS		Y	
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 004 8497393		Dec 15, 2028	DS		Y	
<u>TRETINOIN - ALTRENO</u>						
N 209353 001					NDF	Aug 23, 2021
<u>TRYPAN BLUE - VISIONBLUE</u>						
N 021670 001 6367480		Oct 26, 2019	U-2321			
	6720314	May 07, 2019	U-2321			
<u>UMECLIDINIUM BROMIDE - INCRUSE ELLIPTA</u>						
N 205382 001 8534281		Mar 08, 2030	DP			
<u>UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE - ANORO ELLIPTA</u>						
N 203975 001 8534281		Mar 08, 2030	DP			
<u>URIDINE TRIACETATE - VISTOGARD</u>						
N 208159 001 6258795		Jul 10, 2019	DP			
<u>URIDINE TRIACETATE - XURIDEN</u>						
N 208169 001 6258795		Jul 10, 2019	DP			
<u>VALBENAZINE TOSYLATE - INGREZZA</u>						
N 209241 001 >A> 10065952		Oct 28, 2036	DS DP U-1995			
<u>VALBENAZINE TOSYLATE - INGREZZA</u>						
N 209241 002 >A> 10065952		Oct 28, 2036	DS DP U-1995			
<u>VANDETANIB - CAPRELSA</u>						
N 022405 001 7173038		Aug 14, 2021	DS DP			
	8642608	Feb 06, 2022	U-1490			
<u>VANDETANIB - CAPRELSA</u>						
N 022405 002 7173038		Aug 14, 2021	DS DP			
	8642608	Feb 06, 2022	U-1490			
<u>VASOPRESSIN - VASOSTRICT</u>						
N 204485 002 9937223		Jan 30, 2035	U-1857			

## PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 09 - September 2018

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
<u><b>VENETOCLAX - VENCLEXTA</b></u>						
N 208573 001	9174982	May 26, 2030	U-2323	I-782 M-228 ODE-185	Jun 08, 2021 Jun 08, 2021 Jun 08, 2025	
<u><b>VENETOCLAX - VENCLEXTA</b></u>						
N 208573 002	9174982	May 26, 2030	U-2323	I-782 M-228 ODE-185	Jun 08, 2021 Jun 08, 2021 Jun 08, 2025	
<u><b>VENETOCLAX - VENCLEXTA</b></u>						
N 208573 003	9174982	May 26, 2030	U-2323	I-782 M-228 ODE-185	Jun 08, 2021 Jun 08, 2021 Jun 08, 2025	
<u><b>VORAPAXAR SULFATE - ZONTIVITY</b></u>						
N 204886 001	7713999	May 30, 2024	DS DP U-2291			
<u><b>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</b></u>						
N 204447 001	9125908	Jun 15, 2027	U-2309	M-227	May 02, 2021	
	9125909	Jun 15, 2027	U-2309			
	9125910	Jun 15, 2027	U-2309			
	9861630	Jun 15, 2027	U-1668			
<u><b>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</b></u>						
N 204447 002	9125908	Jun 15, 2027	U-2309	M-227	May 02, 2021	
	9125909	Jun 15, 2027	U-2309			
	9125910	Jun 15, 2027	U-2309			
	9861630	Jun 15, 2027	U-1668			
<u><b>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</b></u>						
N 204447 003	9125908	Jun 15, 2027	U-2309	M-227	May 02, 2021	
	9125909	Jun 15, 2027	U-2309			
	9125910	Jun 15, 2027	U-2309			
	9861630	Jun 15, 2027	U-1668			
<u><b>VORTIOXETINE HYDROBROMIDE - TRINTELLIX</b></u>						
N 204447 004	9125908	Jun 15, 2027	U-2309	M-227	May 02, 2021	
	9125909	Jun 15, 2027	U-2309			
	9125910	Jun 15, 2027	U-2309			
	9861630	Jun 15, 2027	U-1668			

## 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.

## 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, 38<sup>th</sup> Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of patent terms is available at  
[http://www.accessdata.fda.gov/scripts/cder/ob/results\\_patent.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/results_patent.cfm)

The current complete list of exclusivity terms is available at  
[http://www.accessdata.fda.gov/scripts/cder/ob/results\\_exclusivity.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/results_exclusivity.cfm)