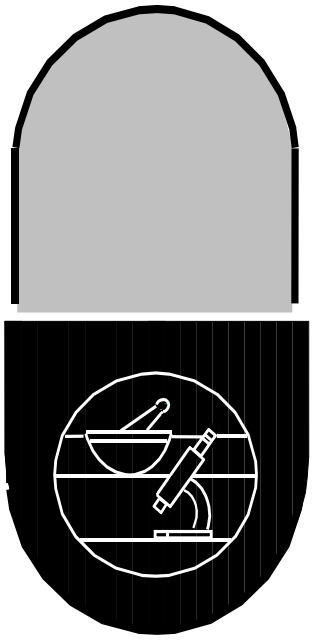
CUMULATIVE SUPPLEMENT 1
January 2026



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

46th 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

2026

Prepared By
Food and Drug Administration
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CONTENTS

PAGE

Contents

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January 2026

1.0 INTRODUCTION

This Cumulative Supplement is one of a series of monthly updates to the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the List, commonly known as the Orange Book). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; drug products with approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) administered by the Center for Biologics Evaluation and Research; and approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the next Edition. The current Annual Edition Section

2., How To Use The Drug Product Lists, describes the layout and usage of the List.

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
  o Refer to CS Section 1.7 Cumulative Supplement Legend for types of changes
- New Drug Application (NDA) approvals appear in the CS month they were approved.

- Patent information, also updated daily in the EOB, is current to the date of publication.

- Exclusivity information is updated monthly and is current as of the date of publication.

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

1.3 APPLICANT NAME CHANGES

Previously FDA had noted in this Applicant Name Changes section that it was not practical to identify in the Cumulative Supplement each product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, and that the cumulation of these transfers and name changes would therefore be identified in this section only. However, FDA is now able to identify in the Cumulative Supplement each product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, these are not identified in this section for this Cumulative Supplement, and this Applicant Name Changes section will no longer appear starting with the next Cumulative Supplement.

1.4 LEVOTHYROXINE SODIUM[1]

Because there are multiple reference listed drugs for levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character therapeutic equivalence codes may be potentially confusing and inadequate for these drug products. Looking at the Orange Book listing alone for a product identified as a reference listed drug or reference standard, it may be difficult to determine to which therapeutic equivalence code the reference listed drugs and/or reference standard designation corresponds. For example, Unithroid 0.3 mg strength has been assigned the therapeutic equivalence codes AB1, AB2, and AB3 and it is identified as the reference listed drug and reference standard, but it is unclear that the reference listed drug and reference standard designations are associated with the AB1 therapeutic equivalence code.

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

- Therapeutic equivalence has been established between products that have the same AB+number therapeutic equivalence code (i.e. AB1, AB2, AB3 or AB4).

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

- More than one therapeutic equivalence code may apply to some products. One common therapeutic equivalence code indicates therapeutic equivalence between products. For example, Unithroid has been assigned therapeutic equivalence codes AB1, AB2, and AB3 therefore Unithroid tablets are considered therapeutically equivalent to other levothyroxine sodium products of the same strength with these therapeutic equivalence codes.

TE Code	Proprietary Name	Applicant	Strength	Appl No	RLD	RS
AB1	UNITHROID	STEVENS J	0.3MG	N021210	RLD	RS
AB2	SYNTHROID	ABBVIE	0.3MG	N021402	RLD	RS
AB3	LEVOXYL	KING PHARMS	0.2MG	N021301	RLD	RS
AB4	THYRO-TABS	ALVOGEN INC	0.3MG	N021116	RLD	–
AB4	LEVOTHYROXINE SODIUM[3]	MYLAN	0.3MG	A076187	–	RS

1.5 AVAILABILITY OF THE EDITION

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

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper versions.

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

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

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

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

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

CATEGORIES COUNTED	DEC 2025	MAR 2026	JUN 2026	SEP 2026	DEC 2026
DRUG PRODUCTS	24120				
LISTED SINGLE SOURCE	2765 (11.5%)				
MULTISOURCE	21355 (88.5%)				
THERAPEUTICALLY EQUIVALENT	21260 (87.1%)				
NOT THERAPEUTICALLY EQUIVALENT	95 (0.4%)				
EXCEPTIONS[4]	47 (0.2%)				
NEW MOLECULAR ENTITIES APPROVED	19				
NUMBER OF APPLICANTS	1198				

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
NFTG	New first-time generic approval

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

CAHN[5]	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 TE Code is added when a first time generic for an innovator is approved.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMKT	Change. RX to OTC marketing status switch.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug
CHRS	Change. Reference Standard
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will appear in the discontinued section in the next edition.

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

ABARELIX

>D>		INJECTABLE;INTRAMUSCULAR						
>D>		PLENAXIS						
>D>	@	SPECIALITY EUROPEAN	100MG/VIAL	N021320	001	Nov 25, 2003	Jan CDFR
>A>		POWDER;INTRAMUSCULAR						
>A>		PLENAXIS						
>A>	@	SPECIALITY EUROPEAN	100MG/VIAL	N021320	001	Nov 25, 2003	Jan CDFR

ACETAMINOPHEN; HYDROCODONE BITARTRATE

		TABLET;ORAL						
		HYDROCODONE BITARTRATE AND ACETAMINOPHEN						
>D>	AA	STRIDES PHARMA INTL	325MG;5MG	A040655	001	Jan 19, 2006	Jan DISC
>A>	@		325MG;5MG	A040655	001	Jan 19, 2006	Jan DISC
>D>	AA		325MG;7.5MG	A040656	001	Jan 19, 2006	Jan DISC
>A>	@		325MG;7.5MG	A040656	001	Jan 19, 2006	Jan DISC
>D>	AA		325MG;10MG	A040355	001	May 31, 2000	Jan DISC
>A>	@		325MG;10MG	A040355	001	May 31, 2000	Jan DISC

ACYCLOVIR

		TABLET;ORAL						
		ACYCLOVIR						
>D>	AB	STRIDES PHARMA INTL	400MG	A074946	001	Nov 19, 1997	Jan DISC
>A>	@		400MG	A074946	001	Nov 19, 1997	Jan DISC
>D>	AB		800MG	A074946	002	Nov 19, 1997	Jan DISC
>A>	@		800MG	A074946	002	Nov 19, 1997	Jan DISC

ADAPALENE

		SOLUTION;TOPICAL						
		ADAPALENE						
>D>	AB	CALL INC	0.1%	A203981	001	Sep 23, 2016	Jan CAHN
>D>	AB		0.1%	A204593	001	Jan 05, 2016	Jan CAHN
>A>	AB	WAYLIS THERAP	0.1%	A203981	001	Sep 23, 2016	Jan CAHN
>A>	AB		0.1%	A204593	001	Jan 05, 2016	Jan CAHN

>D>		ALCOHOL						
>D>		SOLUTION;INTRA-ARTERIAL						
>D>		ABLYSINOL						
>D>	@ +	BPI LABS	99% (1ML)	N207987	001	Jun 21, 2018	Jan CAIN
>D>	AP +!		99% (5ML)	N207987	002	Jun 21, 2018	Jan CAIN
>D>		DEHYDRATED ALCOHOL						
>D>	AP	ACCORD HLTHCARE	99% (5ML)	A217845	001	Jun 23, 2025	Jan CAIN
>D>	AP	BRECKENRIDGE	99% (5ML)	A219444	001	Jun 23, 2025	Jan CAIN
>D>	AP	INGENUS PHARMS LLC	99% (5ML)	A219569	001	Jul 09, 2025	Jan CAIN
>D>	AP	XGEN PHARMS	99% (5ML)	A219400	001	Jun 23, 2025	Jan CAIN
>D>		SOLUTION;INTRAVENOUS						
>D>		DEHYDRATED ALCOHOL						
>D>	+!	ROYAL PHARMS	98% (5ML)	N214988	001	Oct 23, 2025	Jan CAIN

ALISKIREN HEMIFUMARATE

		TABLET;ORAL						
		TEKTURNA						
>A>	AB +	LXO IRELAND	EQ 150MG BASE	N021985	001	Mar 05, 2007	Jan CAHN
>A>	AB +!		EQ 300MG BASE	N021985	002	Mar 05, 2007	Jan CAHN
>D>	AB +	NODEN PHARMA	EQ 150MG BASE	N021985	001	Mar 05, 2007	Jan CAHN
>D>	AB +!		EQ 300MG BASE	N021985	002	Mar 05, 2007	Jan CAHN

ALPRAZOLAM

		TABLET;ORAL						
		ALPRAZOLAM						
>D>	AB	STRIDES PHARMA INTL	0.25MG	A090248	001	Sep 17, 2010	Jan DISC
>A>	@		0.25MG	A090248	001	Sep 17, 2010	Jan DISC
>D>	AB		0.5MG	A090248	002	Sep 17, 2010	Jan DISC
>A>	@		0.5MG	A090248	002	Sep 17, 2010	Jan DISC
>D>	AB		1MG	A090248	003	Sep 17, 2010	Jan DISC
>A>	@		1MG	A090248	003	Sep 17, 2010	Jan DISC
>D>	AB		2MG	A090248	004	Sep 17, 2010	Jan DISC
>A>	@		2MG	A090248	004	Sep 17, 2010	Jan DISC

AMLODIPINE BESYLATE

FOR SOLUTION;ORAL

SDAMLO

>D>		@ +	BRILLIAN PHARMA	EQ 2.5MG BASE/BOT	N219531	001	Jul 24, 2025	Jan CMFD
>A>		+!		EQ 2.5MG BASE/BOT	N219531	001	Jul 24, 2025	Jan CMFD
>D>		@ +		EQ 5MG BASE/BOT	N219531	002	Jul 24, 2025	Jan CMFD
>A>		+!		EQ 5MG BASE/BOT	N219531	002	Jul 24, 2025	Jan CMFD
>D>		@ +		EQ 10MG BASE/BOT	N219531	003	Jul 24, 2025	Jan CMFD
>A>		+!		EQ 10MG BASE/BOT	N219531	003	Jul 24, 2025	Jan CMFD

TABLET;ORAL

AMLODIPINE BESYLATE

>A>	AB		TEVA PHARMS INC	EQ 2.5MG BASE	A219686	001	Jan 22, 2026	Jan NEWA
>A>	AB			EQ 5MG BASE	A219686	002	Jan 22, 2026	Jan NEWA
>A>	AB			EQ 10MG BASE	A219686	003	Jan 22, 2026	Jan NEWA

AMLODIPINE BESYLATE; TELMISARTAN

TABLET;ORAL

TELMISARTAN AND AMLODIPINE

>D>	AB		LUPIN LTD	EQ 5MG BASE;40MG	A201586	001	Jan 08, 2014	Jan DISC
>A>		@		EQ 5MG BASE;40MG	A201586	001	Jan 08, 2014	Jan DISC
>D>	AB			EQ 5MG BASE;80MG	A201586	003	Jan 08, 2014	Jan DISC
>A>		@		EQ 5MG BASE;80MG	A201586	003	Jan 08, 2014	Jan DISC
>D>	AB			EQ 10MG BASE;40MG	A201586	002	Jan 08, 2014	Jan DISC
>A>		@		EQ 10MG BASE;40MG	A201586	002	Jan 08, 2014	Jan DISC
>D>	AB			EQ 10MG BASE;80MG	A201586	004	Jan 08, 2014	Jan DISC
>A>		@		EQ 10MG BASE;80MG	A201586	004	Jan 08, 2014	Jan DISC
>D>	AB		MYLAN	EQ 5MG BASE;40MG	A202516	001	Aug 26, 2014	Jan DISC
>A>		@		EQ 5MG BASE;40MG	A202516	001	Aug 26, 2014	Jan DISC
>D>	AB			EQ 5MG BASE;80MG	A202516	003	Aug 26, 2014	Jan DISC
>A>		@		EQ 5MG BASE;80MG	A202516	003	Aug 26, 2014	Jan DISC
>D>	AB			EQ 10MG BASE;40MG	A202516	002	Aug 26, 2014	Jan DISC
>A>		@		EQ 10MG BASE;40MG	A202516	002	Aug 26, 2014	Jan DISC
>D>	AB	!		EQ 10MG BASE;80MG	A202516	004	Aug 26, 2014	Jan DISC
>A>		@		EQ 10MG BASE;80MG	A202516	004	Aug 26, 2014	Jan DISC

AMMONIUM LACTATE

CREAM;TOPICAL

AMMONIUM LACTATE

>D>	AB	!	PADAGIS ISRAEL	EQ 12% BASE	A075774	001	May 01, 2002	Jan CHRS
>A>	AB			EQ 12% BASE	A075774	001	May 01, 2002	Jan CHRS
>D>	AB		SUN PHARMA CANADA	EQ 12% BASE	A075883	001	Apr 10, 2003	Jan CHRS
>A>	AB	!		EQ 12% BASE	A075883	001	Apr 10, 2003	Jan CHRS

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET, EXTENDED RELEASE;ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

>D>		!	SANDOZ	1GM;EQ 62.5MG BASE	A090227	001	Apr 21, 2010	Jan CTEC
>A>	AB	!		1GM;EQ 62.5MG BASE	A090227	001	Apr 21, 2010	Jan CTEC

AUGMENTIN XR

>D>		@ +	US ANTIBIOTICS	1GM;EQ 62.5MG BASE	N050785	001	Sep 25, 2002	Jan CMFD
>A>	AB	+		1GM;EQ 62.5MG BASE	N050785	001	Sep 25, 2002	Jan CMFD

ARMODAFINIL

TABLET;ORAL

ARMODAFINIL

>D>		@	COREPHARMA	50MG	A201514	001	Mar 25, 2019	Jan CMFD
>A>	AB			50MG	A201514	001	Mar 25, 2019	Jan CMFD
>D>		@		150MG	A201514	002	Mar 25, 2019	Jan CMFD
>A>	AB			150MG	A201514	002	Mar 25, 2019	Jan CMFD
>D>		@		250MG	A201514	003	Mar 25, 2019	Jan CMFD
>A>	AB			250MG	A201514	003	Mar 25, 2019	Jan CMFD

ATENOLOL

TABLET;ORAL

ATENOLOL

>D>		@	IPCA LABS LTD	25MG	A077877	001	Dec 27, 2006	Jan CMFD
>A>	AB			25MG	A077877	001	Dec 27, 2006	Jan CMFD
>D>		@		50MG	A077877	002	Dec 27, 2006	Jan CMFD
>A>	AB			50MG	A077877	002	Dec 27, 2006	Jan CMFD
>D>		@		100MG	A077877	003	Dec 27, 2006	Jan CMFD
>A>	AB			100MG	A077877	003	Dec 27, 2006	Jan CMFD

AZTREONAM

INJECTABLE;INJECTION

AZTREONAM

>A>	AP		HIKMA	1GM/VIAL	A207069	001	Feb 05, 2026	Jan NEWA
>A>	AP			2GM/VIAL	A207069	002	Feb 05, 2026	Jan NEWA

BACLOFEN

GRANULES;ORAL

LYVISPAH

>D>		@ +	AMNEAL	5MG/PACKET	N215422	001	Nov 22, 2021	Jan CAHN
>D>		@ +		10MG/PACKET	N215422	002	Nov 22, 2021	Jan CAHN
>D>		@ +		20MG/PACKET	N215422	003	Nov 22, 2021	Jan CAHN
>A>		@ +	STRIDES PHARMA INTL	5MG/PACKET	N215422	001	Nov 22, 2021	Jan CAHN
>A>		@ +		10MG/PACKET	N215422	002	Nov 22, 2021	Jan CAHN
>A>		@ +		20MG/PACKET	N215422	003	Nov 22, 2021	Jan CAHN

TABLET;ORAL

BACLOFEN

>D>	AB	!	RUBICON RESEARCH	5MG	A209102	001	Nov 28, 2017	Jan CHRS
>A>	AB			5MG	A209102	001	Nov 28, 2017	Jan CHRS

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET;ORAL

BENAZEPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>D>	AB		SANDOZ	20MG;25MG	A076631	004	Feb 11, 2004	Jan CHRS
>A>	AB	!		20MG;25MG	A076631	004	Feb 11, 2004	Jan CHRS

LOTENSIN HCT

>D>	AB	+!	VALIDUS PHARMS	20MG;25MG	N020033	003	May 19, 1992	Jan CHRS
>A>	AB	+		20MG;25MG	N020033	003	May 19, 1992	Jan CHRS

BETAMETHASONE DIPROPIONATE

CREAM;TOPICAL

BETAMETHASONE DIPROPIONATE

>A>	AB		AUROBINDO PHARMA LTD	EQ 0.05% BASE	A219348	001	Jan 26, 2026	Jan NEWA

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET;ORAL

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

>A>	AB		AUROBINDO PHARMA LTD	2.5MG;6.25MG	A217922	001	Jan 21, 2026	Jan NEWA
>A>	AB			5MG;6.25MG	A217922	002	Jan 21, 2026	Jan NEWA
>A>	AB			10MG;6.25MG	A217922	003	Jan 21, 2026	Jan NEWA

BORTEZOMIB

INJECTABLE;INTRAVENOUS, SUBCUTANEOUS

BORTEZOMIB

>A>	AP		CAPLIN ONE LABS	3.5MG/VIAL	A203654	001	Jul 26, 2022	Jan CAHN
>D>	AP		SANDOZ	3.5MG/VIAL	A203654	001	Jul 26, 2022	Jan CAHN

BRIGATINIB

TABLET;ORAL

ALUNBRIG

>D>		+	TAKEDA PHARMS USA	90MG	N208772	002	Apr 28, 2017	Jan CHRS
>A>		+!		90MG	N208772	002	Apr 28, 2017	Jan CHRS
>D>		+!		180MG	N208772	003	Oct 02, 2017	Jan CHRS
>A>		+		180MG	N208772	003	Oct 02, 2017	Jan CHRS

>A> BRIMONIDINE TARTRATE; CARBACHOL

>A> SOLUTION/DROPS;OPHTHALMIC

>A> YUVEZZI

>A>		+!	VISUS	0.1%;2.75%	N220142	001	Jan 28, 2026	Jan NEWA

BRIVARACETAM

TABLET;ORAL

BRIVARACETAM

>D>		@	AUROBINDO PHARMA LTD	50MG	A214848	001	Jan 06, 2023	Jan CMFD
>A>	AB			50MG	A214848	001	Jan 06, 2023	Jan CMFD
>D>		@		100MG	A214848	002	Jan 06, 2023	Jan CMFD
>A>	AB			100MG	A214848	002	Jan 06, 2023	Jan CMFD
>D>		@	SUNSHINE	10MG	A214748	001	Jun 09, 2022	Jan CMFD
>A>	AB			10MG	A214748	001	Jun 09, 2022	Jan CMFD
>D>		@		25MG	A214748	002	Jun 09, 2022	Jan CMFD
>A>	AB			25MG	A214748	002	Jun 09, 2022	Jan CMFD

TABLET;ORAL
BRIVARACETAM

>D>		@		50MG	A214748	003	Jun 09, 2022	Jan CMFD
>A>	AB			50MG	A214748	003	Jun 09, 2022	Jan CMFD
>D>		@		75MG	A214748	004	Jun 09, 2022	Jan CMFD
>A>	AB			75MG	A214748	004	Jun 09, 2022	Jan CMFD
>D>		@		100MG	A214748	005	Jun 09, 2022	Jan CMFD
>A>	AB			100MG	A214748	005	Jun 09, 2022	Jan CMFD

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP;ORAL
BROMFED-DM

>D>	AA	+	PHARMOBEDIENT	2MG/5ML;10MG/5ML;30MG/5ML	A088811	001	Jun 07, 1985	Jan DISC
>A>		@ +		2MG/5ML;10MG/5ML;30MG/5ML	A088811	001	Jun 07, 1985	Jan DISC

BUDESONIDE

SUSPENSION;INHALATION
PULMICORT RESPULES

>D>	AN	+	ASTRAZENECA	0.25MG/2ML	N020929	001	Aug 08, 2000	Jan CHRS
>A>	AN	+!		0.25MG/2ML	N020929	001	Aug 08, 2000	Jan CHRS
>D>	AN	+		0.5MG/2ML	N020929	002	Aug 08, 2000	Jan CHRS
>A>	AN	+!		0.5MG/2ML	N020929	002	Aug 08, 2000	Jan CHRS

BUMETANIDE

TABLET;ORAL
BUMETANIDE

>A>	AB		MSN	0.5MG	A215362	001	Feb 05, 2026	Jan NEWA
>A>	AB			1MG	A215362	002	Feb 05, 2026	Jan NEWA
>A>	AB			2MG	A215362	003	Feb 05, 2026	Jan NEWA

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

FILM;BUCCAL, SUBLINGUAL
BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

>A>	AB		ASCENT PHARMS INC	EQ 2MG BASE;EQ 0.5MG BASE	A219850	001	Jan 21, 2026	Jan NEWA
>A>	AB			EQ 4MG BASE;EQ 1MG BASE	A219850	002	Jan 21, 2026	Jan NEWA
>A>	AB			EQ 8MG BASE;EQ 2MG BASE	A219850	003	Jan 21, 2026	Jan NEWA
>A>	AB			EQ 12MG BASE;EQ 3MG BASE	A219850	004	Jan 21, 2026	Jan NEWA

CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

TABLET;ORAL
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE

>D>	AB		ANDA REPOSITORY	16MG;12.5MG	A202965	001	Jun 03, 2013	Jan CAHN
>D>	AB			32MG;12.5MG	A202965	002	Jun 03, 2013	Jan CAHN
>D>	AB			32MG;25MG	A202965	003	Jun 03, 2013	Jan CAHN
>A>	AB		SENORES PHARMS	16MG;12.5MG	A202965	001	Jun 03, 2013	Jan CAHN
>A>	AB			32MG;12.5MG	A202965	002	Jun 03, 2013	Jan CAHN
>A>	AB			32MG;25MG	A202965	003	Jun 03, 2013	Jan CAHN

CAPECITABINE

TABLET;ORAL
CAPECITABINE

>D>	AB		DR REDDYS	500MG	A204345	002	Dec 04, 2020	Jan CHRS
>A>	AB	!		500MG	A204345	002	Dec 04, 2020	Jan CHRS
>D>		XELODA						
>D>	AB	+	CHEPLAPHARM	150MG	N020896	001	Apr 30, 1998	Jan DISC
>A>		@ +		150MG	N020896	001	Apr 30, 1998	Jan DISC
>D>	AB	+!		500MG	N020896	002	Apr 30, 1998	Jan DISC
>A>		@ +		500MG	N020896	002	Apr 30, 1998	Jan DISC

CARBIDOPA; ENTACAPONE; LEVODOPA

TABLET;ORAL
CARBIDOPA, LEVODOPA AND ENTACAPONE

>A>	AB		ALEMBIC	12.5MG;200MG;50MG	A218535	001	Feb 05, 2026	Jan NEWA
>A>	AB			18.75MG;200MG;75MG	A218535	002	Feb 05, 2026	Jan NEWA
>A>	AB			25MG;200MG;100MG	A218535	003	Feb 05, 2026	Jan NEWA
>A>	AB			31.25MG;200MG;125MG	A218535	004	Feb 05, 2026	Jan NEWA
>A>	AB			37.5MG;200MG;150MG	A218535	005	Feb 05, 2026	Jan NEWA
>A>	AB			50MG;200MG;200MG	A218535	006	Feb 05, 2026	Jan NEWA

CARBOPLATIN

INJECTABLE;INTRAVENOUS

CARBOPLATIN

>A>	AP		QILU PHARM HAINAN	50MG/5ML (10MG/ML)	A219999	001	Feb 04, 2026	Jan NEWA
>A>	AP			150MG/15ML (10MG/ML)	A219999	002	Feb 04, 2026	Jan NEWA
>A>	AP			450MG/45ML (10MG/ML)	A219999	003	Feb 04, 2026	Jan NEWA
>A>	AP			600MG/60ML (10MG/ML)	A219999	004	Feb 04, 2026	Jan NEWA

CARIPRAZINE HYDROCHLORIDE

CAPSULE;ORAL

CARIPRAZINE HYDROCHLORIDE

>D>								
>D>	AB		AUROBINDO PHARMA LTD	EQ 1.5MG BASE	A213982	001	Dec 16, 2025	Jan DISC
>A>		@		EQ 1.5MG BASE	A213982	001	Dec 16, 2025	Jan DISC
>D>	AB			EQ 3MG BASE	A213982	002	Dec 16, 2025	Jan DISC
>A>		@		EQ 3MG BASE	A213982	002	Dec 16, 2025	Jan DISC
>D>	AB			EQ 6MG BASE	A213982	003	Dec 16, 2025	Jan DISC
>A>		@		EQ 6MG BASE	A213982	003	Dec 16, 2025	Jan DISC

VRAYLAR

>D>	AB	+!	ABBVIE	EQ 1.5MG BASE	N204370	001	Sep 17, 2015	Jan CTEC
>A>		+!		EQ 1.5MG BASE	N204370	001	Sep 17, 2015	Jan CTEC
>D>	AB	+		EQ 3MG BASE	N204370	002	Sep 17, 2015	Jan CTEC
>A>		+		EQ 3MG BASE	N204370	002	Sep 17, 2015	Jan CTEC
>D>	AB	+		EQ 6MG BASE	N204370	004	Sep 17, 2015	Jan CTEC
>A>		+		EQ 6MG BASE	N204370	004	Sep 17, 2015	Jan CTEC

CEFIXIME

TABLET;ORAL

CEFIXIME

>D>		@	FDC LTD	400MG	A206358	001	Dec 17, 2024	Jan CMFD
>A>		!		400MG	A206358	001	Dec 17, 2024	Jan CMFD

CEFTAROLINE FOSAMIL

POWDER;INTRAVENOUS

CEFTAROLINE FOSAMIL

>D>		@	APOTEX	400MG/VIAL	A208075	001	Sep 21, 2021	Jan CMFD
>A>	AP			400MG/VIAL	A208075	001	Sep 21, 2021	Jan CMFD
>D>		@		600MG/VIAL	A208075	002	Sep 21, 2021	Jan CMFD
>A>	AP			600MG/VIAL	A208075	002	Sep 21, 2021	Jan CMFD

TEFLARO

>D>		+!	ABBVIE	400MG/VIAL	N200327	001	Oct 29, 2010	Jan CTEC
>A>	AP	+!		400MG/VIAL	N200327	001	Oct 29, 2010	Jan CTEC
>D>		+!		600MG/VIAL	N200327	002	Oct 29, 2010	Jan CTEC
>A>	AP	+!		600MG/VIAL	N200327	002	Oct 29, 2010	Jan CTEC

>D> CHLOROTHIAZIDE

>D> SUSPENSION;ORAL

>D> DIURIL

>D>		+!	SALIX PHARMS	250MG/5ML	N011870	001		Jan DISC
>A>		@ +		250MG/5ML	N011870	001		Jan DISC

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE;INJECTION

CHLORPROMAZINE HYDROCHLORIDE

>A>	AP		MSN	25MG/ML	A216092	001	Jan 26, 2026	Jan NEWA

TABLET;ORAL

CHLORPROMAZINE HYDROCHLORIDE

>D>	AB		CHARTWELL RX	10MG	A212630	001	Nov 29, 2021	Jan CAHN
>D>	AB			25MG	A212630	002	Nov 29, 2021	Jan CAHN
>D>	AB			50MG	A212630	003	Nov 29, 2021	Jan CAHN
>D>	AB			100MG	A212630	004	Nov 29, 2021	Jan CAHN
>D>	AB			200MG	A212630	005	Nov 29, 2021	Jan CAHN
>A>	AB		ZAMEER PHARMS	10MG	A212630	001	Nov 29, 2021	Jan CAHN
>A>	AB			25MG	A212630	002	Nov 29, 2021	Jan CAHN
>A>	AB			50MG	A212630	003	Nov 29, 2021	Jan CAHN
>A>	AB			100MG	A212630	004	Nov 29, 2021	Jan CAHN
>A>	AB			200MG	A212630	005	Nov 29, 2021	Jan CAHN

CHLORZOXAZONE
TABLET;ORAL
CHLORZOXAZONE

>D>	AA		ANDA REPOSITORY	500MG	A210961	001	Jan 22, 2024	Jan CAHN
>A>	AA		SENORES PHARMS	500MG	A210961	001	Jan 22, 2024	Jan CAHN

CHOLESTYRAMINE
POWDER;ORAL
CHOLESTYRAMINE

>A>	AB		PHARMOBEDIENT	EQ 4GM RESIN/PACKET	A209597	001	Mar 09, 2021	Jan CAHN
>A>	AB			EQ 4GM RESIN/SCOOPFUL	A209597	002	Mar 09, 2021	Jan CAHN
>D>	AB		TAGI	EQ 4GM RESIN/PACKET	A209597	001	Mar 09, 2021	Jan CAHN
>D>	AB			EQ 4GM RESIN/SCOOPFUL	A209597	002	Mar 09, 2021	Jan CAHN

CLONAZEPAM
TABLET;ORAL
CLONAZEPAM

>D>		@	CHARTWELL RX	0.5MG	A074925	001	Sep 30, 1997	Jan CMFD
>A>	AB			0.5MG	A074925	001	Sep 30, 1997	Jan CMFD
>D>		@		1MG	A074925	002	Sep 30, 1997	Jan CMFD
>A>	AB			1MG	A074925	002	Sep 30, 1997	Jan CMFD
>D>		@		2MG	A074925	003	Sep 30, 1997	Jan CMFD
>A>	AB			2MG	A074925	003	Sep 30, 1997	Jan CMFD

>A> COPPER HISTIDINATE
>A> POWDER;SUBCUTANEOUS
>A> ZYCUBO

>A>		+!	SENTYNL THERAPS INC	2.9MG/VIAL	N211241	001	Jan 12, 2026	Jan NEWA

CUPRIC CHLORIDE
INJECTABLE;INJECTION
CUPRIC CHLORIDE

>A>	AP		AMNEAL	EQ 0.4MG COPPER/ML	A217287	001	Jan 26, 2026	Jan NEWA

CYCLOPHOSPHAMIDE
INJECTABLE;INJECTION
CYCLOPHOSPHAMIDE

>D>	AP		HAINAN POLY	500MG/VIAL	A218632	001	Dec 26, 2024	Jan DISC
>A>		@		500MG/VIAL	A218632	001	Dec 26, 2024	Jan DISC
>D>	AP			1GM/VIAL	A218632	002	Dec 26, 2024	Jan DISC
>A>		@		1GM/VIAL	A218632	002	Dec 26, 2024	Jan DISC
>D>	AP			2GM/VIAL	A218632	003	Dec 26, 2024	Jan DISC
>A>		@		2GM/VIAL	A218632	003	Dec 26, 2024	Jan DISC

CYCLOSPORINE
EMULSION;OPHTHALMIC
CYCLOSPORINE

>A>	AB		TWI PHARMS	0.05%	A209064	001	Jan 21, 2026	Jan NEWA

CYPROHEPTADINE HYDROCHLORIDE
SYRUP;ORAL
CYPROHEPTADINE HYDROCHLORIDE

>D>	AA		INVATECH	2MG/5ML	A209108	001	Oct 16, 2018	Jan CAHN
>A>	AA		ST JOHN PHARM	2MG/5ML	A209108	001	Oct 16, 2018	Jan CAHN

DAPTOMYCIN
POWDER;INTRAVENOUS
DAPTOMYCIN

>D>	AP		HENGRUI PHARMA	500MG/VIAL	A212022	001	Aug 22, 2019	Jan DISC
>A>		@		500MG/VIAL	A212022	001	Aug 22, 2019	Jan DISC

DEFLAZACORT
SUSPENSION;ORAL
DEFLAZACORT

>A>	AB		SUN PHARM INDS INC	22.75MG/ML	A219930	001	Jan 27, 2026	Jan NEWA

>A>		DEHYDRATED ALCOHOL						
>A>		SOLUTION;INTRA-ARTERIAL						
>A>		ABLYSINOL						
>A>		@ + BPI LABS	99% (1ML)	N207987	001	Jun 21, 2018	Jan CAIN
>A>	AP	+!	99% (5ML)	N207987	002	Jun 21, 2018	Jan CAIN
>A>		DEHYDRATED ALCOHOL						
>A>	AP	ACCORD HLTHCARE	99% (5ML)	A217845	001	Jun 23, 2025	Jan CAIN
>A>	AP	BRECKENRIDGE	99% (5ML)	A219444	001	Jun 23, 2025	Jan CAIN
>A>	AP	INGENUS PHARMS LLC	99% (5ML)	A219569	001	Jul 09, 2025	Jan CAIN
>A>	AP	XGEN PHARMS	99% (5ML)	A219400	001	Jun 23, 2025	Jan CAIN
>A>		SOLUTION;INTRAVENOUS						
>A>		DEHYDRATED ALCOHOL						
>A>		+! ROYAL PHARMS	98% (5ML)	N214988	001	Oct 23, 2025	Jan CAIN
		DESIPRAMINE HYDROCHLORIDE						
		TABLET;ORAL						
		DESIPRAMINE HYDROCHLORIDE						
>D>	AB	HERITAGE	10MG	A207433	001	May 05, 2016	Jan DISC
>A>		@	10MG	A207433	001	May 05, 2016	Jan DISC
>D>	AB		25MG	A207433	002	May 05, 2016	Jan DISC
>A>		@	25MG	A207433	002	May 05, 2016	Jan DISC
>D>	AB		50MG	A207433	003	May 05, 2016	Jan DISC
>A>		@	50MG	A207433	003	May 05, 2016	Jan DISC
>D>	AB		75MG	A207433	004	May 05, 2016	Jan DISC
>A>		@	75MG	A207433	004	May 05, 2016	Jan DISC
>D>	AB		100MG	A207433	005	May 05, 2016	Jan DISC
>A>		@	100MG	A207433	005	May 05, 2016	Jan DISC
>D>	AB		150MG	A207433	006	May 05, 2016	Jan DISC
>A>		@	150MG	A207433	006	May 05, 2016	Jan DISC
		DEXAMETHASONE						
		CONCENTRATE;ORAL						
		DEXAMETHASONE INTENSOL						
>D>		! HIKMA	1MG/ML	A088252	001	Sep 01, 1983	Jan CRLD
>A>		+!	1MG/ML	A088252	001	Sep 01, 1983	Jan CRLD
		DEXAMETHASONE SODIUM PHOSPHATE						
		SOLUTION/DROPS;OPHTHALMIC, OTIC						
		DEXAMETHASONE SODIUM PHOSPHATE						
>A>		@ CAPLIN	EQ 0.1% PHOSPHATE	A088771	001	Jan 16, 1985	Jan CAHN
>D>		@ SANDOZ	EQ 0.1% PHOSPHATE	A088771	001	Jan 16, 1985	Jan CAHN
		DEXMEDETOMIDINE HYDROCHLORIDE						
		FILM;BUCCAL, SUBLINGUAL						
		IGALMI						
>D>		+! BIOXCEL	EQ 0.18MG BASE	N215390	002	Apr 05, 2022	Jan CHRS
>A>		+	EQ 0.18MG BASE	N215390	002	Apr 05, 2022	Jan CHRS
		INJECTABLE;INJECTION						
		DEXMEDETOMIDINE HYDROCHLORIDE						
>A>	AP	CAPLIN	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)	A091465	001	Jun 14, 2016	Jan CAHN
>D>	AP	SANDOZ	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)	A091465	001	Jun 14, 2016	Jan CAHN
		DEXTROAMPHETAMINE SULFATE						
		CAPSULE, EXTENDED RELEASE;ORAL						
		DEXTROAMPHETAMINE SULFATE						
>D>	AB	STRIDES PHARMA INTL	5MG	A205673	001	Oct 31, 2017	Jan DISC
>A>		@	5MG	A205673	001	Oct 31, 2017	Jan DISC
>D>	AB		10MG	A205673	002	Oct 31, 2017	Jan DISC
>A>		@	10MG	A205673	002	Oct 31, 2017	Jan DISC
>D>	AB		15MG	A205673	003	Oct 31, 2017	Jan DISC
>A>		@	15MG	A205673	003	Oct 31, 2017	Jan DISC
		DIAZEPAM						
		TABLET;ORAL						
		DIAZEPAM						
>D>	AB	STRIDES PHARMA INTL	2MG	A077749	001	Mar 31, 2006	Jan DISC
>A>		@	2MG	A077749	001	Mar 31, 2006	Jan DISC
>D>	AB		5MG	A077749	002	Mar 31, 2006	Jan DISC
>A>		@	5MG	A077749	002	Mar 31, 2006	Jan DISC
>D>	AB		10MG	A077749	003	Mar 31, 2006	Jan DISC

TABLET;ORAL
DIAZEPAM

>A>		@		10MG		A077749	003	Mar 31, 2006 Jan DISC

DIFLUPREDNATE

EMULSION;OPHTHALMIC
DIFLUPREDNATE

>A>	AB		ALEMBIC	0.05%		A213774	001	Jan 26, 2026 Jan NEWA

DILTIAZEM HYDROCHLORIDE

TABLET;ORAL
DILTIAZEM HYDROCHLORIDE

>D>	AB		ZYDUS LIFESCIENCES	30MG		A219253	001	Aug 08, 2025 Jan DISC
>A>		@		30MG		A219253	001	Aug 08, 2025 Jan DISC
>D>	AB			60MG		A219253	002	Aug 08, 2025 Jan DISC
>A>		@		60MG		A219253	002	Aug 08, 2025 Jan DISC
>D>	AB			90MG		A219253	003	Aug 08, 2025 Jan DISC
>A>		@		90MG		A219253	003	Aug 08, 2025 Jan DISC
>D>	AB			120MG		A219253	004	Aug 08, 2025 Jan DISC
>A>		@		120MG		A219253	004	Aug 08, 2025 Jan DISC

DOFETILIDE

CAPSULE;ORAL
DOFETILIDE

>D>	AB		STRIDES PHARMA INTL	0.125MG		A208519	001	Oct 09, 2018 Jan DISC
>A>		@		0.125MG		A208519	001	Oct 09, 2018 Jan DISC
>D>	AB			0.25MG		A208519	002	Oct 09, 2018 Jan DISC
>A>		@		0.25MG		A208519	002	Oct 09, 2018 Jan DISC
>D>	AB			0.5MG		A208519	003	Oct 09, 2018 Jan DISC
>A>		@		0.5MG		A208519	003	Oct 09, 2018 Jan DISC

DOXERCALCIFEROL

INJECTABLE;INJECTION
DOXERCALCIFEROL

>A>	AP		CAPLIN	4MCG/2ML (2MCG/ML)		A200926	001	Feb 04, 2014 Jan CAHN
>D>	AP		SANDOZ	4MCG/2ML (2MCG/ML)		A200926	001	Feb 04, 2014 Jan CAHN

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL;INJECTION
DOXORUBICIN HYDROCHLORIDE

>A>	AB		QILU PHARM HAINAN	20MG/10ML (2MG/ML)		A219881	001	Feb 03, 2026 Jan NEWA
>A>	AB			50MG/25ML (2MG/ML)		A219881	002	Feb 03, 2026 Jan NEWA

DOXYCYCLINE

CAPSULE;ORAL
DOXYCYCLINE

>A>	AB		AIPING PHARM INC	40MG		A219978	001	Oct 01, 2025 Jan CAHN
>D>	AB		CHANGZHOU PHARM	40MG		A219978	001	Oct 01, 2025 Jan CAHN

DOXYCYCLINE HYCLATE

TABLET;ORAL
DOXYCYCLINE HYCLATE

>D>	AB		APOTEX	EQ 75MG BASE		A209243	001	Apr 15, 2019 Jan DISC
>A>		@		EQ 75MG BASE		A209243	001	Apr 15, 2019 Jan DISC
>D>	AB			EQ 150MG BASE		A209243	002	Apr 15, 2019 Jan DISC
>A>		@		EQ 150MG BASE		A209243	002	Apr 15, 2019 Jan DISC

DRONABINOL

SOLUTION;ORAL
SYNDROS

>D>		@ +	BENUVIA OPERATIONS	5MG/ML		N205525	001	Mar 23, 2017 Jan CAHN
>A>		@ +	WELLHOUSE PHARMA	5MG/ML		N205525	001	Mar 23, 2017 Jan CAHN

ELTROMBOPAG OLAMINE

TABLET;ORAL
ELTROMBOPAG OLAMINE

>A>	AB		AMNEAL	EQ 12.5MG ACID		A212884	001	Jan 14, 2026 Jan NEWA
>A>	AB			EQ 25MG ACID		A212884	003	Jan 14, 2026 Jan NEWA
>A>	AB			EQ 50MG ACID		A212884	002	Jan 14, 2026 Jan NEWA
>A>	AB			EQ 75MG ACID		A212884	004	Jan 14, 2026 Jan NEWA
>A>	AB		MSN	EQ 12.5MG ACID		A220250	001	Jan 14, 2026 Jan NEWA
>A>	AB			EQ 25MG ACID		A220250	002	Jan 14, 2026 Jan NEWA

TABLET;ORAL
ELTROMBOPAG OLAMINE

>A>	AB			EQ 50MG ACID	A220250	003	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 75MG ACID	A220250	004	Jan 14, 2026	Jan NEWA
>A>	AB		SOMERSET THERAPS LLC	EQ 12.5MG ACID	A219638	001	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 25MG ACID	A219638	002	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 50MG ACID	A219638	003	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 75MG ACID	A219638	004	Jan 14, 2026	Jan NEWA
>A>	AB		ZYDUS PHARMS	EQ 12.5MG ACID	A216281	001	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 25MG ACID	A216281	002	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 50MG ACID	A216281	003	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 75MG ACID	A216281	004	Jan 14, 2026	Jan NEWA

EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR ALAFENAMIDE FUMARATE

TABLET;ORAL
>A> EMTRICITABINE, RILPIVIRINE, AND TENOFOVIR ALAFENAMIDE

>A>	AB		APOTEX	200MG;EQ 25MG BASE;EQ 25MG BASE	A214095	001	Jan 30, 2026	Jan NFTG

ODEFSEY

>D>		+!	GILEAD SCIENCES INC	200MG;EQ 25MG BASE;EQ 25MG BASE	N208351	001	Mar 01, 2016	Jan CFTG
>A>	AB	+!		200MG;EQ 25MG BASE;EQ 25MG BASE	N208351	001	Mar 01, 2016	Jan CFTG

ESTRADIOL

GEL;TRANSDERMAL
ESTRADIOL

>D>	AB		CHEMO RESEARCH SL	0.1% (0.25GM/PACKET)	A211783	001	Aug 10, 2022	Jan CAHN
>D>	AB			0.1% (0.5GM/PACKET)	A211783	002	Aug 10, 2022	Jan CAHN
>D>	AB			0.1% (1GM/PACKET)	A211783	003	Aug 10, 2022	Jan CAHN
>A>	AB		XIROMED	0.1% (0.25GM/PACKET)	A211783	001	Aug 10, 2022	Jan CAHN
>A>	AB			0.1% (0.5GM/PACKET)	A211783	002	Aug 10, 2022	Jan CAHN
>A>	AB			0.1% (1GM/PACKET)	A211783	003	Aug 10, 2022	Jan CAHN

GEL, METERED;TRANSDERMAL
ESTRADIOL

>A>	AB		LONG GROVE PHARMS	0.06% (1.25GM/ACTIVATION)	A215096	001	Feb 02, 2026	Jan NEWA

ESTRADIOL ACETATE

INSERT, EXTENDED RELEASE;VAGINAL
FEMRING

>A>		+	MILLICENT MFG PR	EQ 0.05MG BASE/24HR	N021367	001	Mar 20, 2003	Jan CAHN
>A>		+!		EQ 0.1MG BASE/24HR	N021367	002	Mar 20, 2003	Jan CAHN
>D>		+	MILLICENT PR	EQ 0.05MG BASE/24HR	N021367	001	Mar 20, 2003	Jan CAHN
>D>		+!		EQ 0.1MG BASE/24HR	N021367	002	Mar 20, 2003	Jan CAHN

ETODOLAC

TABLET;ORAL
ETODOLAC

>D>		@	ANDA REPOSITORY	400MG	A074839	001	Jul 11, 1997	Jan CAHN
>A>		@	SENORES PHARMS	400MG	A074839	001	Jul 11, 1997	Jan CAHN

ETOPOSIDE

CAPSULE;ORAL
ETOPOSIDE

>D>		!	MYLAN	50MG	A075635	001	Sep 19, 2001	Jan CTEC
>A>	AB	!		50MG	A075635	001	Sep 19, 2001	Jan CTEC

VEPESID

>D>		@ +	ONESOURCE SPECIALTY	50MG	N019557	001	Dec 30, 1986	Jan CMFD
>A>	AB	+		50MG	N019557	001	Dec 30, 1986	Jan CMFD

EVEROLIMUS

TABLET;ORAL
EVEROLIMUS

>D>	AB		PH HEALTH	2.5MG	A207934	001	Dec 09, 2019	Jan DISC
>A>		@		2.5MG	A207934	001	Dec 09, 2019	Jan DISC
>D>	AB			5MG	A207934	002	Dec 09, 2019	Jan DISC
>A>		@		5MG	A207934	002	Dec 09, 2019	Jan DISC
>D>	AB			7.5MG	A207934	003	Dec 09, 2019	Jan DISC
>A>		@		7.5MG	A207934	003	Dec 09, 2019	Jan DISC
>D>	AB			10MG	A207934	004	Dec 09, 2020	Jan DISC
>A>		@		10MG	A207934	004	Dec 09, 2020	Jan DISC

TABLET, FOR SUSPENSION;ORAL
EVEROLIMUS

>A> AB	BIOCON PHARMA	2MG	A217216	001	Jan 09, 2026	Jan NEWA
>A> AB		3MG	A217216	002	Jan 09, 2026	Jan NEWA
>A> AB		5MG	A217216	003	Jan 09, 2026	Jan NEWA

FAMOTIDINE

TABLET;ORAL
FAMOTIDINE

>D> AB	ALKEM LABS LTD	20MG	A215630	001	Jan 07, 2022	Jan CAHN
>D> AB		40MG	A215630	002	Jan 07, 2022	Jan CAHN
>A> AB	VKT PHARMA	20MG	A215630	001	Jan 07, 2022	Jan CAHN
>A> AB		40MG	A215630	002	Jan 07, 2022	Jan CAHN

FENOFIBRATE

CAPSULE;ORAL
LIPOFEN

>D>	@ CIPHER PHARMS INC	100MG	N021612	002	Jan 11, 2006	Jan CRLD
>A>	@ +	100MG	N021612	002	Jan 11, 2006	Jan CRLD

TABLET;ORAL
FENOFIBRATE

>A> AB	MACLEODS PHARMS LTD	54MG	A210379	001	Jan 21, 2026	Jan NEWA
>A> AB		160MG	A210379	002	Jan 21, 2026	Jan NEWA

TRIGLIDE

>A>	@ JAGOTEC	50MG	N021350	001	May 07, 2005	Jan CAHN
>A>	@ +	160MG	N021350	002	May 07, 2005	Jan CAHN
>D>	@ SKYEPHARMA AG	50MG	N021350	001	May 07, 2005	Jan CAHN
>D>	@ +	160MG	N021350	002	May 07, 2005	Jan CAHN

FIDAXOMICIN

TABLET;ORAL
FIDAXOMICIN

>A> AB	APOTEX	200MG	A219559	001	Feb 02, 2026	Jan NEWA
>A> AB	TORRENT	200MG	A220374	001	Jan 27, 2026	Jan NEWA

FLUDARABINE PHOSPHATE

INJECTABLE;INJECTION
FLUDARABINE PHOSPHATE

>A>	@ + CAPLIN ONE LABS	50MG/2ML (25MG/ML)	N022137	001	Sep 21, 2007	Jan CAHN
>D>	@ + SANDOZ	50MG/2ML (25MG/ML)	N022137	001	Sep 21, 2007	Jan CAHN

FLUDROCORTISONE ACETATE

TABLET;ORAL
FLUDROCORTISONE ACETATE

>A> AB	HIBROW HLTHCARE	0.1MG	A220308	001	Feb 10, 2026	Jan NEWA

FLUOROMETHOLONE

SUSPENSION/DROPS;OPHTHALMIC
FLUOROMETHOLONE

>A> AB	DIFGEN PHARMS	0.1%	A218819	001	Feb 12, 2026	Jan NEWA

FLUOXETINE HYDROCHLORIDE

CAPSULE;ORAL
FLUOXETINE HYDROCHLORIDE

>D> AB1	STRIDES PHARMA INTL	EQ 10MG BASE	A076922	001	Dec 16, 2004	Jan DISC
>A>	@	EQ 10MG BASE	A076922	001	Dec 16, 2004	Jan DISC
>D> AB1		EQ 20MG BASE	A076922	002	Dec 16, 2004	Jan DISC
>A>	@	EQ 20MG BASE	A076922	002	Dec 16, 2004	Jan DISC
>D> AB		EQ 40MG BASE	A076922	003	Dec 16, 2004	Jan DISC
>A>	@	EQ 40MG BASE	A076922	003	Dec 16, 2004	Jan DISC

FLUPHENAZINE HYDROCHLORIDE

TABLET;ORAL
FLUPHENAZINE HYDROCHLORIDE

>D> AB	CHARTWELL RX	1MG	A215141	001	Oct 20, 2021	Jan CAHN
>D> AB		2.5MG	A215141	002	Oct 20, 2021	Jan CAHN
>D> AB		5MG	A215141	003	Oct 20, 2021	Jan CAHN
>D> AB		10MG	A215141	004	Oct 20, 2021	Jan CAHN
>A> AB	ZAMEER PHARMS	1MG	A215141	001	Oct 20, 2021	Jan CAHN
>A> AB		2.5MG	A215141	002	Oct 20, 2021	Jan CAHN
>A> AB		5MG	A215141	003	Oct 20, 2021	Jan CAHN
>A> AB		10MG	A215141	004	Oct 20, 2021	Jan CAHN

FLUTICASONE FUROATE; VILANTEROL TRIFENATATE

POWDER;INHALATION

BREO ELLIPTA

>D>		+	GLAXO GRP LTD	0.05MG/INH;EQ 0.025MG BASE/INH	N204275	003	May 12, 2023	Jan CHRS
>A>		+!		0.05MG/INH;EQ 0.025MG BASE/INH	N204275	003	May 12, 2023	Jan CHRS

FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE

POWDER;INHALATION

AIRDUO RESPICLICK

>D>		+	TEVA PHARM	0.055MG/INH;EQ 0.014MG BASE/INH	N208799	001	Jan 27, 2017	Jan CHRS
>A>		+!		0.055MG/INH;EQ 0.014MG BASE/INH	N208799	001	Jan 27, 2017	Jan CHRS
>D>		+		0.113MG/INH;EQ 0.014MG BASE/INH	N208799	002	Jan 27, 2017	Jan CHRS
>A>		+!		0.113MG/INH;EQ 0.014MG BASE/INH	N208799	002	Jan 27, 2017	Jan CHRS

FLUTICASONE PROPIONATE AND SALMETEROL XINAFOATE

>A>	AB	RESPIRENT PHARMS	0.1MG/INH;EQ 0.05MG BASE/INH	A214464	001	Jan 12, 2026	Jan NEWA
>A>	AB		0.25MG/INH;EQ 0.05MG BASE/INH	A214464	002	Jan 12, 2026	Jan NEWA

>A> FOLIC ACID

>A> SOLUTION;ORAL

>A> QUIOFIC

>A>		+!	CMP DEV LLC	0.2MG/ML	N216395	001	Jan 26, 2026	Jan NEWA

FONDAPARINUX SODIUM

>D> INJECTABLE;SUBCUTANEOUS

>D> ARIXTRA

>D>	AP	+!	MYLAN IRELAND LTD	2.5MG/0.5ML	N021345	001	Dec 07, 2001	Jan CDFR
>D>	AP	+!		5MG/0.4ML	N021345	002	May 28, 2004	Jan CDFR
>D>	AP	+!		7.5MG/0.6ML	N021345	003	May 28, 2004	Jan CDFR
>D>	AP	+!		10MG/0.8ML	N021345	004	May 28, 2004	Jan CDFR

>D> FONDAPARINUX SODIUM

>D>		@	BRIGHTGENE	2.5MG/0.5ML	A218312	001	Dec 18, 2024	Jan CDFR
>D>	AP		DR REDDYS LABS LTD	2.5MG/0.5ML	A091316	001	Jul 11, 2011	Jan CDFR
>D>	AP			5MG/0.4ML	A091316	002	Jul 11, 2011	Jan CDFR
>D>	AP			7.5MG/0.6ML	A091316	003	Jul 11, 2011	Jan CDFR
>D>	AP			10MG/0.8ML	A091316	004	Jul 11, 2011	Jan CDFR
>D>	AP		EUGIA PHARMA	2.5MG/0.5ML	A206918	001	Dec 26, 2017	Jan CDFR
>D>	AP			5MG/0.4ML	A206918	002	Dec 26, 2017	Jan CDFR
>D>	AP			7.5MG/0.6ML	A206918	003	Dec 26, 2017	Jan CDFR
>D>	AP			10MG/0.8ML	A206918	004	Dec 26, 2017	Jan CDFR
>D>		@	HANGZHOU ZHONGMEI	2.5MG/0.5ML	A216493	001	Aug 19, 2024	Jan CDFR
>D>		@		5MG/0.4ML	A216493	002	Aug 19, 2024	Jan CDFR
>D>		@		7.5MG/0.6ML	A216493	003	Aug 19, 2024	Jan CDFR
>D>		@		10MG/0.8ML	A216493	004	Aug 19, 2024	Jan CDFR
>D>	AP		HENGRUI PHARMA	2.5MG/0.5ML	A206812	001	May 15, 2018	Jan CDFR
>D>	AP			5MG/0.4ML	A206812	002	May 15, 2018	Jan CDFR
>D>	AP			7.5MG/0.6ML	A206812	003	May 15, 2018	Jan CDFR
>D>	AP			10MG/0.8ML	A206812	004	May 15, 2018	Jan CDFR
>D>	AP		SCINOPHARM TAIWAN	2.5MG/0.5ML	A208615	001	Nov 14, 2018	Jan CDFR
>D>	AP			5MG/0.4ML	A208615	002	Nov 14, 2018	Jan CDFR
>D>	AP			7.5MG/0.6ML	A208615	003	Nov 14, 2018	Jan CDFR
>D>	AP			10MG/0.8ML	A208615	004	Nov 14, 2018	Jan CDFR

>A> SOLUTION;SUBCUTANEOUS

>A> ARIXTRA

>A>	AP	+!	MYLAN IRELAND LTD	2.5MG/0.5ML	N021345	001	Dec 07, 2001	Jan CDFR
>A>	AP	+!		5MG/0.4ML	N021345	002	May 28, 2004	Jan CDFR
>A>	AP	+!		7.5MG/0.6ML	N021345	003	May 28, 2004	Jan CDFR
>A>	AP	+!		10MG/0.8ML	N021345	004	May 28, 2004	Jan CDFR

>A> FONDAPARINUX SODIUM

>A>		@	BRIGHTGENE	2.5MG/0.5ML	A218312	001	Dec 18, 2024	Jan CDFR
>A>	AP		DR REDDYS LABS LTD	2.5MG/0.5ML	A091316	001	Jul 11, 2011	Jan CDFR
>A>	AP			5MG/0.4ML	A091316	002	Jul 11, 2011	Jan CDFR
>A>	AP			7.5MG/0.6ML	A091316	003	Jul 11, 2011	Jan CDFR
>A>	AP			10MG/0.8ML	A091316	004	Jul 11, 2011	Jan CDFR
>A>	AP		EUGIA PHARMA	2.5MG/0.5ML	A206918	001	Dec 26, 2017	Jan CDFR
>A>	AP			5MG/0.4ML	A206918	002	Dec 26, 2017	Jan CDFR
>A>	AP			7.5MG/0.6ML	A206918	003	Dec 26, 2017	Jan CDFR
>A>	AP			10MG/0.8ML	A206918	004	Dec 26, 2017	Jan CDFR
>A>		@	HANGZHOU ZHONGMEI	2.5MG/0.5ML	A216493	001	Aug 19, 2024	Jan CDFR
>A>		@		5MG/0.4ML	A216493	002	Aug 19, 2024	Jan CDFR

>A>		SOLUTION;SUBCUTANEOUS						
>A>		FONDAPARINUX SODIUM						
>A>		@		7.5MG/0.6ML	A216493	003	Aug 19, 2024	Jan CDFR
>A>		@		10MG/0.8ML	A216493	004	Aug 19, 2024	Jan CDFR
>A>	AP		HENGRUI PHARMA	2.5MG/0.5ML	A206812	001	May 15, 2018	Jan CDFR
>A>	AP			5MG/0.4ML	A206812	002	May 15, 2018	Jan CDFR
>A>	AP			7.5MG/0.6ML	A206812	003	May 15, 2018	Jan CDFR
>A>	AP			10MG/0.8ML	A206812	004	May 15, 2018	Jan CDFR
>A>	AP		SCINOPHARM TAIWAN	2.5MG/0.5ML	A208615	001	Nov 14, 2018	Jan CDFR
>A>	AP			5MG/0.4ML	A208615	002	Nov 14, 2018	Jan CDFR
>A>	AP			7.5MG/0.6ML	A208615	003	Nov 14, 2018	Jan CDFR
>A>	AP			10MG/0.8ML	A208615	004	Nov 14, 2018	Jan CDFR
		FOSAPREPITANT DIMEGLUMINE						
		POWDER;INTRAVENOUS						
		FOSAPREPITANT DIMEGLUMINE						
>A>		@	CAPLIN	EQ 150MG BASE/VIAL	A203939	001	Dec 08, 2020	Jan CAHN
>D>		@	SANDOZ	EQ 150MG BASE/VIAL	A203939	001	Dec 08, 2020	Jan CAHN
		FUROSEMIDE						
		INJECTABLE;INJECTION						
		FUROSEMIDE						
>A>	AP		MICRO LABS	10MG/ML	A218188	001	Jan 08, 2026	Jan NEWA
		GALANTAMINE HYDROBROMIDE						
		TABLET;ORAL						
		GALANTAMINE HYDROBROMIDE						
>D>	AB		ANDA REPOSITORY	EQ 4MG BASE	A077593	001	Sep 11, 2008	Jan CAHN
>D>	AB			EQ 8MG BASE	A077593	002	Sep 11, 2008	Jan CAHN
>D>	AB			EQ 12MG BASE	A077593	003	Sep 11, 2008	Jan CAHN
>A>	AB		SENORES PHARMS	EQ 4MG BASE	A077593	001	Sep 11, 2008	Jan CAHN
>A>	AB			EQ 8MG BASE	A077593	002	Sep 11, 2008	Jan CAHN
>A>	AB			EQ 12MG BASE	A077593	003	Sep 11, 2008	Jan CAHN
		GEFITINIB						
		TABLET;ORAL						
		GEFITINIB						
>D>	AB		APOTEX	250MG	A209532	001	Sep 23, 2022	Jan DISC
>A>		@		250MG	A209532	001	Sep 23, 2022	Jan DISC
		GLATIRAMER ACETATE						
		INJECTABLE;SUBCUTANEOUS						
		GLATIRAMER ACETATE						
>A>	AP		HYBIO	20MG/ML	A213382	001	Feb 11, 2026	Jan NEWA
>A>	AP			40MG/ML	A214022	001	Feb 11, 2026	Jan NEWA
		GLIPIZIDE						
		TABLET;ORAL						
>A>		GLIPIZIDE						
>A>		!	RUBICON RESEARCH	15MG	A214874	004	Feb 04, 2026	Jan NFTG
		GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE						
		SOLUTION/DROPS;OPHTHALMIC						
>D>		NEOSPORIN						
>D>	AT	!	MONARCH PHARMS	0.025MG/ML;EQ 1.75MG BASE/ML;10,000 UNITS/ML	A060582	001		Jan DISC
>A>		@		0.025MG/ML;EQ 1.75MG BASE/ML;10,000 UNITS/ML	A060582	001		Jan DISC
		HYDRALAZINE HYDROCHLORIDE						
		TABLET;ORAL						
		HYDRALAZINE HYDROCHLORIDE						
>D>	AA		STRIDES PHARMA INTL	10MG	A087836	001	Oct 05, 1982	Jan DISC
>A>		@		10MG	A087836	001	Oct 05, 1982	Jan DISC
>D>	AA			25MG	A086961	002		Jan DISC
>A>		@		25MG	A086961	002		Jan DISC
>D>	AA			50MG	A086962	001		Jan DISC
>A>		@		50MG	A086962	001		Jan DISC
>D>	AA			100MG	A088391	001	Sep 27, 1983	Jan DISC
>A>		@		100MG	A088391	001	Sep 27, 1983	Jan DISC

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE;ORAL

HYDRA-ZIDE

>D>			STRIDES PHARMA INTL	25MG;25MG	A088957	001	Oct 21, 1985	Jan DISC
>A>		@		25MG;25MG	A088957	001	Oct 21, 1985	Jan DISC
>D>		!		50MG;50MG	A088946	001	Oct 21, 1985	Jan DISC
>A>		@		50MG;50MG	A088946	001	Oct 21, 1985	Jan DISC

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET;ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

>A>		@	STRIDES PHARMA INTL	15MG;250MG	A070614	002	Feb 02, 1987	Jan CMS1
>A>		@		25MG;250MG	A070614	003	Feb 02, 1987	Jan CMS1
>A>		@		30MG;500MG	A070614	004	Feb 02, 1987	Jan CMS1

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE;INJECTION

HYDROCORTISONE SODIUM SUCCINATE

>A>	AP		APOTEX	EQ 100MG BASE/VIAL	A219856	001	Feb 05, 2026	Jan NEWA

HYDROXYCHLOROQUINE SULFATE

TABLET;ORAL

HYDROXYCHLOROQUINE SULFATE

>D>	AB		ANDA REPOSITORY	200MG	A212902	001	May 14, 2020	Jan CAHN
>A>	AB		SENORES PHARMS	200MG	A212902	001	May 14, 2020	Jan CAHN

ISOSULFAN BLUE

SOLUTION;SUBCUTANEOUS

ISOSULFAN BLUE

>A>		!	MYLAN INSTITUTIONAL	10MG/ML (10MG/ML)	A090874	002	Jan 28, 2026	Jan NFTG
>A>		!		30MG/3ML (10MG/ML)	A090874	003	Jan 28, 2026	Jan NFTG

IVABRADINE HYDROCHLORIDE

TABLET;ORAL

>D>			CORLANOR					
>D>	AB	+	AMGEN INC	EQ 5MG BASE	N206143	001	Apr 15, 2015	Jan DISC
>A>		@ +		EQ 5MG BASE	N206143	001	Apr 15, 2015	Jan DISC
>D>	AB	+!		EQ 7.5MG BASE	N206143	002	Apr 15, 2015	Jan DISC
>A>		@ +		EQ 7.5MG BASE	N206143	002	Apr 15, 2015	Jan DISC

IVABRADINE HYDROCHLORIDE

>D>	AB		INGENUS PHARMS LLC	EQ 7.5MG BASE	A214051	002	Dec 30, 2021	Jan CHRS
>A>	AB	!		EQ 7.5MG BASE	A214051	002	Dec 30, 2021	Jan CHRS

KETOCONAZOLE

CREAM;TOPICAL

KETOCONAZOLE

>D>	AB		PADAGIS US	2%	A215185	001	Nov 17, 2021	Jan DISC
>A>		@		2%	A215185	001	Nov 17, 2021	Jan DISC

LACOSAMIDE

SOLUTION;INTRAVENOUS

LACOSAMIDE

>A>	AP		ANTHEA PHARMA	200MG/20ML (10MG/ML)	A220268	001	Jan 21, 2026	Jan NEWA

SOLUTION;ORAL

LACOSAMIDE

>A>	AA		INDOCO	10MG/ML	A220386	001	Jan 29, 2026	Jan NEWA
>A>	AA		REGCON HOLDINGS	10MG/ML	A220386	001	Jan 29, 2026	Jan CAHN

LAMIVUDINE

TABLET;ORAL

LAMIVUDINE

>D>	AB		LUPIN LTD	150MG	A205217	001	Dec 18, 2014	Jan DISC
>A>		@		150MG	A205217	001	Dec 18, 2014	Jan DISC
>D>	AB			300MG	A205217	002	Dec 18, 2014	Jan DISC
>A>		@		300MG	A205217	002	Dec 18, 2014	Jan DISC

LAMOTRIGINE

TABLET, ORALLY DISINTEGRATING;ORAL

LAMOTRIGINE

>A>	AB		TORRENT	25MG	A217100	001	Jan 08, 2026	Jan NEWA
>A>	AB			50MG	A217100	002	Jan 08, 2026	Jan NEWA
>A>	AB			100MG	A217100	003	Jan 08, 2026	Jan NEWA
>A>	AB			200MG	A217100	004	Jan 08, 2026	Jan NEWA

LENALIDOMIDE

CAPSULE;ORAL

LENALIDOMIDE

>A>	AB		ALVOGEN	2.5MG	A210480	005	Mar 06, 2023	Jan CAHN
>A>	AB			5MG	A210480	001	Aug 31, 2022	Jan CAHN
>A>	AB			10MG	A210480	002	Aug 31, 2022	Jan CAHN
>A>	AB			15MG	A210480	003	Aug 31, 2022	Jan CAHN
>A>	AB			20MG	A210480	006	Mar 06, 2023	Jan CAHN
>A>	AB			25MG	A210480	004	Aug 31, 2022	Jan CAHN
>A>	AB		CIPLA	5MG	A213165	001	Feb 02, 2026	Jan NEWA
>A>	AB			10MG	A213165	002	Feb 02, 2026	Jan NEWA
>A>	AB			15MG	A213165	003	Feb 02, 2026	Jan NEWA
>A>	AB			20MG	A213165	004	Feb 02, 2026	Jan NEWA
>A>	AB			25MG	A213165	005	Feb 02, 2026	Jan NEWA
>D>	AB		LOTUS PHARM CO LTD	2.5MG	A210480	005	Mar 06, 2023	Jan CAHN
>D>	AB			5MG	A210480	001	Aug 31, 2022	Jan CAHN
>D>	AB			10MG	A210480	002	Aug 31, 2022	Jan CAHN
>D>	AB			15MG	A210480	003	Aug 31, 2022	Jan CAHN
>D>	AB			20MG	A210480	006	Mar 06, 2023	Jan CAHN
>D>	AB			25MG	A210480	004	Aug 31, 2022	Jan CAHN
>A>	AB		TORRENT	2.5MG	A213405	005	Feb 10, 2026	Jan NEWA
>A>	AB			5MG	A213405	006	Feb 10, 2026	Jan NEWA

LEUPROLIDE MESYLATE

EMULSION;SUBCUTANEOUS

CAMCEVI ETM

>A>		+!	ACCORD	EQ 21MG BASE	N219745	001	Aug 25, 2025	Jan CAHN
>D>		+!	FORESEE PHARMS	EQ 21MG BASE	N219745	001	Aug 25, 2025	Jan CAHN

LEVETIRACETAM

TABLET;ORAL

LEVETIRACETAM

>D>	AB		ANDA REPOSITORY	250MG	A076920	001	Jan 15, 2009	Jan CAHN
>D>	AB			500MG	A076920	002	Jan 15, 2009	Jan CAHN
>D>	AB			750MG	A076920	003	Jan 15, 2009	Jan CAHN
>D>	AB			1GM	A078904	001	Jan 15, 2009	Jan CAHN
>A>	AB		SENORES PHARMS	250MG	A076920	001	Jan 15, 2009	Jan CAHN
>A>	AB			500MG	A076920	002	Jan 15, 2009	Jan CAHN
>A>	AB			750MG	A076920	003	Jan 15, 2009	Jan CAHN
>A>	AB			1GM	A078904	001	Jan 15, 2009	Jan CAHN

LIDOCAINE

PATCH;TOPICAL

LIDOCAINE

>A>	AB		USPHARMA	5%	A207059	001	Feb 09, 2026	Jan NEWA

LIDOCAINE HYDROCHLORIDE

INJECTABLE;INJECTION

LIDOCAINE HYDROCHLORIDE

>A>	AP		ANTHEA PHARMA	2%	A219535	002	Feb 06, 2026	Jan NEWA

LIRAGLUTIDE

SOLUTION;SUBCUTANEOUS

LIRAGLUTIDE

>A>	AP1		ORBICULAR	18MG/3ML (6MG/ML)	A217590	001	Jan 14, 2026	Jan NEWA

LUBIPROSTONE

CAPSULE;ORAL

LUBIPROSTONE

>D>		@	AMNEAL	8MCG	A209450	001	Nov 30, 2021	Jan CMFD
>A>	AB			8MCG	A209450	001	Nov 30, 2021	Jan CMFD
>D>		@		24MCG	A209450	002	Nov 30, 2021	Jan CMFD
>A>	AB			24MCG	A209450	002	Nov 30, 2021	Jan CMFD

MACIMORELIN ACETATE

FOR SOLUTION;ORAL

MACRILEN

>A>		@ +	AETERNA ZENTARIS	EQ 60MG BASE/POUCH	N205598	001	Dec 20, 2017	Jan CAHN
>D>		@ +	NOVO	EQ 60MG BASE/POUCH	N205598	001	Dec 20, 2017	Jan CAHN

MAGNESIUM SULFATE

INJECTABLE;INJECTION

>A> MAGNESIUM SULFATE

>A>		!	BAXTER HLTHCARE CORP	3GM/100ML (30MG/ML)	A211966	004	Jan 08, 2026	Jan NFTG

MEPIVACAINE HYDROCHLORIDE

INJECTABLE;INJECTION

POLOCAINE

>D>			FRESENIUS KABI USA	1%	A089407	001	Dec 01, 1986	Jan CHRS
>A>		!		1%	A089407	001	Dec 01, 1986	Jan CHRS
>D>				2%	A089410	001	Dec 01, 1986	Jan CHRS
>A>		!		2%	A089410	001	Dec 01, 1986	Jan CHRS

POLOCAINE-MPF

>D>			FRESENIUS KABI USA	1%	A089406	001	Dec 01, 1986	Jan CHRS
>A>		!		1%	A089406	001	Dec 01, 1986	Jan CHRS
>D>				1.5%	A089408	001	Dec 01, 1986	Jan CHRS
>A>		!		1.5%	A089408	001	Dec 01, 1986	Jan CHRS
>D>				2%	A089409	001	Dec 01, 1986	Jan CHRS
>A>		!		2%	A089409	001	Dec 01, 1986	Jan CHRS

MESNA

INJECTABLE;INTRAVENOUS

MESNA

>A>	AP		EUGIA PHARMA	100MG/ML	A220518	001	Jan 27, 2026	Jan NEWA

METFORMIN HYDROCHLORIDE

TABLET;ORAL

METFORMIN HYDROCHLORIDE

>D>			CHARTWELL	625MG	A075972	005	Jan 24, 2002	Jan CTEC
>A>	AB			625MG	A075972	005	Jan 24, 2002	Jan CTEC
>D>				750MG	A075972	004	Jan 24, 2002	Jan CTEC
>A>	AB			750MG	A075972	004	Jan 24, 2002	Jan CTEC
>A>	AB		SCIEGEN PHARMS	625MG	A203769	004	Feb 09, 2026	Jan NEWA
>A>	AB			750MG	A203769	005	Feb 09, 2026	Jan NEWA

TABLET, EXTENDED RELEASE;ORAL

METFORMIN HYDROCHLORIDE

>D>	AB3		RK PHARMA	500MG	A215629	001	Jun 20, 2023	Jan DISC
>A>		@		500MG	A215629	001	Jun 20, 2023	Jan DISC
>D>	AB3			1GM	A215629	002	Jun 20, 2023	Jan DISC
>A>		@		1GM	A215629	002	Jun 20, 2023	Jan DISC

METHAZOLAMIDE

TABLET;ORAL

METHAZOLAMIDE

>A>	AB		AJANTA PHARMA LTD	25MG	A217408	001	Feb 09, 2026	Jan NEWA
>A>	AB			50MG	A217408	002	Feb 09, 2026	Jan NEWA

METHOTREXATE SODIUM

INJECTABLE;INJECTION

METHOTREXATE SODIUM PRESERVATIVE FREE

>A>	AP		CAPLIN ONE LABS	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A090039	001	Mar 31, 2009	Jan CAHN
>A>	AP			EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A090039	002	Mar 31, 2009	Jan CAHN
>A>	AP			EQ 1GM BASE/40ML (EQ 25MG BASE/ML)	A090029	001	Mar 31, 2009	Jan CAHN
>D>	AP		SANDOZ	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A090039	001	Mar 31, 2009	Jan CAHN
>D>	AP			EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A090039	002	Mar 31, 2009	Jan CAHN
>D>	AP			EQ 1GM BASE/40ML (EQ 25MG BASE/ML)	A090029	001	Mar 31, 2009	Jan CAHN

METHYLENE BLUE
SOLUTION;INTRAVENOUS
METHYLENE BLUE

>A>		!	ZYDUS LIFESCIENCES	5MG/ML (5MG/ML)	A215636	003	Feb 02, 2026	Jan NFTG

METHYLPREDNISOLONE ACETATE
INJECTABLE;INJECTION
METHYLPREDNISOLONE ACETATE

>A>	AB		CAPLIN	40MG/ML	A220556	001	Jan 26, 2026	Jan NEWA
>A>	AB			80MG/ML	A220556	002	Jan 26, 2026	Jan NEWA

METOCLOPRAMIDE HYDROCHLORIDE
TABLET;ORAL
METOCLOPRAMIDE HYDROCHLORIDE

>D>	AB		STRIDES PHARMA INTL	EQ 10MG BASE	A070581	001	Oct 17, 1985	Jan DISC
>A>		@		EQ 10MG BASE	A070581	001	Oct 17, 1985	Jan DISC

METRONIDAZOLE
INJECTABLE;INJECTION
METRO I.V. IN PLASTIC CONTAINER

>D>	AP	+!	B BRAUN	500MG/100ML	N018900	001	Sep 29, 1983	Jan DISC
>A>		@ +		500MG/100ML	N018900	001	Sep 29, 1983	Jan DISC

METRONIDAZOLE IN PLASTIC CONTAINER

>D>	AP		INFORLIFE	500MG/100ML	A206191	001	Feb 25, 2019	Jan CHRS
>A>	AP	!		500MG/100ML	A206191	001	Feb 25, 2019	Jan CHRS

MICAFUNGIN SODIUM
INJECTABLE;INTRAVENOUS
MICAFUNGIN SODIUM

>A>	AP		HISUN PHARM HANGZHOU	EQ 50MG BASE/VIAL	A219712	001	Jan 21, 2026	Jan NEWA
>A>	AP			EQ 100MG BASE/VIAL	A219712	002	Jan 21, 2026	Jan NEWA

MILNACIPRAN HYDROCHLORIDE
TABLET;ORAL
MILNACIPRAN HYDROCHLORIDE

>D>		@	AMNEAL PHARMS	12.5MG	A205081	001	Apr 22, 2016	Jan CMFD
>A>	AB			12.5MG	A205081	001	Apr 22, 2016	Jan CMFD
>D>		@		25MG	A205081	002	Apr 22, 2016	Jan CMFD
>A>	AB			25MG	A205081	002	Apr 22, 2016	Jan CMFD
>D>		@		50MG	A205081	003	Apr 22, 2016	Jan CMFD
>A>	AB			50MG	A205081	003	Apr 22, 2016	Jan CMFD
>D>		@		100MG	A205081	004	Apr 22, 2016	Jan CMFD
>A>	AB			100MG	A205081	004	Apr 22, 2016	Jan CMFD
>D>		@	BRECKENRIDGE	12.5MG	A205071	001	Jan 27, 2016	Jan CMFD
>A>	AB			12.5MG	A205071	001	Jan 27, 2016	Jan CMFD
>D>		@		25MG	A205071	002	Jan 27, 2016	Jan CMFD
>A>	AB			25MG	A205071	002	Jan 27, 2016	Jan CMFD
>D>		@		50MG	A205071	003	Jan 27, 2016	Jan CMFD
>A>	AB			50MG	A205071	003	Jan 27, 2016	Jan CMFD
>D>		@		100MG	A205071	004	Jan 27, 2016	Jan CMFD
>A>	AB			100MG	A205071	004	Jan 27, 2016	Jan CMFD

SAVELLA

>D>		+	ABBVIE	12.5MG	N022256	001	Jan 14, 2009	Jan CTEC
>A>	AB	+		12.5MG	N022256	001	Jan 14, 2009	Jan CTEC
>D>		+		25MG	N022256	002	Jan 14, 2009	Jan CTEC
>A>	AB	+		25MG	N022256	002	Jan 14, 2009	Jan CTEC
>D>		+!		50MG	N022256	003	Jan 14, 2009	Jan CTEC
>A>	AB	+!		50MG	N022256	003	Jan 14, 2009	Jan CTEC
>D>		+		100MG	N022256	004	Jan 14, 2009	Jan CTEC
>A>	AB	+		100MG	N022256	004	Jan 14, 2009	Jan CTEC

MIRABEGRON
FOR SUSPENSION, EXTENDED RELEASE;ORAL
MIRABEGRON

>A>								
>A>	AB		ALKEM LABS LTD	8MG/ML	A219323	001	Jan 20, 2026	Jan NFTG

MYRBETRIQ GRANULES

>D>		+!	APGDI	8MG/ML	N213801	001	Mar 25, 2021	Jan CFTG
>A>	AB	+!		8MG/ML	N213801	001	Mar 25, 2021	Jan CFTG

MIRTAZAPINE

TABLET;ORAL

MIRTAZAPINE

>A>	AB		NOVITIUM PHARMA	7.5MG	A219919	001	Feb 02, 2026	Jan NEWA
>A>	AB			15MG	A219919	002	Feb 02, 2026	Jan NEWA
>A>	AB			30MG	A219919	003	Feb 02, 2026	Jan NEWA
>A>	AB			45MG	A219919	004	Feb 02, 2026	Jan NEWA

MITAPIVAT SULFATE

TABLET;ORAL

AQVESME

>A>		+!	AGIOS PHARMS INC	EQ 100MG BASE	N216196	004	Dec 23, 2025	Jan NEWA

MONTELUKAST SODIUM

TABLET, CHEWABLE;ORAL

MONTELUKAST SODIUM

>D>	AB		ANDA REPOSITORY	EQ 4MG BASE	A201581	001	Aug 06, 2012	Jan CAHN
>D>	AB			EQ 5MG BASE	A201581	002	Aug 06, 2012	Jan CAHN
>A>	AB		SENORES PHARMS	EQ 4MG BASE	A201581	001	Aug 06, 2012	Jan CAHN
>A>	AB			EQ 5MG BASE	A201581	002	Aug 06, 2012	Jan CAHN

MORPHINE SULFATE

TABLET, EXTENDED RELEASE;ORAL

MORPHINE SULFATE

>D>	AB		STRIDES PHARMA INTL	15MG	A075295	001	Oct 28, 1998	Jan DISC
>A>		@		15MG	A075295	001	Oct 28, 1998	Jan DISC
>D>	AB			30MG	A075295	002	Oct 28, 1998	Jan DISC
>A>		@		30MG	A075295	002	Oct 28, 1998	Jan DISC
>D>	AB			60MG	A075295	003	Oct 28, 1998	Jan DISC
>A>		@		60MG	A075295	003	Oct 28, 1998	Jan DISC
>D>	AB			100MG	A075295	004	Sep 15, 2000	Jan DISC
>A>		@		100MG	A075295	004	Sep 15, 2000	Jan DISC
>D>	AB			200MG	A075295	005	Sep 15, 2000	Jan DISC
>A>		@		200MG	A075295	005	Sep 15, 2000	Jan DISC

MYCOPHENOLATE SODIUM

TABLET, DELAYED RELEASE;ORAL

MYCOPHENOLATE SODIUM

>D>	AB		RK PHARMA	EQ 180MG BASE	A091248	002	Jan 08, 2014	Jan DISC
>A>		@		EQ 180MG BASE	A091248	002	Jan 08, 2014	Jan DISC
>D>	AB			EQ 360MG BASE	A091248	001	Jan 08, 2014	Jan DISC
>A>		@		EQ 360MG BASE	A091248	001	Jan 08, 2014	Jan DISC

NABUMETONE

TABLET;ORAL

NABUMETONE

>D>			LGM PHARMA	1GM	A203166	003	Aug 30, 2019	Jan CHRS
>A>		!		1GM	A203166	003	Aug 30, 2019	Jan CHRS

NALOXONE HYDROCHLORIDE

SPRAY;NASAL

REZENOPY

>D>		@ +	SCIENTURE	10MG/SPRAY	N215487	001	Apr 19, 2024	Jan CMFD
>A>		+!		10MG/SPRAY	N215487	001	Apr 19, 2024	Jan CMFD

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION;IRRIGATION

NEOMYCIN AND POLYMYXIN B SULFATE

>D>	AT		WATSON LABS	EQ 40MG BASE/ML;200,000 UNITS/ML	A062664	001	Apr 08, 1986	Jan DISC
>A>		@		EQ 40MG BASE/ML;200,000 UNITS/ML	A062664	001	Apr 08, 1986	Jan DISC
>D>	AT		XGEN PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	A065106	001	Jan 31, 2006	Jan CHRS
>A>	AT	!		EQ 40MG BASE/ML;200,000 UNITS/ML	A065106	001	Jan 31, 2006	Jan CHRS
>A>		!		EQ 40MG BASE/ML;200,000 UNITS/ML	A065106	001	Jan 31, 2006	Jan CTEC
>D>	AT			EQ 40MG BASE/ML;200,000 UNITS/ML	A065108	001	Jan 31, 2006	Jan CHRS
>A>	AT	!		EQ 40MG BASE/ML;200,000 UNITS/ML	A065108	001	Jan 31, 2006	Jan CHRS
>A>		!		EQ 40MG BASE/ML;200,000	A065108	001	Jan 31, 2006	Jan CTEC

		SOLUTION;IRRIGATION						
		NEOMYCIN AND POLYMYXIN B SULFATE						
			UNITS/ML					
>D>		NEOSPORIN G.U. IRRIGANT						
>D>	AT	! MONARCH PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	A060707	001			Jan DISC
>A>		@	EQ 40MG BASE/ML;200,000 UNITS/ML	A060707	001			Jan DISC
		NICARDIPINE HYDROCHLORIDE						
		CAPSULE;ORAL						
		NICARDIPINE HYDROCHLORIDE						
>D>	AB	ANDA REPOSITORY	20MG	A215377	001	Jul 17, 2023	Jan CAHN	
>D>	AB		30MG	A215377	002	Jul 17, 2023	Jan CAHN	
>A>	AB	SENORES PHARMS	20MG	A215377	001	Jul 17, 2023	Jan CAHN	
>A>	AB		30MG	A215377	002	Jul 17, 2023	Jan CAHN	
		INJECTABLE;INJECTION						
		CARDENE						
>D>		@ + CHIESI	25MG/10ML (2.5MG/ML)	N019734	001	Jan 30, 1992	Jan CMFD	
>A>	AP	+	25MG/10ML (2.5MG/ML)	N019734	001	Jan 30, 1992	Jan CMFD	
		NICARDIPINE HYDROCHLORIDE						
>D>	AP	RK PHARMA	25MG/10ML (2.5MG/ML)	A090664	001	Nov 17, 2009	Jan CAHN	
>A>	AP	SOMERSET THERAPS LLC	25MG/10ML (2.5MG/ML)	A090664	001	Nov 17, 2009	Jan CAHN	
		NITROGLYCERIN						
		FILM, EXTENDED RELEASE;TRANSDERMAL						
		NITRO-DUR						
>D>		+! USPHARMA	0.1MG/HR	N020145	001	Apr 04, 1995	Jan CHRS	
>A>		+	0.1MG/HR	N020145	001	Apr 04, 1995	Jan CHRS	
>D>		+!	0.2MG/HR	N020145	002	Apr 04, 1995	Jan CHRS	
>A>		+	0.2MG/HR	N020145	002	Apr 04, 1995	Jan CHRS	
>D>		+!	0.3MG/HR	N020145	003	Apr 04, 1995	Jan CHRS	
>A>		+	0.3MG/HR	N020145	003	Apr 04, 1995	Jan CHRS	
>D>		+!	0.6MG/HR	N020145	005	Apr 04, 1995	Jan CHRS	
>A>		+	0.6MG/HR	N020145	005	Apr 04, 1995	Jan CHRS	
>D>		+!	0.8MG/HR	N020145	006	Apr 04, 1995	Jan CHRS	
>A>		+	0.8MG/HR	N020145	006	Apr 04, 1995	Jan CHRS	
		NITROGLYCERIN						
>D>	AB2	! MYLAN TECHNOLOGIES	0.1MG/HR	A074559	004	Feb 06, 1998	Jan CHRS	
>A>	AB2		0.1MG/HR	A074559	004	Feb 06, 1998	Jan CHRS	
>D>	AB2	!	0.2MG/HR	A074559	003	Aug 30, 1996	Jan CHRS	
>A>	AB2		0.2MG/HR	A074559	003	Aug 30, 1996	Jan CHRS	
>D>	AB2	!	0.6MG/HR	A074559	001	Aug 30, 1996	Jan CHRS	
>A>	AB2		0.6MG/HR	A074559	001	Aug 30, 1996	Jan CHRS	
		NYSTATIN						
		SUSPENSION;ORAL						
		NYSTATIN						
>D>	AA	MLV	100,000 UNITS/ML	A062832	001	Dec 27, 1991	Jan CAHN	
>A>	AA	SCIEGEN PHARMS	100,000 UNITS/ML	A062832	001	Dec 27, 1991	Jan CAHN	
>A>	AA	STERANCO HLTHCARE	100,000 UNITS/ML	A220367	001	Feb 05, 2026	Jan NEWA	
		OLANZAPINE						
>D>		INJECTABLE;INTRAMUSCULAR						
>D>		OLANZAPINE						
>D>	AP	AM REGENT	10MG/VIAL	A201741	001	Mar 20, 2012	Jan CDFR	
>D>	AP	ASPIRO	10MG/VIAL	A217466	001	Mar 22, 2023	Jan CDFR	
>D>	AP	EUGIA PHARMA	10MG/VIAL	A210968	001	Oct 22, 2020	Jan CDFR	
>D>	AP	QILU	10MG/VIAL	A218116	001	May 16, 2025	Jan CDFR	
>D>	AP	SANDOZ INC	10MG/VIAL	A201588	001	Oct 24, 2011	Jan CDFR	
>D>	AP	UBI	10MG/VIAL	A211072	001	Jun 11, 2025	Jan CDFR	
>D>		ZYPREXA						
>D>	AP	+! CHEPLAPHARM	10MG/VIAL	N021253	001	Mar 29, 2004	Jan CDFR	
>A>		POWDER;INTRAMUSCULAR						
>A>		OLANZAPINE						
>A>	AP	AM REGENT	10MG/VIAL	A201741	001	Mar 20, 2012	Jan CDFR	
>A>	AP	ASPIRO	10MG/VIAL	A217466	001	Mar 22, 2023	Jan CDFR	
>A>	AP	EUGIA PHARMA	10MG/VIAL	A210968	001	Oct 22, 2020	Jan CDFR	
>A>	AP	OMNIVIUM PHARMS	10MG/VIAL	A219048	001	Jan 23, 2026	Jan NEWA	
>A>	AP	QILU	10MG/VIAL	A218116	001	May 16, 2025	Jan CDFR	
>A>	AP	SANDOZ INC	10MG/VIAL	A201588	001	Oct 24, 2011	Jan CDFR	
>A>	AP	UBI	10MG/VIAL	A211072	001	Jun 11, 2025	Jan CDFR	

>A>		POWDER;INTRAMUSCULAR						
>A>		ZYPREXA						
>A>	AP	+! CHEPLAPHARM	10MG/VIAL	N021253	001	Mar 29, 2004	Jan	CDFR
		TABLET;ORAL						
		OLANZAPINE						
>D>		@ TORRENT PHARMS LTD	2.5MG	A091434	001	Apr 23, 2012	Jan	CMFD
>A>	AB		2.5MG	A091434	001	Apr 23, 2012	Jan	CMFD
>D>		@	5MG	A091434	002	Apr 23, 2012	Jan	CMFD
>A>	AB		5MG	A091434	002	Apr 23, 2012	Jan	CMFD
>D>		@	7.5MG	A091434	003	Apr 23, 2012	Jan	CMFD
>A>	AB		7.5MG	A091434	003	Apr 23, 2012	Jan	CMFD
>D>		@	10MG	A091434	004	Apr 23, 2012	Jan	CMFD
>A>	AB		10MG	A091434	004	Apr 23, 2012	Jan	CMFD
>D>		@	15MG	A091434	005	Apr 23, 2012	Jan	CMFD
>A>	AB		15MG	A091434	005	Apr 23, 2012	Jan	CMFD
>D>		@	20MG	A091434	006	Apr 23, 2012	Jan	CMFD
>A>	AB		20MG	A091434	006	Apr 23, 2012	Jan	CMFD
		OSELTAMIVIR PHOSPHATE						
		CAPSULE;ORAL						
		OSELTAMIVIR PHOSPHATE						
>A>	AB	UPSHER SMITH LABS	EQ 30MG BASE	A213437	001	Jan 22, 2026	Jan	NEWA
>A>	AB		EQ 45MG BASE	A213437	002	Jan 22, 2026	Jan	NEWA
>A>	AB		EQ 75MG BASE	A213437	003	Jan 22, 2026	Jan	NEWA
		OXALIPLATIN						
		INJECTABLE;INTRAVENOUS						
		OXALIPLATIN						
>A>	AP	SHANDONG	50MG/10ML (5MG/ML)	A219765	001	Jan 15, 2026	Jan	NEWA
>A>	AP		100MG/20ML (5MG/ML)	A219765	002	Jan 15, 2026	Jan	NEWA
		OXYBUTYNIN CHLORIDE						
		TABLET;ORAL						
		OXYBUTYNIN CHLORIDE						
>D>	AB	NOVITIUM PHARMA	5MG	A209823	001	Oct 23, 2017	Jan	CHRS
>A>	AB	!	5MG	A209823	001	Oct 23, 2017	Jan	CHRS
>D>	AB	! STRIDES PHARMA INTL	5MG	A075079	001	Oct 31, 1997	Jan	CHRS
>A>	AB		5MG	A075079	001	Oct 31, 1997	Jan	CHRS
		TABLET, EXTENDED RELEASE;ORAL						
		OXYBUTYNIN CHLORIDE						
>D>	AB	! ACCORD HLTHCARE	15MG	A207138	003	Feb 29, 2016	Jan	CHRS
>A>	AB		15MG	A207138	003	Feb 29, 2016	Jan	CHRS
>D>	AB	ZYDUS PHARMS	15MG	A202332	003	Jun 26, 2017	Jan	CHRS
>A>	AB	!	15MG	A202332	003	Jun 26, 2017	Jan	CHRS
		OZENOXACIN						
		CREAM;TOPICAL						
		XEPI						
>D>		@ + FERRER INTERNACIONAL	1%	N208945	001	Dec 11, 2017	Jan	CAHN
>A>		@ + LNHC	1%	N208945	001	Dec 11, 2017	Jan	CAHN
		PALIPERIDONE						
		TABLET, EXTENDED RELEASE;ORAL						
		PALIPERIDONE						
>A>	AB	APOTEX	3MG	A203279	001	Jan 26, 2026	Jan	NEWA
>A>	AB		6MG	A203279	002	Jan 26, 2026	Jan	NEWA
>A>	AB		9MG	A203279	003	Jan 26, 2026	Jan	NEWA
>D>	AB	RK PHARMA	1.5MG	A203802	001	Sep 24, 2015	Jan	DISC
>A>		@	1.5MG	A203802	001	Sep 24, 2015	Jan	DISC
>D>	AB		3MG	A203802	002	Sep 24, 2015	Jan	DISC
>A>		@	3MG	A203802	002	Sep 24, 2015	Jan	DISC
>D>	AB		6MG	A203802	003	Sep 24, 2015	Jan	DISC
>A>		@	6MG	A203802	003	Sep 24, 2015	Jan	DISC
>D>	AB		9MG	A203802	004	Sep 24, 2015	Jan	DISC
>A>		@	9MG	A203802	004	Sep 24, 2015	Jan	DISC
		PALIPERIDONE PALMITATE						
		SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR						
		INVEGA HAFYERA						
>D>		+ JANSSEN PHARMS	1.092GM/3.5ML (312MG/ML)	N207946	005	Aug 30, 2021	Jan	CHRS
>A>		+!	1.092GM/3.5ML (312MG/ML)	N207946	005	Aug 30, 2021	Jan	CHRS
>D>		+	1.560GM/5ML (312MG/ML)	N207946	006	Aug 30, 2021	Jan	CHRS

SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR
INVEGA HAFYERA

>A>		+!		1.560GM/5ML (312MG/ML)	N207946	006	Aug 30, 2021	Jan CHRS

PANTOPRAZOLE SODIUM

INJECTABLE;INTRAVENOUS
PANTOPRAZOLE SODIUM

>D>		@	NORVIUM BIOSCIENCE	EQ 40MG BASE/VIAL	A208580	001	May 04, 2018	Jan CAHN
>A>		@	PHARMOBEDIENT	EQ 40MG BASE/VIAL	A208580	001	May 04, 2018	Jan CAHN

PARICALCITOL

SOLUTION;INTRAVENOUS
PARICALCITOL

>D>	AP		EUGIA PHARMA	0.002MG/ML (0.002MG/ML)	A205982	001	Oct 09, 2018	Jan DISC
>A>		@		0.002MG/ML (0.002MG/ML)	A205982	001	Oct 09, 2018	Jan DISC
>D>	AP			0.005MG/ML (0.005MG/ML)	A205982	002	Oct 09, 2018	Jan DISC
>A>		@		0.005MG/ML (0.005MG/ML)	A205982	002	Oct 09, 2018	Jan DISC
>D>	AP			0.01MG/2ML (0.005MG/ML)	A205982	003	Oct 09, 2018	Jan DISC
>A>		@		0.01MG/2ML (0.005MG/ML)	A205982	003	Oct 09, 2018	Jan DISC

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION;INTRAVENOUS
PHENYLEPHRINE HYDROCHLORIDE

>D>		@	HAINAN POLY	10MG/ML (10MG/ML)	A218412	001	Mar 14, 2024	Jan CMFD
>A>	AP1			10MG/ML (10MG/ML)	A218412	001	Mar 14, 2024	Jan CMFD
>D>		@		50MG/5ML (10MG/ML)	A218412	002	Mar 14, 2024	Jan CMFD
>A>	AP1			50MG/5ML (10MG/ML)	A218412	002	Mar 14, 2024	Jan CMFD
>D>		@		100MG/10ML (10MG/ML)	A218412	003	Mar 14, 2024	Jan CMFD
>A>	AP1			100MG/10ML (10MG/ML)	A218412	003	Mar 14, 2024	Jan CMFD

PHYTONADIONE

INJECTABLE;INJECTION
PHYTONADIONE

>A>	AB1		SUNNY	10MG/ML	A215090	001	Jan 09, 2026	Jan NEWA

PILOCARPINE HYDROCHLORIDE

TABLET;ORAL
PILOCARPINE HYDROCHLORIDE

>D>	AB		AUROBINDO PHARMA LTD	5MG	A212377	001	Aug 13, 2019	Jan CAHN
>D>	AB			7.5MG	A212377	002	Aug 13, 2019	Jan CAHN
>A>	AB		AUROBINDO PHARMA USA	5MG	A212377	001	Aug 13, 2019	Jan CAHN
>A>	AB			7.5MG	A212377	002	Aug 13, 2019	Jan CAHN

PIVMECILLINAM HYDROCHLORIDE

TABLET;ORAL
PIVYA

>A>		+!	ALEMBIC THERAP	EQ 185MG BASE	N216483	001	Apr 24, 2024	Jan CAHN
>D>		+!	UTILITY THERAP	EQ 185MG BASE	N216483	001	Apr 24, 2024	Jan CAHN

PODOFILOX

GEL;TOPICAL
CONDYLOX

>D>	AB	+!	ALLERGAN	0.5%	N020529	001	Mar 13, 1997	Jan DISC
>A>		@ +		0.5%	N020529	001	Mar 13, 1997	Jan DISC

PODOFILOX

>D>	AB		PADAGIS US	0.5%	A211871	001	Nov 22, 2023	Jan CTEC
>A>				0.5%	A211871	001	Nov 22, 2023	Jan CTEC
>A>		!		0.5%	A211871	001	Nov 22, 2023	Jan CHRS

POMALIDOMIDE

CAPSULE;ORAL
POMALIDOMIDE

>D>		@	APOTEX	1MG	A210164	001	Jun 11, 2024	Jan CMFD
>A>	AB			1MG	A210164	001	Jun 11, 2024	Jan CMFD
>D>		@		2MG	A210164	002	Jun 11, 2024	Jan CMFD
>A>	AB			2MG	A210164	002	Jun 11, 2024	Jan CMFD
>D>		@		3MG	A210164	003	Jun 11, 2024	Jan CMFD
>A>	AB			3MG	A210164	003	Jun 11, 2024	Jan CMFD
>D>		@		4MG	A210164	004	Jun 11, 2024	Jan CMFD
>A>	AB			4MG	A210164	004	Jun 11, 2024	Jan CMFD
>D>		@	BRECKENRIDGE	1MG	A210111	001	Oct 30, 2020	Jan CMFD
>A>	AB			1MG	A210111	001	Oct 30, 2020	Jan CMFD

CAPSULE;ORAL
POMALIDOMIDE

>D>		@		2MG	A210111	002	Oct 30, 2020	Jan CMFD
>A>	AB			2MG	A210111	002	Oct 30, 2020	Jan CMFD
>D>		@		3MG	A210111	003	Oct 30, 2020	Jan CMFD
>A>	AB			3MG	A210111	003	Oct 30, 2020	Jan CMFD
>D>		@		4MG	A210111	004	Oct 30, 2020	Jan CMFD
>A>	AB			4MG	A210111	004	Oct 30, 2020	Jan CMFD
>D>		@	EUGIA PHARMA	1MG	A210249	001	Oct 30, 2020	Jan CMFD
>A>	AB			1MG	A210249	001	Oct 30, 2020	Jan CMFD
>D>		@		2MG	A210249	002	Oct 30, 2020	Jan CMFD
>A>	AB			2MG	A210249	002	Oct 30, 2020	Jan CMFD
>D>		@		3MG	A210249	003	Oct 30, 2020	Jan CMFD
>A>	AB			3MG	A210249	003	Oct 30, 2020	Jan CMFD
>D>		@		4MG	A210249	004	Oct 30, 2020	Jan CMFD
>A>	AB			4MG	A210249	004	Oct 30, 2020	Jan CMFD
>D>		@	HETERO LABS LTD V	1MG	A210236	001	Sep 26, 2024	Jan CMFD
>A>	AB			1MG	A210236	001	Sep 26, 2024	Jan CMFD
>D>		@		2MG	A210236	002	Sep 26, 2024	Jan CMFD
>A>	AB			2MG	A210236	002	Sep 26, 2024	Jan CMFD
>D>		@		3MG	A210236	003	Sep 26, 2024	Jan CMFD
>A>	AB			3MG	A210236	003	Sep 26, 2024	Jan CMFD
>D>		@		4MG	A210236	004	Sep 26, 2024	Jan CMFD
>A>	AB			4MG	A210236	004	Sep 26, 2024	Jan CMFD
>D>		@	TEVA PHARMS USA	1MG	A209956	001	May 04, 2022	Jan CMFD
>A>	AB			1MG	A209956	001	May 04, 2022	Jan CMFD
>D>		@		2MG	A209956	002	May 04, 2022	Jan CMFD
>A>	AB			2MG	A209956	002	May 04, 2022	Jan CMFD
>D>		@		3MG	A209956	003	May 04, 2022	Jan CMFD
>A>	AB			3MG	A209956	003	May 04, 2022	Jan CMFD
>D>		@		4MG	A209956	004	May 04, 2022	Jan CMFD
>A>	AB			4MG	A209956	004	May 04, 2022	Jan CMFD

POMALYST

>D>		+	BRISTOL	1MG	N204026	001	Feb 08, 2013	Jan CTEC
>A>	AB	+		1MG	N204026	001	Feb 08, 2013	Jan CTEC
>D>		+		2MG	N204026	002	Feb 08, 2013	Jan CTEC
>A>	AB	+		2MG	N204026	002	Feb 08, 2013	Jan CTEC
>D>		+		3MG	N204026	003	Feb 08, 2013	Jan CTEC
>A>	AB	+		3MG	N204026	003	Feb 08, 2013	Jan CTEC
>D>		+!		4MG	N204026	004	Feb 08, 2013	Jan CTEC
>A>	AB	+!		4MG	N204026	004	Feb 08, 2013	Jan CTEC

PONATINIB HYDROCHLORIDE

TABLET;ORAL
ICLUSIG

>D>		+	TAKEDA PHARMS USA	EQ 10MG BASE	N203469	004	Dec 18, 2020	Jan CHRS
>A>		+!		EQ 10MG BASE	N203469	004	Dec 18, 2020	Jan CHRS
>D>		+!		EQ 45MG BASE	N203469	002	Dec 14, 2012	Jan CHRS
>A>		+		EQ 45MG BASE	N203469	002	Dec 14, 2012	Jan CHRS

POSACONAZOLE

SOLUTION;INTRAVENOUS
>D> NOXAFIL

>D>	AP	+!	MERCK SHARP DOHME	300MG/16.7ML (18MG/ML)	N205596	001	Mar 13, 2014	Jan DISC
>A>		@ +		300MG/16.7ML (18MG/ML)	N205596	001	Mar 13, 2014	Jan DISC

POSACONAZOLE

>D>	AP		GLAND	300MG/16.7ML (18MG/ML)	A217553	001	Dec 26, 2023	Jan CHRS
>A>	AP	!		300MG/16.7ML (18MG/ML)	A217553	001	Dec 26, 2023	Jan CHRS

POTASSIUM ACETATE

INJECTABLE;INJECTION
POTASSIUM ACETATE

>D>	AP		EXELA PHARMA	2MEQ/ML	A206203	001	Dec 29, 2015	Jan DISC
>A>		@		2MEQ/ML	A206203	001	Dec 29, 2015	Jan DISC

PRASUGREL HYDROCHLORIDE

TABLET;ORAL
PRASUGREL

>D>		@	ANDA REPOSITORY	EQ 5MG BASE	A205926	001	Jul 07, 2020	Jan CAHN
>D>		@		EQ 10MG BASE	A205926	002	Jul 07, 2020	Jan CAHN
>A>		@	SENORES PHARMS	EQ 5MG BASE	A205926	001	Jul 07, 2020	Jan CAHN
>A>		@		EQ 10MG BASE	A205926	002	Jul 07, 2020	Jan CAHN

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE;INJECTION

PROCAINAMIDE HYDROCHLORIDE

>D>	AP		GLAND	100MG/ML	A218135	001	Jul 22, 2024	Jan CHRS
>A>	AP	!		100MG/ML	A218135	001	Jul 22, 2024	Jan CHRS
>D>	AP			500MG/ML	A218135	002	Jul 22, 2024	Jan CHRS
>A>	AP	!		500MG/ML	A218135	002	Jul 22, 2024	Jan CHRS
>D>	AP	!	HOSPIRA	100MG/ML	A089069	001	Feb 12, 1986	Jan CHRS
>A>	AP			100MG/ML	A089069	001	Feb 12, 1986	Jan CHRS
>D>	AP	!		500MG/ML	A089070	001	Feb 12, 1986	Jan DISC
>A>		@		500MG/ML	A089070	001	Feb 12, 1986	Jan DISC

PROPRANOLOL HYDROCHLORIDE

TABLET;ORAL

PROPRANOLOL HYDROCHLORIDE

>A>	AB		MANKIND PHARMA	10MG	A216663	001	Jan 27, 2026	Jan NEWA
>A>	AB			20MG	A216663	002	Jan 27, 2026	Jan NEWA
>A>	AB			40MG	A216663	003	Jan 27, 2026	Jan NEWA
>A>	AB			60MG	A216663	004	Jan 27, 2026	Jan NEWA
>A>	AB			80MG	A216663	005	Jan 27, 2026	Jan NEWA

PRUCALOPRIDE SUCCINATE

TABLET;ORAL

PRUCALOPRIDE SUCCINATE

>A>	AB		AJANTA PHARMA LTD	EQ 1MG BASE	A219220	001	Jan 16, 2026	Jan NEWA
>A>	AB			EQ 2MG BASE	A219220	002	Jan 16, 2026	Jan NEWA
>A>	AB		TEVA PHARMS INC	EQ 1MG BASE	A219071	001	Feb 05, 2026	Jan NEWA
>A>	AB			EQ 2MG BASE	A219071	002	Feb 05, 2026	Jan NEWA

PYRIDOSTIGMINE BROMIDE

TABLET, EXTENDED RELEASE;ORAL

PYRIDOSTIGMINE BROMIDE

>D>	AB		IMPAX LABS INC	180MG	A203184	001	Sep 15, 2015	Jan DISC
>A>		@		180MG	A203184	001	Sep 15, 2015	Jan DISC

RABEPRAZOLE SODIUM

TABLET, DELAYED RELEASE;ORAL

RABEPRAZOLE SODIUM

>D>	AB		AUROBINDO PHARMA	20MG	A205761	001	Feb 17, 2017	Jan CAHN
>A>	AB		AUROBINDO PHARMA USA	20MG	A205761	001	Feb 17, 2017	Jan CAHN

RAMIPRIL

CAPSULE;ORAL

RAMIPRIL

>D>	AB		ANDA REPOSITORY	1.25MG	A078191	001	Jun 18, 2008	Jan CAHN
>D>	AB			2.5MG	A078191	002	Jun 18, 2008	Jan CAHN
>D>	AB			5MG	A078191	003	Jun 18, 2008	Jan CAHN
>D>	AB			10MG	A078191	004	Jun 18, 2008	Jan CAHN
>A>	AB		SENORES PHARMS	1.25MG	A078191	001	Jun 18, 2008	Jan CAHN
>A>	AB			2.5MG	A078191	002	Jun 18, 2008	Jan CAHN
>A>	AB			5MG	A078191	003	Jun 18, 2008	Jan CAHN
>A>	AB			10MG	A078191	004	Jun 18, 2008	Jan CAHN

RILPIVIRINE HYDROCHLORIDE

TABLET;ORAL

EDURANT

>D>		+!	JANSSEN PRODS	EQ 25MG BASE	N202022	001	May 20, 2011	Jan CFTG
>A>	AB	+!		EQ 25MG BASE	N202022	001	May 20, 2011	Jan CFTG

RILPIVIRINE HYDROCHLORIDE

>A>	AB		SOMERSET THERAPS LLC	EQ 25MG BASE	A218798	001	Jan 29, 2026	Jan NFTG

RISPERIDONE

INJECTABLE;INTRAMUSCULAR

RISPERDAL CONSTA

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

RISPERIDONE

>D>	AB		AMNEAL	12.5MG/VIAL	A218586	001	Sep 02, 2025	Jan CDFR
>D>	AB			25MG/VIAL	A218586	002	Sep 02, 2025	Jan CDFR

>D>		INJECTABLE;INTRAMUSCULAR						
>D>		RISPERIDONE						
>D>	AB		37.5MG/VIAL	A218586	003	Sep 02, 2025	Jan CDFR	
>D>	AB		50MG/VIAL	A218586	004	Sep 02, 2025	Jan CDFR	
>D>	AB	NANOMI	25MG/VIAL	A211220	001	Sep 02, 2025	Jan CDFR	
>D>	AB		37.5MG/VIAL	A211220	002	Sep 02, 2025	Jan CDFR	
>D>	AB		50MG/VIAL	A211220	003	Sep 02, 2025	Jan CDFR	
>D>	AB	TEVA PHARMS USA INC	12.5MG/VIAL	A214068	001	Dec 05, 2023	Jan CDFR	
>D>	AB		25MG/VIAL	A214068	002	Dec 05, 2023	Jan CDFR	
>D>	AB		37.5MG/VIAL	A214068	003	Dec 05, 2023	Jan CDFR	
>D>	AB		50MG/VIAL	A214068	004	Dec 05, 2023	Jan CDFR	
>A>		POWDER;INTRAMUSCULAR						
>A>		RISPERDAL CONSTA						
>A>	AB	+ JANSSEN PHARMS	12.5MG/VIAL	N021346	004	Apr 12, 2007	Jan CDFR	
>A>	AB	+!	12.5MG/VIAL	N021346	004	Apr 12, 2007	Jan CHRS	
>A>	AB	+!	25MG/VIAL	N021346	001	Oct 29, 2003	Jan CDFR	
>A>	AB	+	37.5MG/VIAL	N021346	002	Oct 29, 2003	Jan CDFR	
>A>	AB	+!	37.5MG/VIAL	N021346	002	Oct 29, 2003	Jan CHRS	
>A>	AB	+	50MG/VIAL	N021346	003	Oct 29, 2003	Jan CDFR	
>A>	AB	+!	50MG/VIAL	N021346	003	Oct 29, 2003	Jan CHRS	
>A>		RISPERIDONE						
>A>	AB	AMNEAL	12.5MG/VIAL	A218586	001	Sep 02, 2025	Jan CDFR	
>A>	AB		25MG/VIAL	A218586	002	Sep 02, 2025	Jan CDFR	
>A>	AB		37.5MG/VIAL	A218586	003	Sep 02, 2025	Jan CDFR	
>A>	AB		50MG/VIAL	A218586	004	Sep 02, 2025	Jan CDFR	
>A>	AB	NANOMI	25MG/VIAL	A211220	001	Sep 02, 2025	Jan CDFR	
>A>	AB		37.5MG/VIAL	A211220	002	Sep 02, 2025	Jan CDFR	
>A>	AB		50MG/VIAL	A211220	003	Sep 02, 2025	Jan CDFR	
>A>	AB	TEVA PHARMS USA INC	12.5MG/VIAL	A214068	001	Dec 05, 2023	Jan CDFR	
>A>	AB		25MG/VIAL	A214068	002	Dec 05, 2023	Jan CDFR	
>A>	AB		37.5MG/VIAL	A214068	003	Dec 05, 2023	Jan CDFR	
>A>	AB		50MG/VIAL	A214068	004	Dec 05, 2023	Jan CDFR	
		RITONAVIR						
		TABLET;ORAL						
		NORVIR						
>D>	AB	+! ABBVIE	100MG	N022417	001	Feb 10, 2010	Jan CHRS	
>A>	AB	+	100MG	N022417	001	Feb 10, 2010	Jan CHRS	
		RITONAVIR						
>D>	AB	AUROBINDO PHARMA LTD	100MG	A206614	001	Sep 17, 2018	Jan CHRS	
>A>	AB	!	100MG	A206614	001	Sep 17, 2018	Jan CHRS	
		SACUBITRIL; VALSARTAN						
		TABLET;ORAL						
		SACUBITRIL AND VALSARTAN						
>A>	AB	SOMERSET THERAPS LLC	24MG;26MG	A219983	001	Jan 20, 2026	Jan NEWA	
>A>	AB		49MG;51MG	A219983	002	Jan 20, 2026	Jan NEWA	
>A>	AB		97MG;103MG	A219983	003	Jan 20, 2026	Jan NEWA	
		SAPROPTERIN DIHYDROCHLORIDE						
		POWDER;ORAL						
		KUVAN						
>D>	AB	+ BIOMARIN PHARM	500MG/PACKET	N205065	002	Oct 27, 2015	Jan CHRS	
>A>	AB	+!	500MG/PACKET	N205065	002	Oct 27, 2015	Jan CHRS	
		SAPROPTERIN DIHYDROCHLORIDE						
>A>	AB	MICRO LABS	100MG/PACKET	A219511	001	Jan 08, 2026	Jan NEWA	
>A>	AB		500MG/PACKET	A219511	002	Jan 08, 2026	Jan NEWA	
		SELENIOUS ACID						
		SOLUTION;INTRAVENOUS						
		SELENIOUS ACID						
>D>	AP	CIPLA	EQ 12MCG SELENIUM/2ML (EQ 6MCG SELENIUM/ML)	A218661	001	Jul 21, 2025	Jan DISC	
>A>		@	EQ 12MCG SELENIUM/2ML (EQ 6MCG SELENIUM/ML)	A218661	001	Jul 21, 2025	Jan DISC	
>D>	AP		EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML)	A218661	002	Jul 21, 2025	Jan DISC	
>A>		@	EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML)	A218661	002	Jul 21, 2025	Jan DISC	
>A>	AP	KINDOS	EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML)	A219472	001	Feb 03, 2026	Jan NEWA	

SERTRALINE HYDROCHLORIDE

CAPSULE;ORAL

SERTRALINE HYDROCHLORIDE

>A>	AB		APPCO	EQ 150MG BASE	A218712	001	Jan 20, 2026	Jan NEWA
>A>	AB			EQ 200MG BASE	A218712	002	Jan 20, 2026	Jan NEWA
>A>	AB		NOVITIUM PHARMA	EQ 150MG BASE	A219714	001	Jan 20, 2026	Jan NEWA
>A>	AB			EQ 200MG BASE	A219714	002	Jan 20, 2026	Jan NEWA
>A>	AB		SKG PHARMA	EQ 150MG BASE	A219655	001	Jan 28, 2026	Jan NEWA
>A>	AB			EQ 200MG BASE	A219655	002	Jan 28, 2026	Jan NEWA
>A>	AB		UMEDICA	EQ 150MG BASE	A218342	001	Jan 20, 2026	Jan NEWA
>A>	AB			EQ 200MG BASE	A218342	002	Jan 20, 2026	Jan NEWA
>A>	AB		ZYDUS LIFESCIENCES	EQ 150MG BASE	A220275	001	Jan 29, 2026	Jan NEWA
>A>	AB			EQ 200MG BASE	A220275	002	Jan 29, 2026	Jan NEWA

TABLET;ORAL

SERTRALINE HYDROCHLORIDE

>A>		@	APPCO	EQ 25MG BASE	A077713	001	Feb 06, 2007	Jan CAHN
>A>		@		EQ 50MG BASE	A077713	002	Feb 06, 2007	Jan CAHN
>A>		@		EQ 100MG BASE	A077713	003	Feb 06, 2007	Jan CAHN
>D>		@	SOMERSET THERAPS LLC	EQ 25MG BASE	A077713	001	Feb 06, 2007	Jan CAHN
>D>		@		EQ 50MG BASE	A077713	002	Feb 06, 2007	Jan CAHN
>D>		@		EQ 100MG BASE	A077713	003	Feb 06, 2007	Jan CAHN

SITAGLIPTIN PHOSPHATE

TABLET;ORAL

SITAGLIPTIN PHOSPHATE

>A>	AB		APOTEX	EQ 25MG BASE	A202425	001	Jan 20, 2026	Jan NEWA
>A>	AB			EQ 50MG BASE	A202425	002	Jan 20, 2026	Jan NEWA
>A>	AB			EQ 100MG BASE	A202425	003	Jan 20, 2026	Jan NEWA
>A>	AB		SANDOZ	EQ 25MG BASE	A202387	001	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 50MG BASE	A202387	002	Jan 14, 2026	Jan NEWA
>A>	AB			EQ 100MG BASE	A202387	003	Jan 14, 2026	Jan NEWA

SODIUM BICARBONATE

SOLUTION;INTRAVENOUS

SODIUM BICARBONATE

>A>	AP		AMNEAL	50MEQ/50ML (1MEQ/ML)	A217523	001	Jan 13, 2026	Jan NEWA

SODIUM PHENYLBUTYRATE

POWDER;ORAL

>D>			BUPHENYL					
>D>	AB	+!	HORIZON THERAP US	3GM/TEASPOONFUL	N020573	001	Apr 30, 1996	Jan DISC
>A>		@ +		3GM/TEASPOONFUL	N020573	001	Apr 30, 1996	Jan DISC
			SODIUM PHENYLBUTYRATE					
>D>	AB		PH HEALTH	3GM/TEASPOONFUL	A203918	001	Jun 15, 2016	Jan CHRS
>A>	AB	!		3GM/TEASPOONFUL	A203918	001	Jun 15, 2016	Jan CHRS

TABLET;ORAL

>D>			BUPHENYL					
>D>	AB	+!	HORIZON THERAP US	500MG	N020572	001	May 13, 1996	Jan DISC
>A>		@ +		500MG	N020572	001	May 13, 1996	Jan DISC
			SODIUM PHENYLBUTYRATE					
>D>	AB		PH HEALTH	500MG	A204395	001	Apr 15, 2016	Jan CHRS
>A>	AB	!		500MG	A204395	001	Apr 15, 2016	Jan CHRS

TAFAMIDIS MEGLUMINE

CAPSULE;ORAL

>D>			VYNDAQEL					
>D>		+!	FOLDRX PHARMS	20MG	N211996	001	May 03, 2019	Jan DISC
>A>		@ +		20MG	N211996	001	May 03, 2019	Jan DISC

TAPENTADOL HYDROCHLORIDE

SOLUTION;ORAL

>A>			TAPENTADOL HYDROCHLORIDE					
>A>			NOVITIUM PHARMA	EQ 20MG BASE/ML	A219119	001	Jan 26, 2026	Jan NFTG

TABLET;ORAL

NUCYNTA

>D>		+	COLLEGIUM PHARM INC	EQ 50MG BASE	N022304	001	Nov 20, 2008	Jan CFTG
>A>	AB	+		EQ 50MG BASE	N022304	001	Nov 20, 2008	Jan CFTG
>D>		+		EQ 75MG BASE	N022304	002	Nov 20, 2008	Jan CFTG
>A>	AB	+		EQ 75MG BASE	N022304	002	Nov 20, 2008	Jan CFTG
>D>		+!		EQ 100MG BASE	N022304	003	Nov 20, 2008	Jan CFTG
>A>	AB	+!		EQ 100MG BASE	N022304	003	Nov 20, 2008	Jan CFTG

TABLET;ORAL
TAPENTADOL HYDROCHLORIDE

>A>	AB		HIKMA	EQ 50MG BASE	A205057	001	Feb 10, 2026	Jan NEWA
>A>	AB			EQ 75MG BASE	A205057	002	Feb 10, 2026	Jan NEWA
>A>	AB			EQ 100MG BASE	A205057	003	Feb 10, 2026	Jan NEWA
>A>	AB		HUMANWELL	EQ 50MG BASE	A214378	001	Jan 27, 2026	Jan NFTG
>A>	AB			EQ 75MG BASE	A214378	002	Jan 27, 2026	Jan NFTG
>A>	AB			EQ 100MG BASE	A214378	003	Jan 27, 2026	Jan NFTG

TAVABOROLE

SOLUTION;TOPICAL
TAVABOROLE

>D>	AB		CIPLA	5%	A212224	001	Feb 09, 2021	Jan DISC
>A>		@		5%	A212224	001	Feb 09, 2021	Jan DISC

TAZAROTENE

CREAM;TOPICAL
TAZAROTENE

>D>	AB		LONG GROVE PHARMS	0.05%	A214560	001	Nov 24, 2025	Jan CAHN
>A>	AB		SOLARIS PHARMA CORP	0.05%	A214560	001	Nov 24, 2025	Jan CAHN

TEMAZEPAM

CAPSULE;ORAL
TEMAZEPAM

>D>		@	AMNEAL PHARMS	7.5MG	A203482	001	May 23, 2016	Jan CMFD
>A>	AB			7.5MG	A203482	001	May 23, 2016	Jan CMFD
>D>		@		15MG	A203482	002	May 23, 2016	Jan CMFD
>A>	AB			15MG	A203482	002	May 23, 2016	Jan CMFD
>D>		@		22.5MG	A203482	003	May 23, 2016	Jan CMFD
>A>	AB			22.5MG	A203482	003	May 23, 2016	Jan CMFD
>D>		@		30MG	A203482	004	May 23, 2016	Jan CMFD
>A>	AB			30MG	A203482	004	May 23, 2016	Jan CMFD

TESTOSTERONE CYPIONATE

INJECTABLE;INJECTION
TESTOSTERONE CYPIONATE

>A>	AO		CAPLIN ONE LABS	100MG/ML	A040615	001	Aug 10, 2006	Jan CAHN
>A>	AO			200MG/ML	A040615	002	Aug 10, 2006	Jan CAHN
>D>	AO		SANDOZ	100MG/ML	A040615	001	Aug 10, 2006	Jan CAHN
>D>	AO			200MG/ML	A040615	002	Aug 10, 2006	Jan CAHN

THEOPHYLLINE

SOLUTION, ELIXIR;ORAL
>D> ELIXOPHYLLIN

>D>	AA	+!	SOLIS PHARMS	80MG/15ML	A085186	001		Jan DISC
>A>		@ +		80MG/15ML	A085186	001		Jan DISC

THEOPHYLLINE

>D>	AA		PHARM ASSOC	80MG/15ML	A206344	001	Dec 16, 2016	Jan CTEC
>A>				80MG/15ML	A206344	001	Dec 16, 2016	Jan CTEC
>A>		!		80MG/15ML	A206344	001	Dec 16, 2016	Jan CHRS

THIOTEPA

POWDER;INTRAVENOUS
TEPADINA AND SODIUM CHLORIDE

>A>		+!	ADIENNE SA	400MG	N208264	004	Jan 15, 2026	Jan NEWA

TICAGRELOR

TABLET;ORAL
TICAGRELOR

>A>	AB		MANKIND PHARMA	60MG	A217679	001	Feb 06, 2026	Jan NEWA
>A>	AB			90MG	A217679	002	Feb 06, 2026	Jan NEWA

TIRZEPATIDE

SOLUTION;SUBCUTANEOUS
MOUNJARO

>A>		+!	ELI LILLY AND CO	10MG/2.4ML (4.17MG/ML)	N215866	013	Jan 07, 2026	Jan NEWA
>A>		+!		20MG/2.4ML (8.33MG/ML)	N215866	014	Jan 07, 2026	Jan NEWA
>A>		+!		30MG/2.4ML (12.5MG/ML)	N215866	015	Jan 07, 2026	Jan NEWA
>A>		+!		40MG/2.4ML (16.7MG/ML)	N215866	016	Jan 07, 2026	Jan NEWA
>A>		+!		50MG/2.4ML (20.8MG/ML)	N215866	017	Jan 07, 2026	Jan NEWA
>A>		+!		60MG/2.4ML (25MG/ML)	N215866	018	Jan 07, 2026	Jan NEWA

SOLUTION;SUBCUTANEOUS

>A>		MOUNJARO KWIKPEN						
>A>	+!	ELI LILLY AND CO	10MG/2.4ML (4.17MG/ML)	N215866	019	Jan 20, 2026	Jan NEWA	
>A>	+!		20MG/2.4ML (8.33MG/ML)	N215866	020	Jan 20, 2026	Jan NEWA	
>A>	+!		30MG/2.4ML (12.5MG/ML)	N215866	021	Jan 20, 2026	Jan NEWA	
>A>	+!		40MG/2.4ML (16.7MG/ML)	N215866	022	Jan 20, 2026	Jan NEWA	
>A>	+!		50MG/2.4ML (20.8MG/ML)	N215866	023	Jan 20, 2026	Jan NEWA	
>A>	+!		60MG/2.4ML (25MG/ML)	N215866	024	Jan 20, 2026	Jan NEWA	
		ZEPBOUND						
>A>	+!	ELI LILLY AND CO	10MG/2.4ML (4.17MG/ML)	N217806	013	Jan 07, 2026	Jan NEWA	
>A>	+!		20MG/2.4ML (8.33MG/ML)	N217806	014	Jan 07, 2026	Jan NEWA	
>A>	+!		30MG/2.4ML (12.5MG/ML)	N217806	015	Jan 07, 2026	Jan NEWA	
>A>	+!		40MG/2.4ML (16.7MG/ML)	N217806	016	Jan 07, 2026	Jan NEWA	
>A>	+!		50MG/2.4ML (20.8MG/ML)	N217806	017	Jan 07, 2026	Jan NEWA	
>A>	+!		60MG/2.4ML (25MG/ML)	N217806	018	Jan 07, 2026	Jan NEWA	
>A>		ZEPBOUND KWIKPEN						
>A>	+!	ELI LILLY AND CO	10MG/2.4ML (4.17MG/ML)	N217806	019	Jan 20, 2026	Jan NEWA	
>A>	+!		20MG/2.4ML (8.33MG/ML)	N217806	020	Jan 20, 2026	Jan NEWA	
>A>	+!		30MG/2.4ML (12.5MG/ML)	N217806	021	Jan 20, 2026	Jan NEWA	
>A>	+!		40MG/2.4ML (16.7MG/ML)	N217806	022	Jan 20, 2026	Jan NEWA	
>A>	+!		50MG/2.4ML (20.8MG/ML)	N217806	023	Jan 20, 2026	Jan NEWA	
>A>	+!		60MG/2.4ML (25MG/ML)	N217806	024	Jan 20, 2026	Jan NEWA	

TIZANIDINE HYDROCHLORIDE

CAPSULE;ORAL

TIZANIDINE HYDROCHLORIDE

>D> AB	ANDA REPOSITORY	EQ 4MG BASE	A213365	001	May 13, 2024	Jan CAHN	
>D> AB		EQ 6MG BASE	A213365	002	May 13, 2024	Jan CAHN	
>A> AB	SENORES PHARMS	EQ 4MG BASE	A213365	001	May 13, 2024	Jan CAHN	
>A> AB		EQ 6MG BASE	A213365	002	May 13, 2024	Jan CAHN	

TOFACITINIB CITRATE

TABLET, EXTENDED RELEASE;ORAL

TOFACITINIB CITRATE

>D> AB	AJANTA PHARMA LTD	EQ 11MG BASE	A219542	001	Aug 19, 2025	Jan DISC	
>A> @		EQ 11MG BASE	A219542	001	Aug 19, 2025	Jan DISC	

TOPIRAMATE

CAPSULE;ORAL

TOPIRAMATE

>D> AB	ANDA REPOSITORY	15MG	A218642	001	Oct 10, 2024	Jan CAHN	
>D> AB		25MG	A218642	002	Oct 10, 2024	Jan CAHN	
>A> AB	SENORES PHARMS	15MG	A218642	001	Oct 10, 2024	Jan CAHN	
>A> AB		25MG	A218642	002	Oct 10, 2024	Jan CAHN	
>A> AB	STRIDES PHARMA	50MG	A078418	003	Feb 02, 2026	Jan NEWA	

CAPSULE, EXTENDED RELEASE;ORAL

TOPIRAMATE

>A> AB1	ASCENT PHARMS INC	25MG	A217443	001	Jan 12, 2026	Jan NEWA	
>A> AB1		50MG	A217443	002	Jan 12, 2026	Jan NEWA	
>A> AB1		100MG	A217443	003	Jan 12, 2026	Jan NEWA	
>A> AB1		200MG	A217443	004	Jan 12, 2026	Jan NEWA	

TABLET;ORAL

TOPIRAMATE

>D> @	ANDA REPOSITORY	25MG	A090353	001	Sep 01, 2010	Jan CAHN	
>D> @		50MG	A090353	002	Sep 01, 2010	Jan CAHN	
>D> @		100MG	A090353	003	Sep 01, 2010	Jan CAHN	
>D> @		200MG	A090353	004	Sep 01, 2010	Jan CAHN	
>A> @	SENORES PHARMS	25MG	A090353	001	Sep 01, 2010	Jan CAHN	
>A> @		50MG	A090353	002	Sep 01, 2010	Jan CAHN	
>A> @		100MG	A090353	003	Sep 01, 2010	Jan CAHN	
>A> @		200MG	A090353	004	Sep 01, 2010	Jan CAHN	

TRANDOLAPRIL

TABLET;ORAL

TRANDOLAPRIL

>D> @	ANDA REPOSITORY	1MG	A078493	001	Aug 25, 2008	Jan CAHN	
>D> @		2MG	A078493	002	Aug 25, 2008	Jan CAHN	
>D> @		4MG	A078493	003	Aug 25, 2008	Jan CAHN	
>A> @	SENORES PHARMS	1MG	A078493	001	Aug 25, 2008	Jan CAHN	
>A> @		2MG	A078493	002	Aug 25, 2008	Jan CAHN	
>A> @		4MG	A078493	003	Aug 25, 2008	Jan CAHN	

TRANEXAMIC ACID

TABLET;ORAL

TRANEXAMIC ACID

>A>	AB		I 3 PHARMS	650MG	A219702	001	Jan 26, 2026	Jan NEWA

TRETINOIN

CREAM;TOPICAL

TRETINOIN

>A>	AB		ENCUBE	0.1%	A217833	001	Feb 10, 2026	Jan NEWA

TRIAMCINOLONE ACETONIDE

INJECTABLE;INJECTION

KENALOG-10

>D>	AB	+	APOTHECON	10MG/ML	N012041	001		Jan CHRS
>A>	AB	+!		10MG/ML	N012041	001		Jan CHRS

TRIAMCINOLONE ACETONIDE

>A>		@	CAPLIN	10MG/ML	A090166	001	May 27, 2009	Jan CAHN
>D>		@	SANDOZ	10MG/ML	A090166	001	May 27, 2009	Jan CAHN

TRIENTINE HYDROCHLORIDE

CAPSULE;ORAL

TRIENTINE HYDROCHLORIDE

>D>			RISING	500MG	A212238	002	Sep 22, 2023	Jan CHRS
>A>		!		500MG	A212238	002	Sep 22, 2023	Jan CHRS

TROSPIUM CHLORIDE

TABLET;ORAL

TROSPIUM CHLORIDE

>D>	AB		CHARTWELL RX	20MG	A215781	001	Feb 16, 2022	Jan CAHN
>A>	AB		ZAMEER PHARMS	20MG	A215781	001	Feb 16, 2022	Jan CAHN

URSODIOL

CAPSULE;ORAL

>A> URSODIOL

>A>			STRIDES PHARMA	150MG	A210344	002	Jan 16, 2026	Jan NFTG

VANCOMYCIN HYDROCHLORIDE

POWDER;INTRAVENOUS

>A> VANCOMYCIN HYDROCHLORIDE

>A>			SAMSON MEDCL	EQ 100GM BASE	A091532	001	Jan 06, 2016	Jan CTNA
>A>		!		EQ 100GM BASE	A091532	001	Jan 06, 2016	Jan CHRS

VANCOMYCIN HYDROCHLORIDE IN PLASTIC CONTAINER

>D>			SAMSON MEDCL	EQ 100GM BASE	A091532	001	Jan 06, 2016	Jan CTNA

VARENICLINE TARTRATE

TABLET;ORAL

VARENICLINE TARTRATE

>D>		@	PIRAMAL	EQ 0.5MG BASE	A217115	001	Jul 23, 2024	Jan CMFD
>A>	AB			EQ 0.5MG BASE	A217115	001	Jul 23, 2024	Jan CMFD
>D>		@		EQ 1MG BASE	A217115	002	Jul 23, 2024	Jan CMFD
>A>	AB			EQ 1MG BASE	A217115	002	Jul 23, 2024	Jan CMFD
>A>	AB		UMEDICA	EQ 0.5MG BASE	A218985	001	Jan 09, 2026	Jan NEWA
>A>	AB			EQ 1MG BASE	A218985	002	Jan 09, 2026	Jan NEWA

VIGABATRIN

FOR SOLUTION;ORAL

VIGABATRIN

>D>	AA		TEVA PHARMS USA	500MG/PACKET	A209824	001	Apr 23, 2018	Jan DISC
>A>		@		500MG/PACKET	A209824	001	Apr 23, 2018	Jan DISC

ZOLEDRONIC ACID

INJECTABLE;INTRAVENOUS

ZOLEDRONIC ACID

>A>	AP		GLAND	EQ 4MG BASE/100ML	A219984	001	Feb 05, 2026	Jan NEWA
>D>	AP		HOSPIRA INC	EQ 5MG BASE/100ML	A202837	001	Apr 05, 2013	Jan DISC
>A>		@		EQ 5MG BASE/100ML	A202837	001	Apr 05, 2013	Jan DISC

ZOLPIDEM TARTRATE

TABLET;ORAL

ZOLPIDEM TARTRATE

>D>		@	ANDA REPOSITORY	5MG	A077985	001	Apr 23, 2007	Jan CAHN
>D>		@		10MG	A077985	002	Apr 23, 2007	Jan CAHN
>A>		@	SENORES PHARMS	5MG	A077985	001	Apr 23, 2007	Jan CAHN
>A>		@		10MG	A077985	002	Apr 23, 2007	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL

ZOLPIDEM TARTRATE

>D>		@	BRECKENRIDGE	6.25MG	A213592	001	Jun 04, 2020	Jan CMFD
>A>	AB			6.25MG	A213592	001	Jun 04, 2020	Jan CMFD
>D>		@		12.5MG	A213592	002	Jun 04, 2020	Jan CMFD
>A>	AB			12.5MG	A213592	002	Jun 04, 2020	Jan CMFD

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

CUMULATIVE SUPPLEMENT NUMBER 01 JANUARY 2026

NO JANUARY 2026 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of Orphan Designations and Approvals is available at:

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

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

NO JANUARY 2026 APPROVALS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ABIRATERONE ACETATE; NIRAPARIB TOSYLATE - AKEEGA							
N 216793	001	>A> 11207311	Jul 28, 2037	U-2830		>A> I-980	Dec 12, 2028
		>A> 11207311	Jul 28, 2037	U-4368			
		>A> 11673877	Mar 27, 2038	DS DP U-2830			
		>A> 11673877	Mar 27, 2038	DS DP U-4368			
		>A> 11986468	Jul 28, 2037	U-2830			
		>A> 11986468	Jul 28, 2037	U-4368			
		>A> 11986469	Jul 28, 2037	U-2830			
		>A> 11986469	Jul 28, 2037	U-4368			
		>A> 11986470	Jul 28, 2037	U-4368			
		>A> 11992486	Jul 28, 2037	U-2830			
		>A> 11992486	Jul 28, 2037	U-4368			
		>A> 12383543	Jul 28, 2037	U-2830			
		>A> 12383543	Jul 28, 2037	U-4368			
		>A> 8071579	Aug 12, 2027	U-2830			
		>A> 8071579	Aug 12, 2027	U-4368			
		>A> 8143241	Aug 12, 2027	U-2830			
		>A> 8143241	Aug 12, 2027	U-4368			
		>A> 8859562	Aug 04, 2031	U-2830			
		>A> 8859562	Aug 04, 2031	U-4368			
ABIRATERONE ACETATE; NIRAPARIB TOSYLATE - AKEEGA							
N 216793	002	>A> 11207311	Jul 28, 2037	U-2830		>A> I-980	Dec 12, 2028
		>A> 11207311	Jul 28, 2037	U-4368			
		>A> 11673877	Mar 27, 2038	DS DP U-2830			
		>A> 11673877	Mar 27, 2038	DS DP U-4368			
		>A> 11986468	Jul 28, 2037	U-2830			
		>A> 11986468	Jul 28, 2037	U-4368			
		>A> 11986469	Jul 28, 2037	U-2830			
		>A> 11986469	Jul 28, 2037	U-4368			
		>A> 11986470	Jul 28, 2037	U-4368			
		>A> 11992486	Jul 28, 2037	U-2830			
		>A> 11992486	Jul 28, 2037	U-4368			
		>A> 12383543	Jul 28, 2037	U-2830			
		>A> 12383543	Jul 28, 2037	U-4368			
		>A> 8071579	Aug 12, 2027	U-2830			
		>A> 8071579	Aug 12, 2027	U-4368			
		>A> 8143241	Aug 12, 2027	U-2830			
		>A> 8143241	Aug 12, 2027	U-4368			
		>A> 8859562	Aug 04, 2031	U-2830			
		>A> 8859562	Aug 04, 2031	U-4368			
AFICAMTEN - MYQORZO							
N 219083	001	>A> 10836755	Jan 18, 2039	DS DP U-4371			
		>A> 12370179	Jul 15, 2042	U-4371			
AFICAMTEN - MYQORZO							
N 219083	002	>A> 10836755	Jan 18, 2039	DS DP U-4371			
		>A> 12370179	Jul 15, 2042	U-4371			
AFICAMTEN - MYQORZO							
N 219083	003	>A> 10836755	Jan 18, 2039	DS DP U-4371			
		>A> 12370179	Jul 15, 2042	U-4371			
AFICAMTEN - MYQORZO							
N 219083	004	>A> 10836755	Jan 18, 2039	DS DP U-4371			
		>A> 12370179	Jul 15, 2042	U-4371			
AMOXICILLIN; CLARITHROMYCIN; VONOPRAZAN FUMARATE - VOQUEZNA TRIPLE PAK							
N 215152	001	>A> 7977488	Apr 10, 2030	DS			
ATRASENTAN HYDROCHLORIDE - VANRAFIA							
N 219208	001	>A> 12521369	Feb 23, 2041	U-3980			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO			PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
AVACINCAPTAD PEGOL SODIUM - IZERVAY								
N 217225	001	>A>	7579456	Feb 14, 2027	DS			
		>A>	9617546	Feb 14, 2027	DS		U-3673	
AVACOPAN - TAVNEOS								
N 214487	001	>A>	8906938	Jan 06, 2034	DS DP			
AVUTOMETINIB POTASSIUM; DEFACTINIB HYDROCHLORIDE - AVMAPKI FAKZYNJA CO-PACK (COPACKAGED)								
N 219616	001	>A>	12509450	Dec 29, 2042	DP			
BALOXAVIR MARBOXIL - XOFLUZA								
N 210854	001	>A>	8987441	Oct 24, 2032	DS DP			
BALOXAVIR MARBOXIL - XOFLUZA								
N 210854	002	>A>	8987441	Oct 24, 2032	DS DP			
BALOXAVIR MARBOXIL - XOFLUZA								
N 210854	003	>A>	8987441	Oct 24, 2032	DS DP			
BALOXAVIR MARBOXIL - XOFLUZA								
N 214410	001	>A>	8987441	Oct 24, 2032	DS DP			
BALOXAVIR MARBOXIL - XOFLUZA								
N 214410	002	>A>	8987441	Oct 24, 2032	DS DP			
BALOXAVIR MARBOXIL - XOFLUZA								
N 214410	003	>A>	8987441	Oct 24, 2032	DS DP			
CABAZITAXEL - JEVTANA KIT								
N 201023	001	>A>	10583110	Oct 27, 2030			U-2753	
		>A>	10583110*PED	Apr 27, 2031				
		>A>	10716777	Oct 27, 2030			U-2856	
		>A>	10716777*PED	Apr 27, 2031				
		>A>	12453712	Oct 27, 2030			U-4334	
		>A>	12453712*PED	Apr 27, 2031				
CARIPRAZINE HYDROCHLORIDE - VRAYLAR								
N 204370	005	>A>	7737142	Sep 17, 2029	DS DP		U-2543	
		>A>	7737142	Sep 17, 2029	DS DP		U-2544	
		>A>	7737142	Sep 17, 2029	DS DP		U-2545	
		>A>	7737142	Sep 17, 2029	DS DP		U-3503	
		>A>	7943621	Dec 20, 2028	DS DP			
		>A>	RE47350	Jul 16, 2029			U-2543	
		>A>	RE47350	Jul 16, 2029			U-2544	
		>A>	RE47350	Jul 16, 2029			U-2545	
		>A>	RE47350	Jul 16, 2029			U-3503	
		>A>	RE49110	Jul 16, 2029			U-2543	
		>A>	RE49110	Jul 16, 2029			U-2544	
		>A>	RE49110	Jul 16, 2029			U-2545	
		>A>	RE49110	Jul 16, 2029			U-3503	
CARIPRAZINE HYDROCHLORIDE - VRAYLAR								
N 204370	006	>A>	7737142	Sep 17, 2029	DS DP		U-2543	
		>A>	7737142	Sep 17, 2029	DS DP		U-2544	
		>A>	7737142	Sep 17, 2029	DS DP		U-2545	
		>A>	7737142	Sep 17, 2029	DS DP		U-3503	
		>A>	7943621	Dec 20, 2028	DS DP			
		>A>	RE47350	Jul 16, 2029			U-2543	
		>A>	RE47350	Jul 16, 2029			U-2544	
		>A>	RE47350	Jul 16, 2029			U-2545	
		>A>	RE47350	Jul 16, 2029			U-3503	
		>A>	RE49110	Jul 16, 2029			U-2543	
		>A>	RE49110	Jul 16, 2029			U-2544	
		>A>	RE49110	Jul 16, 2029			U-2545	
		>A>	RE49110	Jul 16, 2029			U-3503	

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
CARIPRAZINE HYDROCHLORIDE - VRAYLAR							
N 204370	006	>A> 7737142	Sep 17, 2029	DS DP U-2543			
		>A> 7737142	Sep 17, 2029	DS DP U-2544			
		>A> 7737142	Sep 17, 2029	DS DP U-2545			
		>A> 7737142	Sep 17, 2029	DS DP U-3503			
		>A> 7943621	Dec 20, 2028	DS DP			
		>A> RE47350	Jul 16, 2029	U-2543			
		>A> RE47350	Jul 16, 2029	U-2544			
		>A> RE47350	Jul 16, 2029	U-2545			
		>A> RE47350	Jul 16, 2029	U-3503			
		>A> RE49110	Jul 16, 2029	U-2543			
		>A> RE49110	Jul 16, 2029	U-2544			
		>A> RE49110	Jul 16, 2029	U-2545			
		>A> RE49110	Jul 16, 2029	U-3503			
CLADRIBINE - MAVENCLAD							
N 022561	001	>A> 12533408	Sep 10, 2041	U-4395			
		>A> 12539329	Sep 10, 2041	U-4399			
COLCHICINE - GLOPERBA							
N 210942	001	>A> 12514819	Nov 22, 2036	U-2814			
COPPER HISTIDINATE - ZYCUBO							
N 211241	001					>A> NCE	Jan 12, 2031
CYTARABINE; DAUNORUBICIN - VYXEOS							
N 209401	001	>A> 10028912	Oct 15, 2032	DP U-3149		>A> ODE-350	Mar 30, 2028
		>A> 10028912	Oct 15, 2032	DP U-3150		>A> PED	Sep 30, 2028
		>A> 10028912*PED	Apr 15, 2033				
		>A> 10166184	Oct 15, 2032	DP U-3149			
		>A> 10166184*PED	Apr 15, 2033				
		>A> 10835492	Oct 15, 2032	U-3150			
		>A> 10835492*PED	Apr 15, 2033				
		>A> 7850990	Jan 23, 2027	DP U-3147			
		>A> 7850990*PED	Jul 23, 2027				
		>A> 8022279	Sep 14, 2027	DP U-3147			
		>A> 8022279*PED	Mar 14, 2028				
		>A> 8092828	Apr 01, 2029	U-3147			
		>A> 8092828*PED	Oct 01, 2029				
		>A> 9271931	Jan 23, 2027	DP			
		>A> 9271931*PED	Jul 23, 2027				
DAROLUTAMIDE - NUBEQA							
N 212099	001	>A> 12329742	Jun 17, 2042	DP			
DEGARELIX ACETATE - FIRMAGON							
N 022201	001	>A> 12514898	Feb 20, 2029	U-1978			
DEGARELIX ACETATE - FIRMAGON							
N 022201	002	>A> 12514898	Feb 20, 2029	U-1978			
DEUCRAVACITINIB - SOTYKTU							
N 214958	001	>A> 12521390	Feb 11, 2043	DP U-3434			
DIAZEPAM - VALTOCO							
N 211635	001	>A> 12521400	Mar 27, 2029	DP			
DIAZEPAM - VALTOCO							
N 211635	002	>A> 12521400	Mar 27, 2029	DP			
DIAZEPAM - VALTOCO							
N 211635	003	>A> 12521400	Mar 27, 2029	DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
EDARAVONE - RADICAVA ORS						
N 215446 001	>A> 12527769	Nov 12, 2041	U-4111			
ELAMIPRETIDE HYDROCHLORIDE - FORZINITY						
N 215244 001	>A> 7576061	Jan 20, 2027	DS DP			
ELINZANETANT - LYNKUET						
N 219469 001	>A> 12533358	May 14, 2045	U-4402			
EMPAGLIFLOZIN - JARDIANCE						
N 204629 001	>A> 12527810	Apr 22, 2033	U-4403			
EMPAGLIFLOZIN - JARDIANCE						
N 204629 002	>A> 12527810	Apr 22, 2033	U-4403			
EPINEPHRINE - EPINEPHRINE						
N 215425 001	>A> 12539283	Jan 17, 2045	DP			
ETRIPAMIL - CARDAMYST						
N 218571 001	>A> 10010522	Jun 19, 2028	U-38			
	>A> 10010523	Jun 19, 2028	DS			
	>A> 10117848	Apr 13, 2036	DP U-4370			
	>A> 12257224	Jul 15, 2042	U-4370			
	>A> 9227918	Jun 19, 2028	DP			
	>A> 9463179	Jun 19, 2028	U-4370			
FERRIC CARBOXYMALTOSE - INJECTAFER						
N 203565 001	>A> 7612109	Feb 05, 2027	DS DP			
FERRIC CARBOXYMALTOSE - INJECTAFER						
N 203565 002	>A> 7612109	Feb 05, 2027	DS DP			
FERRIC CARBOXYMALTOSE - INJECTAFER						
N 203565 003	>A> 7612109	Feb 05, 2027	DS DP			
FERRIC CARBOXYMALTOSE - INJECTAFER						
N 203565 004	>A> 7612109	Feb 05, 2027	DS DP			
FINERENONE - KERENDIA						
N 215341 001	>A> 8436180	Aug 26, 2033	DS DP			
FINERENONE - KERENDIA						
N 215341 002	>A> 8436180	Aug 26, 2033	DS DP			
FINERENONE - KERENDIA						
N 215341 003	>A> 8436180	Aug 26, 2033	DS DP			
FLURPIRIDAZ F-18 - FLYRCADO						
N 215168 001	>A> 12527884	May 13, 2042	DP U-4406			
FOSFOMYCIN DISODIUM - CONTEPO						
N 212271 001					>A> NP	Oct 22, 2028
					>A> GAIN	Oct 22, 2033
GIVINOSTAT HYDROCHLORIDE - DUVYZAT						
N 217865 001	>A> 7329689	Jan 15, 2027	DS DP			
GLASDEGIB MALEATE - DAURISMO						
N 210656 001	>A> 8148401	Apr 14, 2029	DS DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
GLASDEGIB MALEATE - DAURISMO							
N 210656	002	>A> 8148401	Apr 14, 2029	DS DP			
IMETELSTAT SODIUM - RYTELO							
N 217779	001	>A> 7494982	Dec 27, 2026	DS DP			
IMETELSTAT SODIUM - RYTELO							
N 217779	002	>A> 7494982	Dec 27, 2026	DS DP			
IOHEXOL - IOHEXOL							
A 217737	001					>A> CGT	Jul 26, 2026
LETROZOLE; RIBOCICLIB SUCCINATE - KISQALI FEMARA CO-PACK (COPACKAGED)							
N 209935	001	>A> 12544380	Aug 07, 2034	U-3264			
		>A> 12544380	Aug 07, 2034	U-3998			
LINACLOTIDE - LINZESS							
N 202811	001					>A> NPP	Nov 04, 2028
						>A> PED	May 04, 2029
LOTEPREDNOL ETABONATE; TOBRAMYCIN - LOTEPREDNOL ETABONATE AND TOBRAMYCIN							
A 217597	001					>A> CGT	Jul 14, 2026
MEROPENEM; VABORBACTAM - VABOMERE							
N 209776	001	>A> 12533342	May 20, 2039	U-3421			
MITAPIVAT SULFATE - AQVESME							
N 216196	004	>A> 10632114	May 03, 2032	U-4391			
		>A> 11254652	Nov 21, 2038	DS DP			
		>A> 11878049	Jul 31, 2041	U-4390			
		>A> 9193701	Oct 26, 2032	U-4393			
		>A> 9682080	May 03, 2032	U-4392			
		>A> RE49582	Feb 24, 2031	DS DP			
NALOXONE HYDROCHLORIDE - REZENOPY							
N 215487	001	>A> 12514854	Feb 05, 2041	U-4397			
NERANDOMILAST - JASCAYD							
N 218764	001	>A> 11406638	Oct 22, 2038	U-4297		>A> I-979	Dec 19, 2028
		>A> 11406638	Oct 22, 2038	U-4373			
		>A> 11813266	Oct 22, 2038	U-4292			
		>A> 11813266	Oct 22, 2038	U-4372			
NERANDOMILAST - JASCAYD							
N 218764	002	>A> 11406638	Oct 22, 2038	U-4297		>A> I-979	Dec 19, 2028
		>A> 11406638	Oct 22, 2038	U-4373			
		>A> 11813266	Oct 22, 2038	U-4292			
		>A> 11813266	Oct 22, 2038	U-4372			
NOREPINEPHRINE BITARTRATE - NOREPINEPHRINE BITARTRATE IN 0.9% SODIUM CHLORIDE							
N 215700	004	>A> 10888534	Apr 26, 2039	DP			
		>A> RE49422	Feb 26, 2035	DP			
		>A> RE49443	Feb 26, 2035	DP			
OCTREOTIDE ACETATE - OCTREOTIDE ACETATE							
A 216589	001					>A> CGT	Aug 02, 2026
OCTREOTIDE ACETATE - OCTREOTIDE ACETATE							
A 216589	002					>A> CGT	Jul 27, 2026
OCTREOTIDE ACETATE - OCTREOTIDE ACETATE							
A 216589	003					>A> CGT	Jul 27, 2026

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ODEVIXIBAT - BYLVAY							
N 215498	001	>A> 12508234	Jun 20, 2039	U-3186			
		>A> 12508234	Jun 20, 2039	U-3648			
ODEVIXIBAT - BYLVAY							
N 215498	002	>A> 12508234	Jun 20, 2039	U-3186			
		>A> 12508234	Jun 20, 2039	U-3648			
ODEVIXIBAT - BYLVAY							
N 215498	003	>A> 12508234	Jun 20, 2039	U-3186			
		>A> 12508234	Jun 20, 2039	U-3648			
ODEVIXIBAT - BYLVAY							
N 215498	004	>A> 12508234	Jun 20, 2039	U-3186			
		>A> 12508234	Jun 20, 2039	U-3648			
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	001	>A> 10300054	May 31, 2033	DP U-3140			
		>A> 10300054	May 31, 2033	DP U-3141			
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	002	>A> 10300054	May 31, 2033	DP U-3140			
		>A> 10300054	May 31, 2033	DP U-3141			
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	003	>A> 10300054	May 31, 2033	DP U-3140			
		>A> 10300054	May 31, 2033	DP U-3141			
OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI							
N 213378	004	>A> 10300054	May 31, 2033	DP U-3140			
		>A> 10300054	May 31, 2033	DP U-3141			
OLEZARSEN SODIUM - TRYNGOLZA (AUTOINJECTOR)							
N 218614	001	>A> 12509684	May 01, 2034	U-4050			
ORITAVANCIN DIPHOSPHATE - ORBACTIV							
N 206334	001	>A> 12514899	Aug 29, 2029	U-4398			
ORITAVANCIN DIPHOSPHATE - KIMYRSA							
N 214155	001	>A> 12514899	Aug 29, 2029	U-4398			
OXYCODONE - XTAMPZA ER							
N 208090	001	>A> 7771707	Oct 09, 2028	DP			
OXYCODONE - XTAMPZA ER							
N 208090	002	>A> 7771707	Oct 09, 2028	DP			
OXYCODONE - XTAMPZA ER							
N 208090	003	>A> 7771707	Oct 09, 2028	DP			
OXYCODONE - XTAMPZA ER							
N 208090	004	>A> 7771707	Oct 09, 2028	DP			
OXYCODONE - XTAMPZA ER							
N 208090	005	>A> 7771707	Oct 09, 2028	DP			
PEGCETACOPLAN - SYFOVRE							
N 217171	001	>A> 12528836	Oct 07, 2036	U-4394			
PIRTOBRUTINIB - JAYPIRCA							
N 216059	001					>A> I-981	Dec 02, 2028

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
PIRTOBRUTINIB - JAYPIRCA							
N 216059	002					>A> I-981	Dec 02, 2028
POTASSIUM CHLORIDE - POTASSIUM CHLORIDE							
N 206814	001	>A> 12539314	Mar 07, 2039	DP			
POTASSIUM CHLORIDE - POTASSIUM CHLORIDE							
N 206814	002	>A> 12539314	Mar 07, 2039	DP			
RIBOCICLIB SUCCINATE - KISQALI							
N 209092	001	>A> 12544379	Aug 07, 2034			U-3975	
		>A> 12544380	Aug 07, 2034			U-4404	
		>A> 12544380	Aug 07, 2034			U-4405	
RIOCIGUAT - ADEMPAS							
N 204819	001	>A> 12503469	Feb 18, 2034	DP		U-2834	
		>A> 12503469	Feb 18, 2034	DP		U-2835	
RIOCIGUAT - ADEMPAS							
N 204819	002	>A> 12503469	Feb 18, 2034	DP		U-2834	
		>A> 12503469	Feb 18, 2034	DP		U-2835	
RIOCIGUAT - ADEMPAS							
N 204819	003	>A> 12503469	Feb 18, 2034	DP		U-2834	
		>A> 12503469	Feb 18, 2034	DP		U-2835	
RIOCIGUAT - ADEMPAS							
N 204819	004	>A> 12503469	Feb 18, 2034	DP		U-2834	
		>A> 12503469	Feb 18, 2034	DP		U-2835	
RIOCIGUAT - ADEMPAS							
N 204819	005	>A> 12503469	Feb 18, 2034	DP		U-2834	
		>A> 12503469	Feb 18, 2034	DP		U-2835	
SELEXIPAG - UPTRAVI							
N 207947	001	>A> 10821108	Dec 01, 2036	DP		U-2992	
		>A> 10821108*PED	Jun 01, 2037				
		>A> 10828298	Dec 01, 2036	DP		U-2991	
		>A> 10828298*PED	Jun 01, 2037				
		>A> 7205302	Oct 31, 2026	DS DP		U-1797	
		>A> 7205302*PED	Apr 30, 2027				
		>A> 8791122	Aug 01, 2030	DS DP			
		>A> 8791122*PED	Feb 01, 2031				
		>A> 9173881	Aug 12, 2029			U-1798	
		>A> 9173881*PED	Feb 12, 2030				
		>A> 9284280	Jun 25, 2030			U-1831	
		>A> 9284280*PED	Dec 25, 2030				
SELEXIPAG - UPTRAVI							
N 207947	002	>A> 10821108	Dec 01, 2036	DP		U-2992	
		>A> 10821108*PED	Jun 01, 2037				
		>A> 10828298	Dec 01, 2036	DP		U-2991	
		>A> 10828298*PED	Jun 01, 2037				
		>A> 7205302	Oct 31, 2026	DS DP		U-1797	
		>A> 7205302*PED	Apr 30, 2027				
		>A> 8791122	Aug 01, 2030	DS DP			
		>A> 8791122*PED	Feb 01, 2031				
		>A> 9173881	Aug 12, 2029			U-1798	
		>A> 9173881*PED	Feb 12, 2030				
		>A> 9284280	Jun 25, 2030			U-1831	
		>A> 9284280*PED	Dec 25, 2030				
SELEXIPAG - UPTRAVI							
N 207947	003	>A> 10821108	Dec 01, 2036	DP		U-2992	
		>A> 10821108*PED	Jun 01, 2037				

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
SELEXIPAG - UPTRAVI							
N 207947 003	>A>	10828298	Dec 01, 2036	DP		U-2991	
	>A>	10828298*PED	Jun 01, 2037				
	>A>	7205302	Oct 31, 2026	DS DP		U-1797	
	>A>	7205302*PED	Apr 30, 2027				
	>A>	8791122	Aug 01, 2030	DS DP			
	>A>	8791122*PED	Feb 01, 2031				
	>A>	9173881	Aug 12, 2029			U-1798	
	>A>	9173881*PED	Feb 12, 2030				
	>A>	9284280	Jun 25, 2030			U-1831	
	>A>	9284280*PED	Dec 25, 2030				
SELEXIPAG - UPTRAVI							
N 207947 004	>A>	10821108	Dec 01, 2036	DP		U-2992	
	>A>	10821108*PED	Jun 01, 2037				
	>A>	10828298	Dec 01, 2036	DP		U-2991	
	>A>	10828298*PED	Jun 01, 2037				
	>A>	7205302	Oct 31, 2026	DS DP		U-1797	
	>A>	7205302*PED	Apr 30, 2027				
	>A>	8791122	Aug 01, 2030	DS DP			
	>A>	8791122*PED	Feb 01, 2031				
	>A>	9173881	Aug 12, 2029			U-1798	
	>A>	9173881*PED	Feb 12, 2030				
	>A>	9284280	Jun 25, 2030			U-1831	
	>A>	9284280*PED	Dec 25, 2030				
SELEXIPAG - UPTRAVI							
N 207947 005	>A>	10821108	Dec 01, 2036	DP		U-2992	
	>A>	10821108*PED	Jun 01, 2037				
	>A>	10828298	Dec 01, 2036	DP		U-2991	
	>A>	10828298*PED	Jun 01, 2037				
	>A>	7205302	Oct 31, 2026	DS DP		U-1797	
	>A>	7205302*PED	Apr 30, 2027				
	>A>	8791122	Aug 01, 2030	DS DP			
	>A>	8791122*PED	Feb 01, 2031				
	>A>	9173881	Aug 12, 2029			U-1798	
	>A>	9173881*PED	Feb 12, 2030				
	>A>	9284280	Jun 25, 2030			U-1831	
	>A>	9284280*PED	Dec 25, 2030				
SELEXIPAG - UPTRAVI							
N 207947 006	>A>	10821108	Dec 01, 2036	DP		U-2992	
	>A>	10821108*PED	Jun 01, 2037				
	>A>	10828298	Dec 01, 2036	DP		U-2991	
	>A>	10828298*PED	Jun 01, 2037				
	>A>	7205302	Oct 31, 2026	DS DP		U-1797	
	>A>	7205302*PED	Apr 30, 2027				
	>A>	8791122	Aug 01, 2030	DS DP			
	>A>	8791122*PED	Feb 01, 2031				
	>A>	9173881	Aug 12, 2029			U-1798	
	>A>	9173881*PED	Feb 12, 2030				
	>A>	9284280	Jun 25, 2030			U-1831	
	>A>	9284280*PED	Dec 25, 2030				
SELEXIPAG - UPTRAVI							
N 207947 007	>A>	10821108	Dec 01, 2036	DP		U-2992	
	>A>	10821108*PED	Jun 01, 2037				
	>A>	10828298	Dec 01, 2036	DP		U-2991	
	>A>	10828298*PED	Jun 01, 2037				
	>A>	7205302	Oct 31, 2026	DS DP		U-1797	
	>A>	7205302*PED	Apr 30, 2027				
	>A>	8791122	Aug 01, 2030	DS DP			
	>A>	8791122*PED	Feb 01, 2031				
	>A>	9173881	Aug 12, 2029			U-1798	
	>A>	9173881*PED	Feb 12, 2030				
	>A>	9284280	Jun 25, 2030			U-1831	
	>A>	9284280*PED	Dec 25, 2030				

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
SELEXIPAG - UPTRAVI							
N 207947 008	>A>	10821108	Dec 01, 2036	DP		U-2992	
	>A>	10821108*PED	Jun 01, 2037				
	>A>	10828298	Dec 01, 2036	DP		U-2991	
	>A>	10828298*PED	Jun 01, 2037				
	>A>	7205302	Oct 31, 2026	DS DP		U-1797	
	>A>	7205302*PED	Apr 30, 2027				
	>A>	8791122	Aug 01, 2030	DS DP			
	>A>	8791122*PED	Feb 01, 2031				
	>A>	9173881	Aug 12, 2029			U-1798	
	>A>	9173881*PED	Feb 12, 2030				
	>A>	9284280	Jun 25, 2030			U-1831	
	>A>	9284280*PED	Dec 25, 2030				
SELEXIPAG - UPTRAVI							
N 214275 001	>A>	7205302	Oct 31, 2026	DS DP		U-1797	
	>A>	7205302*PED	Apr 30, 2027				
	>A>	8791122	Aug 01, 2030	DS DP			
	>A>	8791122*PED	Feb 01, 2031				
	>A>	9173881	Aug 12, 2029			U-1798	
	>A>	9173881*PED	Feb 12, 2030				
	>A>	9284280	Jun 25, 2030			U-1831	
	>A>	9284280*PED	Dec 25, 2030				
SEMAGLUTIDE - RYBELSUS							
N 213051 001	>A>	12514822	May 02, 2034			U-2628	
SEMAGLUTIDE - RYBELSUS							
N 213051 002	>A>	12514822	May 02, 2034			U-2628	
SEMAGLUTIDE - RYBELSUS							
N 213051 003	>A>	12514822	May 02, 2034			U-2628	
SEMAGLUTIDE - RYBELSUS							
N 213051 004	>A>	12514822	May 02, 2034			U-2628	
SEMAGLUTIDE - RYBELSUS							
N 213051 005	>A>	12514822	May 02, 2034			U-2628	
SEMAGLUTIDE - RYBELSUS							
N 213051 006	>A>	12514822	May 02, 2034			U-2628	
SEMAGLUTIDE - WEGOVY							
N 218316 001	>A>	10278923	May 02, 2034			U-4389	
	>A>	11382957	Dec 16, 2031	DP			
	>A>	11833248	Feb 01, 2039	DP		U-4387	
	>A>	12239739	May 02, 2034			U-4388	
	>A>	12396953	Feb 01, 2039	DP		U-4387	
	>A>	8129343	Dec 05, 2031	DS DP			
	>A>	8536122	Mar 20, 2026	DS DP			
SEMAGLUTIDE - WEGOVY							
N 218316 002	>A>	10278923	May 02, 2034			U-4389	
	>A>	11382957	Dec 16, 2031	DP			
	>A>	11833248	Feb 01, 2039	DP		U-4387	
	>A>	12239739	May 02, 2034			U-4388	
	>A>	12396953	Feb 01, 2039	DP		U-4387	
	>A>	8129343	Dec 05, 2031	DS DP			
	>A>	8536122	Mar 20, 2026	DS DP			
SEMAGLUTIDE - WEGOVY							
N 218316 003	>A>	10278923	May 02, 2034			U-4389	
	>A>	11382957	Dec 16, 2031	DP			
	>A>	11833248	Feb 01, 2039	DP		U-4387	
	>A>	12239739	May 02, 2034			U-4388	
	>A>	12396953	Feb 01, 2039	DP		U-4387	

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
SEMAGLUTIDE - WEGOVY							
N 218316	003	>A> 8129343	Dec 05, 2031	DS DP			
		>A> 8536122	Mar 20, 2026	DS DP			
		>A> 9278123	Dec 16, 2031	DP U-4389			
SEMAGLUTIDE - WEGOVY							
N 218316	004	>A> 10278923	May 02, 2034	U-4389			
		>A> 11382957	Dec 16, 2031	DP			
		>A> 11833248	Feb 01, 2039	DP U-4387			
		>A> 12239739	May 02, 2034	U-4388			
		>A> 12396953	Feb 01, 2039	DP U-4387			
		>A> 8129343	Dec 05, 2031	DS DP			
		>A> 8536122	Mar 20, 2026	DS DP			
		>A> 9278123	Dec 16, 2031	DP U-4389			
SEVABERTINIB - HYRNUO							
N 219972	001	>A> 10428063	Oct 10, 2035	DS DP			
SILDENAFIL CITRATE - VYBRIQUE							
N 210858	001	>A> 11123287	Dec 16, 2033	DP		>A> NP	Dec 16, 2028
SILDENAFIL CITRATE - VYBRIQUE							
N 210858	002	>A> 11123287	Dec 16, 2033	DP		>A> NP	Dec 16, 2028
SILDENAFIL CITRATE - VYBRIQUE							
N 210858	003	>A> 11123287	Dec 16, 2033	DP		>A> NP	Dec 16, 2028
SILDENAFIL CITRATE - VYBRIQUE							
N 210858	004	>A> 11123287	Dec 16, 2033	DP		>A> NP	Dec 16, 2028
TENAPANOR HYDROCHLORIDE - IBSRELA							
N 211801	001	>A> 12539299	Nov 26, 2042	DP			
TENAPANOR HYDROCHLORIDE - XPHOZAH							
N 213931	001	>A> 12539299	Nov 26, 2042	DP			
TENAPANOR HYDROCHLORIDE - XPHOZAH							
N 213931	002	>A> 12539299	Nov 26, 2042	DP			
TENAPANOR HYDROCHLORIDE - XPHOZAH							
N 213931	003	>A> 12539299	Nov 26, 2042	DP			
TIRZEPATIDE - MOUNJARO (AUTOINJECTOR)							
N 215866	001	>A> 12343382	Jul 22, 2039	U-4229			
		>A> 12343382	Jul 22, 2039	U-4230			
		>A> 12343382	Jul 22, 2039	U-4231			
		>A> 12343382	Jul 22, 2039	U-4232			
		>A> 12343382	Jul 22, 2039	U-4400			
		>A> 12343382	Jul 22, 2039	U-4401			
		>A> 12453755	Jun 14, 2039	U-4375			
		>A> 12453755	Jun 14, 2039	U-4376			
		>A> 12453755	Jun 14, 2039	U-4377			
		>A> 12453755	Jun 14, 2039	U-4378			
		>A> 12453755	Jun 14, 2039	U-4379			
		>A> 12453755	Jun 14, 2039	U-4380			
		>A> 12453755	Jun 14, 2039	U-4381			
		>A> 12453755	Jun 14, 2039	U-4382			
		>A> 12453755	Jun 14, 2039	U-4383			
		>A> 12453755	Jun 14, 2039	U-4384			
		>A> 12453755	Jun 14, 2039	U-4385			
		>A> 12453755	Jun 14, 2039	U-4386			
		>A> 9474780	Jan 05, 2036	DS DP U-4374			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
TIRZEPATIDE - MOUNJARO (AUTOINJECTOR)							
N 215866 002	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	12453755	Jun 14, 2039	U-4375			
	>A>	12453755	Jun 14, 2039	U-4376			
	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			
	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO (AUTOINJECTOR)							
N 215866 003	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	12453755	Jun 14, 2039	U-4375			
	>A>	12453755	Jun 14, 2039	U-4376			
	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			
	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO (AUTOINJECTOR)							
N 215866 004	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	12453755	Jun 14, 2039	U-4375			
	>A>	12453755	Jun 14, 2039	U-4376			
	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			
	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO (AUTOINJECTOR)							
N 215866 005	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
TIRZEPATIDE - MOUNJARO (AUTOINJECTOR)							
N 215866	005	>A> 12343382	Jul 22, 2039	U-4400			
		>A> 12343382	Jul 22, 2039	U-4401			
		>A> 12453755	Jun 14, 2039	U-4375			
		>A> 12453755	Jun 14, 2039	U-4376			
		>A> 12453755	Jun 14, 2039	U-4377			
		>A> 12453755	Jun 14, 2039	U-4378			
		>A> 12453755	Jun 14, 2039	U-4379			
		>A> 12453755	Jun 14, 2039	U-4380			
		>A> 12453755	Jun 14, 2039	U-4381			
		>A> 12453755	Jun 14, 2039	U-4382			
		>A> 12453755	Jun 14, 2039	U-4383			
		>A> 12453755	Jun 14, 2039	U-4384			
		>A> 12453755	Jun 14, 2039	U-4385			
		>A> 12453755	Jun 14, 2039	U-4386			
		>A> 9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO (AUTOINJECTOR)							
N 215866	006	>A> 12343382	Jul 22, 2039	U-4229			
		>A> 12343382	Jul 22, 2039	U-4230			
		>A> 12343382	Jul 22, 2039	U-4231			
		>A> 12343382	Jul 22, 2039	U-4232			
		>A> 12343382	Jul 22, 2039	U-4400			
		>A> 12343382	Jul 22, 2039	U-4401			
		>A> 12453755	Jun 14, 2039	U-4375			
		>A> 12453755	Jun 14, 2039	U-4376			
		>A> 12453755	Jun 14, 2039	U-4377			
		>A> 12453755	Jun 14, 2039	U-4378			
		>A> 12453755	Jun 14, 2039	U-4379			
		>A> 12453755	Jun 14, 2039	U-4380			
		>A> 12453755	Jun 14, 2039	U-4381			
		>A> 12453755	Jun 14, 2039	U-4382			
		>A> 12453755	Jun 14, 2039	U-4383			
		>A> 12453755	Jun 14, 2039	U-4384			
		>A> 12453755	Jun 14, 2039	U-4385			
		>A> 12453755	Jun 14, 2039	U-4386			
		>A> 9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866	007	>A> 12343382	Jul 22, 2039	U-4229			
		>A> 12343382	Jul 22, 2039	U-4230			
		>A> 12343382	Jul 22, 2039	U-4231			
		>A> 12343382	Jul 22, 2039	U-4232			
		>A> 12343382	Jul 22, 2039	U-4400			
		>A> 12343382	Jul 22, 2039	U-4401			
		>A> 12453755	Jun 14, 2039	U-4375			
		>A> 12453755	Jun 14, 2039	U-4376			
		>A> 12453755	Jun 14, 2039	U-4377			
		>A> 12453755	Jun 14, 2039	U-4378			
		>A> 12453755	Jun 14, 2039	U-4379			
		>A> 12453755	Jun 14, 2039	U-4380			
		>A> 12453755	Jun 14, 2039	U-4381			
		>A> 12453755	Jun 14, 2039	U-4382			
		>A> 12453755	Jun 14, 2039	U-4383			
		>A> 12453755	Jun 14, 2039	U-4384			
		>A> 12453755	Jun 14, 2039	U-4385			
		>A> 12453755	Jun 14, 2039	U-4386			
		>A> 9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866	008	>A> 12343382	Jul 22, 2039	U-4229			
		>A> 12343382	Jul 22, 2039	U-4230			
		>A> 12343382	Jul 22, 2039	U-4231			
		>A> 12343382	Jul 22, 2039	U-4232			
		>A> 12343382	Jul 22, 2039	U-4400			
		>A> 12343382	Jul 22, 2039	U-4401			
		>A> 12453755	Jun 14, 2039	U-4375			
		>A> 12453755	Jun 14, 2039	U-4376			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
TIRZEPATIDE - MOUNJARO							
N 215866 008	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			
	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 009	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	12453755	Jun 14, 2039	U-4375			
	>A>	12453755	Jun 14, 2039	U-4376			
	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			
	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 010	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	12453755	Jun 14, 2039	U-4375			
	>A>	12453755	Jun 14, 2039	U-4376			
	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			
	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 011	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	12453755	Jun 14, 2039	U-4375			
	>A>	12453755	Jun 14, 2039	U-4376			
	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
TIRZEPATIDE - MOUNJARO							
N 215866 011	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 012	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	12453755	Jun 14, 2039	U-4375			
	>A>	12453755	Jun 14, 2039	U-4376			
	>A>	12453755	Jun 14, 2039	U-4377			
	>A>	12453755	Jun 14, 2039	U-4378			
	>A>	12453755	Jun 14, 2039	U-4379			
	>A>	12453755	Jun 14, 2039	U-4380			
	>A>	12453755	Jun 14, 2039	U-4381			
	>A>	12453755	Jun 14, 2039	U-4382			
	>A>	12453755	Jun 14, 2039	U-4383			
	>A>	12453755	Jun 14, 2039	U-4384			
	>A>	12453755	Jun 14, 2039	U-4385			
	>A>	12453755	Jun 14, 2039	U-4386			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 013	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 014	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 015	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 016	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
TIRZEPATIDE - MOUNJARO							
N 215866 016	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO							
N 215866 017	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO KWIKPEN							
N 215866 019	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
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N 215866 020	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO KWIKPEN							
N 215866 021	>A>	12295987	Dec 30, 2041	U-4192			
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	>A>	12343382	Jul 22, 2039	U-4229			
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	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO KWIKPEN							
N 215866 022	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			
	>A>	12343382	Jul 22, 2039	U-4231			
	>A>	12343382	Jul 22, 2039	U-4232			
	>A>	12343382	Jul 22, 2039	U-4400			
	>A>	12343382	Jul 22, 2039	U-4401			
	>A>	9474780	Jan 05, 2036	DS DP U-4374			
TIRZEPATIDE - MOUNJARO KWIKPEN							
N 215866 023	>A>	12295987	Dec 30, 2041	U-4192			
	>A>	12295987	Dec 30, 2041	U-4193			
	>A>	12343382	Jul 22, 2039	U-4229			
	>A>	12343382	Jul 22, 2039	U-4230			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
TIRZEPATIDE - MOUNJARO KWIKPEN							
N 215866	023	>A> 12343382	Jul 22, 2039	U-4231			
		>A> 12343382	Jul 22, 2039	U-4232			
		>A> 12343382	Jul 22, 2039	U-4400			
		>A> 12343382	Jul 22, 2039	U-4401			
		>A> 9474780	Jan 05, 2036	DS DP U-4374			
TRADIPITANT - NEREUS							
N 220152	001	>A> 10772880	Mar 04, 2036	U-4396			
		>A> 10821099	Mar 04, 2036	U-4396			
		>A> 11324735	Mar 04, 2036	U-4396			
		>A> 12318375	Aug 09, 2036	U-4396			
TRILACICLIB DIHYDROCHLORIDE - COSELA							
N 214200	001	>A> 12527798	Dec 05, 2037	U-3504			
TROFINETIDE - DAYBUE							
N 217026	001	>A> 12492167	Jul 12, 2042	DS DP U-3556			
TROFINETIDE - DAYBUE STIX							
N 219884	001	>A> 11370755	Aug 03, 2040	DS DP			
		>A> 11827600	Jul 12, 2042	DS DP U-3556			
		>A> 12492167	Jul 12, 2042	DS DP U-3556			
		>A> 9212204	Jan 27, 2032	U-3556			
TROFINETIDE - DAYBUE STIX							
N 219884	002	>A> 11370755	Aug 03, 2040	DS DP			
		>A> 11827600	Jul 12, 2042	DS DP U-3556			
		>A> 12492167	Jul 12, 2042	DS DP U-3556			
		>A> 9212204	Jan 27, 2032	U-3556			
TROFINETIDE - DAYBUE STIX							
N 219884	003	>A> 11370755	Aug 03, 2040	DS DP			
		>A> 11827600	Jul 12, 2042	DS DP U-3556			
		>A> 12492167	Jul 12, 2042	DS DP U-3556			
		>A> 9212204	Jan 27, 2032	U-3556			
VIMSELTINIB - ROMVIMZA							
N 219304	001	>A> 12509443	Apr 30, 2045	DP			
		>A> 12528787	Dec 06, 2044	DS DP			
VIMSELTINIB - ROMVIMZA							
N 219304	002	>A> 12509443	Apr 30, 2045	DP			
		>A> 12528787	Dec 06, 2044	DS DP			
VIMSELTINIB - ROMVIMZA							
N 219304	003	>A> 12509443	Apr 30, 2045	DP			
		>A> 12528787	Dec 06, 2044	DS DP			
VOCLOSPORIN - LUPKYNIS							
N 213716	001	>A> 7332472	Oct 17, 2027	DS DP U-3056			
VONOPRAZAN FUMARATE - VOQUEZNA							
N 215151	001	>A> 7977488	Apr 10, 2030	DS			
VONOPRAZAN FUMARATE - VOQUEZNA							
N 215151	002	>A> 7977488	Apr 10, 2030	DS			
VOSORITIDE - VOXZOGO							
N 214938	001	>A> 12514906	Aug 01, 2036	DP U-3927			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2026

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
VOSORITIDE - VOXZOGO						
N 214938 002	>A> 12514906	Aug 01, 2036	DP		U-3927	
VOSORITIDE - VOXZOGO						
N 214938 003	>A> 12514906	Aug 01, 2036	DP		U-3927	
ZIFTOMENIB - KOMZIFTI						
N 220305 001	>A> 12521396	Jul 16, 2044	DP			
ZOLIFLODACIN - NUZOLVENCE						
N 219491 001	>A> 8658641	Jun 20, 2030	DS			
	>A> 8889671	Jan 21, 2034	DS		U-4369	
	>A> 9040528	Oct 13, 2029			U-4369	
	>A> 9187495	Jan 21, 2034	DS		U-4369	
	>A> 9540394	Jan 21, 2034			U-4369	
	>A> 9839641	Jan 21, 2034			U-4369	

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, 46TH Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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