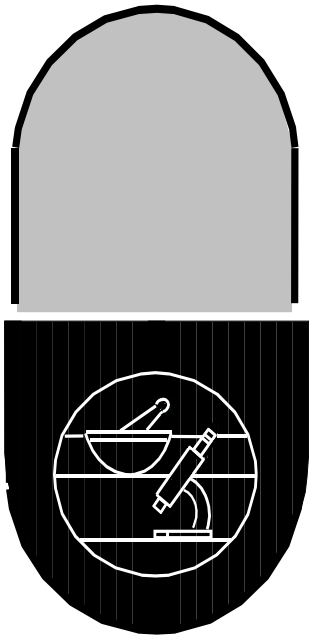
CUMULATIVE SUPPLEMENT 1
JANUARY 2021



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

41st 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

2021

Prepared By
Food and Drug Administration
Office of Medical Products and Tobacco
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January 2021

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CUMULATIVE SUPPLEMENT 1
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1.0 INTRODUCTION

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for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of this Edition List will then be added to the "Discontinued Drug Product List" appearing in the next Edition. The current Annual Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.

- All product changes received and processed as of the date of publication.
  - Refer to CS Section 1.7 Cumulative Supplement Legend for types of changes

- New Drug Application (NDA) approvals appear in the CS month they were approved.

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

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

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

1.3 APPLICANT NAME CHANGES

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

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

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)

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).

- 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

[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.

AB4	THYRO-TABS	ALVOGEN GROUP HOLDINGS 4 LLC	0.3MG	N021116	RLD	-
AB4	LEVOTHYROXINE SODIUM[3]	MYLAN	0.3MG	A076187	-	RS

1.5 AVAILABILITY OF THE EDITION

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

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

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

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

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,

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

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, 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 2020	MAR 2021	JUN 2021	SEP 2021	DEC 2021
DRUG PRODUCTS	20478				
LISTED SINGLE SOURCE	2659 (13.0%)				

MULTISOURCE	17819 (87.0%)
THERAPEUTICALLY EQUIVALENT	17746 (86.7%)
NOT THERAPEUTICALLY EQUIVALENT	73 (0.4%)
EXCEPTIONS[4]	54 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	22
NUMBER OF APPLICANTS	1185

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
CAHN[5]	Applicant holder firm name has changed

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

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

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

ACETAMINOPHEN

POWDER;INTRAVENOUS

ACETAMINOPHEN

>A>		+ @	MYLAN LABS LTD	1GM/VIAL	N206610	001	Jan 15, 2021	Jan NEWA

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE;ORAL

BUTALBITAL, ACETAMINOPHEN, CAFFEINE AND CODEINE PHOSPHATE

>A>	AB		NOSTRUM LABS INC	325MG;50MG;40MG;30MG	A075929	001	Apr 22, 2002	Jan CAHN
>D>	AB		VINTAGE PHARMS	325MG;50MG;40MG;30MG	A075929	001	Apr 22, 2002	Jan CAHN

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET;ORAL

OXYCODONE AND ACETAMINOPHEN

>D>	AA		ANDA REPOSITORY	325MG;5MG	A207834	001	Aug 15, 2019	Jan CAHN
>D>	AA			325MG;7.5MG	A207834	002	Aug 15, 2019	Jan CAHN
>D>	AA			325MG;10MG	A207834	003	Aug 15, 2019	Jan CAHN
>A>	AA		CHARTWELL	325MG;5MG	A207834	001	Aug 15, 2019	Jan CAHN
>A>	AA			325MG;7.5MG	A207834	002	Aug 15, 2019	Jan CAHN
>A>	AA			325MG;10MG	A207834	003	Aug 15, 2019	Jan CAHN

ROXICET

>D>	AA		HIKMA	325MG;5MG	A087003	001		Jan DISC
>A>		@		325MG;5MG	A087003	001		Jan DISC

ACYCLOVIR

SUSPENSION;ORAL

ACYCLOVIR

>A>	AB		VISTAPHARM	200MG/5ML	A213951	001	Jan 11, 2021	Jan NEWA

ACYCLOVIR SODIUM

INJECTABLE;INJECTION

ACYCLOVIR SODIUM

>D>		!	ZYDUS PHARMS	EQ 500MG BASE/VIAL	A206535	001	Aug 31, 2018	Jan CHRS
>A>	AP			EQ 50MG BASE/ML	A206535	001	Aug 31, 2018	Jan CHRS

ALBENDAZOLE

TABLET;ORAL

ALBENDAZOLE

>A>	AB		DR REDDYS	200MG	A211034	001	Jan 26, 2021	Jan NEWA
>D>	AB		LUPIN LTD	200MG	A211636	001	Jun 10, 2020	Jan DISC
>A>		@		200MG	A211636	001	Jun 10, 2020	Jan DISC
>A>	AB		MSN	200MG	A213435	001	Jan 21, 2021	Jan NEWA

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION;INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

>D>	AN		AUROBINDO PHARMA LTD	EQ 0.083% BASE;0.017%	A206532	001	Jul 08, 2020	Jan DISC
>A>		@		EQ 0.083% BASE;0.017%	A206532	001	Jul 08, 2020	Jan DISC

ALPROSTADIL

INJECTABLE;INJECTION

CAVERJECT

>A>		+ @	PFIZER	0.005MG/VIAL	N020379	003	Jun 27, 1996	Jan CAHN
>A>	AP	+		0.01MG/VIAL	N020379	001	Jul 06, 1995	Jan CAHN
>A>	AP	+!		0.02MG/VIAL	N020379	002	Jul 06, 1995	Jan CAHN
>A>	AP	+!		0.04MG/VIAL	N020379	004	May 19, 1997	Jan CAHN
>D>		+ @	PHARMACIA AND UPJOHN	0.005MG/VIAL	N020379	003	Jun 27, 1996	Jan CAHN
>D>	AP	+		0.01MG/VIAL	N020379	001	Jul 06, 1995	Jan CAHN
>D>	AP	+!		0.02MG/VIAL	N020379	002	Jul 06, 1995	Jan CAHN
>D>	AP	+!		0.04MG/VIAL	N020379	004	May 19, 1997	Jan CAHN

CAVERJECT IMPULSE

>A>			PFIZER	0.01MG/VIAL	N021212	001	Jun 11, 2002	Jan CAHN
>A>				0.02MG/VIAL	N021212	002	Jun 11, 2002	Jan CAHN
>D>			PHARMACIA AND UPJOHN	0.01MG/VIAL	N021212	001	Jun 11, 2002	Jan CAHN
>D>				0.02MG/VIAL	N021212	002	Jun 11, 2002	Jan CAHN

PROSTIN VR PEDIATRIC

>A>	AP	+!	PFIZER	0.5MG/ML	N018484	001		Jan CAHN
>D>	AP	+!	PHARMACIA AND UPJOHN	0.5MG/ML	N018484	001		Jan CAHN

AMANTADINE HYDROCHLORIDE

SYRUP;ORAL

AMANTADINE HYDROCHLORIDE

>D> AA	!	WOCKHARDT BIO AG	50MG/5ML	A075060	001	Dec 24, 1998	Jan DISC
>A>	@		50MG/5ML	A075060	001	Dec 24, 1998	Jan DISC

TABLET;ORAL

AMANTADINE HYDROCHLORIDE

>D> AB		INVAGEN PHARMS	100MG	A207571	001	Jan 31, 2017	Jan DISC
>A>	@		100MG	A207571	001	Jan 31, 2017	Jan DISC

TABLET, EXTENDED RELEASE;ORAL

OSMOLEX ER

>A>	+	ADAMAS PHARMA	EQ 129MG BASE	N209410	001	Feb 16, 2018	Jan CAHN
>A>	+ @		EQ 161MG BASE	N209410	004	Apr 22, 2020	Jan CAHN
>A>	+		EQ 193MG BASE	N209410	002	Feb 16, 2018	Jan CAHN
>A>	+!		EQ 258MG BASE	N209410	003	Feb 16, 2018	Jan CAHN
>D>	+	OSMOTICA PHARM	EQ 129MG BASE	N209410	001	Feb 16, 2018	Jan CAHN
>D>	+ @		EQ 161MG BASE	N209410	004	Apr 22, 2020	Jan CAHN
>D>	+		EQ 193MG BASE	N209410	002	Feb 16, 2018	Jan CAHN
>D>	+!		EQ 258MG BASE	N209410	003	Feb 16, 2018	Jan CAHN

AMINOCAPROIC ACID

SYRUP;ORAL

AMINOCAPROIC ACID

>A> AA	LEADING PHARMA LLC	1.25GM/5ML	A214140	001	Jan 26, 2021	Jan NEWA

AMLODIPINE BESYLATE

TABLET;ORAL

AMLODIPINE BESYLATE

>D> AB		WOCKHARDT	EQ 2.5MG BASE	A078500	001	Sep 06, 2007	Jan DISC
>A>	@		EQ 2.5MG BASE	A078500	001	Sep 06, 2007	Jan DISC
>D> AB			EQ 5MG BASE	A078500	002	Sep 06, 2007	Jan DISC
>A>	@		EQ 5MG BASE	A078500	002	Sep 06, 2007	Jan DISC
>D> AB			EQ 10MG BASE	A078500	003	Sep 06, 2007	Jan DISC
>A>	@		EQ 10MG BASE	A078500	003	Sep 06, 2007	Jan DISC

AMMONIA N-13

INJECTABLE;INTRAVENOUS

AMMONIA N 13

>A> AP	NUKEMED	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204455	001	Apr 23, 2015	Jan CAHN
>D> AP	SPECTRON MRC LLC	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204455	001	Apr 23, 2015	Jan CAHN

AMPHETAMINE ASPARTATE ; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>A> AB	RHODES PHARMS	2.5MG;2.5MG;2.5MG;2.5MG	A213111	003	Jan 13, 2021	Jan NEWA
>A> AB		3.75MG;3.75MG;3.75MG;3.75MG	A213111	005	Jan 13, 2021	Jan NEWA
>A> AB		5MG;5MG;5MG;5MG	A213111	006	Jan 13, 2021	Jan NEWA

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>A> AB	RHODES PHARMS	1.25MG;1.25MG;1.25MG;1.25MG	A213111	001	Jan 13, 2021	Jan NEWA
>A> AB		1.875MG;1.875MG;1.875MG;1.875MG	A213111	002	Jan 13, 2021	Jan NEWA
>A> AB		3.125MG;3.125MG;3.125MG;3.125MG	A213111	004	Jan 13, 2021	Jan NEWA
>A> AB		7.5MG;7.5MG;7.5MG;7.5MG	A213111	007	Jan 13, 2021	Jan NEWA

AMPHETAMINE SULFATE

TABLET;ORAL

AMPHETAMINE SULFATE

>A> AA	GLENMARK PHARMS LTD	5MG	A212186	001	Jan 27, 2021	Jan NEWA
>A> AA		10MG	A212186	002	Jan 27, 2021	Jan NEWA
>D> AA	MAYNE PHARMA	5MG	A213898	001	Jul 14, 2020	Jan DISC
>A>	@	5MG	A213898	001	Jul 14, 2020	Jan DISC
>D> AA		10MG	A213898	002	Jul 14, 2020	Jan DISC
>A>	@	10MG	A213898	002	Jul 14, 2020	Jan DISC
>A> AA	SPECGX LLC	5MG	A213583	001	Jan 22, 2021	Jan NEWA
>A> AA		10MG	A213583	002	Jan 22, 2021	Jan NEWA
>A> AA	SUN PHARM INDS INC	5MG	A214574	001	Jan 27, 2021	Jan NEWA
>A> AA		10MG	A214574	002	Jan 27, 2021	Jan NEWA

ARGATROBAN

INJECTABLE;INJECTION

ARGATROBAN

>A>	AP	CAPLIN	50MG/50ML (1MG/ML)	A214235	001	Jan 21, 2021	Jan NFTG

ARSENIC TRIOXIDE

INJECTABLE;INJECTION

ARSENIC TRIOXIDE

>A>	AP	AMNEAL	1MG/ML	A210739	001	Jan 25, 2021	Jan NEWA
>A>	AP	INGENUS PHARMS LLC	2MG/ML	A209315	002	Jan 14, 2021	Jan NEWA

ATORVASTATIN CALCIUM

TABLET;ORAL

ATORVASTATIN CALCIUM

>A>	AB	ALKEM LABS LTD	EQ 10MG BASE	A209288	001	Dec 21, 2018	Jan CAHN
>A>	AB		EQ 20MG BASE	A209288	002	Dec 21, 2018	Jan CAHN
>A>	AB		EQ 40MG BASE	A209288	003	Dec 21, 2018	Jan CAHN
>A>	AB		EQ 80MG BASE	A209288	004	Dec 21, 2018	Jan CAHN
>D>	AB	THEPHARMANETWORK LLC	EQ 10MG BASE	A209288	001	Dec 21, 2018	Jan CAHN
>D>	AB		EQ 20MG BASE	A209288	002	Dec 21, 2018	Jan CAHN
>D>	AB		EQ 40MG BASE	A209288	003	Dec 21, 2018	Jan CAHN
>D>	AB		EQ 80MG BASE	A209288	004	Dec 21, 2018	Jan CAHN

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET;ORAL

DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE

>A>	AA	WINDER LABS LLC	0.025MG;2.5MG	A211362	001	Jan 27, 2021	Jan NEWA

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE;INJECTION

ENLON-PLUS

>A>		+ @ MYLAN	0.14MG/ML;10MG/ML	N019678	001	Nov 06, 1991	Jan CAHN
>D>		+ @ MYLAN INSTITUTIONAL	0.14MG/ML;10MG/ML	N019678	001	Nov 06, 1991	Jan CAHN

AVIBACTAM SODIUM; CEFTAZIDIME

>A> POWDER;INTRAVENOUS

>A> AVYCAZ

>A>		+! ALLERGAN	EQ 0.5GM BASE;2GM/VIAL	N206494	001	Feb 25, 2015	Jan CDFR

>D> POWDER;IV (INFUSION)

>D> AVYCAZ

>D>		+! ALLERGAN	EQ 0.5GM BASE;2GM/VIAL	N206494	001	Feb 25, 2015	Jan CDFR

BACLOFEN

INJECTABLE;INTRATHECAL

BACLOFEN

>A>	AP	MAIA PHARMS INC	0.05MG/ML	A210777	001	Jan 15, 2021	Jan NEWA

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL;TOPICAL

CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE

>D>	AB	PERRIGO ISRAEL	5%;1.2%	A090979	001	Jun 26, 2012	Jan CHRS
>A>	AB	!	5%;1.2%	A090979	001	Jun 26, 2012	Jan CHRS

DUAC

>D>	AB	+! STIEFEL	5%;1.2%	N050741	001	Aug 26, 2002	Jan CHRS
>A>	AB	+	5%;1.2%	N050741	001	Aug 26, 2002	Jan CHRS

BETHANECHOL CHLORIDE

TABLET;ORAL

BETHANECHOL CHLORIDE

>D>	AA	WOCKHARDT	5MG	A040532	001	Sep 29, 2003	Jan DISC
>A>		@	5MG	A040532	001	Sep 29, 2003	Jan DISC
>D>	AA		50MG	A040518	001	Sep 29, 2003	Jan DISC
>A>		@	50MG	A040518	001	Sep 29, 2003	Jan DISC

BEXAROTENE

CAPSULE;ORAL

BEXAROTENE

>A>	AB	TEVA PHARMS USA	75MG	A209931	001	Jan 14, 2021	Jan NEWA

BIMATOPROST

SOLUTION/DROPS;OPHTHALMIC

BIMATOPROST

>D>	AT		ALEMBIC PHARMS LTD	0.03%	A210263	001	Apr 12, 2019	Jan CHRS
>A>	AT	!		0.03%	A210263	001	Apr 12, 2019	Jan CHRS
>D>	AT	!	LUPIN LTD	0.03%	A203991	001	Feb 20, 2015	Jan CHRS
>A>	AT			0.03%	A203991	001	Feb 20, 2015	Jan CHRS

BUDESONIDE

CAPSULE;ORAL

BUDESONIDE

>D>	AB		BARR LABS DIV TEVA	3MG	A090379	001	Apr 02, 2014	Jan DISC
>A>		@		3MG	A090379	001	Apr 02, 2014	Jan DISC

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

TABLET;SUBLINGUAL

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

>D>	AB		MAYNE PHARMA INC	EQ 2MG BASE;EQ 0.5MG BASE	A206953	001	Jul 17, 2020	Jan DISC
>A>		@		EQ 2MG BASE;EQ 0.5MG BASE	A206953	001	Jul 17, 2020	Jan DISC
>D>	AB			EQ 8MG BASE;EQ 2MG BASE	A206953	002	Jul 17, 2020	Jan DISC
>A>		@		EQ 8MG BASE;EQ 2MG BASE	A206953	002	Jul 17, 2020	Jan DISC

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

BUPROPION HYDROCHLORIDE

>D>	AB1		TORRENT	100MG	A203969	001	Oct 31, 2014	Jan DISC
>A>		@		100MG	A203969	001	Oct 31, 2014	Jan DISC
>D>	AB1			150MG	A203969	002	Oct 31, 2014	Jan DISC
>A>		@		150MG	A203969	002	Oct 31, 2014	Jan DISC
>D>	AB1			200MG	A203969	003	Oct 31, 2014	Jan DISC
>A>		@		200MG	A203969	003	Oct 31, 2014	Jan DISC

CABERGOLINE

TABLET;ORAL

DOSTINEX

>A>		+ @	PFIZER	0.5MG	N020664	001	Dec 23, 1996	Jan CAHN
>D>		+ @	PHARMACIA AND UPJOHN	0.5MG	N020664	001	Dec 23, 1996	Jan CAHN

>A> CABOTEGRAVIR SODIUM

>A> TABLET;ORAL

>A> VOCABRIA

>A>		+!	VIIV HLTHCARE	EQ 30MG BASE	N212887	001	Jan 21, 2021	Jan NEWA

>A> CABOTEGRAVIR; RILPIVIRINE

>A> SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR

>A> CABENUVA KIT

>A>		+!	VIIV HLTHCARE	400MG/2ML (200MG/ML);600MG/2ML (300MG/ML)	N212888	001	Jan 21, 2021	Jan NEWA
>A>		+!		600MG/3ML (200MG/ML);900MG/3ML (300MG/ML)	N212888	002	Jan 21, 2021	Jan NEWA

CELECOXIB

CAPSULE;ORAL

CELECOXIB

>A>	AB		UNICHEM	50MG	A213301	001	Jan 12, 2021	Jan NEWA
>A>	AB			100MG	A213301	002	Jan 12, 2021	Jan NEWA
>A>	AB			200MG	A213301	003	Jan 12, 2021	Jan NEWA
>A>	AB			400MG	A213301	004	Jan 12, 2021	Jan NEWA

CHLORPROMAZINE HYDROCHLORIDE

TABLET;ORAL

CHLORPROMAZINE HYDROCHLORIDE

>A>	AB		LANNETT CO INC	10MG	A212996	001	Jan 22, 2021	Jan NEWA
>A>	AB			25MG	A212996	002	Jan 22, 2021	Jan NEWA
>A>	AB			50MG	A212996	003	Jan 22, 2021	Jan NEWA
>A>	AB			100MG	A212996	004	Jan 22, 2021	Jan NEWA
>A>	AB			200MG	A212996	005	Jan 22, 2021	Jan NEWA

CHLORPROPAMIDE

TABLET;ORAL

CHLORPROPAMIDE

>D>	@ AUROLIFE PHARMA LLC	100MG	A088725	001	Aug 31, 1984	Jan	CAHN
>D>	@	250MG	A088726	001	Aug 31, 1984	Jan	CAHN
>A>	@ RISING	100MG	A088725	001	Aug 31, 1984	Jan	CAHN
>A>	@	250MG	A088726	001	Aug 31, 1984	Jan	CAHN

CILOSTAZOL

TABLET;ORAL

CILOSTAZOL

>D> AB	BRECKENRIDGE PHARM	50MG	A077708	001	Sep 28, 2009	Jan	CAHN
>D> AB		100MG	A077708	002	Sep 28, 2009	Jan	CAHN
>A>	@ EPIC PHARMA LLC	50MG	A077022	002	Mar 11, 2005	Jan	CMS1
>A> AB	NOSTRUM LABS INC	50MG	A077708	001	Sep 28, 2009	Jan	CAHN
>A> AB		100MG	A077708	002	Sep 28, 2009	Jan	CAHN

CLARITHROMYCIN

TABLET;ORAL

CLARITHROMYCIN

>D> AB	WOCKHARDT	250MG	A065266	001	May 31, 2006	Jan	DISC
>A>	@	250MG	A065266	001	May 31, 2006	Jan	DISC
>D> AB		500MG	A065266	002	May 31, 2006	Jan	DISC
>A>	@	500MG	A065266	002	May 31, 2006	Jan	DISC

CLINDAMYCIN PHOSPHATE

GEL;TOPICAL

CLINDAMYCIN PHOSPHATE

>D> AB	GAGE DEVELOPMENT	EQ 1% BASE	A212104	001	Dec 31, 2020	Jan	CAHN
>A> AB	GLENMARK PHARMS LTD	EQ 1% BASE	A214251	001	Feb 10, 2021	Jan	NEWA
>A> AB	PERRIGO UK FINCO	EQ 1% BASE	A212104	001	Dec 31, 2020	Jan	CAHN

INJECTABLE;INJECTION

CLINDAMYCIN PHOSPHATE

>D> AP	MYLAN LABS LTD	EQ 150MG BASE/ML	A204748	001	Oct 10, 2017	Jan	DISC
>A>	@	EQ 150MG BASE/ML	A204748	001	Oct 10, 2017	Jan	DISC

SOLUTION;TOPICAL

>D>	CLEOCIN T						
>D> AT	+! PHARMACIA AND UPJOHN	EQ 1% BASE	N050537	001		Jan	DISC
>A>	+ @	EQ 1% BASE	N050537	001		Jan	DISC

CLINDAMYCIN PHOSPHATE

>D> AT	PERRIGO NEW YORK	EQ 1% BASE	A064050	001	Nov 30, 1995	Jan	CHRS
>A> AT	!	EQ 1% BASE	A064050	001	Nov 30, 1995	Jan	CHRS

CLOBETASOL PROPIONATE

OINTMENT;TOPICAL

CLOBETASOL PROPIONATE

>D> AB	TORRENT	0.05%	A212926	001	Oct 25, 2019	Jan	DISC
>A>	@	0.05%	A212926	001	Oct 25, 2019	Jan	DISC

SOLUTION;TOPICAL

CLOBETASOL PROPIONATE

>A> AT	PRINSTON INC	0.05%	A213139	001	Feb 08, 2021	Jan	NEWA

CLOFARABINE

SOLUTION;INTRAVENOUS

CLOFARABINE

>D> AP	HONG KONG	20MG/20ML (1MG/ML)	A213461	001	Oct 23, 2020	Jan	CAHN
>A> AP	MEITHEAL	20MG/20ML (1MG/ML)	A213461	001	Oct 23, 2020	Jan	CAHN

CLONIDINE

SYSTEM;TRANSDERMAL

CATAPRES-TTS-1

>D> AB	+ BOEHRINGER INGELHEIM	0.1MG/24HR	N018891	001	Oct 10, 1984	Jan	CAHN
>A> AB	+ LAVIPHARM	0.1MG/24HR	N018891	001	Oct 10, 1984	Jan	CAHN

CATAPRES-TTS-2

>D> AB	+ BOEHRINGER INGELHEIM	0.2MG/24HR	N018891	002	Oct 10, 1984	Jan	CAHN
>A> AB	+ LAVIPHARM	0.2MG/24HR	N018891	002	Oct 10, 1984	Jan	CAHN

CATAPRES-TTS-3

>D> AB	+! BOEHRINGER INGELHEIM	0.3MG/24HR	N018891	003	Oct 10, 1984	Jan	CAHN
>A> AB	+! LAVIPHARM	0.3MG/24HR	N018891	003	Oct 10, 1984	Jan	CAHN

CLORAZEPATE DIPOTASSIUM

TABLET;ORAL

CLORAZEPATE DIPOTASSIUM

>A>	AB		AUROLIFE PHARMA LLC	3.75MG	A071858	002	Jul 17, 1987	Jan CAHN
>A>	AB			7.5MG	A071858	003	Jul 17, 1987	Jan CAHN
>A>	AB	!		15MG	A071858	001	Jul 17, 1987	Jan CAHN
>D>	AB		MYLAN	3.75MG	A071858	002	Jul 17, 1987	Jan CAHN
>D>	AB			7.5MG	A071858	003	Jul 17, 1987	Jan CAHN
>D>	AB	!		15MG	A071858	001	Jul 17, 1987	Jan CAHN

CROTAMITON

CREAM;TOPICAL

EURAX

>A>		+ @	JOURNEY	10%	N006927	001		Jan CAHN
>D>		+ @	SUN PHARM INDS INC	10%	N006927	001		Jan CAHN

LOTION;TOPICAL

EURAX

>A>	AT	+!	JOURNEY	10%	N009112	003		Jan CAHN
>D>	AT	+!	SUN PHARM INDS INC	10%	N009112	003		Jan CAHN

CUPRIC SULFATE; MANGANESE SULFATE; SELENIOUS ACID; ZINC SULFATE

SOLUTION;INTRAVENOUS

TRALEMENT

>D>		+!	AM REGENT	EQ 0.3MG COPPER/ML;EQ 55MCG BASE/ML;EQ 60MCG BASE/ML;EQ 3MG BASE/ML	N209376	001	Jul 02, 2020	Jan CPOT
>A>		+!		(1ML) EQ 0.3MG COPPER/ML;EQ 55MCG BASE/ML;EQ 60MCG BASE/ML;EQ 3MG BASE/ML	N209376	001	Jul 02, 2020	Jan CPOT
>A>		+!		(5ML) EQ 0.3MG COPPER/ML;EQ 55MCG BASE/ML;EQ 60MCG BASE/ML;EQ 3MG BASE/ML	N209376	002	Dec 02, 2020	Jan NEWA

DACTINOMYCIN

INJECTABLE;INJECTION

DACTINOMYCIN

>A>	AP		AUROMEDICS PHARMA	0.5MG/VIAL	A203385	001	Nov 09, 2017	Jan CAHN
>D>	AP		MYLAN LABS LTD	0.5MG/VIAL	A203385	001	Nov 09, 2017	Jan CAHN

DEFERASIROX

GRANULE;ORAL

DEFERASIROX

>A>	AB		AMNEAL	180MG	A214194	001	Feb 09, 2021	Jan NEWA
>A>	AB			360MG	A214194	002	Feb 09, 2021	Jan NEWA

DEXRAZOXANE HYDROCHLORIDE

INJECTABLE;INJECTION

DEXRAZOXANE HYDROCHLORIDE

>A>	AP		AUROMEDICS PHARMA	EQ 250MG BASE/VIAL	A200752	001	Oct 19, 2011	Jan CAHN
>A>	AP			EQ 500MG BASE/VIAL	A200752	002	Oct 19, 2011	Jan CAHN
>D>	AP		MYLAN INSTITUTIONAL	EQ 250MG BASE/VIAL	A200752	001	Oct 19, 2011	Jan CAHN
>D>	AP			EQ 500MG BASE/VIAL	A200752	002	Oct 19, 2011	Jan CAHN

DICLOFENAC SODIUM

SOLUTION;TOPICAL

DICLOFENAC SODIUM

>A>	AT		AKORN	1.5%	A206655	001	Jan 28, 2021	Jan NEWA

DICLOXACILLIN SODIUM

CAPSULE;ORAL

DICLOXACILLIN SODIUM

>D>			SANDOZ	EQ 125MG BASE	A061454	002		Jan DISC
>A>		@		EQ 125MG BASE	A061454	002		Jan DISC
>D>	AB			EQ 250MG BASE	A061454	001		Jan DISC
>A>		@		EQ 250MG BASE	A061454	001		Jan DISC
>D>	AB	!		EQ 500MG BASE	A061454	003		Jan DISC
>A>		@		EQ 500MG BASE	A061454	003		Jan DISC
>D>	AB		TEVA	EQ 250MG BASE	A062286	001	Jun 03, 1982	Jan CTEC
>A>				EQ 250MG BASE	A062286	001	Jun 03, 1982	Jan CTEC
>D>	AB			EQ 500MG BASE	A062286	002	Jun 03, 1982	Jan CTEC
>A>		!		EQ 500MG BASE	A062286	002	Jun 03, 1982	Jan CTEC

>D>	DIDANOSINE						
>D>	CAPSULE, DELAYED REL PELLETS;ORAL						
>D>	DIDANOSINE						
>D>	AUROBINDO PHARMA	125MG	A090094	001	Sep 24, 2008	Jan DISC	
>A>	@	125MG	A090094	001	Sep 24, 2008	Jan DISC	
>D>		200MG	A090094	002	Sep 24, 2008	Jan DISC	
>A>	@	200MG	A090094	002	Sep 24, 2008	Jan DISC	
>D>		250MG	A090094	003	Sep 24, 2008	Jan DISC	
>A>	@	250MG	A090094	003	Sep 24, 2008	Jan DISC	
>D>	!	400MG	A090094	004	Sep 24, 2008	Jan DISC	
>A>	@	400MG	A090094	004	Sep 24, 2008	Jan DISC	
	DIHYDROERGOTAMINE MESYLATE						
	INJECTABLE;INJECTION						
	DIHYDROERGOTAMINE MESYLATE						
>D> AP	APOLLO	1MG/ML	A212046	001	Jan 07, 2020	Jan CAHN	
>A> AP	PROVEPHARM SAS	1MG/ML	A212046	001	Jan 07, 2020	Jan CAHN	
	DILTIAZEM HYDROCHLORIDE						
	INJECTABLE;INJECTION						
	DILTIAZEM HYDROCHLORIDE						
>D> AP	INTL MEDICATION	5MG/ML	A075749	001	Nov 21, 2001	Jan DISC	
>A>	@	5MG/ML	A075749	001	Nov 21, 2001	Jan DISC	
	DINOPROSTONE						
	GEL;ENDOCERVICAL						
	PREPIDIL						
>A>	+! PFIZER	0.5MG/3GM	N019617	001	Dec 09, 1992	Jan CAHN	
>D>	+! PHARMACIA AND UPJOHN	0.5MG/3GM	N019617	001	Dec 09, 1992	Jan CAHN	
	SUPPOSITORY;VAGINAL						
	PROSTIN E2						
>A>	+! PFIZER	20MG	N017810	001		Jan CAHN	
>D>	+! PHARMACIA AND UPJOHN	20MG	N017810	001		Jan CAHN	
	DIPYRIDAMOLE						
	TABLET;ORAL						
	DIPYRIDAMOLE						
>D>	@ OXFORD PHARMS	25MG	A040542	001	Apr 21, 2006	Jan CMFD	
>A> AB		25MG	A040542	001	Apr 21, 2006	Jan CMFD	
>D>	@	50MG	A040542	002	Apr 21, 2006	Jan CMFD	
>A> AB		50MG	A040542	002	Apr 21, 2006	Jan CMFD	
>D>	@	75MG	A040542	003	Apr 21, 2006	Jan CMFD	
>A> AB		75MG	A040542	003	Apr 21, 2006	Jan CMFD	
	DOCETAXEL						
	INJECTABLE;INJECTION						
	DOCETAXEL						
>A> AP	HIKMA	20MG/ML (20MG/ML)	A204490	001	Jan 14, 2021	Jan NEWA	
>A> AP		80MG/4ML (20MG/ML)	A204490	002	Jan 14, 2021	Jan NEWA	
>A> AP	SHILPA	20MG/ML (20MG/ML)	N205934	001	Dec 22, 2015	Jan CAHN	
>A> AP		80MG/4ML (20MG/ML)	N205934	002	Dec 22, 2015	Jan CAHN	
>A> AP		160MG/8ML (20MG/ML)	N205934	003	Dec 22, 2015	Jan CAHN	
>D> AP	TEIKOKU PHARMA	20MG/ML (20MG/ML)	N205934	001	Dec 22, 2015	Jan CAHN	
>D> AP		80MG/4ML (20MG/ML)	N205934	002	Dec 22, 2015	Jan CAHN	
>D> AP		160MG/8ML (20MG/ML)	N205934	003	Dec 22, 2015	Jan CAHN	
	DOXEPIN HYDROCHLORIDE						
	TABLET;ORAL						
	DOXEPIN HYDROCHLORIDE						
>D> AB	MYLAN	EQ 3MG BASE	A202337	001	Jan 20, 2016	Jan CAHN	
>D> AB		EQ 6MG BASE	A202337	002	Jan 20, 2016	Jan CAHN	
>D> AB	PAR PHARM INC	EQ 3MG BASE	A202510	001	Jul 24, 2020	Jan DISC	
>A>	@	EQ 3MG BASE	A202510	001	Jul 24, 2020	Jan DISC	
>D> AB		EQ 6MG BASE	A202510	002	Jul 24, 2020	Jan DISC	
>A>	@	EQ 6MG BASE	A202510	002	Jul 24, 2020	Jan DISC	
>A> AB	RK PHARMA	EQ 3MG BASE	A202337	001	Jan 20, 2016	Jan CAHN	
>A> AB		EQ 6MG BASE	A202337	002	Jan 20, 2016	Jan CAHN	

DOXYCYCLINE

CAPSULE;ORAL

DOXYCYCLINE

>A>	@	MYLAN	EQ 50MG BASE	A208942	001	Jan 21, 2021	Jan DISC
>A>	@		EQ 75MG BASE	A208942	002	Jan 21, 2021	Jan DISC
>A>	@		EQ 100MG BASE	A208942	003	Jan 21, 2021	Jan DISC

EFINACONAZOLE

SOLUTION;TOPICAL

EFINACONAZOLE

>D> AT		PERRIGO PHARMA INTL	10%	A211851	001	Dec 16, 2020	Jan DISC
>A>	@		10%	A211851	001	Dec 16, 2020	Jan DISC

EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

>D>	@	LAURUS LABS LTD	200MG;300MG	A212114	001	Jul 26, 2019	Jan CMFD
>A> AB			200MG;300MG	A212114	001	Jul 26, 2019	Jan CMFD
>A> AB		STRIDES PHARMA	200MG;300MG	A091055	001	Jan 13, 2021	Jan NEWA

ESTRADIOL

INSERT, EXTENDED RELEASE;VAGINAL

ESTRING

>A>	+!	PFIZER	0.0075MG/24HR	N020472	001	Apr 26, 1996	Jan CAHN
>D>	+!	PHARMACIA AND UPJOHN	0.0075MG/24HR	N020472	001	Apr 26, 1996	Jan CAHN

ESTROPIPATE

TABLET;ORAL

OGEN .625

>A>	@	PFIZER	0.75MG	A083220	001		Jan CAHN
>D>	@	PHARMACIA AND UPJOHN	0.75MG	A083220	001		Jan CAHN

OGEN 1.25

>A>	@	PFIZER	1.5MG	A083220	002		Jan CAHN
>D>	@	PHARMACIA AND UPJOHN	1.5MG	A083220	002		Jan CAHN

OGEN 2.5

>A>	@	PFIZER	3MG	A083220	003		Jan CAHN
>D>	@	PHARMACIA AND UPJOHN	3MG	A083220	003		Jan CAHN

OGEN 5

>A>		PFIZER	6MG	A083220	004		Jan CAHN
>D>		PHARMACIA AND UPJOHN	6MG	A083220	004		Jan CAHN

ESZOPICLONE

TABLET;ORAL

ESZOPICLONE

>D>	@	BRECKENRIDGE	1MG	A203087	001	May 08, 2019	Jan CAHN
>D>	@		2MG	A203087	002	May 08, 2019	Jan CAHN
>D>	@		3MG	A203087	003	May 08, 2019	Jan CAHN
>A>	@	NOSTRUM LABS INC	1MG	A203087	001	May 08, 2019	Jan CAHN
>A>	@		2MG	A203087	002	May 08, 2019	Jan CAHN
>A>	@		3MG	A203087	003	May 08, 2019	Jan CAHN

ETHINYL ESTRADIOL; ETONOGESTREL

RING;VAGINAL

ETHINYL ESTRADIOL; ETONOGESTREL

>A> AB		TEVA PHARMS USA INC	0.015MG/24HR;0.12MG/24HR	A204305	001	Jan 13, 2021	Jan NEWA

EZETIMIBE; SIMVASTATIN

TABLET;ORAL

EZETIMIBE AND SIMVASTATIN

>D> AB		MYLAN	10MG;10MG	A200082	001	Dec 17, 2020	Jan DISC
>A>	@		10MG;10MG	A200082	001	Dec 17, 2020	Jan DISC
>D> AB			10MG;20MG	A200082	002	Dec 17, 2020	Jan DISC
>A>	@		10MG;20MG	A200082	002	Dec 17, 2020	Jan DISC
>D> AB			10MG;40MG	A200082	003	Dec 17, 2020	Jan DISC
>A>	@		10MG;40MG	A200082	003	Dec 17, 2020	Jan DISC
>D> AB			10MG;80MG	A200082	004	Dec 17, 2020	Jan DISC
>A>	@		10MG;80MG	A200082	004	Dec 17, 2020	Jan DISC

FENOFIBRATE

TABLET;ORAL

FENOFIBRATE

>A> AB		AUSTARPHARMA	48MG	A208476	001	Feb 10, 2021	Jan NEWA
>A> AB			145MG	A208476	002	Feb 10, 2021	Jan NEWA

FENOPROFEN CALCIUM

CAPSULE;ORAL

FENOPROFEN CALCIUM

>D>		@ AUROLIFE PHARMA LLC	EQ 200MG BASE	A072394	001	Oct 17, 1988	Jan CAHN
>D>		@	EQ 300MG BASE	A072395	001	Oct 17, 1988	Jan CAHN
>A>		@ RISING	EQ 200MG BASE	A072394	001	Oct 17, 1988	Jan CAHN
>A>		@	EQ 300MG BASE	A072395	001	Oct 17, 1988	Jan CAHN

FERUMOXYTOL

SOLUTION;INTRAVENOUS

>A> FERUMOXYTOL

>A> AB		SANDOZ INC	EQ 510MG IRON/17ML (EQ 30MG IRON/ML)	A206604	001	Jan 15, 2021	Jan NFTG

FINGOLIMOD HYDROCHLORIDE

CAPSULE;ORAL

FINGOLIMOD HYDROCHLORIDE

>A>		@ MYLAN	EQ 0.5MG BASE	A208005	001	Jan 19, 2021	Jan DISC

FLECAINIDE ACETATE

TABLET;ORAL

TAMBOCOR

>D> AB	+	CNTY LINE PHARMS	50MG	N018830	004	Aug 23, 1988	Jan DISC
>A>	+ @		50MG	N018830	004	Aug 23, 1988	Jan DISC
>D> AB	+		100MG	N018830	001	Oct 31, 1985	Jan DISC
>A>	+ @		100MG	N018830	001	Oct 31, 1985	Jan DISC
>D> AB	+		150MG	N018830	003	Jun 03, 1988	Jan DISC
>A>	+ @		150MG	N018830	003	Jun 03, 1988	Jan DISC

FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS

FLUDEOXYGLUCOSE F18

>D> AP		LANTHEUS MEDICAL	20-200mCi/ML	A203664	001	Feb 04, 2014	Jan CAHN
>A>		NUKEMED	4-500mCi/ML	A203911	001	Apr 22, 2015	Jan CAHN
>A> AP		PHARMALOGIC HLDGS	20-200mCi/ML	A203664	001	Feb 04, 2014	Jan CAHN
>D>		SPECTRON MRC LLC	4-500mCi/ML	A203911	001	Apr 22, 2015	Jan CAHN

FLUOCINOLONE ACETONIDE

OIL/DROPS;OTIC

FLUOCINOLONE ACETONIDE

>A> AT		TASMAN PHARMA	0.01%	A213264	001	Feb 05, 2021	Jan NEWA

>D> FLUOXYMESTERONE

>D> TABLET;ORAL

>D> FLUOXYMESTERONE

>D>	!	UPSHER SMITH LABS	10MG	A088342	001	Oct 21, 1983	Jan DISC
>A>	@		10MG	A088342	001	Oct 21, 1983	Jan DISC

FLUPHENAZINE HYDROCHLORIDE

TABLET;ORAL

FLUPHENAZINE HYDROCHLORIDE

>A> AB		CEROVENE INC	1MG	A214534	001	Jan 07, 2021	Jan NEWA
>A> AB			2.5MG	A214534	002	Jan 07, 2021	Jan NEWA
>A> AB			5MG	A214534	003	Jan 07, 2021	Jan NEWA
>A> AB			10MG	A214534	004	Jan 07, 2021	Jan NEWA

FLURBIPROFEN SODIUM

SOLUTION/DROPS;OPHTHALMIC

FLURBIPROFEN SODIUM

>D> AT		BAUSCH AND LOMB	0.03%	A074447	001	Jan 04, 1995	Jan CHRS
>A>	!		0.03%	A074447	001	Jan 04, 1995	Jan CHRS

>D> OCUFEN

>D> AT	+!	ALLERGAN	0.03%	N019404	001	Dec 31, 1986	Jan DISC
>A>	+ @		0.03%	N019404	001	Dec 31, 1986	Jan DISC

FOSAPREPITANT DIMEGLUMINE

POWDER;INTRAVENOUS

FOSAPREPITANT DIMEGLUMINE

>A>	AP		AUROBINDO PHARMA LTD	EQ 150MG BASE/VIAL	A210625	001	Jan 12, 2021	Jan NEWA

FOSCARNET SODIUM

INJECTABLE;INJECTION

FOSCARNET SODIUM

>A>	AP		FRESENIUS KABI USA	2.4GM/100ML	A212483	001	Jan 29, 2021	Jan NEWA

FOSCAVIR

>D>		+!	CLINIGEN HLTHCARE	2.4GM/100ML	N020068	001	Sep 27, 1991	Jan CTEC
>A>	AP	+!		2.4GM/100ML	N020068	001	Sep 27, 1991	Jan CTEC

FULVESTRANT

INJECTABLE;INTRAMUSCULAR

FULVESTRANT

>A>	AO		AUROMEDICS PHARMA	50MG/ML	A208811	001	Jul 23, 2019	Jan CAHN
>D>	AO		MYLAN INSTITUTIONAL	50MG/ML	A208811	001	Jul 23, 2019	Jan CAHN

FUROSEMIDE

INJECTABLE;INJECTION

FUROSEMIDE

>A>	AP		ATHENEX INC	10MG/ML	A214766	001	Jan 27, 2021	Jan NEWA

GEMCITABINE HYDROCHLORIDE

INJECTABLE;INJECTION

GEMCITABINE HYDROCHLORIDE

>A>	AP		MEITHEAL	200MG/5.26ML (38MG/ML)	A212129	001	Dec 11, 2020	Jan CAHN
>A>	AP			1GM/26.3ML (38MG/ML)	A212129	002	Dec 11, 2020	Jan CAHN
>A>	AP			2GM/52.6ML (38MG/ML)	A212129	003	Dec 11, 2020	Jan CAHN
>D>	AP		NANJING KING-FRIEND	200MG/5.26ML (38MG/ML)	A212129	001	Dec 11, 2020	Jan CAHN
>D>	AP			1GM/26.3ML (38MG/ML)	A212129	002	Dec 11, 2020	Jan CAHN
>D>	AP			2GM/52.6ML (38MG/ML)	A212129	003	Dec 11, 2020	Jan CAHN

GEMFIBROZIL

TABLET;ORAL

GEMFIBROZIL

>A>	AB		ASCENT PHARMS INC	600MG	A214603	001	Jan 13, 2021	Jan NEWA

GLYCOPYRROLATE

INJECTABLE;INJECTION

GLYCOPYRROLATE

>A>	AP		ATHENEX INC	0.2MG/ML	A210083	001	Feb 21, 2020	Jan CAHN
>D>	AP		RICONPHARMA LLC	0.2MG/ML	A210083	001	Feb 21, 2020	Jan CAHN

GRANISETRON HYDROCHLORIDE

SOLUTION;ORAL

GRANISOL

>A>		@	INTRA SANA LABS	EQ 2MG BASE/10ML	A078334	001	Feb 28, 2008	Jan CAHN
>D>		@	PEDIATRX	EQ 2MG BASE/10ML	A078334	001	Feb 28, 2008	Jan CAHN

GUANFACINE HYDROCHLORIDE

TABLET;ORAL

GUANFACINE HYDROCHLORIDE

>D>	AB		AMNEAL PHARM	EQ 2MG BASE	A075109	002	Nov 25, 1998	Jan CHRS
>A>	AB	!		EQ 2MG BASE	A075109	002	Nov 25, 1998	Jan CHRS
>D>	AB		MYLAN	EQ 1MG BASE	A074796	001	Jan 27, 1997	Jan DISC
>A>		@		EQ 1MG BASE	A074796	001	Jan 27, 1997	Jan DISC
>D>	AB	!		EQ 2MG BASE	A074796	002	Jan 27, 1997	Jan DISC
>A>		@		EQ 2MG BASE	A074796	002	Jan 27, 1997	Jan DISC

HEPARIN SODIUM

INJECTABLE;INJECTION

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

>D>	AP		FRESENIUS KABI USA	200 UNITS/100ML	A212441	001	Jul 24, 2020	Jan DISC
>A>		@		200 UNITS/100ML	A212441	001	Jul 24, 2020	Jan DISC

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

>D>	AP		FRESENIUS KABI USA	200 UNITS/100ML	A212441	002	Jul 24, 2020	Jan DISC
>A>		@		200 UNITS/100ML	A212441	002	Jul 24, 2020	Jan DISC

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET;ORAL

ZESTORETIC

>A> AB	+	ALMATICA	12.5MG;10MG	N019888	003	Nov 18, 1993	Jan CAHN
>A> AB	+!		12.5MG;20MG	N019888	001	Sep 20, 1990	Jan CAHN
>A> AB	+!		25MG;20MG	N019888	002	Jul 20, 1989	Jan CAHN
>D> AB	+	ALVOGEN	12.5MG;10MG	N019888	003	Nov 18, 1993	Jan CAHN
>D> AB	+!		12.5MG;20MG	N019888	001	Sep 20, 1990	Jan CAHN
>D> AB	+!		25MG;20MG	N019888	002	Jul 20, 1989	Jan CAHN

HYDROCODONE BITARTRATE; IBUPROFEN

TABLET;ORAL

HYDROCODONE BITARTRATE AND IBUPROFEN

>A> AB	NOSTRUM LABS INC	5MG;200MG	A077727	001	Nov 06, 2006	Jan CAHN
>A> AB		7.5MG;200MG	A077723	001	Nov 06, 2006	Jan CAHN
>A> AB		10MG;200MG	A077723	002	Nov 06, 2006	Jan CAHN
>D> AB	VINTAGE PHARMS	5MG;200MG	A077727	001	Nov 06, 2006	Jan CAHN
>D> AB		7.5MG;200MG	A077723	001	Nov 06, 2006	Jan CAHN
>D> AB		10MG;200MG	A077723	002	Nov 06, 2006	Jan CAHN

IMIQUIMOD

CREAM;TOPICAL

IMIQUIMOD

>A> AB	TARO	3.75%	A205971	001	Jan 26, 2021	Jan NFTG

INDOMETHACIN

CAPSULE;ORAL

INDOMETHACIN

>D> AB	JUBILANT GENERICS	25MG	A205215	001	Aug 25, 2017	Jan DISC
>A>	@	25MG	A205215	001	Aug 25, 2017	Jan DISC
>D> AB		50MG	A205215	002	Aug 25, 2017	Jan DISC
>A>	@	50MG	A205215	002	Aug 25, 2017	Jan DISC

CAPSULE, EXTENDED RELEASE;ORAL

INDOMETHACIN

>D> AB	AUROBINDO PHARMA LTD	75MG	A204243	001	Dec 27, 2016	Jan DISC
>A>	@	75MG	A204243	001	Dec 27, 2016	Jan DISC

IOPAMIDOL

INJECTABLE;INJECTION

ISOVUE-300

>D> AP	+! BRACCO	61%	N018735	002	Dec 31, 1985	Jan CTEC
>A>	+!	61%	N018735	002	Dec 31, 1985	Jan CTEC

ISOVUE-370

>D> AP	+! BRACCO	76%	N018735	003	Dec 31, 1985	Jan CTEC
>A>	+!	76%	N018735	003	Dec 31, 1985	Jan CTEC

>D> SCANLUX-300

>D> AP	SANOCHEMIA CORP USA	61%	A090394	001	Jun 18, 2010	Jan DISC
>A>	@	61%	A090394	001	Jun 18, 2010	Jan DISC

>D> SCANLUX-370

>D> AP	SANOCHEMIA CORP USA	76%	A090394	002	Jun 18, 2010	Jan DISC
>A>	@	76%	A090394	002	Jun 18, 2010	Jan DISC

ISOPROTERENOL HYDROCHLORIDE

INJECTABLE;INJECTION

ISOPROTERENOL HYDROCHLORIDE

>A> AP	AUROBINDO PHARMA LTD	0.2MG/ML	A211864	001	Feb 09, 2021	Jan NEWA

KETAMINE HYDROCHLORIDE

INJECTABLE;INJECTION

KETAMINE HYDROCHLORIDE

>A> AP	AUROMEDICS PHARMA	EQ 10MG BASE/ML	A076092	001	Sep 30, 2008	Jan CAHN
>A> AP		EQ 50MG BASE/ML	A076092	002	Dec 28, 2001	Jan CAHN
>A> AP		EQ 100MG BASE/ML	A076092	003	Oct 25, 2002	Jan CAHN
>D> AP	MYLAN INSTITUTIONAL	EQ 10MG BASE/ML	A076092	001	Sep 30, 2008	Jan CAHN
>D> AP		EQ 50MG BASE/ML	A076092	002	Dec 28, 2001	Jan CAHN
>D> AP		EQ 100MG BASE/ML	A076092	003	Oct 25, 2002	Jan CAHN

KETOPROFEN

CAPSULE;ORAL

KETOPROFEN

>D>		@	AUROLIFE PHARMA LLC	50MG	A074024	001	Dec 29, 1995	Jan CAHN
>D>		@		75MG	A074024	002	Dec 29, 1995	Jan CAHN
>A>		@	RISING	50MG	A074024	001	Dec 29, 1995	Jan CAHN
>A>		@		75MG	A074024	002	Dec 29, 1995	Jan CAHN

LAMOTRIGINE

TABLET, ORALLY DISINTEGRATING;ORAL

LAMOTRIGINE

>A>	AB		AJANTA PHARMA LTD	25MG	A213271	001	Jan 19, 2021	Jan NEWA
>A>	AB			50MG	A213271	002	Jan 19, 2021	Jan NEWA
>A>	AB			100MG	A213271	003	Jan 19, 2021	Jan NEWA
>A>	AB			200MG	A213271	004	Jan 19, 2021	Jan NEWA

LANSOPRAZOLE

TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL

LANSOPRAZOLE

>A>	AB		DR REDDYS LABS LTD	15MG	A210465	001	Feb 01, 2021	Jan NEWA
>A>	AB			30MG	A210465	002	Feb 01, 2021	Jan NEWA

LETROZOLE

TABLET;ORAL

LETROZOLE

>D>	AB		APOTEX INC	2.5MG	A091303	001	Apr 19, 2012	Jan DISC
>A>		@		2.5MG	A091303	001	Apr 19, 2012	Jan DISC

LEVETIRACETAM

TABLET;ORAL

LEVETIRACETAM

>D>	AB		BRECKENRIDGE PHARM	250MG	A090511	001	Aug 18, 2011	Jan CAHN
>D>	AB			500MG	A090511	002	Aug 18, 2011	Jan CAHN
>D>	AB			750MG	A090511	003	Aug 18, 2011	Jan CAHN
>D>	AB			1GM	A090511	004	Aug 18, 2011	Jan CAHN
>A>	AB		NOSTRUM LABS INC	250MG	A090511	001	Aug 18, 2011	Jan CAHN
>A>	AB			500MG	A090511	002	Aug 18, 2011	Jan CAHN
>A>	AB			750MG	A090511	003	Aug 18, 2011	Jan CAHN
>A>	AB			1GM	A090511	004	Aug 18, 2011	Jan CAHN

TABLET, EXTENDED RELEASE;ORAL

ELEPSIA XR

>D>		+	SPARC	1GM	N204417	001	Dec 20, 2018	Jan CAHN
>D>		+!		1.5GM	N204417	002	Dec 20, 2018	Jan CAHN
>A>		+	TRIPOINT	1GM	N204417	001	Dec 20, 2018	Jan CAHN
>A>		+!		1.5GM	N204417	002	Dec 20, 2018	Jan CAHN

LEVORPHANOL TARTRATE

TABLET;ORAL

LEVORPHANOL TARTRATE

>A>	AB		NOVITIUM PHARMA	3MG	A213479	002	Jan 12, 2021	Jan NEWA
>D>		!	SENTYNL THERAPS INC	3MG	A074278	003	Jun 18, 2018	Jan CTEC
>A>	AB	!		3MG	A074278	003	Jun 18, 2018	Jan CTEC

LEVOTHYROXINE SODIUM

SOLUTION;ORAL

TIROSINT-SOL

>A>		+	INSTITUT BIOCHIMIQUE	37.5MCG/ML	N206977	013	Jan 13, 2021	Jan NEWA
>A>		+		44MCG/ML	N206977	014	Jan 13, 2021	Jan NEWA
>A>		+		62.5MCG/ML	N206977	015	Jan 13, 2021	Jan NEWA

LIDOCAINE HYDROCHLORIDE

JELLY;TOPICAL

LIDOCAINE HYDROCHLORIDE

>D>	AT		AKORN	2%	A040433	001	Feb 12, 2003	Jan CHRS
>A>	AT	!		2%	A040433	001	Feb 12, 2003	Jan CHRS

XYLOCAINE

>D>	AT	+!	AKORN	2%	N008816	001		Jan DISC
>A>		+ @		2%	N008816	001		Jan DISC

SOLUTION;ORAL

LIDOCAINE HYDROCHLORIDE VISCOUS

>D>		@	LANNETT CO INC	2%	A040708	001	Feb 27, 2007	Jan CMFD

SOLUTION;ORAL
LIDOCAINE HYDROCHLORIDE VISCOUS

>A> AT			2%	A040708	001	Feb 27, 2007	Jan CMFD

LINACLOTIDE

CAPSULE;ORAL
LINACLOTIDE

>A> AB		MYLAN	145MCG	A209564	001	Feb 09, 2021	Jan NFTG
>A> AB			290MCG	A209564	002	Feb 09, 2021	Jan NFTG

LIOTHYRONINE SODIUM

TABLET;ORAL
LIOTHYRONINE SODIUM

>A> AB		ZYDUS	EQ 0.005MG BASE	A214803	001	Jan 22, 2021	Jan NEWA
>A> AB			EQ 0.025MG BASE	A214803	002	Jan 22, 2021	Jan NEWA
>A> AB			EQ 0.05MG BASE	A214803	003	Jan 22, 2021	Jan NEWA

LOTEPREDNOL ETABONATE

GEL;OPHTHALMIC
LOTEPREDNOL ETABONATE

>A> AB		AKORN	0.5%	A212080	001	Feb 10, 2021	Jan NFTG

LURASIDONE HYDROCHLORIDE

TABLET;ORAL
LURASIDONE HYDROCHLORIDE

>A> AB		WATSON LABS TEVA	20MG	A208016	001	Feb 02, 2021	Jan NEWA
>A> AB			40MG	A208016	002	Feb 02, 2021	Jan NEWA
>A> AB			60MG	A208016	003	Feb 02, 2021	Jan NEWA
>A> AB			80MG	A208016	004	Feb 02, 2021	Jan NEWA
>A> AB			120MG	A208016	005	Feb 02, 2021	Jan NEWA

MELPHALAN

TABLET;ORAL
MELPHALAN

>D>	!	ALVOGEN	2MG	A207809	001	Mar 22, 2017	Jan CAHN
>A>	!		2MG	A207809	001	Mar 22, 2017	Jan CAHN

MELPHALAN HYDROCHLORIDE

INJECTABLE;INJECTION
ALKERAN

>D> AP	+	APOTEX	EQ 50MG BASE/VIAL	N020207	001	Nov 18, 1992	Jan DISC
>A>	+ @		EQ 50MG BASE/VIAL	N020207	001	Nov 18, 1992	Jan DISC

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
METFORMIN HYDROCHLORIDE

>A> AB3		GRANULES	500MG	A213344	001	Jan 12, 2021	Jan NEWA
>A> AB3			1GM	A213344	002	Jan 12, 2021	Jan NEWA

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET;ORAL
PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE

>D> AB		TORRENT PHARMS LTD	500MG;EQ 15MG BASE	A202001	001	Feb 13, 2013	Jan DISC
>A>	@		500MG;EQ 15MG BASE	A202001	001	Feb 13, 2013	Jan DISC
>D> AB			850MG;EQ 15MG BASE	A202001	002	Feb 13, 2013	Jan DISC
>A>	@		850MG;EQ 15MG BASE	A202001	002	Feb 13, 2013	Jan DISC

METHYLERGONOVINE MALEATE

TABLET;ORAL
METHYLERGONOVINE MALEATE

>A> AB		RISING	0.2MG	A211919	001	Jan 15, 2021	Jan NEWA

METHYLPHENIDATE HYDROCHLORIDE

SOLUTION;ORAL
METHYLPHENIDATE HYDROCHLORIDE

>A> AA		ASCENT PHARMS INC	5MG/5ML	A207417	001	Jan 29, 2021	Jan NEWA
>A> AA			10MG/5ML	A207417	002	Jan 29, 2021	Jan NEWA
>D> AA		LANNETT CO INC	5MG/5ML	A207414	001	Dec 16, 2020	Jan DISC
>A>	@		5MG/5ML	A207414	001	Dec 16, 2020	Jan DISC
>D> AA			10MG/5ML	A207414	002	Dec 16, 2020	Jan DISC
>A>	@		10MG/5ML	A207414	002	Dec 16, 2020	Jan DISC

MEXILETINE HYDROCHLORIDE

CAPSULE;ORAL

MEXILETINE HYDROCHLORIDE

>A>	AB	RICONPHARMA LLC	150MG		A214352	001	Jan 25, 2021	Jan NEWA
>A>	AB		200MG		A214352	002	Jan 25, 2021	Jan NEWA
>A>	AB		250MG		A214352	003	Jan 25, 2021	Jan NEWA

MIDODRINE HYDROCHLORIDE

TABLET;ORAL

MIDODRINE HYDROCHLORIDE

>A>	AB	ALEMBIC PHARMS LTD	2.5MG		A214734	001	Jan 21, 2021	Jan NEWA
>A>	AB		5MG		A214734	002	Jan 21, 2021	Jan NEWA
>A>	AB		10MG		A214734	003	Jan 21, 2021	Jan NEWA

MOMETASONE FUROATE

OINTMENT;TOPICAL

MOMETASONE FUROATE

>D>	AB	TORRENT	0.1%		A207899	001	Jul 13, 2018	Jan DISC
>A>		@	0.1%		A207899	001	Jul 13, 2018	Jan DISC

MORPHINE SULFATE

SOLUTION;ORAL

MORPHINE SULFATE

>D>	AA	ANI PHARMS INC	10MG/5ML		A205509	001	Apr 17, 2018	Jan DISC
>A>		@	10MG/5ML		A205509	001	Apr 17, 2018	Jan DISC
>D>	AA		20MG/5ML		A205509	002	Apr 17, 2018	Jan DISC
>A>		@	20MG/5ML		A205509	002	Apr 17, 2018	Jan DISC
>D>	AA		100MG/5ML		A205509	003	Apr 17, 2018	Jan DISC
>A>		@	100MG/5ML		A205509	003	Apr 17, 2018	Jan DISC

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE

>A>	AT1	UPSHER SMITH LABS	EQ 0.5% BASE		A212616	001	Feb 10, 2021	Jan NEWA

MYCOPHENOLATE MOFETIL HYDROCHLORIDE

INJECTABLE;INJECTION

MYCOPHENOLATE MOFETIL HYDROCHLORIDE

>A>	AP	MEITHEAL	500MG/VIAL		A212130	001	Jan 15, 2021	Jan CAHN

MYCOPHENOLIC ACID

TABLET, DELAYED RELEASE;ORAL

MYCOPHENOLIC ACID

>A>	AB	AMTA	180MG		A214376	001	Feb 10, 2021	Jan NEWA
>A>	AB		360MG		A214376	002	Feb 10, 2021	Jan NEWA

NALOXONE HYDROCHLORIDE

INJECTABLE;INJECTION

NALOXONE HYDROCHLORIDE

>A>	AP	AUROBINDO PHARMA LTD	1MG/ML		A213279	001	Jan 14, 2021	Jan NEWA
>A>	AP	BAXTER HLTHCARE CORP	0.4MG/ML		A214785	001	Jan 29, 2021	Jan NEWA

NISOLDIPINE

TABLET, EXTENDED RELEASE;ORAL

NISOLDIPINE

>D>		MYLAN	20MG		A079051	001	Jul 25, 2008	Jan CHRS
>A>	!		20MG		A079051	001	Jul 25, 2008	Jan CHRS
>D>	!		30MG		A079051	002	Jul 25, 2008	Jan CHRS
>A>			30MG		A079051	002	Jul 25, 2008	Jan CHRS

NOREPINEPHRINE BITARTRATE

INJECTABLE;INJECTION

NOREPINEPHRINE BITARTRATE

>A>	AP	ANDERSEN GLOBAL	EQ 1MG BASE/ML		A214455	001	Jan 22, 2021	Jan NEWA
>A>	AP	SUN PHARM	EQ 1MG BASE/ML		A211980	001	Jan 29, 2021	Jan NEWA
>A>		SOLUTION;INTRAVENOUS						
>A>		NOREPINEPHRINE BITARTRATE IN 5% DEXTROSE						
>A>	+!	BAXTER HLTHCARE CORP	EQ 4MG BASE/250ML (EQ 16MCG BASE/ML)		N214313	001	Jan 15, 2021	Jan NEWA
>A>	+!		EQ 8MG BASE/250ML (EQ 32MCG BASE/ML)		N214313	002	Jan 15, 2021	Jan NEWA

NYSTATIN

OINTMENT;TOPICAL

NYSTATIN

>A>	AT		MACLEODS PHARMS LTD	100,000 UNITS/GM	A213826	001	Jan 14, 2021	Jan NEWA

OFLOXACIN

SOLUTION/DROPS;OPHTHALMIC

OFLOXACIN

>D>	AT		ALVOGEN	0.3%	A076830	001	Aug 31, 2004	Jan DISC
>A>		@		0.3%	A076830	001	Aug 31, 2004	Jan DISC

TABLET;ORAL

FLOXIN

>D>		@	JANSSEN PHARMS	200MG	N019735	001	Dec 28, 1990	Jan CRLD
>A>		+ @		200MG	N019735	001	Dec 28, 1990	Jan CRLD
>D>		@		300MG	N019735	002	Dec 28, 1990	Jan CRLD
>A>		+ @		300MG	N019735	002	Dec 28, 1990	Jan CRLD
>D>		@		400MG	N019735	003	Dec 28, 1990	Jan CRLD
>A>		+ @		400MG	N019735	003	Dec 28, 1990	Jan CRLD

OLOPATADINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

OLOPATADINE HYDROCHLORIDE

>D>	AT		ALEMBIC PHARMS LTD	EQ 0.2% BASE	A209420	001	Apr 29, 2019	Jan CMKT
>D>	AT		APOTEX INC	EQ 0.2% BASE	A090918	001	Dec 05, 2017	Jan CMKT

SPRAY, METERED;NASAL

OLOPATADINE HYDROCHLORIDE

>D>	AB		AMNEAL	0.665MG/SPRAY	A210901	001	Jan 28, 2020	Jan DISC
>A>		@		0.665MG/SPRAY	A210901	001	Jan 28, 2020	Jan DISC

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE;ORAL

ORPHENADRINE CITRATE

>D>	AB		IMPAX PHARMS	100MG	A040368	001	Jun 23, 2000	Jan DISC
>A>		@		100MG	A040368	001	Jun 23, 2000	Jan DISC

OSELTAMIVIR PHOSPHATE

CAPSULE;ORAL

OSELTAMIVIR PHOSPHATE

>A>		@	MYLAN	EQ 30MG BASE	A210157	001	Jan 21, 2021	Jan DISC
>A>		@		EQ 45MG BASE	A210157	002	Jan 21, 2021	Jan DISC
>A>		@		EQ 75MG BASE	A210157	003	Jan 21, 2021	Jan DISC

OXYBUTYNIN CHLORIDE

TABLET;ORAL

OXYBUTYNIN CHLORIDE

>A>	AB		APPCO	5MG	A209025	001	Dec 21, 2017	Jan CAHN
>D>	AB		RISING	5MG	A209025	001	Dec 21, 2017	Jan CAHN

PEMETREXED

SOLUTION;INTRAVENOUS

>D>			PEMETREXED					
>D>		+!	ACTAVIS LLC	100MG/4ML (25MG/ML)	N208419	001	Aug 21, 2020	Jan DISC
>A>		+ @		100MG/4ML (25MG/ML)	N208419	001	Aug 21, 2020	Jan DISC
>D>		+!		500MG/20ML (25MG/ML)	N208419	002	Aug 21, 2020	Jan DISC
>A>		+ @		500MG/20ML (25MG/ML)	N208419	002	Aug 21, 2020	Jan DISC
>D>		+!		1GM/40ML (25MG/ML)	N208419	003	Aug 21, 2020	Jan DISC
>A>		+ @		1GM/40ML (25MG/ML)	N208419	003	Aug 21, 2020	Jan DISC

PENTAMIDINE ISETHIONATE

INJECTABLE;INJECTION

PENTAMIDINE ISETHIONATE

>A>	AP		EMCURE PHARMS LTD	300MG/VIAL	A213806	001	Jan 07, 2021	Jan NEWA

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION;INTRAVENOUS

PHENYLEPHRINE HYDROCHLORIDE

>D>	AP1		APOLLO	10MG/ML (10MG/ML)	A211081	001	Jul 17, 2020	Jan CAHN
>D>	AP1			50MG/5ML (10MG/ML)	A211081	002	Jul 17, 2020	Jan CAHN
>D>	AP1			100MG/10ML (10MG/ML)	A211081	003	Jul 17, 2020	Jan CAHN
>A>	AP2		AUROBINDO PHARMA LTD	10MG/ML (10MG/ML)	A210696	001	Jan 07, 2021	Jan NEWA
>A>	AP2	+!	HIKMA	10MG/ML (10MG/ML)	N203826	001	Dec 20, 2012	Jan CAHN

SOLUTION;INTRAVENOUS
PHENYLEPHRINE HYDROCHLORIDE

>A>	AP2	+!		50MG/5ML (10MG/ML)	N203826	002	Jun 19, 2019	Jan CAHN
>A>	AP2	+!		100MG/10ML (10MG/ML)	N203826	003	Jun 19, 2019	Jan CAHN
>A>	AP1		PROVEPHARM SAS	10MG/ML (10MG/ML)	A211081	001	Jul 17, 2020	Jan CAHN
>A>	AP1			50MG/5ML (10MG/ML)	A211081	002	Jul 17, 2020	Jan CAHN
>A>	AP1			100MG/10ML (10MG/ML)	A211081	003	Jul 17, 2020	Jan CAHN
>D>	AP2	+!	WEST WARD PHARM CORP	10MG/ML (10MG/ML)	N203826	001	Dec 20, 2012	Jan CAHN
>D>	AP2	+!		50MG/5ML (10MG/ML)	N203826	002	Jun 19, 2019	Jan CAHN
>D>	AP2	+!		100MG/10ML (10MG/ML)	N203826	003	Jun 19, 2019	Jan CAHN

PIOGLITAZONE HYDROCHLORIDE

TABLET;ORAL
PIOGLITAZONE HYDROCHLORIDE

>A>	AB		ANNORA PHARMA	EQ 15MG BASE	A204133	001	Apr 07, 2014	Jan CAHN
>A>	AB			EQ 30MG BASE	A204133	002	Apr 07, 2014	Jan CAHN
>A>	AB			EQ 45MG BASE	A204133	003	Apr 07, 2014	Jan CAHN
>D>	AB		LUPIN LTD	EQ 15MG BASE	A204133	001	Apr 07, 2014	Jan CAHN
>D>	AB			EQ 30MG BASE	A204133	002	Apr 07, 2014	Jan CAHN
>D>	AB			EQ 45MG BASE	A204133	003	Apr 07, 2014	Jan CAHN
>A>	AB		SHUANGCHENG	EQ 15MG BASE	A210165	001	Jan 22, 2021	Jan NEWA
>A>	AB			EQ 30MG BASE	A210165	002	Jan 22, 2021	Jan NEWA
>A>	AB			EQ 45MG BASE	A210165	003	Jan 22, 2021	Jan NEWA

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE;INJECTION
PIPERACILLIN AND TAZOBACTAM

>D>	AP		APOLLO	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A207847	001	Jan 13, 2017	Jan CAHN
>D>	AP			EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A207847	002	Jan 13, 2017	Jan CAHN
>D>	AP			EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A207848	002	Jan 13, 2017	Jan CAHN
>D>	AP			EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A207847	003	Jan 13, 2017	Jan CAHN
>D>	AP			EQ 12GM BASE/VIAL;EQ 1.5GM BASE/VIAL	A207848	001	May 11, 2018	Jan CAHN
>A>	AP		PROVEPHARM SAS	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A207847	001	Jan 13, 2017	Jan CAHN
>A>	AP			EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A207847	002	Jan 13, 2017	Jan CAHN
>A>	AP			EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A207848	002	Jan 13, 2017	Jan CAHN
>A>	AP			EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A207847	003	Jan 13, 2017	Jan CAHN
>A>	AP			EQ 12GM BASE/VIAL;EQ 1.5GM BASE/VIAL	A207848	001	May 11, 2018	Jan CAHN
>D>	AP		WOCKHARDT BIO AG	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A206996	001	Mar 22, 2017	Jan CHRS
>A>	AP	!		EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A206996	001	Mar 22, 2017	Jan CHRS
>D>	AP			EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A206996	002	Mar 22, 2017	Jan CHRS
>A>	AP	!		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A206996	002	Mar 22, 2017	Jan CHRS
>D>	AP			EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A206996	003	Mar 22, 2017	Jan CHRS
>A>	AP	!		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A206996	003	Mar 22, 2017	Jan CHRS
>D>	AP			EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A207146	001	Mar 17, 2017	Jan CHRS
>A>	AP	!		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A207146	001	Mar 17, 2017	Jan CHRS

ZOSYN

>D>	AP	+!	WYETH PHARMS	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	N050684	001	Oct 22, 1993	Jan DISC
>A>		+ @		EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	N050684	001	Oct 22, 1993	Jan DISC
>D>	AP	+!		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	N050684	002	Oct 22, 1993	Jan DISC
>A>		+ @		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	N050684	002	Oct 22, 1993	Jan DISC
>D>	AP	+!		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	N050684	003	Oct 22, 1993	Jan DISC
>A>		+ @		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	N050684	003	Oct 22, 1993	Jan DISC
>D>	AP	+!		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	N050684	004	Oct 22, 1993	Jan DISC

		INJECTABLE;INJECTION						
		ZOSYN						
>A>		+ @	EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	N050684	004	Oct 22, 1993	Jan DISC	
		PIROXICAM						
		CAPSULE;ORAL						
		PIROXICAM						
>A>	AB	NOSTRUM LABS INC	10MG	A074118	002	Jun 15, 1993	Jan CMS1	
		POSACONAZOLE						
		TABLET, DELAYED RELEASE;ORAL						
		POSACONAZOLE						
>A>	AB	AET PHARMA	100MG	A213454	001	Feb 01, 2021	Jan NEWA	
		POTASSIUM CHLORIDE						
		SOLUTION;ORAL						
		POTASSIUM CHLORIDE						
>A>	AA	GRANULES PHARMS	20MEQ/15ML	A213392	001	Jan 29, 2021	Jan NEWA	
>A>	AA		40MEQ/15ML	A213392	002	Jan 29, 2021	Jan NEWA	
		TABLET, EXTENDED RELEASE;ORAL						
		POTASSIUM CHLORIDE						
>A>	AB1	AMTA	10MEQ	A214395	001	Jan 28, 2021	Jan NEWA	
>A>	AB1		20MEQ	A214395	002	Jan 28, 2021	Jan NEWA	
		POTASSIUM CITRATE						
		TABLET, EXTENDED RELEASE;ORAL						
		POTASSIUM CITRATE						
>A>	AB	ASCENT PHARMS INC	5MEQ	A214420	001	Feb 05, 2021	Jan NEWA	
>A>	AB		10MEQ	A214420	002	Feb 05, 2021	Jan NEWA	
>A>	AB		15MEQ	A214420	003	Feb 05, 2021	Jan NEWA	
		PRASUGREL HYDROCHLORIDE						
		TABLET;ORAL						
		PRASUGREL						
>D>	AB	DR REDDYS LABS LTD	EQ 5MG BASE	A205926	001	Jul 07, 2020	Jan DISC	
>A>		@	EQ 5MG BASE	A205926	001	Jul 07, 2020	Jan DISC	
>D>	AB		EQ 10MG BASE	A205926	002	Jul 07, 2020	Jan DISC	
>A>		@	EQ 10MG BASE	A205926	002	Jul 07, 2020	Jan DISC	
		PRAVASTATIN SODIUM						
		TABLET;ORAL						
		PRAVASTATIN SODIUM						
>D>	AB	BIOCON PHARMA	10MG	A209869	001	Apr 13, 2018	Jan CAHN	
>A>	AB		10MG	A209869	001	Apr 13, 2018	Jan CAHN	
>D>	AB		20MG	A209869	002	Apr 13, 2018	Jan CAHN	
>A>	AB		20MG	A209869	002	Apr 13, 2018	Jan CAHN	
>D>	AB		40MG	A209869	003	Apr 13, 2018	Jan CAHN	
>A>	AB		40MG	A209869	003	Apr 13, 2018	Jan CAHN	
>D>	AB		80MG	A209869	004	Apr 13, 2018	Jan CAHN	
>A>	AB		80MG	A209869	004	Apr 13, 2018	Jan CAHN	
>D>	AB	HISUN PHARM HANGZHOU	20MG	A206061	001	Nov 23, 2018	Jan DISC	
>A>		@	20MG	A206061	001	Nov 23, 2018	Jan DISC	
>D>	AB		40MG	A206061	002	Nov 23, 2018	Jan DISC	
>A>		@	40MG	A206061	002	Nov 23, 2018	Jan DISC	
>D>	AB		80MG	A206061	003	Nov 23, 2018	Jan DISC	
>A>		@	80MG	A206061	003	Nov 23, 2018	Jan DISC	
		PREDNISOLONE						
		TABLET;ORAL						
		PREDNISOLONE						
>D>		@ AUROLIFE PHARMA LLC	5MG	A084773	001		Jan CAHN	
>A>		@ RISING	5MG	A084773	001		Jan CAHN	
		PREDNISONE						
		TABLET;ORAL						
		PREDNISONE						
>D>		@ AUROLIFE PHARMA LLC	10MG	A089983	001	Jan 12, 1989	Jan CAHN	
>D>		@	20MG	A085813	001		Jan CAHN	
>D>		@	50MG	A089984	001	Jan 12, 1989	Jan CAHN	
>A>		@ RISING	10MG	A089983	001	Jan 12, 1989	Jan CAHN	
>A>		@	20MG	A085813	001		Jan CAHN	

TABLET;ORAL
PREDNISONE

>A>	@	50MG	A089984	001	Jan 12, 1989	Jan	CAHN

QUETIAPINE FUMARATE

TABLET, EXTENDED RELEASE;ORAL
QUETIAPINE FUMARATE

>A> AB	MYLAN	EQ 50MG BASE	A202228	001	Feb 02, 2021	Jan	NEWA
>A> AB		EQ 150MG BASE	A202228	002	Feb 02, 2021	Jan	NEWA
>A> AB		EQ 200MG BASE	A202228	003	Feb 02, 2021	Jan	NEWA
>A> AB		EQ 300MG BASE	A202228	004	Feb 02, 2021	Jan	NEWA
>A> AB		EQ 400MG BASE	A202228	005	Feb 02, 2021	Jan	NEWA

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE;ORAL
QUINIDINE GLUCONATE

>D>	@ AUROLIFE PHARMA LLC	324MG	A089894	001	Dec 15, 1988	Jan	CAHN
>A>	@ RISING	324MG	A089894	001	Dec 15, 1988	Jan	CAHN

RANITIDINE HYDROCHLORIDE

TABLET;ORAL
RANITIDINE HYDROCHLORIDE

>D> AB	WOCKHARDT LTD	EQ 150MG BASE	A075208	001	Dec 17, 1998	Jan	DISC
>A>	@	EQ 150MG BASE	A075208	001	Dec 17, 1998	Jan	DISC
>D> AB		EQ 300MG BASE	A075208	002	Dec 17, 1998	Jan	DISC
>A>	@	EQ 300MG BASE	A075208	002	Dec 17, 1998	Jan	DISC

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL
RANOLAZINE

>A> AB	GRAVITI PHARMS	500MG	A212889	001	Jan 28, 2021	Jan	NEWA
>A> AB		1GM	A212889	002	Jan 28, 2021	Jan	NEWA

ROPIVACAINE HYDROCHLORIDE

SOLUTION;INJECTION
ROPIVACAINE HYDROCHLORIDE

>D> AP	MYLAN ASI	150MG/30ML (5MG/ML)	A090318	002	Sep 23, 2014	Jan	DISC
>A>	@	150MG/30ML (5MG/ML)	A090318	002	Sep 23, 2014	Jan	DISC
>D> AP		200MG/20ML (10MG/ML)	A090318	004	Sep 23, 2014	Jan	DISC
>A>	@	200MG/20ML (10MG/ML)	A090318	004	Sep 23, 2014	Jan	DISC

ROSUVASTATIN CALCIUM

TABLET;ORAL
ROSUVASTATIN CALCIUM

>A> AB	INVENTIA	5MG	A207653	001	Feb 05, 2021	Jan	NEWA
>A> AB		10MG	A207653	002	Feb 05, 2021	Jan	NEWA
>A> AB		20MG	A207653	003	Feb 05, 2021	Jan	NEWA
>A> AB		40MG	A207653	004	Feb 05, 2021	Jan	NEWA

SELENIOUS ACID

SOLUTION;INTRAVENOUS
SELENIOUS ACID

>A>	+! AM REGENT	EQ 60MCG BASE/ML (EQ 60MCG BASE/ML)	N209379	002	Jan 25, 2021	Jan	NEWA

SERTRALINE HYDROCHLORIDE

TABLET;ORAL
SERTRALINE HYDROCHLORIDE

>D>	@ ACI HEALTHCARE LTD	EQ 25MG BASE	A076881	001	Feb 06, 2007	Jan	CMFD
>A> AB		EQ 25MG BASE	A076881	001	Feb 06, 2007	Jan	CMFD
>D>	@	EQ 50MG BASE	A076881	002	Feb 06, 2007	Jan	CMFD
>A> AB		EQ 50MG BASE	A076881	002	Feb 06, 2007	Jan	CMFD
>D>	@	EQ 100MG BASE	A076881	003	Feb 06, 2007	Jan	CMFD
>A> AB		EQ 100MG BASE	A076881	003	Feb 06, 2007	Jan	CMFD

SEVELAMER CARBONATE

TABLET;ORAL
SEVELAMER CARBONATE

>A> AB	LUPIN LTD	800MG	A204600	001	Jan 14, 2021	Jan	NEWA

SODIUM FLUORIDE F-18

INJECTABLE;INTRAVENOUS

SODIUM FLUORIDE F-18

>A> AP	NUKEMED	10-200mCi/ML	A203912	001	Apr 22, 2015	Jan	CAHN
>D> AP	SPECTRON MRC LLC	10-200mCi/ML	A203912	001	Apr 22, 2015	Jan	CAHN

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE

TABLET;ORAL

MONOBASIC SODIUM PHOSPHATE AND DIBASIC SODIUM PHOSPHATE

>D>	@ NOVEL LABS INC	0.398GM;1.102GM	A079247	001	Dec 30, 2011	Jan	CMFD
>A> AB		0.398GM;1.102GM	A079247	001	Dec 30, 2011	Jan	CMFD

OSMOPREP

>D>	+! SALIX PHARMS	0.398GM;1.102GM	N021892	001	Mar 16, 2006	Jan	CTEC
>A> AB	+!	0.398GM;1.102GM	N021892	001	Mar 16, 2006	Jan	CTEC

STERILE WATER FOR INJECTION

LIQUID;N/A

STERILE WATER FOR INJECTION

>A>	! NEPHRON	100% (5ML)	A211222	001	Feb 10, 2021	Jan	NEWA

SULFAMETHOXAZOLE

TABLET;ORAL

SULFAMETHOXAZOLE

>D>	@ AUROLIFE PHARMA LLC	500MG	A085844	001		Jan	CAHN
>A>	@ RISING	500MG	A085844	001		Jan	CAHN

SULFISOXAZOLE

TABLET;ORAL

SULFISOXAZOLE

>D>	@ AUROLIFE PHARMA LLC	500MG	A085628	001		Jan	CAHN
>A>	@ RISING	500MG	A085628	001		Jan	CAHN

SUMATRIPTAN SUCCINATE

INJECTABLE;SUBCUTANEOUS

SUMATRIPTAN SUCCINATE

>D> AP	MYLAN ASI	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A090641	001	Jul 28, 2010	Jan	DISC
>A>	@	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A090641	001	Jul 28, 2010	Jan	DISC

TAVABOROLE

SOLUTION;TOPICAL

TAVABOROLE

>A> AB	CIPLA	5%	A212224	001	Feb 09, 2021	Jan	NEWA
>A> AB	FLATWING	5.0%	A211963	001	Feb 03, 2021	Jan	NEWA
>A> AB	LUPIN LTD	5%	A212168	001	Feb 08, 2021	Jan	NEWA

TEMOZOLOMIDE

CAPSULE;ORAL

TEMOZOLOMIDE

>D> AB	WATSON LABS TEVA	5MG	A203959	001	Apr 18, 2017	Jan	DISC
>A>	@	5MG	A203959	001	Apr 18, 2017	Jan	DISC
>D> AB		20MG	A203959	002	Apr 18, 2017	Jan	DISC
>A>	@	20MG	A203959	002	Apr 18, 2017	Jan	DISC
>D> AB		100MG	A203959	003	Apr 18, 2017	Jan	DISC
>A>	@	100MG	A203959	003	Apr 18, 2017	Jan	DISC
>D> AB		140MG	A203959	004	Apr 18, 2017	Jan	DISC
>A>	@	140MG	A203959	004	Apr 18, 2017	Jan	DISC
>D> AB		250MG	A203959	005	Apr 18, 2017	Jan	DISC
>A>	@	250MG	A203959	005	Apr 18, 2017	Jan	DISC

TESTOSTERONE

SOLUTION, METERED;TRANSDERMAL

TESTOSTERONE

>A> AT	FEMPHARM	30MG/1.5ML ACTUATION	A212301	001	Jan 11, 2021	Jan	NEWA

THIORIDAZINE HYDROCHLORIDE

TABLET;ORAL

THIORIDAZINE HYDROCHLORIDE

>D>	AB		MYLAN	10MG	A088004	002	Mar 15, 1983	Jan CTEC
>A>				10MG	A088004	002	Mar 15, 1983	Jan CTEC
>D>	AB			25MG	A088004	003	Mar 15, 1983	Jan CTEC
>A>				25MG	A088004	003	Mar 15, 1983	Jan CTEC
>D>	AB			50MG	A088004	004	Mar 15, 1983	Jan CTEC
>A>				50MG	A088004	004	Mar 15, 1983	Jan CTEC
>D>	AB	!		100MG	A088004	001	Nov 18, 1983	Jan CTEC
>A>		!		100MG	A088004	001	Nov 18, 1983	Jan CTEC
>D>	AB		SUN PHARM INDUSTRIES	10MG	A089953	004	Aug 01, 1986	Jan DISC
>A>		@		10MG	A089953	004	Aug 01, 1986	Jan DISC
>D>	AB			25MG	A089953	003	Aug 01, 1986	Jan DISC
>A>		@		25MG	A089953	003	Aug 01, 1986	Jan DISC
>D>	AB			50MG	A089953	002	Aug 01, 1986	Jan DISC
>A>		@		50MG	A089953	002	Aug 01, 1986	Jan DISC
>D>	AB			100MG	A089953	001	Oct 07, 1988	Jan DISC
>A>		@		100MG	A089953	001	Oct 07, 1988	Jan DISC

TIAGABINE HYDROCHLORIDE

TABLET;ORAL

TIAGABINE HYDROCHLORIDE

>D>	AB		WILSHIRE PHARMS INC	2MG	A206857	001	Oct 13, 2017	Jan DISC
>A>		@		2MG	A206857	001	Oct 13, 2017	Jan DISC
>D>	AB			4MG	A206857	002	Oct 13, 2017	Jan DISC
>A>		@		4MG	A206857	002	Oct 13, 2017	Jan DISC
>D>	AB			12MG	A206857	003	Oct 13, 2017	Jan DISC
>A>		@		12MG	A206857	003	Oct 13, 2017	Jan DISC
>D>	AB			16MG	A206857	004	Oct 13, 2017	Jan DISC
>A>		@		16MG	A206857	004	Oct 13, 2017	Jan DISC

TIZANIDINE HYDROCHLORIDE

TABLET;ORAL

TIZANIDINE HYDROCHLORIDE

>D>	AB		MYLAN	EQ 2MG BASE	A076354	001	Mar 28, 2003	Jan DISC
>A>		@		EQ 2MG BASE	A076354	001	Mar 28, 2003	Jan DISC

TOBRAMYCIN

SOLUTION;INHALATION

TOBRAMYCIN

>A>	AN		AUROBINDO PHARMA LTD	300MG/5ML	A210871	001	Jan 22, 2021	Jan NEWA

TOBRAMYCIN SULFATE

INJECTABLE;INJECTION

TOBRAMYCIN SULFATE (PHARMACY BULK)

>D>		!	FRESENIUS KABI USA	EQ 40MG BASE/ML	A065120	001	Nov 29, 2002	Jan CTEC
>A>	AP	!		EQ 40MG BASE/ML	A065120	001	Nov 29, 2002	Jan CTEC
>A>	AP		GLAND PHARMA LTD	EQ 40MG BASE/ML	A209346	001	Feb 09, 2021	Jan NEWA

TOLCAPONE

TABLET;ORAL

TOLCAPONE

>D>	AB		ALVOGEN	100MG	A207729	001	Jul 29, 2020	Jan DISC
>A>		@		100MG	A207729	001	Jul 29, 2020	Jan DISC

TOLTERODINE TARTRATE

CAPSULE, EXTENDED RELEASE;ORAL

TOLTERODINE TARTRATE

>D>		@	AJANTA PHARMA LTD	2MG	A213397	001	May 19, 2020	Jan CMFD
>A>	AB			2MG	A213397	001	May 19, 2020	Jan CMFD
>D>		@		4MG	A213397	002	May 19, 2020	Jan CMFD
>A>	AB			4MG	A213397	002	May 19, 2020	Jan CMFD
>A>	AB		AMTA	2MG	A213858	001	Feb 02, 2021	Jan NEWA
>A>	AB			4MG	A213858	002	Feb 02, 2021	Jan NEWA

TOPIRAMATE

CAPSULE, EXTENDED RELEASE;ORAL

TOPIRAMATE

>A>	AB2		GLENMARK PHARMS LTD	25MG	A210278	001	Feb 01, 2021	Jan NFTG
>A>	AB2			50MG	A210278	002	Feb 01, 2021	Jan NFTG
>A>	AB2			100MG	A210278	003	Feb 01, 2021	Jan NFTG
>A>	AB2			150MG	A210278	004	Feb 01, 2021	Jan NFTG
>A>	AB2			200MG	A210278	005	Feb 01, 2021	Jan NFTG
>D>	AB		ZYDUS PHARMS	25MG	A207382	001	Nov 24, 2017	Jan CTEC
>A>	AB1			25MG	A207382	001	Nov 24, 2017	Jan CTEC
>D>	AB			50MG	A207382	002	Nov 24, 2017	Jan CTEC
>A>	AB1			50MG	A207382	002	Nov 24, 2017	Jan CTEC
>D>	AB			100MG	A207382	003	Nov 24, 2017	Jan CTEC
>A>	AB1			100MG	A207382	003	Nov 24, 2017	Jan CTEC

TROKENDI XR

>D>	AB	+	SUPERNUS PHARMS	25MG	N201635	001	Aug 16, 2013	Jan CTEC
>A>	AB1	+		25MG	N201635	001	Aug 16, 2013	Jan CTEC
>D>	AB	+		50MG	N201635	002	Aug 16, 2013	Jan CTEC
>A>	AB1	+		50MG	N201635	002	Aug 16, 2013	Jan CTEC
>D>	AB	+		100MG	N201635	003	Aug 16, 2013	Jan CTEC
>A>	AB1	+		100MG	N201635	003	Aug 16, 2013	Jan CTEC

TRANEXAMIC ACID

INJECTABLE;INJECTION

TRANEXAMIC ACID

>D>	AP		APOLLO	100MG/ML	A212676	001	Jul 17, 2019	Jan CAHN
>A>	AP		PROVEPHARM SAS	100MG/ML	A212676	001	Jul 17, 2019	Jan CAHN

TRAZODONE HYDROCHLORIDE

TABLET;ORAL

TRAZODONE HYDROCHLORIDE

>D>		@	AUROLIFE PHARMA LLC	50MG	A072484	001	Apr 30, 1990	Jan CAHN
>A>		@	RISING	50MG	A072484	001	Apr 30, 1990	Jan CAHN

TRIAMCINOLONE ACETONIDE

CREAM;TOPICAL

TRIAMCINOLONE ACETONIDE

>D>	AT		MLV	0.025%	A040671	001	Jun 09, 2006	Jan CAHN
>D>	AT			0.1%	A040671	002	Jun 09, 2006	Jan CAHN
>A>	AT		SAPTALIS PHARMS	0.025%	A040671	001	Jun 09, 2006	Jan CAHN
>A>	AT			0.1%	A040671	002	Jun 09, 2006	Jan CAHN

OINTMENT;TOPICAL

TRIAMCINOLONE ACETONIDE

>A>	AT		PERRIGO ISRAEL	0.05%	A212460	001	Feb 05, 2021	Jan NEWA

URSODIOL

CAPSULE;ORAL

URSODIOL

>A>	AB		STRIDES PHARMA	300MG	A210344	001	Jan 22, 2021	Jan NEWA

VENLAFAXINE HYDROCHLORIDE

TABLET;ORAL

VENLAFAXINE HYDROCHLORIDE

>D>	AB		MYLAN	EQ 25MG BASE	A077166	001	Jun 13, 2008	Jan DISC
>A>		@		EQ 25MG BASE	A077166	001	Jun 13, 2008	Jan DISC
>D>	AB			EQ 37.5MG BASE	A077166	002	Jun 13, 2008	Jan DISC
>A>		@		EQ 37.5MG BASE	A077166	002	Jun 13, 2008	Jan DISC
>D>	AB			EQ 50MG BASE	A077166	003	Jun 13, 2008	Jan DISC
>A>		@		EQ 50MG BASE	A077166	003	Jun 13, 2008	Jan DISC
>D>	AB			EQ 75MG BASE	A077166	004	Jun 13, 2008	Jan DISC
>A>		@		EQ 75MG BASE	A077166	004	Jun 13, 2008	Jan DISC
>D>	AB			EQ 100MG BASE	A077166	005	Jun 13, 2008	Jan DISC
>A>		@		EQ 100MG BASE	A077166	005	Jun 13, 2008	Jan DISC

TABLET, EXTENDED RELEASE;ORAL

VENLAFAXINE HYDROCHLORIDE

>A>	AB		DEXCEL PHARMA	EQ 75MG BASE	A213927	001	Jan 21, 2021	Jan NEWA

>A>	VERICIGUAT						
>A>	TABLET;ORAL						
>A>	VERQUVO						
>A>	+ MERCK SHARP DOHME	2.5MG	N214377	001	Jan 19, 2021	Jan NEWA	
>A>	+	5MG	N214377	002	Jan 19, 2021	Jan NEWA	
>A>	+!	10MG	N214377	003	Jan 19, 2021	Jan NEWA	
	VIGABATRIN						
	FOR SOLUTION;ORAL						
	VIGABATRIN						
>A> AA	ANNORA PHARMA	500MG/PACKET	A213519	001	Jan 26, 2021	Jan NEWA	
	TABLET;ORAL						
	VIGABATRIN						
>A> AB	DR REDDYS	500MG	A211539	001	Jan 29, 2021	Jan NEWA	
	VINORELBINE TARTRATE						
	INJECTABLE;INJECTION						
	VINORELBINE TARTRATE						
>D> AP	FRESENIUS KABI USA	EQ 10MG BASE/ML	A076849	001	Apr 18, 2005	Jan DISC	
>A>	@	EQ 10MG BASE/ML	A076849	001	Apr 18, 2005	Jan DISC	
>A>	VOCLOSPORIN						
>A>	CAPSULE;ORAL						
>A>	LUPKYNIS						
>A>	+! AURINIA	7.9MG	N213716	001	Jan 22, 2021	Jan NEWA	
	ZONISAMIDE						
	CAPSULE;ORAL						
	ZONISAMIDE						
>A> AB	UNICHEM	25MG	A214492	001	Jan 26, 2021	Jan NEWA	
>A> AB		50MG	A214492	002	Jan 26, 2021	Jan NEWA	
>A> AB		100MG	A214492	003	Jan 26, 2021	Jan NEWA	

CETIRIZINE HYDROCHLORIDE

CAPSULE;ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>D>	APOTEX	10MG	A207235	001	Aug 12, 2016	Jan	DISC
>A>	@	10MG	A207235	001	Aug 12, 2016	Jan	DISC

IBUPROFEN

SUSPENSION;ORAL

IBUPROFEN

>D>	@ GUARDIAN DRUG	100MG/5ML	A210149	001	Aug 17, 2018	Jan	CMFD
>A>		100MG/5ML	A210149	001	Aug 17, 2018	Jan	CMFD

LORATADINE

TABLET;ORAL

LORATADINE

>A>	UNIQUE PHARM	10MG	A214684	001	Jan 07, 2021	Jan	NEWA

TABLET, ORALLY DISINTEGRATING;ORAL

LORATADINE

>D>	GLAXOSMITHKLINE	10MG	A075822	001	Feb 10, 2003	Jan	DISC
>A>	@	10MG	A075822	001	Feb 10, 2003	Jan	DISC

OLOPATADINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

OLOPATADINE HYDROCHLORIDE

>A>	ALEMBIC PHARMS LTD	EQ 0.2% BASE	A209420	001	Apr 29, 2019	Jan	CMKT
>A>	APOTEX INC	EQ 0.2% BASE	A090918	001	Dec 05, 2017	Jan	CMKT

RANITIDINE HYDROCHLORIDE

TABLET;ORAL

RANITIDINE HYDROCHLORIDE

>D>	WOCKHARDT	EQ 75MG BASE	A076760	001	Feb 24, 2006	Jan	DISC
>A>	@	EQ 75MG BASE	A076760	001	Feb 24, 2006	Jan	DISC

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 2021

NO JANUARY 2021 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 2021 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2021

APPL/PROD NO		PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
AMANTADINE HYDROCHLORIDE - OSMOLEX ER							
N 209410	001	>A> 8389578	Jan 22, 2028	U-219			
		>A> 8389578	Jan 22, 2028	U-3054			
		>A> 8796337	Nov 23, 2025	U-219			
		>A> 8796337	Nov 23, 2025	U-2497			
		>A> 8796337	Nov 23, 2025	U-3054			
		>A> 8889740	Nov 23, 2025	DP			
		>A> 8895614	Nov 23, 2025	DP			
		>A> 8895615	Nov 23, 2025	U-219			
		>A> 8895615	Nov 23, 2025	U-3054			
		>A> 8895616	Nov 23, 2025	U-219			
		>A> 8895616	Nov 23, 2025	U-3054			
		>A> 8895617	Nov 23, 2025	U-219			
		>A> 8895617	Nov 23, 2025	U-3054			
		>A> 8895618	Nov 23, 2025	DP			
		>A> 8987333	Nov 23, 2025	DP			
		>A> 9072697	Nov 23, 2025	U-219			
		>A> 9072697	Nov 23, 2025	U-3054			
AMANTADINE HYDROCHLORIDE - OSMOLEX ER							
N 209410	002	>A> 8389578	Jan 22, 2028	U-219			
		>A> 8389578	Jan 22, 2028	U-3054			
		>A> 8796337	Nov 23, 2025	U-219			
		>A> 8796337	Nov 23, 2025	U-2497			
		>A> 8796337	Nov 23, 2025	U-3054			
		>A> 8889740	Nov 23, 2025	DP			
		>A> 8895614	Nov 23, 2025	DP			
		>A> 8895615	Nov 23, 2025	U-219			
		>A> 8895615	Nov 23, 2025	U-3054			
		>A> 8895616	Nov 23, 2025	U-219			
		>A> 8895616	Nov 23, 2025	U-3054			
		>A> 8895617	Nov 23, 2025	U-219			
		>A> 8895617	Nov 23, 2025	U-3054			
		>A> 8895618	Nov 23, 2025	DP			
		>A> 8987333	Nov 23, 2025	DP			
		>A> 9072697	Nov 23, 2025	U-219			
		>A> 9072697	Nov 23, 2025	U-3054			
AMANTADINE HYDROCHLORIDE - OSMOLEX ER							
N 209410	003	>A> 8389578	Jan 22, 2028	U-219			
		>A> 8389578	Jan 22, 2028	U-3054			
		>A> 8796337	Nov 23, 2025	U-219			
		>A> 8796337	Nov 23, 2025	U-2497			
		>A> 8796337	Nov 23, 2025	U-3054			
		>A> 8889740	Nov 23, 2025	DP			
		>A> 8895614	Nov 23, 2025	DP			
		>A> 8895615	Nov 23, 2025	U-219			
		>A> 8895615	Nov 23, 2025	U-3054			
		>A> 8895616	Nov 23, 2025	U-219			
		>A> 8895616	Nov 23, 2025	U-3054			
		>A> 8895617	Nov 23, 2025	U-219			
		>A> 8895617	Nov 23, 2025	U-3054			
		>A> 8895618	Nov 23, 2025	DP			
		>A> 8987333	Nov 23, 2025	DP			
		>A> 9072697	Nov 23, 2025	U-219			
		>A> 9072697	Nov 23, 2025	U-3054			
AMANTADINE HYDROCHLORIDE - OSMOLEX ER							
N 209410	004	>A> 8389578	Jan 22, 2028	U-219			
		>A> 8389578	Jan 22, 2028	U-3054			
		>A> 8796337	Nov 23, 2025	U-219			
		>A> 8796337	Nov 23, 2025	U-2497			
		>A> 8796337	Nov 23, 2025	U-3054			
		>A> 8889740	Nov 23, 2025	DP			
		>A> 8895614	Nov 23, 2025	DP			
		>A> 8895615	Nov 23, 2025	U-219			
		>A> 8895615	Nov 23, 2025	U-3054			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2021

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AMANTADINE HYDROCHLORIDE - OSMOLEX ER						
N 209410 004	>A> 8895616	Nov 23, 2025	U-219			
	>A> 8895616	Nov 23, 2025	U-3054			
	>A> 8895617	Nov 23, 2025	U-219			
	>A> 8895617	Nov 23, 2025	U-3054			
	>A> 8895618	Nov 23, 2025	DP			
	>A> 8987333	Nov 23, 2025	DP			
	>A> 9072697	Nov 23, 2025	U-219			
	>A> 9072697	Nov 23, 2025	U-3054			
APOMORPHINE HYDROCHLORIDE - KYNMOBI						
N 210875 001	>A> 10888499	Feb 14, 2022	DP			
APOMORPHINE HYDROCHLORIDE - KYNMOBI						
N 210875 002	>A> 10888499	Feb 14, 2022	DP			
APOMORPHINE HYDROCHLORIDE - KYNMOBI						
N 210875 003	>A> 10888499	Feb 14, 2022	DP			
APOMORPHINE HYDROCHLORIDE - KYNMOBI						
N 210875 004	>A> 10888499	Feb 14, 2022	DP			
APOMORPHINE HYDROCHLORIDE - KYNMOBI						
N 210875 005	>A> 10888499	Feb 14, 2022	DP			
ASENAPINE MALEATE - ASENAPINE MALEATE						
A 206098 001					>A> PC	Jun 08, 2021
ASENAPINE MALEATE - ASENAPINE MALEATE						
A 206098 002					>A> PC	Jun 08, 2021
AXITINIB - INLYTA						
N 202324 001	>A> 10869924	Nov 05, 2036	U-3044			
AXITINIB - INLYTA						
N 202324 002	>A> 10869924	Nov 05, 2036	U-3044			
AZACITIDINE - ONUREG						
N 214120 001					>A> ODE-320	Sep 01, 2027
AZACITIDINE - ONUREG						
N 214120 002					>A> ODE-320	Sep 01, 2027
BEROTRALSTAT HYDROCHLORIDE - ORLADEYO						
N 214094 001					>A> NCE	Dec 03, 2025
BEROTRALSTAT HYDROCHLORIDE - ORLADEYO						
N 214094 002					>A> NCE	Dec 03, 2025
BREXPIPRAZOLE - REXULTI						
N 205422 001	>A> RE48059	Dec 23, 2028	DS			
BREXPIPRAZOLE - REXULTI						
N 205422 002	>A> RE48059	Dec 23, 2028	DS			
BREXPIPRAZOLE - REXULTI						
N 205422 003	>A> RE48059	Dec 23, 2028	DS			
BREXPIPRAZOLE - REXULTI						
N 205422 004	>A> RE48059	Dec 23, 2028	DS			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2021

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
BREXPIPRAZOLE - REXULTI						
N 205422 005	>A> RE48059	Dec 23, 2028	DS			
BREXPIPRAZOLE - REXULTI						
N 205422 006	>A> RE48059	Dec 23, 2028	DS			
BRIVARACETAM - BRIVIACT						
N 205836 001					>A> NPP	May 10, 2021
BRIVARACETAM - BRIVIACT						
N 205836 002					>A> NPP	May 10, 2021
BRIVARACETAM - BRIVIACT						
N 205836 003					>A> NPP	May 10, 2021
BRIVARACETAM - BRIVIACT						
N 205836 004					>A> NPP	May 10, 2021
BRIVARACETAM - BRIVIACT						
N 205836 005					>A> NPP	May 10, 2021
BRIVARACETAM - BRIVIACT						
N 205838 001					>A> NPP	May 10, 2021
BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE - ZUBSOLV						
N 204242 002	>A> 10874661	Sep 18, 2032	DP			
CABAZITAXEL - JEVTANA KIT						
N 201023 001					>A> M-128	Dec 18, 2023
CALCIUM OXYBATE; MAGNESIUM OXYBATE; POTASSIUM OXYBATE; SODIUM OXYBATE - XYWAV						
N 212690 001	>A> 10864181	Mar 15, 2033	U-3017			
CITRIC ACID; LACTIC ACID; POTASSIUM BITARTRATE - PHEXXI						
N 208352 001	>A> 6706276	Mar 06, 2022	DP			
COBICISTAT; DARUNAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - SYMTUZA						
N 210455 001	>A> 10786518	Jul 19, 2038	U-2978			
CYSTEINE HYDROCHLORIDE - ELCYS						
N 210660 001	>A> 10905713	Jan 15, 2039	DP			
	>A> 10905714	Jan 15, 2039	DP			
	>A> 10912795	Jan 15, 2039	DP			
DEFERIPRONE - DEFERIPRONE						
A 208800 001					>A> PC	Mar 27, 2021
DEUTETRABENAZINE - AUSTEDO						
N 208082 001	>A> 9550780	Sep 18, 2033	DS DP U-1846			
	>A> 9550780	Sep 18, 2033	DS DP U-1995			
	>A> 9550780	Sep 18, 2033	DS DP U-3055			
DEUTETRABENAZINE - AUSTEDO						
N 208082 002	>A> 9550780	Sep 18, 2033	DS DP U-1846			
	>A> 9550780	Sep 18, 2033	DS DP U-1995			
	>A> 9550780	Sep 18, 2033	DS DP U-3055			
DEUTETRABENAZINE - AUSTEDO						
N 208082 003	>A> 9550780	Sep 18, 2033	DS DP U-1846			
	>A> 9550780	Sep 18, 2033	DS DP U-1995			
	>A> 9550780	Sep 18, 2033	DS DP U-3055			

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EFINACONAZOLE - JUBLIA							
N 203567	001	>A> 10864274	Oct 02, 2034	U-2720			
ELAGOLIX SODIUM,ESTRADIOL,NORETHINDRONE ACETATE; ELAGOLIX SODIUM - ORIAHNN (COPACKAGED)							
N 213388	001	>A> 10881659	Mar 14, 2034	U-2842			
ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)							
N 212273	001	>A> 10081621	Mar 25, 2031	DP U-2652			
		>A> 10081621	Mar 25, 2031	DP U-3032			
		>A> 10239867	Apr 09, 2027	DS DP U-2653			
		>A> 10239867	Apr 09, 2027	DS DP U-3033			
		>A> 10758534	Oct 06, 2035	DS DP U-2645			
		>A> 10758534	Oct 06, 2035	DS DP U-3028			
		>A> 10793547	Dec 08, 2037	DS DP U-2645			
		>A> 10793547	Dec 08, 2037	DS DP U-3028			
		>A> 8324242	Aug 05, 2027	U-2645			
		>A> 8324242	Aug 05, 2027	U-3028			
		>A> 8354427	Jul 06, 2026	U-2646			
		>A> 8354427	Jul 06, 2026	U-3029			
		>A> 8415387	Nov 12, 2027	U-2645			
		>A> 8415387	Nov 12, 2027	U-3028			
		>A> 8598181	May 01, 2027	U-2645			
		>A> 8598181	May 01, 2027	U-3028			
		>A> 8629162	Jun 24, 2025	U-2648			
		>A> 8629162	Jun 24, 2025	U-3030			
		>A> 9670163	Dec 28, 2026	DP U-2650			
		>A> 9670163	Dec 28, 2026	DP U-3031			
		>A> 9931334	Dec 28, 2026	DP U-2650			
		>A> 9931334	Dec 28, 2026	DP U-3031			
		>A> 9974781	Apr 09, 2027	DP U-2645			
		>A> 9974781	Apr 09, 2027	DP U-3028			
ELIGLUSTAT TARTRATE - CERDELGA							
N 205494	001	>A> 10888544	Dec 13, 2038	U-3040			
		>A> 10888544	Dec 13, 2038	U-3041			
		>A> 10888547	Jan 31, 2031	U-3042			
		>A> 10888547	Jan 31, 2031	U-3043			
EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE							
A 209721	001					>A> PC	Mar 09, 2021
EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE							
A 209721	002					>A> PC	Mar 09, 2021
EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE							
A 209721	003					>A> PC	Mar 09, 2021
EPINEPHRINE - AUVI-Q							
N 201739	002	>A> 10842938	Dec 21, 2037	DP U-2980			
EPINEPHRINE - AUVI-Q							
N 201739	003	>A> 10842938	Dec 21, 2037	DP U-2980			
ESKETAMINE HYDROCHLORIDE - SPRAVATO							
N 211243	001	>A> 10869844	Sep 10, 2035	U-3034			
		>A> 10869844	Sep 10, 2035	U-3035			
		>A> 10869844	Sep 10, 2035	U-3036			
ESLICARBAZEPINE ACETATE - APTIOM							
N 022416	001	>A> 10912781	Oct 23, 2028	DP			
ESLICARBAZEPINE ACETATE - APTIOM							
N 022416	002	>A> 10912781	Oct 23, 2028	DP			

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2021

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ESLICARBAZEPINE ACETATE - APTIOM							
N 022416	003	>A> 10912781	Oct 23, 2028	DP			
ESLICARBAZEPINE ACETATE - APTIOM							
N 022416	004	>A> 10912781	Oct 23, 2028	DP			
ESTRADIOL - IMVEXXY							
N 208564	001	>A> 10888516	Jun 18, 2033	U-2316			
		>A> 10888516	Jun 18, 2033	U-2317			
ESTRADIOL - IMVEXXY							
N 208564	002	>A> 10888516	Jun 18, 2033	U-2316			
		>A> 10888516	Jun 18, 2033	U-2317			
ETHINYL ESTRADIOL; NORETHINDRONE ACETATE - MERZEE							
A 212706	001					>A> CGT	Jul 17, 2021
FERRIC CARBOXYMALTOSE - INJECTAFER							
N 203565	001	>A> 10519252	Oct 20, 2023	DS DP U-2709			
		>A> 10519252	Oct 20, 2023	DS DP U-2710			
		>A> 10519252	Oct 20, 2023	DS DP U-2711			
		>A> 10519252	Oct 20, 2023	DS DP U-2712			
		>A> 10519252	Oct 20, 2023	DS DP U-3048			
		>A> 10519252	Oct 20, 2023	DS DP U-3049			
		>A> 7754702	Feb 15, 2028	U-1432			
		>A> 7754702	Feb 15, 2028	U-2555			
		>A> 7754702	Feb 15, 2028	U-2556			
		>A> 7754702	Feb 15, 2028	U-2557			
		>A> 8895612	Jan 08, 2027	U-1620			
		>A> 8895612	Jan 08, 2027	U-3050			
		>A> 8895612	Jan 08, 2027	U-3051			
FERRIC CARBOXYMALTOSE - INJECTAFER							
N 203565	002	>A> 10519252	Oct 20, 2023	DS DP U-2709			
		>A> 10519252	Oct 20, 2023	DS DP U-2710			
		>A> 10519252	Oct 20, 2023	DS DP U-3048			
		>A> 10519252	Oct 20, 2023	DS DP U-3049			
		>A> 7612109	Feb 05, 2024	DS DP			
		>A> 7754702	Feb 15, 2028	U-2555			
		>A> 7754702	Feb 15, 2028	U-2556			
		>A> 7754702	Feb 15, 2028	U-2557			
		>A> 8895612	Jan 08, 2027	U-1620			
		>A> 8895612	Jan 08, 2027	U-3050			
		>A> 8895612	Jan 08, 2027	U-3051			
		>A> 9376505	Oct 20, 2023	DS DP			
GALLIUM GA-68 PSMA-11 - GALLIUM GA 68 PSMA-11							
N 212642	001					>A> NCE	Dec 01, 2025
						>A> W	Dec 01, 2025
GALLIUM GA-68 PSMA-11 - GALLIUM GA 68 PSMA-11							
N 212643	001					>A> NCE	Dec 01, 2025
						>A> W	Dec 01, 2025
GLUCAGON - BAQSIMI							
N 210134	001	>A> 10894133	Jan 03, 2038	DP			
ICOSAPENT ETHYL - VASCEPA							
N 202057	001	>A> 10881632	Apr 29, 2030	U-3052			
		>A> 10894028	Jun 28, 2033	U-3053			
ICOSAPENT ETHYL - VASCEPA							
N 202057	002	>A> 10881632	Apr 29, 2030	U-3052			
		>A> 10894028	Jun 28, 2033	U-3053			

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APPL/PROD NO			PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
IVACAFTOR; IVACAFTOR, TEZACAFTOR - SYMDEKO (COPACKAGED)								
N 210491	001	>A>	10058546	Jul 15, 2033	U-2399			
		>A>	10058546	Jul 15, 2033	U-2572			
		>A>	10058546	Jul 15, 2033	U-3022			
		>A>	10058546	Jul 15, 2033	U-3023			
		>A>	10081621	Mar 25, 2031	DP U-2420			
		>A>	10081621	Mar 25, 2031	DP U-2571			
		>A>	10081621	Mar 25, 2031	DP U-3024			
		>A>	10081621	Mar 25, 2031	DP U-3025			
		>A>	10206877	Apr 14, 2035	DP U-2498			
		>A>	10206877	Apr 14, 2035	DP U-2570			
		>A>	10206877	Apr 14, 2035	DP U-3026			
		>A>	10206877	Apr 14, 2035	DP U-3027			
		>A>	8354427	Jul 06, 2026	U-3021			
IVACAFTOR; IVACAFTOR, TEZACAFTOR - SYMDEKO (COPACKAGED)								
N 210491	002	>A>	10058546	Jul 15, 2033	U-2399			
		>A>	10058546	Jul 15, 2033	U-2572			
		>A>	10058546	Jul 15, 2033	U-3022			
		>A>	10058546	Jul 15, 2033	U-3023			
		>A>	10081621	Mar 25, 2031	DP U-2420			
		>A>	10081621	Mar 25, 2031	DP U-2571			
		>A>	10081621	Mar 25, 2031	DP U-3024			
		>A>	10081621	Mar 25, 2031	DP U-3025			
		>A>	10206877	Apr 14, 2035	DP U-2498			
		>A>	10206877	Apr 14, 2035	DP U-2570			
		>A>	10206877	Apr 14, 2035	DP U-3026			
		>A>	10206877	Apr 14, 2035	DP U-3027			
		>A>	8354427	Jul 06, 2026	U-3021			
LATANOPROST; NETARSUDIL DIMESYLATE - ROCKLATAN								
N 208259	001	>A>	10882840	Jul 11, 2026	U-1524			
LIRAGLUTIDE RECOMBINANT - SAXENDA								
N 206321	001						>A> NPP	Dec 04, 2023
MANNITOL - BRONCHITOL								
N 202049	001						>A> NP	Oct 30, 2023
MELOXICAM - ANJESO								
N 210583	001	>A>	10881663	Mar 08, 2039	U-3038			
METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET								
N 022044	001						>A> M-187	Dec 04, 2023
							>A> PED	Jun 04, 2024
METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET								
N 022044	002						>A> M-187	Dec 04, 2023
							>A> PED	Jun 04, 2024
METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET XR								
N 202270	001						>A> M-187	Dec 04, 2023
							>A> PED	Jun 04, 2024
METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET XR								
N 202270	002						>A> M-187	Dec 04, 2023
							>A> PED	Jun 04, 2024
MIGALASTAT HYDROCHLORIDE - GALAFOLD								
N 208623	001	>A>	10874655	May 30, 2038	U-2371			
		>A>	10874656	May 30, 2038	U-2371			
		>A>	10874657	May 30, 2038	U-2371			

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NERATINIB MALEATE - NERLYNX							
N 208051	001	>A> 8669273	Jul 18, 2031	U-3047			
		>A> 9265784	Aug 04, 2029	U-3047			
NETARSUDIL MESYLATE - RHOPRESSA							
N 208254	001	>A> 10882840	Jul 11, 2026	U-1524			
NIFURTIMOX - LAMPIT							
N 213464	001					>A> ODE-319	Aug 06, 2027
NIFURTIMOX - LAMPIT							
N 213464	002					>A> ODE-319	Aug 06, 2027
NITRIC OXIDE - GENOSYL							
N 202860	001	>A> 10124142	Aug 18, 2025	U-3037			
		>A> 10814092	Oct 17, 2025	U-3037			
		>A> 7947227	Oct 17, 2026	U-3037			
		>A> 8057742	Jan 18, 2026	U-3037			
		>A> 8226916	Aug 18, 2025	U-3037			
		>A> 8607785	Jul 14, 2030	DP			
		>A> 8609028	Aug 18, 2025	U-3037			
		>A> 8821801	Aug 18, 2025	DP			
		>A> 8944049	Aug 13, 2029	DP			
		>A> 9522249	Aug 18, 2025	DP			
		>A> 9701538	Jan 28, 2029	DP			
		>A> 9956373	Aug 18, 2025	U-3037			
OBETICHOLIC ACID - OCALIVA							
N 207999	001	>A> RE48286	Nov 16, 2027	DS DP			
OBETICHOLIC ACID - OCALIVA							
N 207999	002	>A> RE48286	Nov 16, 2027	DS DP			
OLICERIDINE - OLINVYK							
N 210730	001					>A> NCE	Aug 07, 2025
OLICERIDINE - OLINVYK							
N 210730	002					>A> NCE	Aug 07, 2025
OLICERIDINE - OLINVYK							
N 210730	003					>A> NCE	Aug 07, 2025
OSIMERTINIB MESYLATE - TAGRISSO							
N 208065	001	>A> 10183020	Jan 02, 2035	DP U-1777			
		>A> 10183020	Jan 02, 2035	DP U-2289			
		>A> 10183020	Jan 02, 2035	DP U-3016			
		>A> 8946235	Aug 08, 2032	DS DP U-1777			
		>A> 8946235	Aug 08, 2032	DS DP U-2289			
		>A> 8946235	Aug 08, 2032	DS DP U-3016			
		>A> 9732058	Jul 25, 2032	DS DP U-1777			
		>A> 9732058	Jul 25, 2032	DS DP U-2289			
		>A> 9732058	Jul 25, 2032	DS DP U-3016			
OSIMERTINIB MESYLATE - TAGRISSO							
N 208065	002	>A> 10183020	Jan 02, 2035	DP U-1777			
		>A> 10183020	Jan 02, 2035	DP U-2289			
		>A> 10183020	Jan 02, 2035	DP U-3016			
		>A> 8946235	Aug 08, 2032	DS DP U-1777			
		>A> 8946235	Aug 08, 2032	DS DP U-2289			
		>A> 8946235	Aug 08, 2032	DS DP U-3016			
		>A> 9732058	Jul 25, 2032	DS DP U-1777			
		>A> 9732058	Jul 25, 2032	DS DP U-2289			
		>A> 9732058	Jul 25, 2032	DS DP U-3016			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
OXYMETAZOLINE HYDROCHLORIDE - UPNEEQ						
N 212520 001	>A> 10898573	Dec 16, 2039	DP			
	>A> 10912765	Aug 26, 2031	U-2849			
POMALIDOMIDE - POMALYST						
N 204026 001					>A> M-14	Nov 20, 2023
					>A> PED	May 20, 2024
POMALIDOMIDE - POMALYST						
N 204026 002					>A> M-14	Nov 20, 2023
					>A> PED	May 20, 2024
POMALIDOMIDE - POMALYST						
N 204026 003					>A> M-14	Nov 20, 2023
					>A> PED	May 20, 2024
POMALIDOMIDE - POMALYST						
N 204026 004					>A> M-14	Nov 20, 2023
					>A> PED	May 20, 2024
PONATINIB HYDROCHLORIDE - ICLUSIG						
N 203469 001					>A> I-849	Dec 18, 2023
PONATINIB HYDROCHLORIDE - ICLUSIG						
N 203469 002					>A> I-849	Dec 18, 2023
PONATINIB HYDROCHLORIDE - ICLUSIG						
N 203469 003	>A> 8114874	Jan 24, 2027	DS DP		>A> I-849	Dec 18, 2023
PONATINIB HYDROCHLORIDE - ICLUSIG						
N 203469 004	>A> 8114874	Jan 24, 2027	DS DP		>A> I-849	Dec 18, 2023
	>A> 9029533	Dec 22, 2026	U-1283			
	>A> 9029533	Dec 22, 2026	U-1699			
	>A> 9029533	Dec 22, 2026	U-1700			
	>A> 9029533	Dec 22, 2026	U-1701			
	>A> 9029533	Dec 22, 2026	U-836			
	>A> 9493470	Dec 12, 2033	DS DP U-1700			
	>A> 9493470	Dec 12, 2033	DS DP U-1948			
RELUGOLIX - ORGOVYX						
N 214621 001	>A> 10350170	Feb 25, 2036	DP		>A> NCE	Dec 18, 2025
	>A> 10449191	Sep 29, 2037	U-3020			
	>A> 10786501	Sep 29, 2037	U-3020			
	>A> 7300935	Jan 28, 2024	DS			
	>A> 8058280	Jan 28, 2024	DS DP			
	>A> 8735401	Feb 04, 2024	U-3019			
SELINEXOR - XPOVIO						
N 212306 001	>A> 10519139	Aug 14, 2035	DS DP U-2584			
	>A> 10519139	Aug 14, 2035	DS DP U-2855			
	>A> 10519139	Aug 14, 2035	DS DP U-3018			
	>A> 10544108	Jul 26, 2032	U-2584			
	>A> 10544108	Jul 26, 2032	U-3018			
	>A> 9079865	Jul 26, 2032	U-2584			
	>A> 9079865	Jul 26, 2032	U-2855			
	>A> 9079865	Jul 26, 2032	U-3018			
SITAGLIPTIN PHOSPHATE - JANUVIA						
N 021995 001					>A> M-187	Dec 04, 2023
					>A> PED	Jun 04, 2024
SITAGLIPTIN PHOSPHATE - JANUVIA						
N 021995 002					>A> M-187	Dec 04, 2023
					>A> PED	Jun 04, 2024

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
SITAGLIPTIN PHOSPHATE - JANUVIA						
N 021995 002					>A> M-187	Dec 04, 2023
					>A> PED	Jun 04, 2024
SITAGLIPTIN PHOSPHATE - JANUVIA						
N 021995 003					>A> M-187	Dec 04, 2023
					>A> PED	Jun 04, 2024
SODIUM OXYBATE - XYREM						
N 021196 001	>A> 10864181	Mar 15, 2033	U-1532			
SPIRONOLACTONE - CAROSPIR						
N 209478 001	>A> 10888570	Oct 28, 2036	DP			
SUFENTANIL CITRATE - DSUVIA						
N 209128 001	>A> 10896751	Mar 16, 2030	DP			
TAFENOQUINE SUCCINATE - ARAKODA						
N 210607 001	>A> 10888558	Dec 02, 2035	U-2582			
TAFLUPROST - ZIOPTAN						
N 202514 001	>A> 10864159	May 28, 2029	DP U-778			
TASIMELTEON - HETLIOZ						
N 205677 001	>A> 10610511	Oct 10, 2034	U-2615		>A> I-850	Dec 01, 2023
	>A> 10610511	Oct 10, 2034	U-3007			
TASIMELTEON - HETLIOZ LQ						
N 214517 001					>A> NP	Dec 01, 2023
TESTOSTERONE ENANTHATE - XYOSTED (AUTOINJECTOR)						
N 209863 001	>A> 10881798	Feb 11, 2034	DP			
TESTOSTERONE ENANTHATE - XYOSTED (AUTOINJECTOR)						
N 209863 002	>A> 10881798	Feb 11, 2034	DP			
TESTOSTERONE ENANTHATE - XYOSTED (AUTOINJECTOR)						
N 209863 003	>A> 10881798	Feb 11, 2034	DP			
TIRBANIBULIN - KLISYRI						
N 213189 001	>A> 10323001	Dec 28, 2027	DP		>A> NCE	Dec 14, 2025
	>A> 10617693	Mar 12, 2038	U-3015			
	>A> 10669236	Sep 07, 2038	DS DP			
	>A> 7300931	Feb 06, 2026	DS DP			
	>A> 7851470	Feb 02, 2029	DS DP U-3015			
	>A> 8236799	Dec 28, 2025	DS DP			
	>A> 8980890	Dec 28, 2025	DS DP			
VALBENAZINE TOSYLATE - INGREZZA						
N 209241 001	>A> 10874648	Oct 10, 2037	U-1995			
	>A> 10874648	Oct 10, 2037	U-3046			
VALBENAZINE TOSYLATE - INGREZZA						
N 209241 002	>A> 10874648	Oct 10, 2037	U-1995			
	>A> 10874648	Oct 10, 2037	U-3046			
VERICIGUAT - VERQUVO						
N 214377 001					>A> NCE	Jan 19, 2026
VERICIGUAT - VERQUVO						
N 214377 002					>A> NCE	Jan 19, 2026

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VERICIGUAT - VERQUVO							
N 214377	003					>A> NCE	Jan 19, 2026
VIBEGRON - GEMTESA							
N 213006	001	>A> 8247415	Dec 01, 2030	DS DP U-3045		>A> NCE	Dec 23, 2025
		>A> 8653260	Apr 02, 2029	DS			
VIGABATRIN - VIGABATRIN							
A 211539	001					>A> CGT	Jul 31, 2021
VILTOLARSEN - VILTEPSO							
N 212154	001	>A> 10870676	Aug 31, 2031	DS DP U-3039		>A> ODE-280	Aug 12, 2027

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, 41ST 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