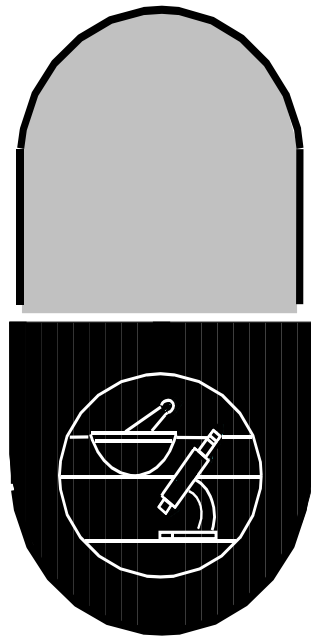


**CUMULATIVE
SUPPLEMENT 1
JANUARY 2020**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

40th 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**

2020

Prepared By
Food and Drug Administration
Office of Medical Products and Tobacco
Center for Drug Evaluation and Research
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**Cumulative Supplement 1
January 2020**

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**APPROVED DRUG PRODUCTS
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40th EDITION

**CUMULATIVE SUPPLEMENT 1
JANUARY 2020**

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for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.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)

AMNEAL PHARMACEUTICALS CO GMBH
(AMNEAL PHARMS CO)

AMNEAL EU LTD
(AMNEAL EU)

ANDA REPOSITORY LLC
(ANDA REPOSITORY)

PHARMACEUTICS INTERNATIONAL INC
(PII)

1.4 LEVOTHYROXINE SODIUM¹

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
AB4	THYRO-TABS	ALVOGEN GROUP	0.3MG	N021116	RLD	-

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.

		LLC				
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,
 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).

<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

<u>CATEGORIES</u>	<u>DEC</u>	<u>MAR</u>	<u>JUN</u>	<u>SEP</u>	<u>DEC</u>
<u>COUNTED</u>	<u>2019</u>	<u>2020</u>	<u>2020</u>	<u>2020</u>	<u>2020</u>
DRUG PRODUCTS LISTED SINGLE SOURCE	20567	2743			(13.3%)
MULTISOURCE	17824				(86.7%)

THERAPEUTICALLY EQUIVALENT	17740 (86.3%)
NOT THERAPEUTICALLY EQUIVALENT	84 (0.4%)
EXCEPTIONS ⁴	54 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	17
NUMBER OF APPLICANTS	1162

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 preceded 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
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

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.

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; HYDROCODONE BITARTRATE

TABLET;ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>A>	AA	XIROMED	325MG;5MG	A211690	001	Feb 07, 2020	Jan	NEWA
>A>	AA		325MG;7.5MG	A211690	002	Feb 07, 2020	Jan	NEWA
>A>	AA		325MG;10MG	A211690	003	Feb 07, 2020	Jan	NEWA

ACYCLOVIR

CREAM;TOPICAL

ACYCLOVIR

>D>	AB	PERRIGO UK FINCO	5%	A208702	001	Feb 04, 2019	Jan	CHRS
>A>	AB	!	5%	A208702	001	Feb 04, 2019	Jan	CHRS

ZOVIRAX

>D>	AB	+!	BAUSCH	5%	N021478	001	Dec 30, 2002	Jan	CHRS
>A>	AB	+		5%	N021478	001	Dec 30, 2002	Jan	CHRS

OINTMENT;TOPICAL

ACYCLOVIR

>A>	AB		XIROMED	5%	A201501	001	Jan 29, 2020	Jan	NEWA
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TABLET;ORAL

ACYCLOVIR

>D>	AB		HETERO LABS LTD V	800MG	A203834	002	Oct 29, 2013	Jan	CHRS
>A>	AB	!		800MG	A203834	002	Oct 29, 2013	Jan	CHRS

ZOVIRAX

>D>	AB	+	MYLAN	400MG	N020089	001	Apr 30, 1991	Jan	DISC
>A>		+	@	400MG	N020089	001	Apr 30, 1991	Jan	DISC
>D>	AB	+	!	800MG	N020089	002	Apr 30, 1991	Jan	DISC
>A>		+	@	800MG	N020089	002	Apr 30, 1991	Jan	DISC

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

EMULSION;INTRAVENOUS

PERIKABIVEN IN PLASTIC CONTAINER

>D>		+	FRESENIUS KABI USA	2.4%;20MG/100ML;6.8GM/100ML;68MG/100ML;124MG/100ML;170MG/100ML;105MG/100ML;3.5GM/100ML (2400ML)	N200656	003	Aug 25, 2014	Jan	CHRS
>A>		+	!	2.4%;20MG/100ML;6.8GM/100ML;68MG/100ML;124MG/100ML;170MG/100ML;105MG/100ML;3.5GM/100ML (2400ML)	N200656	003	Aug 25, 2014	Jan	CHRS

AMITRIPTYLINE HYDROCHLORIDE

TABLET;ORAL

AMITRIPTYLINE HYDROCHLORIDE

>A>	AB		SANDOZ	10MG	A085968	004		Jan	CMS1
>A>	AB	!		25MG	A085968	002		Jan	CMS1
>A>	AB			75MG	A085968	006		Jan	CMS1
>A>	AB			100MG	A085968	003		Jan	CMS1
>A>	AB			150MG	A085968	005		Jan	CMS1

AMOXAPINE

TABLET;ORAL

AMOXAPINE

>D>		@	WATSON PHARMS TEVA	25MG	A072418	001	May 11, 1989	Jan	CMS1
>A>		@		25MG	A072418	001	Aug 01, 1989	Jan	CMS1
>D>		@		50MG	A072419	001	May 11, 1989	Jan	CMS1
>A>		@		50MG	A072419	001	Aug 01, 1989	Jan	CMS1

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>D>	AB		AMERIGEN PHARMS LTD	1.25MG;1.25MG;1.25MG;1.25MG	A205401	001	Jan 22, 2019	Jan	CAHN
>D>	AB			2.5MG;2.5MG;2.5MG;2.5MG	A205401	002	Jan 22, 2019	Jan	CAHN
>D>	AB			3.75MG;3.75MG;3.75MG;3.75MG	A205401	003	Jan 22, 2019	Jan	CAHN
>D>	AB			5MG;5MG;5MG;5MG	A205401	004	Jan 22, 2019	Jan	CAHN
>D>	AB			6.25MG;6.25MG;6.25MG;6.25MG	A205401	005	Jan 22, 2019	Jan	CAHN
>D>	AB			7.5MG;7.5MG;7.5MG;7.5MG	A205401	006	Jan 22, 2019	Jan	CAHN
>A>	AB		ANI PHARMS INC	1.25MG;1.25MG;1.25MG;1.25MG	A205401	001	Jan 22, 2019	Jan	CAHN
>A>	AB			2.5MG;2.5MG;2.5MG;2.5MG	A205401	002	Jan 22, 2019	Jan	CAHN
>A>	AB			3.75MG;3.75MG;3.75MG;3.75MG	A205401	003	Jan 22, 2019	Jan	CAHN
>A>	AB			5MG;5MG;5MG;5MG	A205401	004	Jan 22, 2019	Jan	CAHN
>A>	AB			6.25MG;6.25MG;6.25MG;6.25MG	A205401	005	Jan 22, 2019	Jan	CAHN
>A>	AB			7.5MG;7.5MG;7.5MG;7.5MG	A205401	006	Jan 22, 2019	Jan	CAHN

CAPSULE, EXTENDED RELEASE;ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

>D>	AB	NESHER PHARMS	1.25MG;1.25MG;1.25MG;1.25MG	A210080	001	Jul 17, 2019	Jan DISC
>A>	@		1.25MG;1.25MG;1.25MG;1.25MG	A210080	001	Jul 17, 2019	Jan DISC
>D>	AB		2.5MG;2.5MG;2.5MG;2.5MG	A210080	002	Jul 17, 2019	Jan DISC
>A>	@		2.5MG;2.5MG;2.5MG;2.5MG	A210080	002	Jul 17, 2019	Jan DISC
>D>	AB		3.75MG;3.75MG;3.75MG;3.75MG	A210080	003	Jul 17, 2019	Jan DISC
>A>	@		3.75MG;3.75MG;3.75MG;3.75MG	A210080	003	Jul 17, 2019	Jan DISC
>D>	AB		5MG;5MG;5MG;5MG	A210080	004	Jul 17, 2019	Jan DISC
>A>	@		5MG;5MG;5MG;5MG	A210080	004	Jul 17, 2019	Jan DISC
>D>	AB		6.25MG;6.25MG;6.25MG;6.25MG	A210080	005	Jul 17, 2019	Jan DISC
>A>	@		6.25MG;6.25MG;6.25MG;6.25MG	A210080	005	Jul 17, 2019	Jan DISC
>D>	AB		7.5MG;7.5MG;7.5MG;7.5MG	A210080	006	Jul 17, 2019	Jan DISC
>A>	@		7.5MG;7.5MG;7.5MG;7.5MG	A210080	006	Jul 17, 2019	Jan DISC

AMPHETAMINE SULFATE

TABLET;ORAL

AMPHETAMINE SULFATE

>A>	AA	CEROVENE INC	5MG	A212582	001	Feb 04, 2020	Jan NEWA
>A>	AA		10MG	A212582	002	Feb 04, 2020	Jan NEWA

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE;INJECTION

AMPICILLIN AND SULBACTAM

>D>	@	MUSTAFA NEVZAT ILAC	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A065316	001	Jun 29, 2007	Jan CAHN
>D>	@		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A065316	002	Jun 29, 2007	Jan CAHN
>A>	@	PHARM ASSOC	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A065316	001	Jun 29, 2007	Jan CAHN
>A>	@		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A065316	002	Jun 29, 2007	Jan CAHN

ANASTROZOLE

TABLET;ORAL

ANASTROZOLE

>D>	AB	MYLAN	1MG	A091051	001	Jun 28, 2010	Jan DISC
>A>	@		1MG	A091051	001	Jun 28, 2010	Jan DISC

APIXABAN

TABLET;ORAL

APIXABAN

>D>	AB	MYLAN	2.5MG	A210128	001	Dec 23, 2019	Jan DISC
>A>	@		2.5MG	A210128	001	Dec 23, 2019	Jan DISC
>D>	AB		5MG	A210128	002	Dec 23, 2019	Jan DISC
>A>	@		5MG	A210128	002	Dec 23, 2019	Jan DISC

ASENAPINE MALEATE

TABLET;SUBLINGUAL

SAPHRIS

>D>	+	ALLERGAN	EQ 2.5 BASE	N022117	003	Mar 12, 2015	Jan CMS1
>A>	+		EQ 2.5MG BASE	N022117	003	Mar 12, 2015	Jan CMS1

ATORVASTATIN CALCIUM

TABLET;ORAL

ATORVASTATIN CALCIUM

>D>	@	LUPIN LTD	EQ 10MG BASE	A204991	001	Mar 06, 2019	Jan CMFD
>A>	AB		EQ 10MG BASE	A204991	001	Mar 06, 2019	Jan CMFD
>D>	@		EQ 20MG BASE	A204991	002	Mar 06, 2019	Jan CMFD
>A>	AB		EQ 20MG BASE	A204991	002	Mar 06, 2019	Jan CMFD
>D>	@		EQ 40MG BASE	A204991	003	Mar 06, 2019	Jan CMFD
>A>	AB		EQ 40MG BASE	A204991	003	Mar 06, 2019	Jan CMFD
>D>	@		EQ 80MG BASE	A204991	004	Mar 06, 2019	Jan CMFD
>A>	AB		EQ 80MG BASE	A204991	004	Mar 06, 2019	Jan CMFD

>A> AVAPRITINIB

>A> TABLET;ORAL

>A> AYVAKIT

>A>	+	BLUEPRINT MEDICINES	100MG	N212608	001	Jan 09, 2020	Jan NEWA
>A>	+		200MG	N212608	002	Jan 09, 2020	Jan NEWA
>A>	+	!	300MG	N212608	003	Jan 09, 2020	Jan NEWA

AZITHROMYCIN

TABLET;ORAL

AZITHROMYCIN

>A>	AB	ALEMBIC PHARMS LTD	EQ 250MG BASE	A211791	001	Jan 28, 2020	Jan NEWA
>A>	AB		EQ 500MG BASE	A211792	001	Jan 28, 2020	Jan NEWA
>A>	AB		EQ 600MG BASE	A211793	001	Jan 27, 2020	Jan NEWA
>D>	AB	MYLAN	EQ 600MG BASE	A065360	001	Jan 08, 2007	Jan DISC
>A>		@	EQ 600MG BASE	A065360	001	Jan 08, 2007	Jan DISC

BACLOFEN

TABLET;ORAL

BACLOFEN

>D>	AB	MYLAN	20MG	A077121	002	Jul 29, 2005	Jan DISC
>A>		@	20MG	A077121	002	Jul 29, 2005	Jan DISC

BETHANECHOL CHLORIDE

TABLET;ORAL

BETHANECHOL CHLORIDE

>D>	AA	AMNEAL PHARM	5MG	A040855	001	Nov 21, 2007	Jan CHRS
>A>	AA	!	5MG	A040855	001	Nov 21, 2007	Jan CHRS
>D>	AA		10MG	A040855	002	Nov 21, 2007	Jan CHRS
>A>	AA	!	10MG	A040855	002	Nov 21, 2007	Jan CHRS
>D>	AA		25MG	A040855	003	Nov 21, 2007	Jan CHRS
>A>	AA	!	25MG	A040855	003	Nov 21, 2007	Jan CHRS
>D>		@ IMPAX LABS	25MG	A040721	003	Nov 01, 2016	Jan CMS1
>A>		@	25MG	A040721	003	Nov 01, 2006	Jan CMS1
		URECHOLINE					
>D>	AA	! ODYSSEY PHARMS	5MG	A089095	001	Dec 19, 1985	Jan DISC
>A>		@	5MG	A089095	001	Dec 19, 1985	Jan DISC
>D>	AA	!	10MG	A088440	001	May 29, 1984	Jan DISC
>A>		@	10MG	A088440	001	May 29, 1984	Jan DISC
>D>	AA	!	25MG	A088441	001	May 29, 1984	Jan DISC
>A>		@	25MG	A088441	001	May 29, 1984	Jan DISC

BEXAROTENE

CAPSULE;ORAL

BEXAROTENE

>D>	AB	AMERIGEN PHARMS LTD	75MG	A209861	001	May 08, 2018	Jan CAHN
>A>	AB	ANI PHARMS INC	75MG	A209861	001	May 08, 2018	Jan CAHN

BICALUTAMIDE

TABLET;ORAL

BICALUTAMIDE

>D>	AB	MYLAN	50MG	A079185	001	Jul 06, 2009	Jan DISC
>A>		@	50MG	A079185	001	Jul 06, 2009	Jan DISC

BIMATOPROST

SOLUTION/DROPS;TOPICAL

BIMATOPROST

>A>	AT	ALEMBIC PHARMS LTD	0.03%	A210515	001	Jan 21, 2020	Jan NEWA
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BOSENTAN

TABLET;ORAL

BOSENTAN

>A>	AB	ALEMBIC PHARMS LTD	62.5MG	A211461	001	Jan 23, 2020	Jan NEWA
>A>	AB		125MG	A211461	002	Jan 23, 2020	Jan NEWA
>D>	AB	MYLAN	62.5MG	A205173	001	Jan 15, 2020	Jan DISC
>A>		@	62.5MG	A205173	001	Jan 15, 2020	Jan DISC
>D>	AB		125MG	A205173	002	Jan 15, 2020	Jan DISC
>A>		@	125MG	A205173	002	Jan 15, 2020	Jan DISC

BUMETANIDE

TABLET;ORAL

BUMETANIDE

>D>	AB	CEYONE	0.5MG	A212019	001	Dec 12, 2019	Jan CAHN
>D>	AB		1MG	A212019	002	Dec 12, 2019	Jan CAHN
>D>	AB		2MG	A212019	003	Dec 12, 2019	Jan CAHN
>A>	AB	RISING	0.5MG	A212019	001	Dec 12, 2019	Jan CAHN
>A>	AB		1MG	A212019	002	Dec 12, 2019	Jan CAHN
>A>	AB		2MG	A212019	003	Dec 12, 2019	Jan CAHN

BUPROPION HYDROCHLORIDE

TABLET;ORAL

BUPROPION HYDROCHLORIDE

>A>	AB	CADILA PHARMS LTD	75MG	A208606	001	Jan 16, 2020	Jan NEWA
>A>	AB		100MG	A208606	002	Jan 16, 2020	Jan NEWA

BUPROPION HYDROCHLORIDE; NALTREXONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

CONTRAVE

>D>	+	!	NALPROPION	90MG;8MG	N200063	001	Sep 10, 2014	Jan CAHN
>A>		+		90MG;8MG	N200063	001	Sep 10, 2014	Jan CAHN

CABERGOLINE

TABLET;ORAL

CABERGOLINE

>D>	AB	MYLAN	0.5MG	A202947	001	Dec 02, 2013	Jan DISC
>A>		@	0.5MG	A202947	001	Dec 02, 2013	Jan DISC

CALCITRIOL

INJECTABLE;INJECTION

CALCITRIOL

>D>		!	AKORN	0.001MG/ML	A078066	001	Jan 29, 2008	Jan CTEC
>A>	AP	!		0.001MG/ML	A078066	001	Jan 29, 2008	Jan CTEC
>A>	AP		GLAND PHARMA LTD	0.001MG/ML	A211030	001	Feb 03, 2020	Jan NEWA

CALCIUM ACETATE

CAPSULE;ORAL

CALCIUM ACETATE

>D>	AB		LOTUS PHARM CO LTD	667MG	A203298	001	Jul 26, 2016	Jan DISC
>A>		@		667MG	A203298	001	Jul 26, 2016	Jan DISC

CARBIDOPA

TABLET;ORAL

CARBIDOPA

>D>	AB		AMERIGEN PHARMS LTD	25MG	A203261	001	Mar 10, 2014	Jan CAHN
>A>	AB		ANI PHARMS INC	25MG	A203261	001	Mar 10, 2014	Jan CAHN

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE;ORAL

SINEMET CR

>D>	AB	+	MERCK SHARP DOHME	25MG;100MG	N019856	002	Dec 24, 1992	Jan DISC
>A>		+	@	25MG;100MG	N019856	002	Dec 24, 1992	Jan DISC

CEFIXIME

FOR SUSPENSION;ORAL

SUPRAX

>D>	AB		LUPIN PHARMS	100MG/5ML	A065129	001	Feb 23, 2004	Jan DISC
>A>		@		100MG/5ML	A065129	001	Feb 23, 2004	Jan DISC

TABLET;ORAL

SUPRAX

>D>		!	LUPIN PHARMS	400MG	A065130	001	Feb 12, 2004	Jan DISC
>A>		@		400MG	A065130	001	Feb 12, 2004	Jan DISC

CEFTRIAZONE SODIUM

INJECTABLE;INJECTION

CEFTRIAZONE

>D>	AP		HOSPIRA INC	EQ 10GM BASE/VIAL	A065232	001	Aug 02, 2005	Jan DISC
>A>		@		EQ 10GM BASE/VIAL	A065232	001	Aug 02, 2005	Jan DISC

CELECOXIB

CAPSULE;ORAL

CELECOXIB

>A>	AB		UMEDICA LABS PVT LTD	50MG	A210628	001	Nov 27, 2019	Jan CDFR
>A>	AB			100MG	A210628	002	Nov 27, 2019	Jan CDFR
>A>	AB			200MG	A210628	003	Nov 27, 2019	Jan CDFR
>A>	AB			400MG	A210628	004	Nov 27, 2019	Jan CDFR

TABLET;ORAL

CELECOXIB

>D>	AB		UMEDICA LABS PVT LTD	50MG	A210628	001	Nov 27, 2019	Jan CDFR
>D>	AB			100MG	A210628	002	Nov 27, 2019	Jan CDFR
>D>	AB			200MG	A210628	003	Nov 27, 2019	Jan CDFR

>D> TABLET;ORAL
 >D> CELECOXIB
 >D> AB 400MG A210628 004 Nov 27, 2019 Jan CDFR

CHLORPROMAZINE HYDROCHLORIDE

TABLET;ORAL
 CHLORPROMAZINE HYDROCHLORIDE
 >A> AB ZYDUS 10MG A213368 001 Jan 17, 2020 Jan NEWA
 >A> AB 25MG A213368 002 Jan 17, 2020 Jan NEWA
 >A> AB 50MG A213368 003 Jan 17, 2020 Jan NEWA
 >A> AB 100MG A213368 004 Jan 17, 2020 Jan NEWA
 >A> AB 200MG A213368 005 Jan 17, 2020 Jan NEWA

CHLORTHALIDONE

TABLET;ORAL
 CHLORTHALIDONE
 >A> AB ALKEM LABS LTD 25MG A213412 001 Feb 11, 2020 Jan NEWA
 >A> AB 50MG A213412 002 Feb 11, 2020 Jan NEWA

CHOLESTYRAMINE

POWDER;ORAL
 LOCHOLEST
 >A> @ INVATECH EQ 4GM RESIN/PACKET A074561 001 Aug 15, 1996 Jan CAHN
 >A> @ EQ 4GM RESIN/SCOOPFUL A074561 002 Aug 15, 1996 Jan CAHN
 >D> @ SANDOZ EQ 4GM RESIN/PACKET A074561 001 Aug 15, 1996 Jan CAHN
 >D> @ EQ 4GM RESIN/SCOOPFUL A074561 002 Aug 15, 1996 Jan CAHN

CINACALCET HYDROCHLORIDE

TABLET;ORAL
 CINACALCET HYDROCHLORIDE
 >D> AB LUPIN LTD EQ 30MG BASE A210548 001 Jun 28, 2019 Jan DISC
 >A> @ EQ 30MG BASE A210548 001 Jun 28, 2019 Jan DISC
 >D> AB EQ 60MG BASE A210548 002 Jun 28, 2019 Jan DISC
 >A> @ EQ 60MG BASE A210548 002 Jun 28, 2019 Jan DISC
 >D> AB EQ 90MG BASE A210548 003 Jun 28, 2019 Jan DISC
 >A> @ EQ 90MG BASE A210548 003 Jun 28, 2019 Jan DISC

CISATRACURIUM BESYLATE

INJECTABLE;INJECTION
 CISATRACURIUM BESYLATE
 >D> @ HOSPIRA INC EQ 2MG BASE/ML A203238 001 Mar 30, 2018 Jan CMFD
 >A> AP EQ 2MG BASE/ML A203238 001 Mar 30, 2018 Jan CMFD

CLOBAZAM

SUSPENSION;ORAL
 CLOBAZAM
 >A> AB TEVA PHARMS USA 2.5MG/ML A211032 001 Jan 31, 2020 Jan NEWA

CLOBETASOL PROPIONATE

CREAM;TOPICAL
 CLOBETASOL PROPIONATE
 >A> AB1 ALEOR DERMACEUTICALS 0.05% A213291 001 Jan 27, 2020 Jan NEWA
 SPRAY;TOPICAL
 CLOBETASOL PROPIONATE
 >D> AT ALEOR DERMACEUTICALS 0.05% A211191 001 Oct 02, 2019 Jan DISC
 >A> @ 0.05% A211191 001 Oct 02, 2019 Jan DISC

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE;ORAL
 CLOMIPRAMINE HYDROCHLORIDE
 >A> AB LEADING PHARMA LLC 25MG A211364 001 Feb 07, 2020 Jan NEWA
 >A> AB 50MG A211364 002 Feb 07, 2020 Jan NEWA
 >A> AB 75MG A211364 003 Feb 07, 2020 Jan NEWA
 >D> @ MANKIND PHARMA 25MG A211767 001 Apr 08, 2019 Jan CMFD
 >A> AB 25MG A211767 001 Apr 08, 2019 Jan CMFD
 >D> @ 50MG A211767 002 Apr 08, 2019 Jan CMFD
 >A> AB 50MG A211767 002 Apr 08, 2019 Jan CMFD
 >D> @ 75MG A211767 003 Apr 08, 2019 Jan CMFD
 >A> AB 75MG A211767 003 Apr 08, 2019 Jan CMFD

COCAINE HYDROCHLORIDE

SOLUTION;NASAL
 >A> NUMBRINO
 >A> CODY LABS INC 4% N209575 001 Jan 10, 2020 Jan NEWA

COLCHICINE

TABLET;ORAL
 COLCHICINE
 >D> @ AMNEAL PHARMS 0.6MG A204711 001 Sep 28, 2016 Jan CMFD
 >A> AB 0.6MG A204711 001 Sep 28, 2016 Jan CMFD
 >A> AB GRANULES PHARMS 0.6MG A210425 001 Feb 05, 2020 Jan NEWA

CYCLOPHOSPHAMIDE

CAPSULE;ORAL
 CYCLOPHOSPHAMIDE
 >D> AB AMERIGEN PHARMS LTD 25MG A207014 001 Mar 19, 2018 Jan CAHN
 >D> AB 50MG A207014 002 Mar 19, 2018 Jan CAHN
 >A> AB ANI PHARMS INC 25MG A207014 001 Mar 19, 2018 Jan CAHN
 >A> AB 50MG A207014 002 Mar 19, 2018 Jan CAHN

DEFERASIROX

TABLET;ORAL
 DEFERASIROX
 >A> AB CIPLA 90MG A211852 001 Feb 11, 2020 Jan NEWA
 >A> AB 360MG A211852 002 Feb 11, 2020 Jan NEWA

DESIRUDIN RECOMBINANT

INJECTABLE;SUBCUTANEOUS
 IPRIVASK
 >A> + @ BAUSCH 15MG/VIAL N021271 001 Apr 04, 2003 Jan CAHN
 >D> + @ VALEANT PHARMS NORTH 15MG/VIAL N021271 001 Apr 04, 2003 Jan CAHN

DEXMEDETOMIDINE HYDROCHLORIDE

INJECTABLE;INJECTION
 DEXMEDETOMIDINE
 >A> AP JIANGSU HENGRUI MED EQ 200MCG BASE/2ML (EQ 100MCG A209065 001 Sep 19, 2017 Jan CTNA
 BASE/ML)
 DEXMEDETOMIDINE HYDROCHLORIDE
 >A> AP HIKMA EQ 200MCG BASE/50ML (EQ 4MCG A206407 001 Jan 30, 2020 Jan NEWA
 BASE/ML)
 >A> AP EQ 400MCG BASE/100ML (EQ 4MCG A206407 002 Jan 30, 2020 Jan NEWA
 BASE/ML)
 >D> AP JIANGSU HENGRUI MED EQ 200MCG BASE/2ML (EQ 100MCG A209065 001 Sep 19, 2017 Jan CTNA
 BASE/ML)

DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE;ORAL
 DEXTROAMPHETAMINE SULFATE
 >D> AB PII 5MG A205077 001 Jun 21, 2019 Jan DISC
 >A> @ 5MG A205077 001 Jun 21, 2019 Jan DISC
 >D> AB 10MG A205077 002 Jun 21, 2019 Jan DISC
 >A> @ 10MG A205077 002 Jun 21, 2019 Jan DISC
 >D> AB 15MG A205077 003 Jun 21, 2019 Jan DISC
 >A> @ 15MG A205077 003 Jun 21, 2019 Jan DISC

DIAZEPAM

SPRAY;NASAL
 VALTOCO
 >A> + NEURELIS INC 5MG/SPRAY N211635 001 Jan 10, 2020 Jan NEWA
 >A> + 7.5MG/SPRAY N211635 002 Jan 10, 2020 Jan NEWA
 >A> +! 10MG/SPRAY N211635 003 Jan 10, 2020 Jan NEWA

DICLOFENAC POTASSIUM

TABLET;ORAL
 CATAFLAM
 >D> @ NOVARTIS 50MG N020142 002 Nov 24, 1993 Jan CRLD
 >A> + @ 50MG N020142 002 Nov 24, 1993 Jan CRLD

DICLOFENAC SODIUM

GEL;TOPICAL
DICLOFENAC SODIUM

>A> AB ENCUBE 1% A210986 001 Jan 27, 2020 Jan NEWA

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS;ORAL
DIVALPROEX SODIUM

>D> AB MYLAN EQ 125MG VALPROIC ACID A090407 001 Mar 28, 2011 Jan DISC
>A> @ EQ 125MG VALPROIC ACID A090407 001 Mar 28, 2011 Jan DISC

TABLET, DELAYED RELEASE;ORAL
DIVALPROEX SODIUM

>D> AB MYLAN EQ 125MG VALPROIC ACID A090062 001 Mar 17, 2009 Jan DISC
>A> @ EQ 125MG VALPROIC ACID A090062 001 Mar 17, 2009 Jan DISC
>D> AB EQ 250MG VALPROIC ACID A090062 002 Mar 17, 2009 Jan DISC
>A> @ EQ 250MG VALPROIC ACID A090062 002 Mar 17, 2009 Jan DISC
>D> AB EQ 500MG VALPROIC ACID A090062 003 Mar 17, 2009 Jan DISC
>A> @ EQ 500MG VALPROIC ACID A090062 003 Mar 17, 2009 Jan DISC

DOCETAXEL

INJECTABLE;INJECTION
DOCETAXEL

>D> @ SHILPA MEDICARE LTD 20MG/ML (20MG/ML) A210327 001 May 16, 2019 Jan CMFD
>A> AP 20MG/ML (20MG/ML) A210327 001 May 16, 2019 Jan CMFD
>D> @ 80MG/4ML (20MG/ML) A210327 002 May 16, 2019 Jan CMFD
>A> AP 80MG/4ML (20MG/ML) A210327 002 May 16, 2019 Jan CMFD
>D> @ 160MG/8ML (20MG/ML) A210327 003 May 16, 2019 Jan CMFD
>A> AP 160MG/8ML (20MG/ML) A210327 003 May 16, 2019 Jan CMFD

DOFETILIDE

CAPSULE;ORAL
DOFETILIDE

>A> AB MSN 0.125MG A213220 001 Jan 29, 2020 Jan NEWA
>A> AB 0.25MG A213220 002 Jan 29, 2020 Jan NEWA
>A> AB 0.5MG A213220 003 Jan 29, 2020 Jan NEWA

DOXAZOSIN MESYLATE

TABLET;ORAL
DOXAZOSIN MESYLATE

>D> AB ANI PHARMS INC EQ 1MG BASE A075432 001 Oct 18, 2000 Jan DISC
>A> @ EQ 1MG BASE A075432 001 Oct 18, 2000 Jan DISC
>D> AB EQ 2MG BASE A075432 002 Oct 18, 2000 Jan DISC
>A> @ EQ 2MG BASE A075432 002 Oct 18, 2000 Jan DISC
>D> AB EQ 4MG BASE A075432 003 Oct 18, 2000 Jan DISC
>A> @ EQ 4MG BASE A075432 003 Oct 18, 2000 Jan DISC
>D> AB EQ 8MG BASE A075432 004 Oct 18, 2000 Jan DISC
>A> @ EQ 8MG BASE A075432 004 Oct 18, 2000 Jan DISC

DOXERCALCIFEROL

INJECTABLE;INJECTION
DOXERCALCIFEROL

>A> AP NANJING KING-FRIEND 4MCG/2ML (2MCG/ML) A211670 001 Feb 07, 2020 Jan NEWA

DOXYCYCLINE

CAPSULE;ORAL
DOXYCYCLINE

>D> AB MYLAN PHARMS INC EQ 150MG BASE A202778 001 Jun 08, 2012 Jan DISC
>A> @ EQ 150MG BASE A202778 001 Jun 08, 2012 Jan DISC

DRONABINOL

CAPSULE;ORAL
DRONABINOL

>A> AB ASCENT PHARMS INC 2.5MG A207421 001 Feb 07, 2020 Jan NEWA
>A> AB 5MG A207421 002 Feb 07, 2020 Jan NEWA
>A> AB 10MG A207421 003 Feb 07, 2020 Jan NEWA

MARINOL

>D> AB + ABBVIE 2.5MG N018651 001 May 31, 1985 Jan CAHN
>D> AB +! 5MG N018651 002 May 31, 1985 Jan CAHN
>D> AB + 10MG N018651 003 May 31, 1985 Jan CAHN
>A> AB + ALKEM LABS LTD 2.5MG N018651 001 May 31, 1985 Jan CAHN
>A> AB +! 5MG N018651 002 May 31, 1985 Jan CAHN

CAPSULE;ORAL
 MARINOL
 >A> AB + 10MG N018651 003 May 31, 1985 Jan CAHN

DROSPIRENONE; ETHINYL ESTRADIOL

TABLET;ORAL
 DROSPIRENONE AND ETHINYL ESTRADIOL
 >A> AB ALLIED 3MG;0.02MG A203291 001 Jul 18, 2017 Jan CAHN
 >D> AB ANDA REPOSITORY 3MG;0.02MG A203291 001 Jul 18, 2017 Jan CAHN
 TABLET;ORAL-28
 DROSPIRENONE AND ETHINYL ESTRADIOL
 >A> AB HETERO LABS LTD 3MG;0.03MG A213034 001 Jan 24, 2020 Jan NEWA

DUTASTERIDE

CAPSULE;ORAL
 DUTASTERIDE
 >D> AB ACTAVIS LABS FL INC 0.5MG A202808 001 Nov 20, 2015 Jan DISC
 >A> @ 0.5MG A202808 001 Nov 20, 2015 Jan DISC

EMPAGLIFLOZIN; LINAGLIPTIN; METFORMIN HYDROCHLORIDE

>A>
 TABLET, EXTENDED RELEASE;ORAL
 >A>
 TRIJARDY XR
 >A> + BOEHRINGER INGELHEIM 5MG;2.5MG;1GM N212614 001 Jan 27, 2020 Jan NEWA
 >A> + 10MG;5MG;1GM N212614 002 Jan 27, 2020 Jan NEWA
 >A> + 12.5MG;2.5MG;1GM N212614 003 Jan 27, 2020 Jan NEWA
 >A> +! 25MG;5MG;1GM N212614 004 Jan 27, 2020 Jan NEWA

ENTECAVIR

TABLET;ORAL
 ENTECAVIR
 >D> AB MYLAN 0.5MG A206226 001 Mar 26, 2019 Jan DISC
 >A> @ 0.5MG A206226 001 Mar 26, 2019 Jan DISC
 >D> AB 1MG A206226 002 Mar 26, 2019 Jan DISC
 >A> @ 1MG A206226 002 Mar 26, 2019 Jan DISC

ESCITALOPRAM OXALATE

SOLUTION;ORAL
 ESCITALOPRAM OXALATE
 >D> AA ALLIED EQ 5MG BASE/5ML A203967 001 May 26, 2015 Jan CAHN
 >A> AA ANTRIM PHARMS LLC EQ 5MG BASE/5ML A203967 001 May 26, 2015 Jan CAHN

ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL
 ESTRADIOL AND NORETHINDRONE ACETATE
 >D> AB TEVA PHARMS USA 0.5MG;0.1MG A200747 001 Mar 08, 2012 Jan DISC
 >A> @ 0.5MG;0.1MG A200747 001 Mar 08, 2012 Jan DISC

ESTROPIPATE

TABLET;ORAL
 ESTROPIPATE
 >D>
 >D> MYLAN 0.75MG A040359 001 Aug 26, 1999 Jan DISC
 >A> @ 0.75MG A040359 001 Aug 26, 1999 Jan DISC
 >D> 1.5MG A040359 002 Aug 26, 1999 Jan DISC
 >A> @ 1.5MG A040359 002 Aug 26, 1999 Jan DISC

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET;ORAL
 BALCOLTRA
 >D> AVION PHARMS 0.02MG;0.1MG N208612 001 Jan 09, 2018 Jan CRLD
 >A> +! 0.02MG;0.1MG N208612 001 Jan 09, 2018 Jan CHRS
 >A> + 0.02MG;0.1MG N208612 001 Jan 09, 2018 Jan CRLD

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET;ORAL
 LOESTRIN 24 FE
 >D> AB + APIL 0.02MG;1MG N021871 001 Feb 17, 2006 Jan CAHN
 >A> AB + TEVA BRANDED PHARM 0.02MG;1MG N021871 001 Feb 17, 2006 Jan CAHN
 TABLET;ORAL-21
 LOESTRIN 21 1.5/30
 >D> AB + APIL 0.03MG;1.5MG N017875 001 Jan CAHN
 >A> AB + TEVA BRANDED PHARM 0.03MG;1.5MG N017875 001 Jan CAHN

TABLET;ORAL-21

LOESTRIN 21 1/20

>D>	AB	+	APIL	0.02MG;1MG	N017876	001		Jan	CAHN
>A>	AB	+	TEVA BRANDED PHARM	0.02MG;1MG	N017876	001		Jan	CAHN
LOESTRIN FE 1.5/30									
>D>	AB	+	APIL	0.03MG;1.5MG	N017355	001		Jan	CAHN
>A>	AB	+	TEVA BRANDED PHARM	0.03MG;1.5MG	N017355	001		Jan	CAHN

TABLET;ORAL-28

LOESTRIN FE 1/20

>D>	AB	+	APIL	0.02MG;1MG	N017354	001		Jan	CAHN
>A>	AB	+	TEVA BRANDED PHARM	0.02MG;1MG	N017354	001		Jan	CAHN

EXEMESTANE

TABLET;ORAL

EXEMESTANE

>D>	AB		MAYNE PHARMA INC	25MG	A208764	001	Aug 08, 2019	Jan	DISC
>A>			@	25MG	A208764	001	Aug 08, 2019	Jan	DISC

FAMOTIDINE

TABLET;ORAL

FAMOTIDINE

>D>	AB		AUROBINDO PHARMA LTD	40MG	A206530	002	Dec 22, 2015	Jan	CHRS
>A>	AB	!		40MG	A206530	002	Dec 22, 2015	Jan	CHRS
PEPCID									
>D>	AB	+	VALEANT PHARMS NORTH	20MG	N019462	001	Oct 15, 1986	Jan	DISC
>A>		+	@	20MG	N019462	001	Oct 15, 1986	Jan	DISC
>D>	AB	+		40MG	N019462	002	Oct 15, 1986	Jan	DISC
>A>		+	@	40MG	N019462	002	Oct 15, 1986	Jan	DISC

FENOFIBRATE

CAPSULE;ORAL

FENOFIBRATE (MICRONIZED)

>D>	AB		AMERIGEN PHARMS LTD	67MG	A209504	001	Apr 30, 2018	Jan	CAHN
>D>	AB			134MG	A209504	002	Apr 30, 2018	Jan	CAHN
>D>	AB			200MG	A209504	003	Apr 30, 2018	Jan	CAHN
>A>	AB		ANI PHARMS INC	67MG	A209504	001	Apr 30, 2018	Jan	CAHN
>A>	AB			134MG	A209504	002	Apr 30, 2018	Jan	CAHN
>A>	AB			200MG	A209504	003	Apr 30, 2018	Jan	CAHN

TABLET;ORAL

FENOFIBRATE

>A>	AB		ALEMBIC PHARMS LTD	54MG	A213252	001	Jan 17, 2020	Jan	NEWA
>A>	AB			160MG	A213252	002	Jan 17, 2020	Jan	NEWA
>A>	AB		APPCO	54MG	A210670	001	Sep 06, 2019	Jan	CAHN
>A>	AB			160MG	A210670	002	Sep 06, 2019	Jan	CAHN
>D>		@	GRAVITI PHARMS	54MG	A210606	001	Aug 17, 2018	Jan	CMFD
>A>	AB			54MG	A210606	001	Aug 17, 2018	Jan	CMFD
>D>		@		160MG	A210606	002	Aug 17, 2018	Jan	CMFD
>A>	AB			160MG	A210606	002	Aug 17, 2018	Jan	CMFD
>D>	AB		NUVO PHARM	54MG	A210670	001	Sep 06, 2019	Jan	CAHN
>D>	AB			160MG	A210670	002	Sep 06, 2019	Jan	CAHN

>A>	<u>FERRIC DERISOMALTOSE</u>								
>A>	SOLUTION;INTRAVENOUS								
>A>	MONOFERRIC								
>A>		+	PHARMACOSMOS AS	100MG/ML (100MG/ML)	N208171	001	Jan 16, 2020	Jan	NEWA
>A>		+		500MG/5ML (100MG/ML)	N208171	002	Jan 16, 2020	Jan	NEWA
>A>		+		1GM/10ML (100MG/ML)	N208171	003	Jan 16, 2020	Jan	NEWA

FIDAXOMICIN

>A>	FOR SUSPENSION;ORAL								
>A>	DIFICID								
>A>		+	CUBIST PHARMS LLC	40MG/ML	N213138	001	Jan 24, 2020	Jan	NEWA

FLUCONAZOLE

TABLET;ORAL

FLUCONAZOLE

>D>	AB		MYLAN	50MG	A076351	001	Jul 29, 2004	Jan	DISC
>A>		@		50MG	A076351	001	Jul 29, 2004	Jan	DISC
>D>	AB			100MG	A076351	002	Jul 29, 2004	Jan	DISC
>A>		@		100MG	A076351	002	Jul 29, 2004	Jan	DISC
>D>	AB			150MG	A076351	003	Jul 29, 2004	Jan	DISC
>A>		@		150MG	A076351	003	Jul 29, 2004	Jan	DISC

		TABLET;ORAL							
		FLUCONAZOLE							
>D>	AB		200MG	A076351	004	Jul 29, 2004	Jan	DISC	
>A>		@	200MG	A076351	004	Jul 29, 2004	Jan	DISC	
		<u>FLUDEOXYGLUCOSE F-18</u>							
		INJECTABLE;INTRAVENOUS							
		FLUDEOXYGLUCOSE F18							
>A>	AP	UNIV TX SW MEDCTR	20-200mCi/ML	A210265	001	Feb 06, 2020	Jan	NEWA	
		<u>FLUOCINONIDE</u>							
		CREAM;TOPICAL							
		FLUOCINONIDE							
>A>	AB	ZYDUS PHARMS	0.1%	A208989	001	Feb 10, 2020	Jan	NEWA	
		<u>FOLIC ACID</u>							
		INJECTABLE;INJECTION							
		FOLIC ACID							
>D>	AP	EXELA PHARMA SCS LLC	5MG/ML	A202522	001	Nov 06, 2019	Jan	CAHN	
>A>	AP	X-GEN PHARMS INC	5MG/ML	A202522	001	Nov 06, 2019	Jan	CAHN	
		<u>FULVESTRANT</u>							
		INJECTABLE;INTRAMUSCULAR							
		FULVESTRANT							
>A>	AO	CHIA TAI TIANQING	50MG/ML	A211422	001	Feb 07, 2020	Jan	NEWA	
		<u>FUROSEMIDE</u>							
		TABLET;ORAL							
		FUROSEMIDE							
>D>	AB	AVET	20MG	N018413	001	Nov 30, 1983	Jan	DISC	
>A>		@	20MG	N018413	001	Nov 30, 1983	Jan	DISC	
>D>	AB		40MG	N018413	002	Nov 30, 1983	Jan	DISC	
>A>		@	40MG	N018413	002	Nov 30, 1983	Jan	DISC	
		<u>GABAPENTIN</u>							
		CAPSULE;ORAL							
		GABAPENTIN							
>D>		@ CSPC OUYI	100MG	A075477	001	Mar 23, 2005	Jan	CMFD	
>A>	AB		100MG	A075477	001	Mar 23, 2005	Jan	CMFD	
>D>		@	300MG	A075477	002	Mar 23, 2005	Jan	CMFD	
>A>	AB		300MG	A075477	002	Mar 23, 2005	Jan	CMFD	
>D>		@	400MG	A075477	003	Mar 23, 2005	Jan	CMFD	
>A>	AB		400MG	A075477	003	Mar 23, 2005	Jan	CMFD	
		TABLET;ORAL							
		GRALISE							
>A>	BX	+! ALMATICA	300MG	N022544	001	Jan 28, 2011	Jan	CAHN	
>A>	BX	+!	600MG	N022544	002	Jan 28, 2011	Jan	CAHN	
>D>	BX	+! ASSERTIO	300MG	N022544	001	Jan 28, 2011	Jan	CAHN	
>D>	BX	+!	600MG	N022544	002	Jan 28, 2011	Jan	CAHN	
		<u>GEMCITABINE HYDROCHLORIDE</u>							
		INJECTABLE;INJECTION							
		GEMCITABINE HYDROCHLORIDE							
>D>		@ SHILPA MEDICARE LTD	EQ 200MG BASE/VIAL	A207575	001	Feb 22, 2019	Jan	CMFD	
>A>	AP		EQ 200MG BASE/VIAL	A207575	001	Feb 22, 2019	Jan	CMFD	
>D>		@	EQ 1GM BASE/VIAL	A207575	002	Feb 22, 2019	Jan	CMFD	
>A>	AP		EQ 1GM BASE/VIAL	A207575	002	Feb 22, 2019	Jan	CMFD	
		<u>GLYBURIDE</u>							
		TABLET;ORAL							
		GLYBURIDE (MICRONIZED)							
>D>	AB	MYLAN	1.5MG	A074792	001	Jun 26, 1998	Jan	DISC	
>A>		@	1.5MG	A074792	001	Jun 26, 1998	Jan	DISC	
>D>	AB		3MG	A074792	002	Jun 26, 1998	Jan	DISC	
>A>		@	3MG	A074792	002	Jun 26, 1998	Jan	DISC	
>D>	AB		6MG	A074792	003	Aug 17, 1999	Jan	DISC	
>A>		@	6MG	A074792	003	Aug 17, 1999	Jan	DISC	

GRANISETRON HYDROCHLORIDE

TABLET;ORAL

GRANISETRON HYDROCHLORIDE

>D>	AB	MYLAN	EQ 1MG BASE	A 078725	001	Jan 30, 2008	Jan DISC
>A>		@	EQ 1MG BASE	A 078725	001	Jan 30, 2008	Jan DISC

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

TABLET;ORAL

HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE

>D>	AA	NOVEL LABS INC	1.5MG;5MG	A 091528	001	Apr 20, 2011	Jan CHRS
>A>	AA	!	1.5MG;5MG	A 091528	001	Apr 20, 2011	Jan CHRS
>D>		TUSSIGON					
>D>	AA	! KING PHARMS	1.5MG;5MG	A 088508	001	Jul 30, 1985	Jan DISC
>A>		@	1.5MG;5MG	A 088508	001	Jul 30, 1985	Jan DISC

HYDRALAZINE HYDROCHLORIDE

TABLET;ORAL

HYDRALAZINE HYDROCHLORIDE

>D>	AA	STRIDES PHARMA	10MG	A 200770	004	Jun 25, 2019	Jan DISC
>A>		@	10MG	A 200770	004	Jun 25, 2019	Jan DISC

HYDROCHLOROTHIAZIDE

TABLET;ORAL

HYDROCHLOROTHIAZIDE

>D>	AB	MYLAN PHARMS INC	25MG	A 040735	002	Jan 23, 2007	Jan DISC
>A>		@	25MG	A 040735	002	Jan 23, 2007	Jan DISC
>D>	AB		50MG	A 040735	003	Jan 23, 2007	Jan DISC
>A>		@	50MG	A 040735	003	Jan 23, 2007	Jan DISC

HYDROCODONE BITARTRATE

CAPSULE, EXTENDED RELEASE;ORAL

HYDROCODONE BITARTRATE

>A>							
>A>	AB	ALVOGEN	10MG	A 206986	001	Jan 21, 2020	Jan NFTG
>A>	AB		15MG	A 206986	002	Jan 21, 2020	Jan NFTG
>A>	AB		20MG	A 206986	003	Jan 21, 2020	Jan NFTG
>A>	AB		30MG	A 206986	004	Jan 21, 2020	Jan NFTG
>A>	AB		40MG	A 206986	005	Jan 21, 2020	Jan NFTG
>A>	AB		50MG	A 206986	006	Jan 21, 2020	Jan NFTG
		ZOHYDRO ER					
>D>		+! PERSION	10MG	N 202880	001	Oct 25, 2013	Jan CFTG
>A>	AB	+!	10MG	N 202880	001	Oct 25, 2013	Jan CFTG
>D>		+	15MG	N 202880	002	Oct 25, 2013	Jan CFTG
>A>	AB	+	15MG	N 202880	002	Oct 25, 2013	Jan CFTG
>D>		+	20MG	N 202880	003	Oct 25, 2013	Jan CFTG
>A>	AB	+	20MG	N 202880	003	Oct 25, 2013	Jan CFTG
>D>		+	30MG	N 202880	004	Oct 25, 2013	Jan CFTG
>A>	AB	+	30MG	N 202880	004	Oct 25, 2013	Jan CFTG
>D>		+	40MG	N 202880	005	Oct 25, 2013	Jan CFTG
>A>	AB	+	40MG	N 202880	005	Oct 25, 2013	Jan CFTG
>D>		+	50MG	N 202880	006	Oct 25, 2013	Jan CFTG
>A>	AB	+	50MG	N 202880	006	Oct 25, 2013	Jan CFTG

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

DILAUDID

>A>		+! FRESENIUS KABI USA	0.2MG/ML	N 019034	006	Jan 16, 2020	Jan NEWA
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HYDROXYPROGESTERONE CAPROATE

SOLUTION; INTRAMUSCULAR

HYDROXYPROGESTERON CAPROATE

>D>	AP1	AM REGENT	1250MG/5ML (250MG/ML)	A 210724	001	Aug 09, 2019	Jan CMS1
>A>	AP1	AM REGENT	1250MG/5ML (250MG/ML)	A 210724	001	Aug 09, 2019	Jan CMS1

INDAPAMIDE

TABLET;ORAL

INDAPAMIDE

>D>	AB	AMERIGEN PHARMS LTD	1.25MG	A 075201	001	Dec 04, 1998	Jan CAHN
>D>	AB		2.5MG	A 075201	002	Dec 04, 1998	Jan CAHN
>A>	AB	ANI PHARMS INC	1.25MG	A 075201	001	Dec 04, 1998	Jan CAHN
>A>	AB		2.5MG	A 075201	002	Dec 04, 1998	Jan CAHN

INDOMETHACIN

CAPSULE;ORAL
INDOMETHACIN

>A>	AB	HERITAGE	25MG	N018851	001	May 18, 1984	Jan	CAHN
>A>	AB		50MG	N018851	002	May 18, 1984	Jan	CAHN
>D>	AB	HERITAGE PHARMS INC	25MG	N018851	001	May 18, 1984	Jan	CAHN
>D>	AB		50MG	N018851	002	May 18, 1984	Jan	CAHN

INSULIN LISPRO RECOMBINANT

INJECTABLE;INJECTION
HUMALOG KWIKPEN

>D>	+	LILLY	200UNITS/ML	N020563	004	Nov 15, 2019	Jan	CMS1
>A>	+		200UNITS/ML	N020563	004	Jan 06, 2017	Jan	CMS1

IPRATROPIUM BROMIDE

SPRAY, METERED;NASAL
IPRATROPIUM BROMIDE

>D>	@	APOTEX INC	0.021MG/SPRAY	A076156	001	Apr 18, 2003	Jan	CMFD
>A>	AB		0.021MG/SPRAY	A076156	001	Apr 18, 2003	Jan	CMFD

LABETALOL HYDROCHLORIDE

INJECTABLE;INJECTION
NORMODYNE

>D>	@	SCHERING	5MG/ML	N018686	001	Aug 01, 1984	Jan	CRLD
>A>	+	@	5MG/ML	N018686	001	Aug 01, 1984	Jan	CRLD

>A> LASMIDITAN SUCCINATE

TABLET;ORAL
REYVOW

>A>	+	ELI LILLY AND CO	50MG	N211280	001	Jan 31, 2020	Jan	NEWA
>A>	+		100MG	N211280	002	Jan 31, 2020	Jan	NEWA

LEFLUNOMIDE

TABLET;ORAL
LEFLUNOMIDE

>A>	AB	LUPIN LTD	10MG	A211863	001	Feb 04, 2020	Jan	NEWA
>A>	AB		20MG	A211863	002	Feb 04, 2020	Jan	NEWA

LEVOTHYROXINE SODIUM **

**See current Annual Edition, 1.8 Description of Special Situations, Levothyroxine Sodium

TABLET;ORAL
THYRO-TABS

>D>	AB2, AB4	ALVOGEN	0.3MG	N021116	009	Oct 24, 2002	Jan	CHRS
>A>	AB2, AB4		0.3MG	N021116	009	Oct 24, 2002	Jan	CHRS

LIOTHYRONINE SODIUM

TABLET;ORAL
LIOTHYRONINE SODIUM

>D>	@	SUN PHARM	EQ 0.005MG BASE	A091382	001	Apr 20, 2016	Jan	CMFD
>A>	AB		EQ 0.005MG BASE	A091382	001	Apr 20, 2016	Jan	CMFD
>D>	@		EQ 0.025MG BASE	A091382	002	Apr 20, 2016	Jan	CMFD
>A>	AB		EQ 0.025MG BASE	A091382	002	Apr 20, 2016	Jan	CMFD
>D>	@		EQ 0.05MG BASE	A091382	003	Apr 20, 2016	Jan	CMFD
>A>	AB		EQ 0.05MG BASE	A091382	003	Apr 20, 2016	Jan	CMFD

LITHIUM CARBONATE

CAPSULE;ORAL
LITHIUM CARBONATE

>D>	AB	+	HIKMA	150MG	N017812	002	Jan 28, 1987	Jan	CAHN
>A>	AB	+		150MG	N017812	002	Jan 28, 1987	Jan	CAHN
>D>	AB	+		300MG	N017812	001		Jan	CAHN
>A>	AB	+		300MG	N017812	001		Jan	CAHN
>D>	AB	+		600MG	N017812	003	Jan 28, 1987	Jan	CAHN
>A>	AB	+		600MG	N017812	003	Jan 28, 1987	Jan	CAHN
>D>	AB		MYLAN	150MG	A076243	002	Feb 24, 2003	Jan	DISC
>A>		@		150MG	A076243	002	Feb 24, 2003	Jan	DISC
>D>	AB			300MG	A076243	001	Jun 27, 2002	Jan	DISC
>A>		@		300MG	A076243	001	Jun 27, 2002	Jan	DISC

LITHIUM CITRATESYRUP;ORAL
LITHIUM CITRATE

>D>	AA	+!	HIKMA	EQ 300MG CARBONATE/5ML	N018421	001		Jan	CAHN
>A>	AA	+!		EQ 300MG CARBONATE/5ML	N018421	001		Jan	CAHN

MAZINDOLTABLET;ORAL
SANOREX

>D>		+	@	HEXIM	1MG	N017247	001	Jan	CAHN
>D>		+	@		2MG	N017247	002	Jan	CAHN
>A>		+	@	NOVARTIS	1MG	N017247	001	Jan	CAHN
>A>		+	@		2MG	N017247	002	Jan	CAHN

MECLIZINE HYDROCHLORIDETABLET;ORAL
MECLIZINE HYDROCHLORIDE

>D>	AA			MYLAN PHARMS INC	12.5MG	A202640	001	Sep 17, 2012	Jan	DISC
>A>			@		12.5MG	A202640	001	Sep 17, 2012	Jan	DISC
>D>	AA				25MG	A202640	002	Sep 17, 2012	Jan	DISC
>A>			@		25MG	A202640	002	Sep 17, 2012	Jan	DISC

MELPHALAN HYDROCHLORIDEINJECTABLE;INJECTION
MELPHALAN HYDROCHLORIDE

>D>	AP			NORATECH	EQ 50MG BASE/VIAL	A211463	001	Sep 13, 2019	Jan	DISC
>A>			@	TWI PHARMS	EQ 50MG BASE/VIAL	A211463	001	Sep 13, 2019	Jan	DISC

MESALAMINESUPPOSITORY;RECTAL
MESALAMINE

>A>	AB			ZYDUS PHARMS	1GM	A208953	001	Feb 12, 2020	Jan	NEWA
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METFORMIN HYDROCHLORIDESOLUTION;ORAL
RIOMET

>A>		+	!	RANBAXY	500MG/5ML	N021591	001	Sep 11, 2003	Jan	CAHN
>D>		+	!	SUN PHARM INDS LTD	500MG/5ML	N021591	001	Sep 11, 2003	Jan	CAHN

TABLET;ORAL
METFORMIN HYDROCHLORIDE

>D>	AB			MYLAN	500MG	A075976	001	Jan 24, 2002	Jan	DISC
>A>			@		500MG	A075976	001	Jan 24, 2002	Jan	DISC
>D>	AB				850MG	A075976	002	Jan 24, 2002	Jan	DISC
>A>			@		850MG	A075976	002	Jan 24, 2002	Jan	DISC
>D>	AB				1GM	A075976	003	Jan 24, 2002	Jan	DISC
>A>			@		1GM	A075976	003	Jan 24, 2002	Jan	DISC

METHOTREXATE SODIUMINJECTABLE;INJECTION
METHOTREXATE SODIUM PRESERVATIVE FREE

>D>	AP			MYLAN LABS LTD	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A201529	001	Mar 29, 2012	Jan	DISC
>A>			@		EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A201529	001	Mar 29, 2012	Jan	DISC
>D>	AP				EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	A201529	002	Mar 29, 2012	Jan	DISC
>A>			@		EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	A201529	002	Mar 29, 2012	Jan	DISC
>D>	AP				EQ 200MG BASE/8ML (EQ 25MG BASE/ML)	A201529	003	Mar 29, 2012	Jan	DISC
>A>			@		EQ 200MG BASE/8ML (EQ 25MG BASE/ML)	A201529	003	Mar 29, 2012	Jan	DISC
>D>	AP			PHARMACHEMIE BV	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	A040843	003	Feb 27, 2012	Jan	CTEC
>A>					EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	A040843	003	Feb 27, 2012	Jan	CTEC

TABLET;ORAL
METHOTREXATE SODIUM

>A>	AB			ACCORD HLTHCARE	EQ 2.5MG BASE	A213343	001	Jan 24, 2020	Jan	NEWA
>A>	AB			EUGIA PHARMA	EQ 2.5MG BASE	A210454	001	Jan 30, 2020	Jan	NEWA

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE;ORAL
METOPROLOL SUCCINATE

>D>	AB	ACTAVIS LABS FL INC	EQ 25MG TARTRATE	A 076862	002	Aug 03, 2009	Jan	DISC
>A>		@	EQ 25MG TARTRATE	A 076862	002	Aug 03, 2009	Jan	DISC
>D>	AB		EQ 100MG TARTRATE	A 077298	001	Apr 15, 2010	Jan	DISC
>A>		@	EQ 100MG TARTRATE	A 077298	001	Apr 15, 2010	Jan	DISC
>D>	AB		EQ 200MG TARTRATE	A 077298	002	Apr 15, 2010	Jan	DISC
>A>		@	EQ 200MG TARTRATE	A 077298	002	Apr 15, 2010	Jan	DISC

METOPROLOL TARTRATE

TABLET;ORAL
METOPROLOL TARTRATE

>A>	AB	YOUNGTECH PHARMS INC	25MG	A 208955	001	Feb 05, 2020	Jan	NEWA
>A>	AB		50MG	A 208955	002	Feb 05, 2020	Jan	NEWA
>A>	AB		100MG	A 208955	003	Feb 05, 2020	Jan	NEWA

MIDAZOLAM HYDROCHLORIDE

INJECTABLE;INJECTION
MIDAZOLAM HYDROCHLORIDE PRESERVATIVE FREE

>D>	AP	MYLAN ASI	EQ 1MG BASE/ML	A 090315	001	Nov 29, 2010	Jan	DISC
>A>		@	EQ 1MG BASE/ML	A 090315	001	Nov 29, 2010	Jan	DISC
>D>	AP		EQ 5MG BASE/ML	A 090315	002	Nov 29, 2010	Jan	DISC
>A>		@	EQ 5MG BASE/ML	A 090315	002	Nov 29, 2010	Jan	DISC

MIRABEGRON

TABLET, EXTENDED RELEASE;ORAL
MIRABEGRON

>D>	AB	SAWAI USA	25MG	A 209446	001	Dec 27, 2019	Jan	DISC
>A>		@	25MG	A 209446	001	Dec 27, 2019	Jan	DISC
>D>	AB	MYRBETRIQ	25MG	N 202611	001	Jun 28, 2012	Jan	CTEC
>A>		+	25MG	N 202611	001	Jun 28, 2012	Jan	CTEC

MONTELUKAST SODIUM

TABLET, CHEWABLE;ORAL
MONTELUKAST SODIUM

>D>	AB	JUBILANT GENERICS	EQ 4MG BASE	A 203795	001	Feb 27, 2015	Jan	DISC
>A>		@	EQ 4MG BASE	A 203795	001	Feb 27, 2015	Jan	DISC
>D>	AB		EQ 5MG BASE	A 203795	002	Feb 27, 2015	Jan	DISC
>A>		@	EQ 5MG BASE	A 203795	002	Feb 27, 2015	Jan	DISC

NALOXONE HYDROCHLORIDE

INJECTABLE;INJECTION
NALOXONE HYDROCHLORIDE

>A>	AP	PAR STERILE PRODUCTS	0.4MG/ML	A 211286	001	Jan 17, 2020	Jan	NEWA
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NAPROXEN

TABLET;ORAL
NAPROXEN

>D>	AB	MYLAN	250MG	A 074121	001	Dec 21, 1993	Jan	DISC
>A>		@	250MG	A 074121	001	Dec 21, 1993	Jan	DISC
>D>	AB		375MG	A 074121	002	Dec 21, 1993	Jan	DISC
>A>		@	375MG	A 074121	002	Dec 21, 1993	Jan	DISC
>D>	AB		500MG	A 074121	003	Dec 21, 1993	Jan	DISC
>A>		@	500MG	A 074121	003	Dec 21, 1993	Jan	DISC

NIACIN

TABLET, EXTENDED RELEASE;ORAL
NIACIN

>D>	AB	MYLAN	500MG	A 203742	001	Feb 22, 2019	Jan	DISC
>A>		@	500MG	A 203742	001	Feb 22, 2019	Jan	DISC
>D>	AB		750MG	A 203742	002	Feb 22, 2019	Jan	DISC
>A>		@	750MG	A 203742	002	Feb 22, 2019	Jan	DISC
>D>	AB		1GM	A 203742	003	Feb 22, 2019	Jan	DISC
>A>		@	1GM	A 203742	003	Feb 22, 2019	Jan	DISC

NIRAPARIB TOSYLATECAPSULE;ORAL
ZEJULA

>A>	+	GLAXOSMITHKLINE	EQ 100MG BASE	N208447	001	Mar 27, 2017	Jan CAHN
>D>	+	TESARO INC	EQ 100MG BASE	N208447	001	Mar 27, 2017	Jan CAHN

NORETHINDRONETABLET;ORAL-28
NOR-QD

>D>	AB1	+	APIL	0.35MG	N017060	001	Jan CAHN
>A>	AB1	+	TEVA BRANDED PHARM	0.35MG	N017060	001	Jan CAHN

OCTREOTIDE ACETATE>A> SOLUTION;SUBCUTANEOUS
>A> BYNFEZIA PEN

>A>	+	SUN PHARM	EQ 2.5MG BASE/ML (EQ 2.5MG BASE/ML)	N213224	001	Jan 28, 2020	Jan NEWA
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OLANZAPINETABLET;ORAL
OLANZAPINE

>D>	AB		TEVA PHARMS	2.5MG	A076000	001	Oct 24, 2011	Jan DISC
>A>		@		2.5MG	A076000	001	Oct 24, 2011	Jan DISC
>D>	AB			5MG	A076000	002	Oct 24, 2011	Jan DISC
>A>		@		5MG	A076000	002	Oct 24, 2011	Jan DISC
>D>	AB			7.5MG	A076000	003	Oct 24, 2011	Jan DISC
>A>		@		7.5MG	A076000	003	Oct 24, 2011	Jan DISC
>D>	AB			10MG	A076000	004	Oct 24, 2011	Jan DISC
>A>		@		10MG	A076000	004	Oct 24, 2011	Jan DISC
>D>	AB			15MG	A076000	005	Oct 24, 2011	Jan DISC
>A>		@		15MG	A076000	005	Oct 24, 2011	Jan DISC

OLOPATADINE HYDROCHLORIDESPRAY, METERED;NASAL
OLOPATADINE HYDROCHLORIDE

>A>	AB		AMNEAL PHARMS LLC	0.665MG/SPRAY	A210901	001	Jan 28, 2020	Jan NEWA
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OMEPRAZOLECAPSULE, DELAYED REL PELLETS;ORAL
OMEPRAZOLE

>D>	AB		MYLAN	20MG	A075876	002	May 29, 2003	Jan DISC
>A>		@		20MG	A075876	002	May 29, 2003	Jan DISC

ONDANSETRON HYDROCHLORIDETABLET;ORAL
ONDANSETRON HYDROCHLORIDE

>D>	AB		MYLAN	EQ 4MG BASE	A076930	001	Jun 25, 2007	Jan DISC
>A>		@		EQ 4MG BASE	A076930	001	Jun 25, 2007	Jan DISC
>D>	AB			EQ 8MG BASE	A076930	002	Jun 25, 2007	Jan DISC
>A>		@		EQ 8MG BASE	A076930	002	Jun 25, 2007	Jan DISC

OXYBUTYNIN CHLORIDETABLET, EXTENDED RELEASE;ORAL
OXYBUTYNIN CHLORIDE

>D>	AB		MYLAN PHARMS INC	10MG	A076644	001	Nov 09, 2006	Jan DISC
>A>		@		10MG	A076644	001	Nov 09, 2006	Jan DISC
>D>	AB			15MG	A076644	002	May 10, 2007	Jan DISC
>A>		@		15MG	A076644	002	May 10, 2007	Jan DISC

OXYCODONE HYDROCHLORIDESOLUTION;ORAL
OXYCODONE HYDROCHLORIDE

>D>	AA		ANI PHARMS INC	100MG/5ML	A203447	001	Aug 30, 2017	Jan DISC
>A>		@		100MG/5ML	A203447	001	Aug 30, 2017	Jan DISC
>A>	AA		AUROLIFE PHARMA LLC	5MG/5ML	A212429	001	Jan 27, 2020	Jan NEWA
>A>	AA			100MG/5ML	A212429	002	Jan 27, 2020	Jan NEWA

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAROXETINE HYDROCHLORIDE

>D>	AB	JUBILANT GENERICS	EQ 10MG BASE	A205528	001	Nov 27, 2015	Jan	DISC
>A>	@		EQ 10MG BASE	A205528	001	Nov 27, 2015	Jan	DISC
>D>	AB		EQ 20MG BASE	A205528	002	Nov 27, 2015	Jan	DISC
>A>	@		EQ 20MG BASE	A205528	002	Nov 27, 2015	Jan	DISC
>D>	AB		EQ 30MG BASE	A205528	003	Nov 27, 2015	Jan	DISC
>A>	@		EQ 30MG BASE	A205528	003	Nov 27, 2015	Jan	DISC
>D>	AB		EQ 40MG BASE	A205528	004	Nov 27, 2015	Jan	DISC
>A>	@		EQ 40MG BASE	A205528	004	Nov 27, 2015	Jan	DISC

PAZOPANIB HYDROCHLORIDE

TABLET; ORAL

VOTRIENT

>D>	@	NOVARTIS	EQ 400MG BASE	N022465	002	Oct 19, 2009	Jan	CRLD
>A>	+ @		EQ 400MG BASE	N022465	002	Oct 19, 2009	Jan	CRLD

PEGVISOMANT

INJECTABLE; SUBCUTANEOUS

SOMAVERT

>A>	+	PHARMACIA	10MG/VIAL	N021106	001	Mar 25, 2003	Jan	CAHN
>A>	+		15MG/VIAL	N021106	002	Mar 25, 2003	Jan	CAHN
>A>	+		20MG/VIAL	N021106	003	Mar 25, 2003	Jan	CAHN
>A>	+		25MG/VIAL	N021106	004	Jul 31, 2014	Jan	CAHN
>A>	+		30MG/VIAL	N021106	005	Jul 31, 2014	Jan	CAHN
>D>	+	PHARMACIA AND UPJOHN	10MG/VIAL	N021106	001	Mar 25, 2003	Jan	CAHN
>D>	+		15MG/VIAL	N021106	002	Mar 25, 2003	Jan	CAHN
>D>	+		20MG/VIAL	N021106	003	Mar 25, 2003	Jan	CAHN
>D>	+		25MG/VIAL	N021106	004	Jul 31, 2014	Jan	CAHN
>D>	+		30MG/VIAL	N021106	005	Jul 31, 2014	Jan	CAHN

PENICILLAMINE

CAPSULE; ORAL

PENICILLAMINE

>D>	AB	AMERIGEN PHARMS LTD	250MG	A209921	001	May 07, 2019	Jan	CAHN
>A>	AB	ANI PHARMS INC	250MG	A209921	001	May 07, 2019	Jan	CAHN

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION; INTRAVENOUS

PHENYLEPHRINE HYDROCHLORIDE

>A>	AP1	RICONPHARMA LLC	10MG/ML (10MG/ML)	A209967	001	Jan 16, 2020	Jan	NEWA
>A>	AP1		50MG/5ML (10MG/ML)	A209967	002	Jan 16, 2020	Jan	NEWA
>A>	AP1		100MG/10ML (10MG/ML)	A209967	003	Jan 16, 2020	Jan	NEWA

PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

PIOGLITAZONE HYDROCHLORIDE

>D>	AB	MYLAN PHARMS INC	EQ 15MG BASE	A076801	001	Aug 17, 2012	Jan	DISC
>A>	@		EQ 15MG BASE	A076801	001	Aug 17, 2012	Jan	DISC
>D>	AB		EQ 30MG BASE	A076801	002	Aug 17, 2012	Jan	DISC
>A>	@		EQ 30MG BASE	A076801	002	Aug 17, 2012	Jan	DISC
>D>	AB		EQ 45MG BASE	A076801	003	Aug 17, 2012	Jan	DISC
>A>	@		EQ 45MG BASE	A076801	003	Aug 17, 2012	Jan	DISC

PODOFILOX

SOLUTION; TOPICAL

CONDYLOX

>D>	AT	ALLERGAN	0.5%	N019795	001	Dec 13, 1990	Jan	CAHN
>A>	AT	TEVA BRANDED PHARM	0.5%	N019795	001	Dec 13, 1990	Jan	CAHN

POLYMYXIN B SULFATE

INJECTABLE; INJECTION

AEROSPORIN

>D>	@	GLAXOSMITHKLINE	EQ 500,000 U BASE/VIAL	A062036	001		Jan	CMS1
>A>	@		EQ 500,000 UNITS BASE/VIAL	A062036	001		Jan	CMS1

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL

PRAMIPEXOLE DIHYDROCHLORIDE

>D>	AB	MYLAN	0.125MG	A077854	001	Oct 08, 2010	Jan	DISC
>A>		@	0.125MG	A077854	001	Oct 08, 2010	Jan	DISC
>D>	AB		0.25MG	A077854	002	Oct 08, 2010	Jan	DISC
>A>		@	0.25MG	A077854	002	Oct 08, 2010	Jan	DISC
>D>	AB		0.5MG	A077854	003	Oct 08, 2010	Jan	DISC
>A>		@	0.5MG	A077854	003	Oct 08, 2010	Jan	DISC
>D>	AB		0.75MG	A090764	001	Apr 09, 2010	Jan	DISC
>A>		@	0.75MG	A090764	001	Apr 09, 2010	Jan	DISC
>D>	AB		1MG	A077854	004	Oct 08, 2010	Jan	DISC
>A>		@	1MG	A077854	004	Oct 08, 2010	Jan	DISC
>D>	AB		1.5MG	A077854	005	Oct 08, 2010	Jan	DISC
>A>		@	1.5MG	A077854	005	Oct 08, 2010	Jan	DISC

PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC

OMNIPRED

>D>	AB	NOVARTIS	1%	N017469	001		Jan	CRLD
>A>	AB	+	1%	N017469	001		Jan	CHRS
>A>	AB	+	1%	N017469	001		Jan	CRLD

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

>D>	AB	AMNEAL PHARMS NY	EQ 150MG BASE	A077824	001	Oct 13, 2006	Jan	DISC
>A>		@	EQ 150MG BASE	A077824	001	Oct 13, 2006	Jan	DISC
>D>	AB	!	EQ 300MG BASE	A077824	002	Oct 13, 2006	Jan	DISC
>A>		@	EQ 300MG BASE	A077824	002	Oct 13, 2006	Jan	DISC
>D>	AB	STRIDES PHARMA	EQ 150MG BASE	A210010	001	Aug 01, 2018	Jan	DISC
>A>		@	EQ 150MG BASE	A210010	001	Aug 01, 2018	Jan	DISC
>D>	AB		EQ 300MG BASE	A205512	002	Aug 22, 2016	Jan	CHRS
>A>	AB	!	EQ 300MG BASE	A205512	002	Aug 22, 2016	Jan	CHRS
>D>	AB		EQ 300MG BASE	A210010	002	Aug 01, 2018	Jan	DISC
>A>		@	EQ 300MG BASE	A210010	002	Aug 01, 2018	Jan	DISC

RANOLAZINE

TABLET, EXTENDED RELEASE; ORAL

RANOLAZINE

>D>	AB	AMERIGEN PHARMS LTD	500MG	A210482	001	Oct 29, 2019	Jan	CAHN
>D>	AB		1GM	A210482	002	Oct 29, 2019	Jan	CAHN
>A>	AB	ANI PHARMS INC	500MG	A210482	001	Oct 29, 2019	Jan	CAHN
>A>	AB		1GM	A210482	002	Oct 29, 2019	Jan	CAHN
>A>	AB	MANKIND PHARMA	500MG	A212284	001	Feb 12, 2020	Jan	NEWA
>A>	AB		1GM	A212284	002	Feb 12, 2020	Jan	NEWA

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

YUTOPAR

>D>		@	ASTRAZENECA	15MG/ML	N018580	002		Jan	CMS1
>A>		@		15MG/ML	N018580	002	Sep 27, 1984	Jan	CMS1

SELEXIPAG

TABLET; ORAL

UPTRAVI

>D>		+	ACTELION PHARMS LTD	0.4MG	N207947	002	Dec 21, 2015	Jan	CHRS
>A>		+		0.4MG	N207947	002	Dec 21, 2015	Jan	CHRS
>D>		+		1.6MG	N207947	008	Dec 21, 2015	Jan	CHRS
>A>		+		1.6MG	N207947	008	Dec 21, 2015	Jan	CHRS

SEMAGLUTIDE

SOLUTION; SUBCUTANEOUS

OZEMPIC

>A>		+	NOVO	4MG/3ML (1.34MG/ML)	N209637	002	Apr 09, 2019	Jan	NEWA
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SODIUM IODIDE I-131

SOLUTION;ORAL
HICON

>D>	+	JUBILANT DRAXIMAGE	250-1000mCi	N021305	007	Dec 05, 2011	Jan CFTG
>A>	AA	+	250-1000mCi	N021305	007	Dec 05, 2011	Jan CFTG
>A>		SODIUM IODIDE I 131					
>A>	AA	INTL ISOTOPES	250-1000mCi	A209166	001	Feb 05, 2020	Jan NFTG

SODIUM PHENYLEBUTYRATE

TABLET;ORAL
SODIUM PHENYLEBUTYRATE

>D>	AB	ALVOGEN	500MG	A090910	001	Nov 18, 2011	Jan DISC
>A>		@	500MG	A090910	001	Nov 18, 2011	Jan DISC

SOLRIAMFETOL

TABLET;ORAL
SUNOSI

>D>	+	JAZZ	75MG	N211230	001	Jun 17, 2019	Jan CAIN
>D>	+		150MG	N211230	002	Jun 17, 2019	Jan CAIN

SOLRIAMFETOL HYDROCHLORIDE

TABLET;ORAL
SUNOSI

>A>	+	JAZZ	EQ 75MG BASE	N211230	001	Jun 17, 2019	Jan CPOT
>A>	+		75MG	N211230	001	Jun 17, 2019	Jan CAIN
>A>	+		EQ 150MG BASE	N211230	002	Jun 17, 2019	Jan CPOT
>A>	+		150MG	N211230	002	Jun 17, 2019	Jan CAIN

SOMATROPIN

INJECTABLE;INJECTION
ACCRETROPIN

>A>		@ EMERGENT	5MG/ML (5MG/ML)	N021538	001	Jan 23, 2008	Jan CAIN
>A>		HUMATROPE					
>A>		@ LILLY	2MG/VIAL	N019640	001	Jun 23, 1987	Jan CAIN
>A>	BX	+	5MG/VIAL	N019640	004	Mar 08, 1987	Jan CAIN
>A>	BX	+	6MG/VIAL	N019640	005	Feb 04, 1999	Jan CAIN
>A>		+	12MG/VIAL	N019640	006	Feb 04, 1999	Jan CAIN
>A>		+	24MG/VIAL	N019640	007	Feb 04, 1999	Jan CAIN

SOMATROPIN RECOMBINANT

INJECTABLE;INJECTION
ACCRETROPIN

>D>		@ EMERGENT	5MG/ML (5MG/ML)	N021538	001	Jan 23, 2008	Jan CAIN
>D>		HUMATROPE					
>D>		@ LILLY	2MG/VIAL	N019640	001	Jun 23, 1987	Jan CAIN
>D>	BX	+	5MG/VIAL	N019640	004	Mar 08, 1987	Jan CAIN
>D>	BX	+	6MG/VIAL	N019640	005	Feb 04, 1999	Jan CAIN
>D>		+	12MG/VIAL	N019640	006	Feb 04, 1999	Jan CAIN
>D>		+	24MG/VIAL	N019640	007	Feb 04, 1999	Jan CAIN

TAZEMETOSTAT HYDROBROMIDE

TABLET;ORAL
TAZVERIK

>A>		+	EPIZYME INC	EQ 200MG BASE	N211723	001	Jan 23, 2020	Jan NEWA
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TECHNETIUM TC-99M MERTIATIDE KIT

INJECTABLE;INJECTION
TECHNETIUM TC99M MERTIATIDE KIT

>A>	AP		SOMMER PHARMS II LLC	N/A	A206489	001	Feb 06, 2020	Jan NEWA
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TELMISARTAN

TABLET;ORAL
TELMISARTAN

>D>	AB		JUBILANT GENERICS	20MG	A204164	001	Aug 22, 2016	Jan DISC
>A>		@		20MG	A204164	001	Aug 22, 2016	Jan DISC
>D>	AB			40MG	A204164	002	Aug 22, 2016	Jan DISC
>A>		@		40MG	A204164	002	Aug 22, 2016	Jan DISC
>D>	AB			80MG	A204164	003	Aug 22, 2016	Jan DISC
>A>		@		80MG	A204164	003	Aug 22, 2016	Jan DISC

>A> TERIPARATIDE
 >A> INJECTABLE;SUBCUTANEOUS
 >A> FORTEO
 >A> +! LILLY 0.6MG/2.4ML (0.25MG/ML) N021318 002 Jun 25, 2008 Jan CAIN
 >A> @ 0.75MG/3ML (0.25MG/ML) N021318 001 Nov 26, 2002 Jan CAIN
 >A> SOLUTION;SUBCUTANEOUS
 >A> BONSTITY
 >A> ALVOGEN 0.62MG/2.48ML (0.25MG/ML) N211939 001 Oct 04, 2019 Jan CAIN
 >A> FORTEO
 >A> +! LILLY 0.6MG/2.4ML (0.25MG/ML) N021318 002 Jun 25, 2008 Jan CDFR
 >A> @ 0.75MG/3ML (0.25MG/ML) N021318 001 Nov 26, 2002 Jan CDFR

TERIPARATIDE RECOMBINANT HUMAN

>D> INJECTABLE;SUBCUTANEOUS
 >D> FORTEO
 >D> +! LILLY 0.6MG/2.4ML (0.25MG/ML) N021318 002 Jun 25, 2008 Jan CAIN
 >D> @ 0.75MG/3ML (0.25MG/ML) N021318 001 Nov 26, 2002 Jan CAIN
 >D> SOLUTION;SUBCUTANEOUS
 >D> BONSTITY
 >D> ALVOGEN 0.62MG/2.48ML (0.25MG/ML) N211939 001 Oct 04, 2019 Jan CAIN

TETRABENAZINE

TABLET;ORAL
 TETRABENAZINE
 >A> AB PIRAMAL HLTHCARE UK 12.5MG A213316 001 Jan 22, 2020 Jan NEWA
 >A> AB 25MG A213316 002 Jan 22, 2020 Jan NEWA

TOLTERODINE TARTRATE

TABLET;ORAL
 TOLTERODINE TARTRATE
 >D> AB MYLAN PHARMS INC 1MG A202641 001 Nov 27, 2012 Jan DISC
 >A> @ 1MG A202641 001 Nov 27, 2012 Jan DISC
 >D> AB 2MG A202641 002 Nov 27, 2012 Jan DISC
 >A> @ 2MG A202641 002 Nov 27, 2012 Jan DISC
 >A> AB UNIQUE PHARM LABS 1MG A204721 001 Jan 24, 2020 Jan NEWA
 >A> AB 2MG A204721 002 Jan 24, 2020 Jan NEWA

TRANEXAMIC ACID

INJECTABLE;INJECTION
 TRANEXAMIC ACID
 >D> AP CAPLIN 100MG/ML A212360 001 Jul 17, 2019 Jan DISC
 >A> @ 100MG/ML A212360 001 Jul 17, 2019 Jan DISC
 TABLET;ORAL
 TRANEXAMIC ACID
 >D> @ AMERIGEN PHARMS LTD 650MG A203256 001 Jul 25, 2016 Jan CAHN
 >A> @ ANI PHARMS INC 650MG A203256 001 Jul 25, 2016 Jan CAHN

TRAZODONE HYDROCHLORIDE

TABLET;ORAL
 TRAZODONE HYDROCHLORIDE
 >A> AB AUROLIFE PHARMA LLC 50MG A204852 001 Feb 05, 2020 Jan NEWA
 >A> AB 100MG A204852 002 Feb 05, 2020 Jan NEWA
 >A> AB 150MG A204852 003 Feb 05, 2020 Jan NEWA
 >A> AB 300MG A204852 004 Feb 05, 2020 Jan NEWA

TRIAZOLAM

TABLET;ORAL
 TRIAZOLAM
 >D> AB MYLAN PHARMS INC 0.125MG A074031 001 Mar 25, 1994 Jan DISC
 >A> @ 0.125MG A074031 001 Mar 25, 1994 Jan DISC
 >D> AB 0.25MG A074031 002 Mar 25, 1994 Jan DISC
 >A> @ 0.25MG A074031 002 Mar 25, 1994 Jan DISC

URSODIOL

CAPSULE;ORAL
 URSODIOL
 >A> AB RISING 300MG A213200 001 Feb 12, 2020 Jan NEWA

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

VALACYCLOVIR HYDROCHLORIDE

>D>	AB	TEVA PHARMS	EQ 500MG BASE	A077655	001	May 24, 2010	Jan DISC
>A>		@	EQ 500MG BASE	A077655	001	May 24, 2010	Jan DISC
>D>	AB		EQ 1GM BASE	A077655	002	May 24, 2010	Jan DISC
>A>		@	EQ 1GM BASE	A077655	002	May 24, 2010	Jan DISC

VALGANCICLOVIR HYDROCHLORIDE

FOR SOLUTION; ORAL

VALGANCICLOVIR HYDROCHLORIDE

>A>	AB	GRANULES PHARMS	50MG/ML	A213306	001	Jan 31, 2020	Jan NEWA
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VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOMYCIN HYDROCHLORIDE

>D>	AP	MUSTAFA NEVZAT ILAC	EQ 500MG BASE/VIAL	A065401	001	Jun 30, 2008	Jan CAHN
>D>	AP		EQ 1GM BASE/VIAL	A065401	002	Jun 30, 2008	Jan CAHN
>A>	AP	PHARM ASSOC	EQ 500MG BASE/VIAL	A065401	001	Jun 30, 2008	Jan CAHN
>A>	AP		EQ 1GM BASE/VIAL	A065401	002	Jun 30, 2008	Jan CAHN

CETIRIZINE HYDROCHLORIDE

SOLUTION;ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

>D> QUAGEN 5MG/5ML A212266 001 May 16, 2019 Jan CDFR

>A> SYRUP;ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

>A> QUAGEN 5MG/5ML A212266 001 May 16, 2019 Jan CDFR

FAMOTIDINE

TABLET;ORAL

FAMOTIDINE

>A> DR REDDYS LABS LTD 10MG A077367 002 Aug 17, 2001 Jan CMS1

>D> MYLAN 10MG A075674 001 Dec 21, 2001 Jan DISC

>A> @ 10MG A075674 001 Dec 21, 2001 Jan DISC

LEVONORGESTREL

TABLET;ORAL

LEVONORGESTREL

>D> AMNEAL PHARMS 1.5MG A204044 001 Jul 03, 2018 Jan CAHN

>D> @ APOTEX 1.5MG A205329 001 Sep 18, 2018 Jan CMFD

>A> 1.5MG A205329 001 Sep 18, 2018 Jan CMFD

>A> LABORATOIRE HRA 1.5MG A204044 001 Jul 03, 2018 Jan CAHN

LORATADINE

TABLET;ORAL

LORATADINE

>D> MYLAN 10MG A075790 001 Nov 07, 2008 Jan DISC

>A> @ 10MG A075790 001 Nov 07, 2008 Jan DISC

>D> 10MG A078447 001 Aug 12, 2011 Jan DISC

>A> @ 10MG A078447 001 Aug 12, 2011 Jan DISC

POLYETHYLENE GLYCOL 3350

FOR SOLUTION;ORAL

GLYCOLAX

>D> @ LANNETT CO INC 17GM/PACKET A090600 001 Oct 06, 2009 Jan CMFD

>A> 17GM/PACKET A090600 001 Oct 06, 2009 Jan CMFD

>D> @ 17GM/SCOOPFUL A090600 002 Oct 06, 2009 Jan CMFD

>A> 17GM/SCOOPFUL A090600 002 Oct 06, 2009 Jan CMFD

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

CUMULATIVE SUPPLEMENT NUMBER 01 JANUARY 2020

NO JANUARY 2020 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.](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 2020 ADDITIONS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 01 - January 2020

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ACETAMINOPHEN; BUTALBITAL - BUTALBITAL AND ACETAMINOPHEN</u>						
A 213115	001				>A> CGT	Jul 28, 2020
<u>ARIPIPRAZOLE - ABILIFY MAINTENA KIT</u>						
N 202971	001	>A> 10525057	Mar 08, 2034	U-1632		
		>A> 10525057	Mar 08, 2034	U-2723		
		>A> 10525057	Mar 08, 2034	U-543		
<u>ARIPIPRAZOLE - ABILIFY MAINTENA KIT</u>						
N 202971	002	>A> 10525057	Mar 08, 2034	U-1632		
		>A> 10525057	Mar 08, 2034	U-2723		
		>A> 10525057	Mar 08, 2034	U-543		
<u>ARIPIPRAZOLE - ABILIFY MAINTENA KIT</u>						
N 202971	003	>A> 10525057	Mar 08, 2034	U-1632		
		>A> 10525057	Mar 08, 2034	U-2723		
		>A> 10525057	Mar 08, 2034	U-543		
<u>ARIPIPRAZOLE - ABILIFY MAINTENA KIT</u>						
N 202971	004	>A> 10525057	Mar 08, 2034	U-1632		
		>A> 10525057	Mar 08, 2034	U-2723		
		>A> 10525057	Mar 08, 2034	U-543		
<u>ARIPIPRAZOLE - ABILIFY MYCITE KIT</u>						
N 207202	001	>A> 10517507	Jun 13, 2032	DP		
<u>ARIPIPRAZOLE - ABILIFY MYCITE KIT</u>						
N 207202	002	>A> 10517507	Jun 13, 2032	DP		
<u>ARIPIPRAZOLE - ABILIFY MYCITE KIT</u>						
N 207202	003	>A> 10517507	Jun 13, 2032	DP		
<u>ARIPIPRAZOLE - ABILIFY MYCITE KIT</u>						
N 207202	004	>A> 10517507	Jun 13, 2032	DP		
<u>ARIPIPRAZOLE - ABILIFY MYCITE KIT</u>						
N 207202	005	>A> 10517507	Jun 13, 2032	DP		
<u>ARIPIPRAZOLE - ABILIFY MYCITE KIT</u>						
N 207202	006	>A> 10517507	Jun 13, 2032	DP		
<u>AVAPRITINIB - AYVAKIT</u>						
N 212608	001	>A> 9200002	Oct 15, 2034	DS DP U-2726	>A> NCE	Jan 09, 2025
		>A> 9944651	Oct 15, 2034	DS DP U-2726		
		>A> 9994575	Oct 15, 2034	DS DP U-2726		
<u>AVAPRITINIB - AYVAKIT</u>						
N 212608	002	>A> 9200002	Oct 15, 2034	DS DP U-2726	>A> NCE	Jan 09, 2025
		>A> 9944651	Oct 15, 2034	DS DP U-2726		
		>A> 9994575	Oct 15, 2034	DS DP U-2726		
<u>AVAPRITINIB - AYVAKIT</u>						
N 212608	003	>A> 9200002	Oct 15, 2034	DS DP U-2726	>A> NCE	Jan 09, 2025
		>A> 9944651	Oct 15, 2034	DS DP U-2726		
		>A> 9994575	Oct 15, 2034	DS DP U-2726		
<u>AVIBACTAM SODIUM; CEFTAZIDIME - AVYCAZ</u>						
N 206494	001	>A> 7112592	Jan 07, 2026	DS DP U-2244		
		>A> 7112592	Jan 07, 2026	DS DP U-2508		
		>A> 7112592	Jan 07, 2026	DS DP U-282		

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>AVIBACTAM SODIUM; CEFTAZIDIME - AVYCAZ</u>						
N 206494	001	>A> 7112592	Jan 07, 2026	DS DP U-2244		
		>A> 7112592	Jan 07, 2026	DS DP U-2508		
		>A> 7112592	Jan 07, 2026	DS DP U-282		
<u>BRILLIANT BLUE G - TISSUEBLUE</u>						
N 209569	001				>A> NCE	Dec 20, 2024
					>A> ODE-282	Dec 20, 2026
<u>CYSTEINE HYDROCHLORIDE - NOURESS</u>						
N 212535	001	>A> 10493051	Mar 15, 2039	DP		
		>A> 10543186	Mar 15, 2039	U-2722		
<u>DACLATASVIR DIHYDROCHLORIDE - DAKLINZA</u>						
N 206843	001	>A> 8329159	Jul 24, 2029	DS		
<u>DACLATASVIR DIHYDROCHLORIDE - DAKLINZA</u>						
N 206843	002	>A> 8329159	Jul 24, 2029	DS		
<u>DEFERIPRONE - FERRIPROX</u>						
N 021825	002	>A> 7049328	Jun 28, 2021	U-735		
<u>DEOXYCHOLIC ACID - KYBELLA</u>						
N 206333	001	>A> 10500214	Mar 02, 2030	DP		
<u>DEXAMETHASONE - HEMADY</u>						
N 211379	001	>A> 10537585	Dec 18, 2037	DP		
<u>DIAZEPAM - VALTOCO</u>						
N 211635	001	>A> 10265402	May 11, 2025	DP	>A> NP	Jan 10, 2023
		>A> 8895546	Mar 27, 2029	DP	>A> ODE-279	Jan 10, 2027
		>A> 8927497	Jul 21, 2025	DP U-2727		
		>A> 9642913	May 11, 2025	DP		
		>A> 9763876	Mar 27, 2029	DP U-2727		
<u>DIAZEPAM - VALTOCO</u>						
N 211635	002	>A> 10265402	May 11, 2025	DP	>A> NP	Jan 10, 2023
		>A> 8895546	Mar 27, 2029	DP	>A> ODE-279	Jan 10, 2027
		>A> 8927497	Jul 21, 2025	DP U-2727		
		>A> 9642913	May 11, 2025	DP		
		>A> 9763876	Mar 27, 2029	DP U-2727		
<u>DIAZEPAM - VALTOCO</u>						
N 211635	003	>A> 10265402	May 11, 2025	DP	>A> NP	Jan 10, 2023
		>A> 8895546	Mar 27, 2029	DP	>A> ODE-279	Jan 10, 2027
		>A> 8927497	Jul 21, 2025	DP U-2727		
		>A> 9642913	May 11, 2025	DP		
		>A> 9763876	Mar 27, 2029	DP U-2727		
<u>EFINACONAZOLE - JUBLIA</u>						
N 203567	001	>A> 10342875	Oct 02, 2034	DP U-2720		
		>A> 10478601	Apr 25, 2035	DP U-2721		
<u>EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - DESCOVY</u>						
N 208215	001				>A> NPP	Sep 25, 2020
					>A> ODE-284	Sep 28, 2024
					>A> ODE-285	Sep 28, 2024
<u>ENZALUTAMIDE - XTANDI</u>						
N 203415	001	>A> 8183274	Aug 24, 2026	U-1281		
		>A> 8183274	Aug 24, 2026	U-1588		
		>A> 8183274	Aug 24, 2026	U-2345		

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<u>ENZALUTAMIDE - XTANDI</u>						
N 203415 001	>A> 8183274	Aug 24, 2026	U-2708			
	>A> 9126941	May 15, 2026	U-1588			
	>A> 9126941	May 15, 2026	U-2345			
	>A> 9126941	May 15, 2026	U-2708			
<u>EPINEPHRINE - ADRENALIN</u>						
N 020800 003	>A> 10166334	Jan 21, 2025	DP			
<u>EPINEPHRINE - ADRENALIN</u>						
N 020800 004	>A> 10166334	Jan 21, 2025	DP			
<u>ETEPLIRSEN - EXONDYS 51</u>						
N 206488 001	>A> 10533174	May 04, 2021	DP			
<u>ETEPLIRSEN - EXONDYS 51</u>						
N 206488 002	>A> 10533174	May 04, 2021	DP			
<u>FERRIC CARBOXYMALTOSE - INJECTAFER</u>						
N 203565 001	>A> 10519252	Oct 20, 2023	DS U-2709			
	>A> 10519252	Oct 20, 2023	DS U-2710			
	>A> 10519252	Oct 20, 2023	DS U-2711			
	>A> 10519252	Oct 20, 2023	DS U-2712			
<u>FERRIC CITRATE - AURYXIA</u>						
N 205874 001	>A> 5753706	Feb 03, 2021	DP U-1577			
<u>FIDAXOMICIN - DIFICID</u>						
N 201699 001				>A> NPP		Jan 24, 2023
				>A> PED		Jul 24, 2023
<u>FIDAXOMICIN - DIFICID</u>						
N 213138 001				>A> NP		Jan 24, 2023
				>A> PED		Jul 24, 2023
<u>FINGOLIMOD HYDROCHLORIDE - GILENYA</u>						
N 022527 001	>A> 10543179	Dec 25, 2027	U-2719			
<u>GLATIRAMER ACETATE - COPAXONE</u>						
N 020622 003	>A> 8232250	Aug 19, 2030	U-441	Y		
	>A> 8399413	Aug 19, 2030	U-441	Y		
	>A> 8969302	Aug 19, 2030	U-441	Y		
	>A> 9155776	Aug 19, 2030	U-441	Y		
	>A> 9402874	Aug 19, 2030	U-441	Y		
<u>GOLODIRSEN - VYONDYS 53</u>						
N 211970 001	>A> 10533174	May 04, 2021	DP		>A> ODE-280	Dec 12, 2026
<u>HYDROGEN PEROXIDE - ESKATA</u>						
N 209305 001	>A> 10493103	Apr 21, 2035	DP			
<u>LASMIDITAN SUCCINATE - REYVOW</u>						
N 211280 001				>A> NCE		Jan 31, 2025
<u>LASMIDITAN SUCCINATE - REYVOW</u>						
N 211280 002				>A> NCE		Jan 31, 2025
<u>LUMATEPERONE TOSYLATE - CAPLYTA</u>						
N 209500 001	>A> 10464938	Mar 12, 2028	DP		>A> NCE	Dec 20, 2024
	>A> 7183282	Jun 15, 2020	DS DP			
	>A> 8598119	Dec 28, 2029	U-543			
	>A> 8648077	Dec 01, 2029	DS DP			

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<u>LUMATEPERONE TOSYLATE - CAPLYTA</u>						
N 209500 001	>A> 9199995	Mar 12, 2029	U-2713			
	>A> 9586960	Mar 12, 2029	DS DP			
	>A> 9616061	May 27, 2029	DP			
	>A> 9956227	Dec 03, 2034	U-2714			
	>A> RE39680	Jun 15, 2020	DS DP U-543			
<u>MICAFUNGIN SODIUM - MYCAMINE</u>						
N 021506 002					>A> I-821	Dec 20, 2022
					>A> PED	Jun 20, 2023
<u>MICAFUNGIN SODIUM - MYCAMINE</u>						
N 021506 003					>A> I-821	Dec 20, 2022
					>A> PED	Jun 20, 2023
<u>MIGALASTAT HYDROCHLORIDE - GALAFOLD</u>						
N 208623 001	>A> 10525045	Apr 28, 2028	U-2371			
<u>MINOCYCLINE HYDROCHLORIDE - AMZEEQ</u>						
N 212379 001	>A> 10517882	Oct 01, 2030	U-2647			
<u>OCTREOTIDE ACETATE - BYNFEZIA PEN</u>						
N 213224 001	>A> 10342850	May 15, 2038	DP			
<u>OLAPARIB - LYNPARZA</u>						
N 208558 001	>A> 8143241	Aug 12, 2027	U-2101		>A> ODE-283	Dec 27, 2026
	>A> 8143241	Aug 12, 2027	U-2103			
	>A> 8143241	Aug 12, 2027	U-2480			
	>A> 8143241	Aug 12, 2027	U-2481			
	>A> 8143241	Aug 12, 2027	U-2482			
	>A> 8143241	Aug 12, 2027	U-2483			
	>A> 8143241	Aug 12, 2027	U-2716			
	>A> 8859562	Aug 04, 2031	U-2101			
	>A> 8859562	Aug 04, 2031	U-2480			
	>A> 8859562	Aug 04, 2031	U-2481			
	>A> 8859562	Aug 04, 2031	U-2482			
	>A> 8859562	Aug 04, 2031	U-2483			
	>A> 8859562	Aug 04, 2031	U-2716			
	>A> 9566276	Mar 12, 2024	U-2716			
<u>OLAPARIB - LYNPARZA</u>						
N 208558 002	>A> 8143241	Aug 12, 2027	U-2101		>A> ODE-283	Dec 27, 2026
	>A> 8143241	Aug 12, 2027	U-2103			
	>A> 8143241	Aug 12, 2027	U-2480			
	>A> 8143241	Aug 12, 2027	U-2481			
	>A> 8143241	Aug 12, 2027	U-2482			
	>A> 8143241	Aug 12, 2027	U-2483			
	>A> 8143241	Aug 12, 2027	U-2716			
	>A> 8859562	Aug 04, 2031	U-2101			
	>A> 8859562	Aug 04, 2031	U-2480			
	>A> 8859562	Aug 04, 2031	U-2481			
	>A> 8859562	Aug 04, 2031	U-2482			
	>A> 8859562	Aug 04, 2031	U-2483			
	>A> 8859562	Aug 04, 2031	U-2716			
	>A> 9566276	Mar 12, 2024	U-2716			
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N 021087 001					>A> M-251	Aug 02, 2022
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N 021087 002					>A> M-251	Aug 02, 2022

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<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N 021087	003				>A> M-251	Aug 02, 2022
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N 021246	001				>A> M-251	Aug 02, 2022
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N 021246	002				>A> M-251	Aug 02, 2022
<u>PEMETREXED - PEMFEXY</u>						
N 209472	001	>A> 7772209	May 24, 2022	U-2728		
		>A> 7772209	May 24, 2022	U-2729		
<u>REVEFENACIN - YUPELRI</u>						
N 210598	001	>A> 10550081	Jul 14, 2030	DS		
<u>SELINEXOR - XPOVIO</u>						
N 212306	001	>A> 10519139	Aug 14, 2035	DS DP U-2584		
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637	001				>A> I-822	Jan 16, 2023
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637	002				>A> I-822	Jan 16, 2023
<u>SEMAGLUTIDE - RYBELSUS</u>						
N 213051	001				>A> M-252	Jan 16, 2023
<u>SEMAGLUTIDE - RYBELSUS</u>						
N 213051	002				>A> M-252	Jan 16, 2023
<u>SEMAGLUTIDE - RYBELSUS</u>						
N 213051	003				>A> M-252	Jan 16, 2023
<u>SOLRIAMFETOL HYDROCHLORIDE - SUNOSI</u>						
N 211230	001	>A> 10512609	Sep 05, 2037	U-2548		
<u>SOLRIAMFETOL HYDROCHLORIDE - SUNOSI</u>						
N 211230	002	>A> 10512609	Sep 05, 2037	U-2548		
<u>SUMATRIPTAN SUCCINATE - ZEMBRACE SYMTOUCH</u>						
N 208223	001	>A> 10537554	Jan 29, 2036	U-72		
<u>SUVOREXANT - BELSOMRA</u>						
N 204569	001				>A> M-253	Jan 29, 2023
<u>SUVOREXANT - BELSOMRA</u>						
N 204569	002				>A> M-253	Jan 29, 2023
<u>SUVOREXANT - BELSOMRA</u>						
N 204569	003				>A> M-253	Jan 29, 2023
<u>SUVOREXANT - BELSOMRA</u>						
N 204569	004				>A> M-253	Jan 29, 2023
<u>TAZEMETOSTAT HYDROBROMIDE - TAZVERIK</u>						
N 211723	001				>A> NCE	Jan 23, 2025

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<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 001	>A> 8747897	Aug 11, 2031	DP U-2724			
	>A> 8747897	Aug 11, 2031	DP U-2725			
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 002	>A> 8747897	Aug 11, 2031	DP U-2724			
	>A> 8747897	Aug 11, 2031	DP U-2725			
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 003	>A> 8747897	Aug 11, 2031	DP U-2724			
	>A> 8747897	Aug 11, 2031	DP U-2725			
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 004	>A> 8747897	Aug 11, 2031	DP U-2724			
	>A> 8747897	Aug 11, 2031	DP U-2725			
<u>TREPROSTINIL DIOLAMINE - ORENITRAM</u>						
N 203496 005	>A> 8747897	Aug 11, 2031	DP U-2724			
	>A> 8747897	Aug 11, 2031	DP U-2725			
<u>TRIPTORELIN PAMOATE - TRIPTODUR KIT</u>						
N 208956 001	>A> 10166181	Jun 30, 2029	DP			
<u>UBROGEPANT - UBRELVY</u>						
N 211765 001	>A> 10117836	Jan 30, 2035	DP			
	>A> 8754096	Jul 19, 2032	DS DP U-2717			
	>A> 8912210	Nov 10, 2031	DS DP			
	>A> 9499545	Nov 10, 2031	DS DP U-2718			
	>A> 9833448	Nov 10, 2031	U-2718			
<u>UBROGEPANT - UBRELVY</u>						
N 211765 002	>A> 10117836	Jan 30, 2035	DP			
	>A> 8754096	Jul 19, 2032	DS DP U-2717			
	>A> 8912210	Nov 10, 2031	DS DP			
	>A> 9499545	Nov 10, 2031	DS DP U-2718			
	>A> 9833448	Nov 10, 2031	U-2718			
<u>UPADACITINIB - RINVOO</u>						
N 211675 001	>A> 10519164	Oct 17, 2036	DP			
<u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>						
N 022567 001	>A> 7834020	Jun 05, 2022	DS DP U-839			
	>A> 7834020*PED	Dec 05, 2022				
	>A> 8193195	Jun 05, 2022	U-839			
	>A> 8193195*PED	Dec 05, 2022				
	>A> 8236804	Jun 05, 2022	U-839			
	>A> 8236804*PED	Dec 05, 2022				
	>A> 8673921	Jun 05, 2022	DS DP			
	>A> 8673921*PED	Dec 05, 2022				
<u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>						
N 022567 002	>A> 7834020	Jun 05, 2022	DS DP U-839			
	>A> 7834020*PED	Dec 05, 2022				
	>A> 8193195	Jun 05, 2022	U-839			
	>A> 8193195*PED	Dec 05, 2022				
	>A> 8236804	Jun 05, 2022	U-839			
	>A> 8236804*PED	Dec 05, 2022				
	>A> 8673921	Jun 05, 2022	DS DP			
	>A> 8673921*PED	Dec 05, 2022				
<u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>						
N 022567 003	>A> 7834020	Jun 05, 2022	DS DP U-839			
	>A> 7834020*PED	Dec 05, 2022				

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<u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>						
N 022567 003	>A> 8193195	Jun 05, 2022	U-839			
	>A> 8193195*PED	Dec 05, 2022				
	>A> 8236804	Jun 05, 2022	U-839			
	>A> 8236804*PED	Dec 05, 2022				
	>A> 8673921	Jun 05, 2022	DS DP			
	>A> 8673921*PED	Dec 05, 2022				
<u>VOXELOTOR - OXBRYTA</u>						
N 213137 001	>A> 10017491	Dec 28, 2032	DP		>A> ODE-281	Nov 25, 2026
	>A> 10034879	Dec 28, 2032	DS DP			
	>A> 10493035	Oct 12, 2037	DP			
	>A> 9018210	Dec 28, 2032	DS DP			
	>A> 9248199	Jan 29, 2034	U-2676			
	>A> 9248199	Jan 29, 2034	U-2715			
	>A> 9447071	Feb 06, 2035	DS DP			

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, 40th 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

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