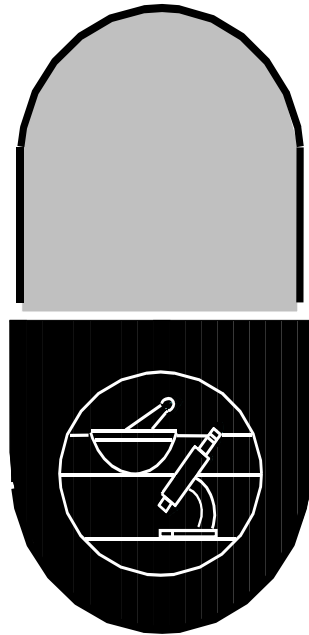


**CUMULATIVE
SUPPLEMENT 2
February 2025**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

45th 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**

Prepared By
Food and Drug Administration
Office of Medical Products and Tobacco
Center for Drug Evaluation and Research
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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

45th EDITION

**CUMULATIVE SUPPLEMENT 2
February 2025**

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for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or that have had their approvals withdrawn for other than safety or efficacy reasons.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 Division of Orange Book Publication and Regulatory Assessment (DOBPR) of any changes or corrections. The DOBPR 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.

| <u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u> | <u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u> |
|--|--|
| MYLAN INSTITUTIONAL LLC (MYLAN INSTITUTIONAL) | NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE) |
| MYLAN LABORATORIES LTD (MYLAN LABS LTD) | NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE) |
| MYLAN PHARMACEUTICALS INC (MYLAN) | NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE) |
| MYLAN PHARMACEUTICALS INC (MYLAN PHARMS INC) | NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE) |
| MYLAN TECHNOLOGIES INC (MYLAN TECHNOLOGIES) | NORVIUM BIOSCIENCE LLC (NORVIUM BIOSCIENCE) |

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 INC | 0.3MG | N021116 | RLD | - |
| AB4 | LEVOTHYROXINE SODIUM ³ | MYLAN | 0.3MG | A076187 | - | 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.

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

1.5 AVAILABILITY OF THE EDITION

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

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

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

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

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

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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).

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>COUNTED</u> | <u>DEC</u> <u>2024</u> | <u>MAR</u> <u>2025</u> | <u>JUN</u> <u>2025</u> | <u>SEP</u> <u>2025</u> | <u>DEC</u> <u>2025</u> |
|-------------------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| DRUG PRODUCTS LISTED SINGLE SOURCE | 23856 | | | | |
| | 2772 | | | | |
| | (11.8%) | | | | |
| MULTISOURCE | 20814 | | | | |
| | (88.2%) | | | | |
| THERAPEUTICALLY EQUIVALENT | 20741 | | | | |
| | (87.9%) | | | | |
| NOT THERAPEUTICALLY EQUIVALENT | 73 | | | | |
| | (0.3%) | | | | |
| EXCEPTIONS ⁴ | 47 | | | | |
| | (0.2%) | | | | |
| NEW MOLECULAR ENTITIES APPROVED | 43 | | | | |
| NUMBER OF APPLICANTS | 1197 | | | | |

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

1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route of Administration and then by trade name (or established name of the active ingredient, if no trade name exists).

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, Reference Standard symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

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

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

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION;ORAL
 ACETAMINOPHEN AND CODEINE PHOSPHATE

| | | | | | | | | |
|-----|----|----------------------|--------------------|----------|-----|--------------|-----|------|
| >D> | AA | CHARTWELL | 120MG/5ML;12MG/5ML | A 089450 | 001 | Oct 27, 1992 | Feb | DISC |
| >A> | | @ | 120MG/5ML;12MG/5ML | A 089450 | 001 | Oct 27, 1992 | Feb | DISC |
| >D> | AA | ! GENUS LIFESCIENCES | 120MG/5ML;12MG/5ML | A 087508 | 001 | | Feb | CTEC |
| >A> | | ! | 120MG/5ML;12MG/5ML | A 087508 | 001 | | Feb | CTEC |
| >D> | | @ WOCKHARDT BIO AG | 120MG/5ML;12MG/5ML | A 087006 | 001 | | Feb | CAHN |
| >A> | | @ XTTRIUM LABS INC | 120MG/5ML;12MG/5ML | A 087006 | 001 | | Feb | CAHN |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION;ORAL
 HYDROCODONE BITARTRATE AND ACETAMINOPHEN

| | | | | | | | | |
|-----|----|----------------|-----------------------|----------|-----|--------------|-----|------|
| >D> | AA | ! CHARTWELL | 325MG/15ML;7.5MG/15ML | A 040482 | 001 | Sep 25, 2003 | Feb | DISC |
| >A> | | @ | 325MG/15ML;7.5MG/15ML | A 040482 | 001 | Sep 25, 2003 | Feb | DISC |
| >D> | AA | WES PHARMA INC | 325MG/15ML;7.5MG/15ML | A 211023 | 001 | Mar 08, 2019 | Feb | CHRS |
| >A> | AA | ! | 325MG/15ML;7.5MG/15ML | A 211023 | 001 | Mar 08, 2019 | Feb | CHRS |

TABLET;ORAL
 HYDROCODONE BITARTRATE AND ACETAMINOPHEN

| | | | | | | | | |
|-----|----|-----------------|-------------|----------|-----|--------------|-----|------|
| >D> | AA | ! CHARTWELL | 300MG;5MG | A 040658 | 001 | Jan 19, 2006 | Feb | DISC |
| >A> | | @ | 300MG;5MG | A 040658 | 001 | Jan 19, 2006 | Feb | DISC |
| >D> | AA | ! | 300MG;7.5MG | A 040658 | 002 | Mar 24, 2006 | Feb | DISC |
| >A> | | @ | 300MG;7.5MG | A 040658 | 002 | Mar 24, 2006 | Feb | DISC |
| >D> | AA | ! | 300MG;10MG | A 040658 | 003 | Jun 23, 2004 | Feb | DISC |
| >A> | | @ | 300MG;10MG | A 040658 | 003 | Jun 23, 2004 | Feb | DISC |
| >D> | AA | | 325MG;7.5MG | A 040432 | 001 | Jan 22, 2003 | Feb | DISC |
| >A> | | @ | 325MG;7.5MG | A 040432 | 001 | Jan 22, 2003 | Feb | DISC |
| | | @ RHODES PHARMS | 300MG;5MG | A 207808 | 001 | Mar 30, 2018 | Jan | DISC |
| | | @ | 300MG;7.5MG | A 207808 | 002 | Mar 30, 2018 | Jan | DISC |
| | | @ | 300MG;10MG | A 207808 | 003 | Mar 30, 2018 | Jan | DISC |
| >D> | AA | SPECGX LLC | 300MG;5MG | A 206718 | 001 | Mar 31, 2017 | Feb | CHRS |
| >A> | AA | ! | 300MG;5MG | A 206718 | 001 | Mar 31, 2017 | Feb | CHRS |
| >D> | AA | | 300MG;7.5MG | A 206718 | 002 | Mar 31, 2017 | Feb | CHRS |
| >A> | AA | ! | 300MG;7.5MG | A 206718 | 002 | Mar 31, 2017 | Feb | CHRS |
| >D> | AA | | 300MG;10MG | A 206718 | 003 | Mar 31, 2017 | Feb | CHRS |
| >A> | AA | ! | 300MG;10MG | A 206718 | 003 | Mar 31, 2017 | Feb | CHRS |

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET;ORAL
 OXYCODONE AND ACETAMINOPHEN

| | | | | | | | | |
|-----|----|-----------|-------------|----------|-----|--------------|-----|------|
| >D> | AA | CHARTWELL | 325MG;5MG | A 207834 | 001 | Aug 15, 2019 | Feb | DISC |
| >A> | | @ | 325MG;5MG | A 207834 | 001 | Aug 15, 2019 | Feb | DISC |
| >D> | AA | | 325MG;7.5MG | A 207834 | 002 | Aug 15, 2019 | Feb | DISC |
| >A> | | @ | 325MG;7.5MG | A 207834 | 002 | Aug 15, 2019 | Feb | DISC |
| >D> | AA | | 325MG;10MG | A 207834 | 003 | Aug 15, 2019 | Feb | DISC |
| >A> | | @ | 325MG;10MG | A 207834 | 003 | Aug 15, 2019 | Feb | DISC |

ACETAZOLAMIDE

TABLET;ORAL
 DIAMOX

| | | | | | | | | |
|-----|--|------------------------|-------|----------|-----|--|-----|------|
| >D> | | + @ TEVA BRANDED PHARM | 125MG | N 008943 | 001 | | Feb | CAHN |
| >A> | | + @ | 125MG | N 008943 | 001 | | Feb | CAHN |
| >D> | | + @ | 250MG | N 008943 | 002 | | Feb | CAHN |
| >A> | | + @ | 250MG | N 008943 | 002 | | Feb | CAHN |

ACETYLCYSTEINE

SOLUTION;INHALATION, ORAL
 ACETYLCYSTEINE

| | | | | | | | |
|----|----------------------|-----|----------|-----|--------------|-----|------|
| AN | SOMERSET THERAPS LLC | 10% | A 219194 | 001 | Feb 12, 2025 | Jan | NEWA |
| AN | | 20% | A 219194 | 002 | Feb 12, 2025 | Jan | NEWA |

ACYCLOVIR

OINTMENT;TOPICAL
 ACYCLOVIR

| | | | | | | | | |
|-----|--|-----------------------|----|----------|-----|--------------|-----|------|
| >D> | | @ ANDA REPOSITORY | 5% | A 206437 | 001 | Jul 31, 2017 | Feb | CAHN |
| >A> | | @ APOTEX | 5% | A 210774 | 001 | Sep 06, 2019 | Jan | DISC |
| >A> | | @ CHARTWELL MOLECULAR | 5% | A 206437 | 001 | Jul 31, 2017 | Feb | CAHN |

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR SODIUM

| | | | | | | | |
|-----|----|--------------------|-----------------|---------|-----|--------------|----------|
| >D> | AP | FRESENIUS KABI USA | EQ 50MG BASE/ML | A215404 | 001 | Jun 25, 2024 | Feb DISC |
| >A> | | @ | EQ 50MG BASE/ML | A215404 | 001 | Jun 25, 2024 | Feb DISC |

ALBUTEROL SULFATE

POWDER, METERED; INHALATION
PROAIR DIGIHALER

| | | | | | | | |
|-----|--|------------------------|--------------------|---------|-----|--------------|----------|
| >D> | | + @ TEVA BRANDED PHARM | EQ 0.09MG BASE/INH | N205636 | 002 | Dec 21, 2018 | Feb CAHN |
| >A> | | + @ | EQ 0.09MG BASE/INH | N205636 | 002 | Dec 21, 2018 | Feb CAHN |
| | | PROAIR RESPICLICK | | | | | |
| >D> | | +! TEVA BRANDED PHARM | EQ 0.09MG BASE/INH | N205636 | 001 | Mar 31, 2015 | Feb CAHN |
| >A> | | +! | EQ 0.09MG BASE/INH | N205636 | 001 | Mar 31, 2015 | Feb CAHN |

SOLUTION; INHALATION
ALBUTEROL SULFATE

| | | | | | | | |
|-----|----|-------------------|-----------------|---------|-----|--------------|----------|
| >A> | AN | RITEDOSE CORP | EQ 0.5% BASE | A218386 | 001 | Mar 12, 2025 | Feb NEWA |
| | | SYRUP; ORAL | | | | | |
| | | ALBUTEROL SULFATE | | | | | |
| | | @ COSETTE | EQ 2MG BASE/5ML | A074454 | 001 | Sep 25, 1995 | Jan DISC |

ALPROSTADIL

SUPPOSITORY; URETHRAL
MUSE

| | | | | | | | |
|-----|--|-------------------------|---------|---------|-----|--------------|----------|
| >D> | | + @ MYLAN SPECIALITY LP | 0.125MG | N020700 | 001 | Nov 19, 1996 | Feb CAHN |
| >D> | | + @ | 0.25MG | N020700 | 002 | Nov 19, 1996 | Feb CAHN |
| >D> | | + @ | 0.5MG | N020700 | 003 | Nov 19, 1996 | Feb CAHN |
| >D> | | + @ | 1MG | N020700 | 004 | Nov 19, 1996 | Feb CAHN |
| >A> | | + @ VIATRIS | 0.125MG | N020700 | 001 | Nov 19, 1996 | Feb CAHN |
| >A> | | + @ | 0.25MG | N020700 | 002 | Nov 19, 1996 | Feb CAHN |
| >A> | | + @ | 0.5MG | N020700 | 003 | Nov 19, 1996 | Feb CAHN |
| >A> | | + @ | 1MG | N020700 | 004 | Nov 19, 1996 | Feb CAHN |

AMCINONIDE

LOTION; TOPICAL
AMCINONIDE

| | | | | | | | |
|-----|--|--------------|------|---------|-----|--------------|----------|
| >D> | | ! GENUS | 0.1% | A076329 | 001 | Nov 06, 2002 | Feb CAHN |
| >A> | | ! SOLUBIOMIX | 0.1% | A076329 | 001 | Nov 06, 2002 | Feb CAHN |

AMINOCAPROIC ACID

SOLUTION; ORAL
AMINOCAPROIC ACID

| | | | | | | | |
|----|--|---------------|-----------|---------|-----|--------------|----------|
| AA | | AJENAT PHARMS | 0.25GM/ML | A213825 | 001 | Apr 08, 2021 | Jan CAHN |
|----|--|---------------|-----------|---------|-----|--------------|----------|

AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM

TABLET; ORAL
AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM

| | | | | | | | |
|-----|----|--------------|----------------------------|---------|-----|--------------|----------|
| >A> | AB | APDM PHARMS | EQ 2.5MG BASE;EQ 10MG BASE | A207762 | 001 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 2.5MG BASE;EQ 20MG BASE | A207762 | 002 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 2.5MG BASE;EQ 40MG BASE | A207762 | 003 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 5MG BASE;EQ 10MG BASE | A207762 | 004 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 5MG BASE;EQ 20MG BASE | A207762 | 005 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 5MG BASE;EQ 40MG BASE | A207762 | 006 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 5MG BASE;EQ 80MG BASE | A207762 | 007 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 10MG BASE;EQ 10MG BASE | A207762 | 008 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 10MG BASE;EQ 20MG BASE | A207762 | 009 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 10MG BASE;EQ 40MG BASE | A207762 | 010 | Jan 11, 2019 | Feb CAHN |
| >A> | AB | | EQ 10MG BASE;EQ 80MG BASE | A207762 | 011 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | ZYDUS PHARMS | EQ 2.5MG BASE;EQ 10MG BASE | A207762 | 001 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 2.5MG BASE;EQ 20MG BASE | A207762 | 002 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 2.5MG BASE;EQ 40MG BASE | A207762 | 003 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 5MG BASE;EQ 10MG BASE | A207762 | 004 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 5MG BASE;EQ 20MG BASE | A207762 | 005 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 5MG BASE;EQ 40MG BASE | A207762 | 006 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 5MG BASE;EQ 80MG BASE | A207762 | 007 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 10MG BASE;EQ 10MG BASE | A207762 | 008 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 10MG BASE;EQ 20MG BASE | A207762 | 009 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 10MG BASE;EQ 40MG BASE | A207762 | 010 | Jan 11, 2019 | Feb CAHN |
| >D> | AB | | EQ 10MG BASE;EQ 80MG BASE | A207762 | 011 | Jan 11, 2019 | Feb CAHN |

AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL

TABLET; ORAL

AMLODIPINE AND OLMESARTAN MEDOXOMIL

| | | | | | | | | |
|-----|----|-------------------|-------------------|---------|-----|--------------|-----|------|
| >A> | AB | HETERO LABS LTD V | EQ 5MG BASE;20MG | A209591 | 001 | Feb 14, 2025 | Feb | NEWA |
| >A> | AB | | EQ 5MG BASE;40MG | A209591 | 002 | Feb 14, 2025 | Feb | NEWA |
| >A> | AB | | EQ 10MG BASE;20MG | A209591 | 003 | Feb 14, 2025 | Feb | NEWA |
| >A> | AB | | EQ 10MG BASE;40MG | A209591 | 004 | Feb 14, 2025 | Feb | NEWA |

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

| | | | | | | | | |
|----|--|--------------|-----------------------------|---------|-----|--------------|-----|------|
| AB | | CEDIPROF INC | 1.25MG;1.25MG;1.25MG;1.25MG | A210754 | 001 | Jul 05, 2022 | Jan | CMFD |
| AB | | | 2.5MG;2.5MG;2.5MG;2.5MG | A210754 | 002 | Jul 05, 2022 | Jan | CMFD |
| AB | | | 3.75MG;3.75MG;3.75MG;3.75MG | A210754 | 003 | Jul 05, 2022 | Jan | CMFD |
| AB | | | 5MG;5MG;5MG;5MG | A210754 | 004 | Jul 05, 2022 | Jan | CMFD |
| AB | | | 7.5MG;7.5MG;7.5MG;7.5MG | A210754 | 005 | Jul 05, 2022 | Jan | CMFD |

AMPHETAMINE SULFATE

TABLET; ORAL

AMPHETAMINE SULFATE

| | | | | | | | |
|---|---------------|------|---------|-----|--------------|-----|------|
| @ | RHODES PHARMS | 5MG | A213852 | 001 | Sep 07, 2021 | Jan | DISC |
| @ | | 10MG | A213852 | 002 | Sep 07, 2021 | Jan | DISC |

APIXABAN

TABLET; ORAL

APIXABAN

| | | | | | | | | |
|-----|----|---------------------|-------|---------|-----|--------------|-----|------|
| >A> | AB | IMPAX | 2.5MG | A209810 | 001 | Feb 14, 2025 | Feb | NEWA |
| >A> | AB | | 5MG | A209810 | 002 | Feb 14, 2025 | Feb | NEWA |
| >A> | AB | MACLEODS PHARMS LTD | 2.5MG | A210067 | 001 | Feb 27, 2025 | Feb | NEWA |
| >A> | AB | | 5MG | A210067 | 002 | Feb 27, 2025 | Feb | NEWA |

APOMORPHINE HYDROCHLORIDE

SOLUTION; SUBCUTANEOUS

| | | | | | | | | |
|-----|---|--------|----------------------|---------|-----|--------------|-----|------|
| >A> | | ONAPGO | | | | | | |
| >A> | + | MDD US | 98MG/20ML (4.9MG/ML) | N214056 | 001 | Feb 03, 2025 | Feb | NEWA |

ARFORMOTEROL TARTRATE

SOLUTION; INHALATION

ARFORMOTEROL TARTRATE

| | | | | | | | | |
|-----|----|------------|---------------------|---------|-----|--------------|-----|------|
| AN | | AUCTA | EQ 0.015MG BASE/2ML | A218380 | 001 | Feb 03, 2025 | Jan | NEWA |
| >A> | AN | MICRO LABS | EQ 0.015MG BASE/2ML | A218555 | 001 | Mar 07, 2025 | Feb | NEWA |

ARIPIPIRAZOLE

FOR SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR

ABILIFY MAINTENA KIT

| | | | | | | | |
|---|---------------------|------------|---------|-----|--------------|-----|------|
| + | OTSUKA PHARM CO LTD | 300MG/VIAL | N202971 | 001 | Feb 28, 2013 | Jan | CTEC |
| + | ! | 400MG/VIAL | N202971 | 002 | Feb 28, 2013 | Jan | CTEC |

ARIPIPIRAZOLE

| | | | | | | | |
|---|-------|------------|---------|-----|--------------|-----|------|
| @ | MYLAN | 300MG/VIAL | A216608 | 001 | Dec 03, 2024 | Jan | DISC |
| @ | | 400MG/VIAL | A216608 | 002 | Dec 03, 2024 | Jan | DISC |

SOLUTION; ORAL

ARIPIPIRAZOLE

| | | | | | | | | |
|----|--|----------------|--------|---------|-----|--------------|-----|------|
| AA | | VISTAPHARM LLC | 1MG/ML | A212870 | 001 | Dec 26, 2019 | Jan | CAHN |
|----|--|----------------|--------|---------|-----|--------------|-----|------|

ARMODAFINIL

TABLET; ORAL

NUVIGIL

| | | | | | | | | |
|----|---|-------------|-------|---------|-----|--------------|-----|------|
| AB | + | NUVO PHARMS | 50MG | N021875 | 001 | Jun 15, 2007 | Jan | CAHN |
| | + | @ | 100MG | N021875 | 002 | Mar 26, 2009 | Jan | CAHN |
| AB | + | | 150MG | N021875 | 003 | Jun 15, 2007 | Jan | CAHN |
| AB | + | | 200MG | N021875 | 005 | Mar 26, 2009 | Jan | CAHN |
| AB | + | ! | 250MG | N021875 | 004 | Jun 15, 2007 | Jan | CAHN |

AVIBACTAM SODIUM; AZTREONAM

| | | | | | | | | |
|-----|---|---------------------|-------------------------------|---------|-----|--------------|-----|------|
| >A> | | POWDER; INTRAVENOUS | | | | | | |
| >A> | | EMBLAVEO | | | | | | |
| >A> | + | ABBVIE | EQ 0.5GM BASE/VIAL;1.5GM/VIAL | N217906 | 001 | Feb 07, 2025 | Feb | NEWA |

AZELASTINE HYDROCHLORIDE

SPRAY, METERED;NASAL
ASTEPRO

| | | | | | | | |
|--|---|--------------------------|----------------|---------|-----|--------------|----------|
| | + | @ NORVIUM BIOSCIENCE | 0.137MG/SPRAY | N022203 | 001 | Oct 15, 2008 | Jan CAHN |
| | | @ | 0.2055MG/SPRAY | N022203 | 002 | Aug 31, 2009 | Jan CAHN |
| | | AZELASTINE HYDROCHLORIDE | | | | | |
| | | @ BIONPHARMA | 0.137MG/SPRAY | A090176 | 001 | Jul 28, 2015 | Jan DISC |

AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE

TABLET;ORAL
AZILSARTAN MEDOXOMIL AND CHLORTHALIDONE

| | | | | | | | |
|----|---|----------------|--------------------------|---------|-----|--------------|----------|
| AB | | ALKEM LABS LTD | EQ 40MG MEDOXOMIL;12.5MG | A217490 | 001 | Jan 21, 2025 | Jan NFTG |
| AB | | | EQ 40MG MEDOXOMIL;25MG | A217490 | 002 | Jan 21, 2025 | Jan NFTG |
| | | EDARBYCLOR | | | | | |
| AB | + | AZURITY | EQ 40MG MEDOXOMIL;12.5MG | N202331 | 001 | Dec 20, 2011 | Jan CFTG |
| AB | + | ! | EQ 40MG MEDOXOMIL;25MG | N202331 | 002 | Dec 20, 2011 | Jan CFTG |

AZITHROMYCIN

FOR SUSPENSION;ORAL
AZITHROMYCIN

| | | | | | | | |
|-----|----|----------------|-------------------|---------|-----|--------------|----------|
| >D> | | @ CHARTWELL RX | EQ 100MG BASE/5ML | A065488 | 001 | May 15, 2015 | Feb CMFD |
| >A> | AB | | EQ 100MG BASE/5ML | A065488 | 001 | May 15, 2015 | Feb CMFD |
| >D> | | @ | EQ 200MG BASE/5ML | A065488 | 002 | May 15, 2015 | Feb CMFD |
| >A> | AB | | EQ 200MG BASE/5ML | A065488 | 002 | May 15, 2015 | Feb CMFD |

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT;OPHTHALMIC
LUMI-SPORYN

| | | | | | | | |
|-----|----|---|-------------------|--|---------|-----|----------|
| >D> | AT | + | CASPER PHARMA LLC | EQ 400 UNITS/GM;EQ 3.5MG BASE/GM;EQ 10,000 UNITS/GM | N050417 | 001 | Feb CPOT |
| >A> | AT | + | | 400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM | N050417 | 001 | Feb CPOT |

BACLOFEN

TABLET;ORAL
BACLOFEN

| | | | | | | | |
|----|--|-------|-----|---------|-----|--------------|----------|
| AB | | APPCO | 5MG | A090334 | 003 | Jan 31, 2025 | Jan NEWA |
|----|--|-------|-----|---------|-----|--------------|----------|

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED;NASAL
QNASL

| | | | | | | | | |
|-----|--|---|--------------------|------------------|---------|-----|--------------|----------|
| >D> | | + | TEVA BRANDED PHARM | 0.04MG/ACTUATION | N202813 | 002 | Dec 17, 2014 | Feb CAHN |
| >A> | | + | | 0.04MG/ACTUATION | N202813 | 002 | Dec 17, 2014 | Feb CAHN |
| >D> | | + | ! | 0.08MG/ACTUATION | N202813 | 001 | Mar 23, 2012 | Feb CAHN |
| >A> | | + | ! | 0.08MG/ACTUATION | N202813 | 001 | Mar 23, 2012 | Feb CAHN |

BENZTROPINE MESYLATE

TABLET;ORAL
BENZTROPINE MESYLATE

| | | | | | | | |
|----|--|--------|-------|---------|-----|--------------|----------|
| AA | | QUAGEN | 0.5MG | A212694 | 001 | Feb 11, 2025 | Jan NEWA |
| AA | | | 1MG | A212694 | 002 | Feb 11, 2025 | Jan NEWA |
| AA | | | 2MG | A212694 | 003 | Feb 11, 2025 | Jan NEWA |

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED;TOPICAL
BETAMETHASONE DIPROPIONATE

| | | | | | | | |
|-----|--|-----------------------|---------------|---------|-----|--------------|----------|
| >D> | | @ ANDA REPOSITORY | EQ 0.05% BASE | A076603 | 001 | Jan 23, 2004 | Feb CAHN |
| >A> | | @ CHARTWELL MOLECULAR | EQ 0.05% BASE | A076603 | 001 | Jan 23, 2004 | Feb CAHN |

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE

SUSPENSION;TOPICAL
CALCIPOTRIENE AND BETHAMETHASONE DIPROPIONATE
@ PADAGIS ISRAEL 0.064%;0.005%

| | | | |
|---------|-----|--------------|----------|
| A212367 | 001 | Sep 11, 2020 | Jan DISC |
|---------|-----|--------------|----------|

BEXAROTENE

CAPSULE;ORAL
BEXAROTENE

| | | | | | |
|---------|------|---------|-----|--------------|----------|
| @ CIPLA | 75MG | A210352 | 001 | Dec 10, 2024 | Jan DISC |
|---------|------|---------|-----|--------------|----------|

BOSENTAN

TABLET, FOR SUSPENSION;ORAL
BOSENTAN

| | | | | | | | | |
|----|---|------------------|------|---------|-----|--------------|-----|------|
| AB | | NATCO PHARMA LTD | 32MG | A213154 | 001 | Feb 05, 2025 | Jan | NFTG |
| AB | + | TRACLEER | | | | | | |
| AB | + | ACTELION | 32MG | N209279 | 001 | Sep 05, 2017 | Jan | CFTG |

BREXANOLONE

SOLUTION;INTRAVENOUS
ZULRESSO

| | | | | | | | | |
|--|---|---------------|---------------------|---------|-----|--------------|-----|------|
| | + | @ SAGE THERAP | 100MG/20ML (5MG/ML) | N211371 | 001 | Jun 17, 2019 | Jan | DISC |
|--|---|---------------|---------------------|---------|-----|--------------|-----|------|

BREXPIPIRAZOLE

TABLET;ORAL
BREXPIPIRAZOLE

| | | | | | | | | |
|-----|----|---------|--------|---------|-----|--------------|-----|------|
| AB | | ALEMBIC | 0.25MG | A213683 | 001 | Jan 13, 2025 | Jan | NEWA |
| AB | | | 0.5MG | A213683 | 002 | Jan 13, 2025 | Jan | NEWA |
| AB | | | 1MG | A213683 | 003 | Jan 13, 2025 | Jan | NEWA |
| AB | | | 2MG | A213683 | 004 | Jan 13, 2025 | Jan | NEWA |
| AB | | | 3MG | A213683 | 005 | Jan 13, 2025 | Jan | NEWA |
| AB | | | 4MG | A213683 | 006 | Jan 13, 2025 | Jan | NEWA |
| >A> | AB | APOTEX | 0.25MG | A213731 | 001 | Feb 24, 2025 | Feb | NEWA |
| >A> | AB | | 0.5MG | A213731 | 002 | Feb 24, 2025 | Feb | NEWA |
| >A> | AB | | 1MG | A213731 | 003 | Feb 24, 2025 | Feb | NEWA |
| >A> | AB | | 2MG | A213731 | 004 | Feb 24, 2025 | Feb | NEWA |
| >A> | AB | | 3MG | A213731 | 005 | Feb 24, 2025 | Feb | NEWA |
| | | REXULTI | | | | | | |
| AB | + | OTSUKA | 0.25MG | N205422 | 001 | Jul 10, 2015 | Jan | CTEC |
| AB | + | | 0.5MG | N205422 | 002 | Jul 10, 2015 | Jan | CTEC |
| AB | + | | 1MG | N205422 | 003 | Jul 10, 2015 | Jan | CTEC |
| AB | + | | 2MG | N205422 | 004 | Jul 10, 2015 | Jan | CTEC |
| AB | + | | 3MG | N205422 | 005 | Jul 10, 2015 | Jan | CTEC |
| AB | + | | 4MG | N205422 | 006 | Jul 10, 2015 | Jan | CTEC |

BRIMONIDINE TARTRATE; TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC
BRIMONIDINE TARTRATE AND TIMOLOL MALEATE

| | | | | | | | | |
|-----|----|----------|-------------------|---------|-----|--------------|-----|------|
| >A> | AB | @ AMNEAL | 0.2%;EQ 0.5% BASE | A217288 | 001 | Dec 30, 2024 | Jan | DISC |
| >A> | AB | CAPLIN | 0.2%;EQ 0.5% BASE | A219093 | 001 | Feb 25, 2025 | Feb | NEWA |

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP;ORAL
BROMFED-DM

| | | | | | | | | | |
|-----|----|---|------------------|---------------------------|---------|-----|--------------|-----|------|
| >D> | AA | + | WOCKHARDT BIO AG | 2MG/5ML;10MG/5ML;30MG/5ML | A088811 | 001 | Jun 07, 1985 | Feb | CAHN |
| >A> | AA | + | XTTRIUM LABS INC | 2MG/5ML;10MG/5ML;30MG/5ML | A088811 | 001 | Jun 07, 1985 | Feb | CAHN |

BUDESONIDE

SUSPENSION;INHALATION
BUDESONIDE

| | | | | | | | | | |
|-----|----|---|--------|------------|---------|-----|--------------|-----|------|
| >D> | AN | | SANDOZ | 0.25MG/2ML | A201966 | 003 | Sep 27, 2013 | Feb | DISC |
| >A> | | @ | | 0.25MG/2ML | A201966 | 003 | Sep 27, 2013 | Feb | DISC |
| >D> | AN | | | 0.5MG/2ML | A201966 | 002 | Sep 27, 2013 | Feb | DISC |
| >A> | | @ | | 0.5MG/2ML | A201966 | 002 | Sep 27, 2013 | Feb | DISC |
| >D> | AN | | | 1MG/2ML | A201966 | 001 | Sep 27, 2013 | Feb | DISC |
| >A> | | @ | | 1MG/2ML | A201966 | 001 | Sep 27, 2013 | Feb | DISC |

BUMETANIDE

INJECTABLE;INJECTION
BUMETANIDE

| | | | | | | | | | |
|-----|----|--|--------|-----------|---------|-----|--------------|-----|------|
| >A> | AP | | ASPIRO | 0.25MG/ML | A218746 | 001 | Feb 27, 2025 | Feb | NEWA |
|-----|----|--|--------|-----------|---------|-----|--------------|-----|------|

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE;INJECTION
BUPRENORPHINE HYDROCHLORIDE

| | | | | | | | | |
|----|--|----------------------|------------------|---------|-----|--------------|-----|------|
| AP | | SOMERSET THERAPS LLC | EQ 0.3MG BASE/ML | A219302 | 001 | Jan 30, 2025 | Jan | NEWA |
|----|--|----------------------|------------------|---------|-----|--------------|-----|------|

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

FILM;BUCCAL, SUBLINGUAL

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE

| | | | | | | | |
|-----|----|---------------|---------------------------|---------|-----|--------------|----------|
| >A> | AB | DIFGEN PHARMS | EQ 2MG BASE;EQ 0.5MG BASE | A212756 | 003 | Feb 13, 2025 | Feb NEWA |
| >A> | AB | | EQ 4MG BASE;EQ 1MG BASE | A212756 | 004 | Feb 13, 2025 | Feb NEWA |

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL

BUPROPION HYDROCHLORIDE

| | | | | | | | |
|-----|-----|-----------|-------|---------|-----|--------------|----------|
| >D> | AB3 | SUN PHARM | 150MG | A200216 | 001 | Nov 30, 2020 | Feb DISC |
| >A> | | @ | 150MG | A200216 | 001 | Nov 30, 2020 | Feb DISC |
| >D> | AB3 | | 300MG | A203650 | 001 | Dec 31, 2020 | Feb DISC |
| >A> | | @ | 300MG | A203650 | 001 | Dec 31, 2020 | Feb DISC |

BUSPIRONE HYDROCHLORIDE

CAPSULE;ORAL

BUSPIRONE HYDROCHLORIDE

| | | | | | | | |
|-----|--|-----------------|-------|---------|-----|--------------|----------|
| >A> | | EPIC PHARMA LLC | 7.5MG | A218628 | 001 | Mar 13, 2025 | Feb NEWA |
| >A> | | | 10MG | A218628 | 002 | Mar 13, 2025 | Feb NEWA |
| >A> | | | 15MG | A218628 | 003 | Mar 13, 2025 | Feb NEWA |

BUSULFAN

INJECTABLE;INJECTION

BUSULFAN

@ APOTEX

6MG/ML

A210448 001 May 07, 2019 Jan DISC

CAFFEINE CITRATE

SOLUTION;ORAL

CAFFEINE CITRATE

| | | | | | | | |
|-----|----|-----------|------------------------------------|---------|-----|--------------|----------|
| >D> | AA | SUN PHARM | EQ 30MG BASE/3ML (EQ 10MG BASE/ML) | A090357 | 001 | Sep 30, 2009 | Feb DISC |
| >A> | | @ | EQ 30MG BASE/3ML (EQ 10MG BASE/ML) | A090357 | 001 | Sep 30, 2009 | Feb DISC |

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

INJECTABLE;INJECTION

PRISMASOL B22GK 2/0 IN PLASTIC CONTAINER

| | | | | | | | |
|-----|-----|----------------------|---|---------|-----|--------------|----------|
| >D> | + @ | BAXTER HLTHCARE CORP | N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.157GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 010 | Oct 10, 2008 | Feb CAHN |
|-----|-----|----------------------|---|---------|-----|--------------|----------|

| | | | | | | | |
|-----|-----|---------------------|---|---------|-----|--------------|----------|
| >A> | + @ | VANTIVE US HLTHCARE | N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.157GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 010 | Oct 10, 2008 | Feb CAHN |
|-----|-----|---------------------|---|---------|-----|--------------|----------|

PRISMASOL B22GK 2/2.5 IN PLASTIC CONTAINER

| | | | | | | | |
|-----|---|----------------------|--|---------|-----|--------------|----------|
| >D> | @ | BAXTER HLTHCARE CORP | 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.157GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 012 | Oct 10, 2008 | Feb CAHN |
|-----|---|----------------------|--|---------|-----|--------------|----------|

| | | | | | | | |
|-----|---|---------------------|--|---------|-----|--------------|----------|
| >A> | @ | VANTIVE US HLTHCARE | 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.157GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 012 | Oct 10, 2008 | Feb CAHN |
|-----|---|---------------------|--|---------|-----|--------------|----------|

PRISMASOL B22GK 4/0 IN PLASTIC CONTAINER

| | | | | | | | |
|-----|----|----------------------|---|---------|-----|--------------|----------|
| >D> | +! | BAXTER HLTHCARE CORP | N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 011 | Oct 10, 2008 | Feb CAHN |
|-----|----|----------------------|---|---------|-----|--------------|----------|

| | | | | | | | |
|-----|----|---------------------|---|---------|-----|--------------|----------|
| >A> | +! | VANTIVE US HLTHCARE | N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 011 | Oct 10, 2008 | Feb CAHN |
|-----|----|---------------------|---|---------|-----|--------------|----------|

PRISMASOL B22GK 4/2.5 IN PLASTIC CONTAINER

| | | | | | | | |
|-----|-----|----------------------|--|---------|-----|--------------|----------|
| >D> | + @ | BAXTER HLTHCARE CORP | 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 013 | Oct 10, 2008 | Feb CAHN |
|-----|-----|----------------------|--|---------|-----|--------------|----------|

| | | | | | | | |
|-----|-----|---------------------|--|---------|-----|--------------|----------|
| >A> | + @ | VANTIVE US HLTHCARE | 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;7.07GM/1000ML (5000ML) | N021703 | 013 | Oct 10, 2008 | Feb CAHN |
|-----|-----|---------------------|--|---------|-----|--------------|----------|

PRISMASOL BGK 0/2.5 IN PLASTIC CONTAINER

| | | | | | | | |
|-----|----|----------------------|--|---------|-----|--------------|----------|
| >D> | +! | BAXTER HLTHCARE CORP | 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46 | N021703 | 006 | Oct 25, 2006 | Feb CAHN |
|-----|----|----------------------|--|---------|-----|--------------|----------|

INJECTABLE; INJECTION

PRISMASOL BGK 0/2.5 IN PLASTIC CONTAINER

>A> +! VANTIVE US HLTHCARE GM/1000ML (5000ML)
 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 006 Oct 25, 2006 Feb CAHN

PRISMASOL BGK 2/0 IN PLASTIC CONTAINER

>D> +! BAXTER HLTHCARE CORP N/A/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.157GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 002 Oct 25, 2006 Feb CAHN

>A> +! VANTIVE US HLTHCARE N/A/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.157GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 002 Oct 25, 2006 Feb CAHN

PRISMASOL BGK 2/3.5 IN PLASTIC CONTAINER

>D> +! BAXTER HLTHCARE CORP 5.15GM/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.157GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 003 Oct 25, 2006 Feb CAHN

>A> +! VANTIVE US HLTHCARE 5.15GM/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.157GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 003 Oct 25, 2006 Feb CAHN

PRISMASOL BGK 4/0 IN PLASTIC CONTAINER

>D> @ BAXTER HLTHCARE CORP N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 005 Oct 25, 2006 Feb CAHN

>A> @ VANTIVE US HLTHCARE N/A/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 005 Oct 25, 2006 Feb CAHN

PRISMASOL BGK 4/0/1.2 IN PLASTIC CONTAINER

>D> +! BAXTER HLTHCARE CORP N/A/1000ML;20GM/1000ML;5.4GM/1000ML;2.44GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 015 Oct 10, 2008 Feb CAHN

>A> +! VANTIVE US HLTHCARE N/A/1000ML;20GM/1000ML;5.4GM/1000ML;2.44GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 015 Oct 10, 2008 Feb CAHN

PRISMASOL BGK 4/2.5 IN PLASTIC CONTAINER

>D> +! BAXTER HLTHCARE CORP 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 004 Oct 25, 2006 Feb CAHN

>A> +! VANTIVE US HLTHCARE 3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 004 Oct 25, 2006 Feb CAHN

PRISMASOL BGK 4/3.5 IN PLASTIC CONTAINER

>D> @ BAXTER HLTHCARE CORP 5.15GM/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 008 Oct 25, 2006 Feb CAHN

>A> @ VANTIVE US HLTHCARE 5.15GM/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 008 Oct 25, 2006 Feb CAHN

PRISMASOL BK 0/0 IN PLASTIC CONTAINER

>D> @ BAXTER HLTHCARE CORP N/A/1000ML;N/A/1000ML;5.4GM/1000ML;3.05GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 007 Oct 25, 2006 Feb CAHN

>A> @ VANTIVE US HLTHCARE N/A/1000ML;N/A/1000ML;5.4GM/1000ML;3.05GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 007 Oct 25, 2006 Feb CAHN

PRISMASOL BK 0/0/1.2 IN PLASTIC CONTAINER

>D> +! BAXTER HLTHCARE CORP N/A/1000ML;N/A/1000ML;5.4GM/1000ML;2.44GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 014 Oct 10, 2008 Feb CAHN

>A> +! VANTIVE US HLTHCARE N/A/1000ML;N/A/1000ML;5.4GM/1000ML;2.44GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML) N021703 014 Oct 10, 2008 Feb CAHN

INJECTABLE; INJECTION

PRISMASOL BK 0/3.5 IN PLASTIC CONTAINER

>D> + @ BAXTER HLTHCARE CORP 5.15GM/1000ML;N/A/1000ML;5.4GM/100 N021703 001 Oct 25, 2006 Feb CAHN
 OML;2.03GM/1000ML;N/A/1000ML;3.09G
 M/1000ML;6.46GM/1000ML (5000ML)

>A> + @ VANTIVE US HLTHCARE 5.15GM/1000ML;N/A/1000ML;5.4GM/100 N021703 001 Oct 25, 2006 Feb CAHN
 OML;2.03GM/1000ML;N/A/1000ML;3.09G
 M/1000ML;6.46GM/1000ML (5000ML)

PRISMASOL BK 4/2.5 IN PLASTIC CONTAINER

>D> @ BAXTER HLTHCARE CORP 3.68GM/1000ML;N/A/1000ML;5.4GM/100 N021703 009 Oct 25, 2006 Feb CAHN
 OML;3.05GM/1000ML;0.314GM/1000ML;3
 .09GM/1000ML;6.46GM/1000ML
 (5000ML)

>A> @ VANTIVE US HLTHCARE 3.68GM/1000ML;N/A/1000ML;5.4GM/100 N021703 009 Oct 25, 2006 Feb CAHN
 OML;3.05GM/1000ML;0.314GM/1000ML;3
 .09GM/1000ML;6.46GM/1000ML
 (5000ML)

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DELFLX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>D> AT +! FRESENIUS MEDCL 25.7MG/100ML;1.5GM/100ML;15.2MG/10 N018883 001 Nov 30, 1984 Feb CTEC
 OML;567MG/100ML;392MG/100ML

>A> +! 25.7MG/100ML;1.5GM/100ML;15.2MG/10 N018883 001 Nov 30, 1984 Feb CTEC
 OML;567MG/100ML;392MG/100ML

DELFLX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

>D> AT +! FRESENIUS MEDCL 25.7MG/100ML;2.5GM/100ML;15.2MG/10 N018883 002 Nov 30, 1984 Feb CTEC
 OML;567MG/100ML;392MG/100ML

>A> +! 25.7MG/100ML;2.5GM/100ML;15.2MG/10 N018883 002 Nov 30, 1984 Feb CTEC
 OML;567MG/100ML;392MG/100ML

DELFLX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

>D> AT +! FRESENIUS MEDCL 25.7MG/100ML;4.25GM/100ML;15.2MG/1 N018883 003 Nov 30, 1984 Feb CTEC
 OML;567MG/100ML;392MG/100ML

>A> +! 25.7MG/100ML;4.25GM/100ML;15.2MG/1 N018883 003 Nov 30, 1984 Feb CTEC
 OML;567MG/100ML;392MG/100ML

DIANEAL 137 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>D> @ BAXTER HLTHCARE 25.7MG/100ML;1.5GM/100ML;15.2MG/10 N017512 001 Feb CAHN
 OML;567MG/100ML;392MG/100ML

>A> @ VANTIVE US HLTHCARE 25.7MG/100ML;1.5GM/100ML;15.2MG/10 N017512 001 Feb CAHN
 OML;567MG/100ML;392MG/100ML

DIANEAL 137 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

>D> @ BAXTER HLTHCARE 25.7MG/100ML;2.5GM/100ML;15.2MG/10 N017512 003 Feb CAHN
 OML;567MG/100ML;392MG/100ML

>A> @ VANTIVE US HLTHCARE 25.7MG/100ML;2.5GM/100ML;15.2MG/10 N017512 003 Feb CAHN
 OML;567MG/100ML;392MG/100ML

DIANEAL 137 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

>D> @ BAXTER HLTHCARE 25.7MG/100ML;4.25GM/100ML;15.2MG/1 N017512 002 Feb CAHN
 OML;567MG/100ML;392MG/100ML

>A> @ VANTIVE US HLTHCARE 25.7MG/100ML;4.25GM/100ML;15.2MG/1 N017512 002 Feb CAHN
 OML;567MG/100ML;392MG/100ML

DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>D> AT + BAXTER HLTHCARE 18.3MG/100ML;1.5GM/100ML;5.08MG/10 N020183 001 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

>A> AT + VANTIVE US HLTHCARE 18.3MG/100ML;1.5GM/100ML;5.08MG/10 N020183 001 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

DIANEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

>D> AT + BAXTER HLTHCARE 18.3MG/100ML;2.5GM/100ML;5.08MG/10 N020183 002 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

>A> AT + VANTIVE US HLTHCARE 18.3MG/100ML;2.5GM/100ML;5.08MG/10 N020183 002 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

>D> + @ BAXTER HLTHCARE 18.3MG/100ML;3.5GM/100ML;5.08MG/10 N020183 003 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

>A> + @ VANTIVE US HLTHCARE 18.3MG/100ML;3.5GM/100ML;5.08MG/10 N020183 003 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

DIANEAL LOW CALCIUM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

>D> AT + BAXTER HLTHCARE 18.3MG/100ML;4.25GM/100ML;5.08MG/1 N020183 004 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

>A> AT + VANTIVE US HLTHCARE 18.3MG/100ML;4.25GM/100ML;5.08MG/1 N020183 004 Dec 04, 1992 Feb CAHN
 OML;538MG/100ML;448MG/100ML

DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>D> AT + BAXTER HLTHCARE 18.3MG/100ML;1.5GM/100ML;5.08MG/10 N017512 012 Jan 10, 1989 Feb CAHN
 OML;538MG/100ML;448MG/100ML

>A> AT + VANTIVE US HLTHCARE 18.3MG/100ML;1.5GM/100ML;5.08MG/10 N017512 012 Jan 10, 1989 Feb CAHN
 OML;538MG/100ML;448MG/100ML

SOLUTION;INTRAPERITONEAL

DIANEAL LOW CALCIUM W/DEXTROSE 2.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|----|---|---------------------|---|---------|-----|--------------|----------|
| >D> | AT | + | BAXTER HLTHCARE | 18.3MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 013 | Jul 11, 1990 | Feb CAHN |
| >A> | AT | + | VANTIVE US HLTHCARE | 18.3MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 013 | Jul 11, 1990 | Feb CAHN |

DIANEAL LOW CALCIUM W/DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|----|---|---------------------|---|---------|-----|--------------|----------|
| >D> | AT | + | BAXTER HLTHCARE | 18.3MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 014 | Jul 11, 1990 | Feb CAHN |
| >A> | AT | + | VANTIVE US HLTHCARE | 18.3MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 014 | Jul 11, 1990 | Feb CAHN |
| >A> | | + | | 18.3MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 014 | Jul 11, 1990 | Feb CTEC |

DIANEAL LOW CALCIUM W/DEXTROSE 4.25% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|----|---|---------------------|--|---------|-----|--------------|----------|
| >D> | AT | + | BAXTER HLTHCARE | 18.3MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 015 | Jul 11, 1990 | Feb CAHN |
| >A> | AT | + | VANTIVE US HLTHCARE | 18.3MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 015 | Jul 11, 1990 | Feb CAHN |

DIANEAL PD-1 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|--|---|---------------------|---|---------|-----|--------------|----------|
| >D> | | @ | BAXTER HLTHCARE | 25.7MG/100ML;1.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 007 | Jul 09, 1984 | Feb CAHN |
| >A> | | @ | VANTIVE US HLTHCARE | 25.7MG/100ML;1.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 007 | Jul 09, 1984 | Feb CAHN |

DIANEAL PD-1 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|--|---|---------------------|---|---------|-----|--------------|----------|
| >D> | | @ | BAXTER HLTHCARE | 25.7MG/100ML;2.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 008 | Jul 09, 1984 | Feb CAHN |
| >A> | | @ | VANTIVE US HLTHCARE | 25.7MG/100ML;2.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 008 | Jul 09, 1984 | Feb CAHN |

DIANEAL PD-1 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|--|---|---------------------|---|---------|-----|--------------|----------|
| >D> | | @ | BAXTER HLTHCARE | 25.7MG/100ML;3.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 010 | Nov 18, 1985 | Feb CAHN |
| >A> | | @ | VANTIVE US HLTHCARE | 25.7MG/100ML;3.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 010 | Nov 18, 1985 | Feb CAHN |

DIANEAL PD-1 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|--|---|---------------------|--|---------|-----|--------------|----------|
| >D> | | @ | BAXTER HLTHCARE | 25.7MG/100ML;4.25GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 009 | Jul 09, 1984 | Feb CAHN |
| >A> | | @ | VANTIVE US HLTHCARE | 25.7MG/100ML;4.25GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML | N017512 | 009 | Jul 09, 1984 | Feb CAHN |

DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|----|---|---------------------|---|---------|-----|--------------|----------|
| >D> | AT | + | BAXTER HLTHCARE | 25.7MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 004 | | Feb CAHN |
| >D> | AT | + | | 25.7MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020163 | 001 | Dec 04, 1992 | Feb CAHN |
| >A> | AT | + | VANTIVE US HLTHCARE | 25.7MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 004 | | Feb CAHN |
| >A> | AT | + | | 25.7MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020163 | 001 | Dec 04, 1992 | Feb CAHN |

DIANEAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|----|---|---------------------|---|---------|-----|--------------|----------|
| >D> | AT | + | BAXTER HLTHCARE | 25.7MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 005 | | Feb CAHN |
| >D> | AT | + | | 25.7MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020163 | 002 | Dec 04, 1992 | Feb CAHN |
| >A> | AT | + | VANTIVE US HLTHCARE | 25.7MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 005 | | Feb CAHN |
| >A> | AT | + | | 25.7MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020163 | 002 | Dec 04, 1992 | Feb CAHN |

DIANEAL PD-2 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|--|---|-----------------------|---|---------|-----|--------------|----------|
| >D> | | + | @ BAXTER HLTHCARE | 25.7MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 011 | Nov 18, 1985 | Feb CAHN |
| >A> | | + | @ VANTIVE US HLTHCARE | 25.7MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 011 | Nov 18, 1985 | Feb CAHN |

DIANEAL PD-2 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|----|---|---------------------|--|---------|-----|--------------|----------|
| >D> | AT | + | BAXTER HLTHCARE | 25.7MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 006 | | Feb CAHN |
| >D> | AT | + | | 25.7MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020163 | 003 | Dec 04, 1992 | Feb CAHN |
| >A> | AT | + | VANTIVE US HLTHCARE | 25.7MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N017512 | 006 | | Feb CAHN |
| >A> | AT | + | | 25.7MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML | N020163 | 003 | Dec 04, 1992 | Feb CAHN |

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

INJECTABLE;INJECTION

PHOXILLUM B22K 4/0 IN PLASTIC CONTAINER

| | | | | | | | | | |
|-----|--|---|---|----------------------|---|---------|-----|--------------|----------|
| >D> | | + | ! | BAXTER HLTHCARE CORP | N/A/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;6.95GM/1000ML;0.187GM/1000ML (5000ML) | N207026 | 002 | Jan 13, 2015 | Feb CAHN |
| >A> | | + | ! | VANTIVE US HLTHCARE | N/A/1000ML;3.05GM/1000ML;0.314 | N207026 | 002 | Jan 13, 2015 | Feb CAHN |

INJECTABLE; INJECTION

PHOXILLUM B22K 4/0 IN PLASTIC CONTAINER

GM/1000ML; 2.21GM/1000ML; 6.95GM/1000ML; 0.187GM/1000ML (5000ML)

PHOXILLUM BK 4/2.5 IN PLASTIC CONTAINER

| | | | | | | | | |
|-----|---|----------------------|--|---------|-----|--------------|-----|------|
| >D> | + | BAXTER HLTHCARE CORP | 3.68GM/1000ML; 3.05GM/1000ML; 0.314GM/1000ML | N207026 | 001 | Jan 13, 2015 | Feb | CAHN |
| >A> | + | VANTIVE US HLTHCARE | 3.68GM/1000ML; 3.05GM/1000ML; 0.314GM/1000ML; 3.09GM/1000ML; 6.34GM/1000ML; 0.187GM/1000ML | N207026 | 001 | Jan 13, 2015 | Feb | CAHN |

CANDESARTAN CILEXETIL

TABLET; ORAL

CANDESARTAN CILEXETIL

| | | | | | | | | |
|----|--|--------------------|------|---------|-----|--------------|-----|------|
| AB | | ZYDUS LIFESCIENCES | 4MG | A091390 | 001 | Aug 23, 2017 | Jan | CMFD |
| AB | | | 8MG | A091390 | 002 | Aug 23, 2017 | Jan | CMFD |
| AB | | | 16MG | A091390 | 003 | Aug 23, 2017 | Jan | CMFD |
| AB | | | 32MG | A091390 | 004 | Aug 23, 2017 | Jan | CMFD |

CARBAMAZEPINE

TABLET, EXTENDED RELEASE; ORAL

CARBAMAZEPINE

| | | | | | | | | |
|----|--|-------------------|-------|---------|-----|--------------|-----|------|
| AB | | ALKEM LABS LTD | 100MG | A217277 | 001 | Jan 14, 2025 | Jan | NEWA |
| AB | | | 200MG | A217277 | 002 | Jan 14, 2025 | Jan | NEWA |
| AB | | | 400MG | A217277 | 003 | Jan 14, 2025 | Jan | NEWA |
| AB | | TORRENT | 100MG | A212524 | 001 | Jan 13, 2025 | Jan | NEWA |
| AB | | | 200MG | A212524 | 002 | Jan 13, 2025 | Jan | NEWA |
| AB | | | 400MG | A212524 | 003 | Jan 13, 2025 | Jan | NEWA |
| AB | | YICHANG HUMANWELL | 100MG | A219072 | 001 | Jan 16, 2025 | Jan | NEWA |
| AB | | | 200MG | A219072 | 002 | Jan 16, 2025 | Jan | NEWA |
| AB | | | 400MG | A219072 | 003 | Jan 16, 2025 | Jan | NEWA |

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

| | | | | | | | | |
|----|--|-------------------|-------------|---------|-----|--------------|-----|------|
| AB | | ASCENT PHARMS INC | 10MG; 100MG | A218939 | 001 | Jan 14, 2025 | Jan | NEWA |
| AB | | | 25MG; 100MG | A218939 | 002 | Jan 14, 2025 | Jan | NEWA |
| AB | | | 25MG; 250MG | A218939 | 003 | Jan 14, 2025 | Jan | NEWA |

CARBINOXAMINE MALEATE

TABLET; ORAL

CARBINOXAMINE MALEATE

@ SENORES PHARMS

4MG

A090435 001 Apr 15, 2010 Jan CAHN

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

| | | | | | | | | |
|----|--|---------------|-------|---------|-----|--------------|-----|------|
| AA | | FOSUN WANBANG | 350MG | A081025 | 001 | Apr 13, 1989 | Jan | CAHN |
|----|--|---------------|-------|---------|-----|--------------|-----|------|

CARVEDILOL

TABLET; ORAL

CARVEDILOL

| | | | | | | | | |
|-----|----|----------------------|---------|---------|-----|--------------|-----|------|
| >D> | AB | DR REDDYS LABS LTD | 3.125MG | A076649 | 001 | Sep 05, 2007 | Feb | CAHN |
| >D> | AB | | 6.25MG | A076649 | 002 | Sep 05, 2007 | Feb | CAHN |
| >D> | AB | | 12.5MG | A076649 | 003 | Sep 05, 2007 | Feb | CAHN |
| >D> | AB | | 25MG | A076649 | 004 | Sep 05, 2007 | Feb | CAHN |
| >A> | AB | GRAVITI PHARMS | 3.125MG | A076649 | 001 | Sep 05, 2007 | Feb | CAHN |
| >A> | AB | | 6.25MG | A076649 | 002 | Sep 05, 2007 | Feb | CAHN |
| >A> | AB | | 12.5MG | A076649 | 003 | Sep 05, 2007 | Feb | CAHN |
| >A> | AB | | 25MG | A076649 | 004 | Sep 05, 2007 | Feb | CAHN |
| >D> | | @ MYLAN | 3.125MG | A077316 | 001 | Sep 05, 2007 | Feb | CAHN |
| >D> | AB | | 6.25MG | A077316 | 002 | Sep 05, 2007 | Feb | CAHN |
| >D> | AB | | 12.5MG | A077316 | 003 | Sep 05, 2007 | Feb | CAHN |
| >D> | AB | | 25MG | A077316 | 004 | Sep 05, 2007 | Feb | CAHN |
| >A> | | @ NORVIUM BIOSCIENCE | 3.125MG | A077316 | 001 | Sep 05, 2007 | Feb | CAHN |
| >A> | AB | | 6.25MG | A077316 | 002 | Sep 05, 2007 | Feb | CAHN |
| >A> | AB | | 12.5MG | A077316 | 003 | Sep 05, 2007 | Feb | CAHN |
| >A> | AB | | 25MG | A077316 | 004 | Sep 05, 2007 | Feb | CAHN |

CEDAZURIDINE; DECITABINE

TABLET; ORAL
INQOVI

| | | | | | | | |
|-----|---|----------------|------------|---------|-----|--------------|----------|
| >D> | + | OTSUKA | 100MG;35MG | N212576 | 001 | Jul 07, 2020 | Feb CAHN |
| >A> | + | TAIHO ONCOLOGY | 100MG;35MG | N212576 | 001 | Jul 07, 2020 | Feb CAHN |

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM
QILU ANTIBIOTICS

| | | | | | | | |
|----|---|--|-------------------|---------|-----|--------------|----------|
| AP | | | EQ 3GM BASE/VIAL | A203661 | 003 | Jan 24, 2024 | Jan CAHN |
| | | | EQ 1GM BASE/VIAL | A203661 | 001 | Dec 28, 2015 | Jan CAHN |
| | | | EQ 2GM BASE/VIAL | A203661 | 002 | Mar 11, 2022 | Jan CAHN |
| AP | ! | | EQ 10GM BASE/VIAL | A209217 | 001 | Oct 17, 2018 | Jan CAHN |

CEFEPIME HYDROCHLORIDE

INJECTABLE; INJECTION
CEFEPIME HYDROCHLORIDE
! QILU ANTIBIOTICS

| | | | | | | | |
|----|---|--|--------------------|---------|-----|--------------|----------|
| AP | ! | | EQ 500MG BASE/VIAL | A203704 | 001 | Feb 01, 2016 | Jan CAHN |
| AP | ! | | EQ 1GM BASE/VIAL | A203704 | 002 | Feb 01, 2016 | Jan CAHN |
| AP | ! | | EQ 2GM BASE/VIAL | A203704 | 003 | Feb 01, 2016 | Jan CAHN |

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
CEFTRIAXONE

| | | | | | | | |
|----|--|------------------|--|---------|-----|--------------|----------|
| AP | | QILU ANTIBIOTICS | EQ 10GM BASE/VIAL | A209218 | 001 | Oct 17, 2018 | Jan CAHN |
| | | | INJECTABLE; INTRAMUSCULAR, INTRAVENOUS | | | | |
| | | | CEFTRIAXONE | | | | |
| AP | | QILU ANTIBIOTICS | EQ 250MG BASE/VIAL | A203702 | 001 | Jun 29, 2016 | Jan CAHN |
| AP | | | EQ 500MG BASE/VIAL | A203702 | 002 | Jun 29, 2016 | Jan CAHN |
| AP | | | EQ 1GM BASE/VIAL | A203702 | 003 | Jun 29, 2016 | Jan CAHN |
| AP | | | EQ 2GM BASE/VIAL | A203702 | 004 | Jun 29, 2016 | Jan CAHN |

CELECOXIB

CAPSULE; ORAL
CELECOXIB

| | | | | | | | |
|-----|---|-------------|-------|---------|-----|--------------|----------|
| >D> | @ | ACIC PHARMS | 200MG | A212925 | 001 | Dec 09, 2020 | Feb CAHN |
| >D> | @ | | 400MG | A212925 | 002 | Dec 09, 2020 | Feb CAHN |
| >A> | @ | PANGEA | 200MG | A212925 | 001 | Dec 09, 2020 | Feb CAHN |
| >A> | @ | | 400MG | A212925 | 002 | Dec 09, 2020 | Feb CAHN |

CETIRIZINE HYDROCHLORIDE

SOLUTION; ORAL
ZYRTEC

| | | | | | | | |
|-----|---|----------------------|---------|---------|-----|--------------|----------|
| >D> | @ | J AND J CONSUMER INC | 5MG/5ML | N020346 | 001 | Sep 27, 1996 | Feb CRLD |
| >A> | + | @ | 5MG/5ML | N020346 | 001 | Sep 27, 1996 | Feb CRLD |

CHENODIOL

TABLET; ORAL
CTEXLI

| | | | | | | | |
|-----|---|-------|-------|---------|-----|--------------|----------|
| >A> | + | MIRUM | 250MG | N219488 | 001 | Feb 21, 2025 | Feb NEWA |
|-----|---|-------|-------|---------|-----|--------------|----------|

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HYDROCHLORIDE

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

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

| | | | | | | | |
|--|---|------------------|------|---------|-----|--|----------|
| | @ | AIPING PHARM INC | 25MG | A087380 | 001 | | Jan CAHN |
| | @ | | 50MG | A087381 | 001 | | Jan CAHN |

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

| | | | | | | | |
|----|---------------|-------|---------|-----|--------------|-----|------|
| AA | AJENAT PHARMS | 250MG | A215540 | 001 | Jan 24, 2023 | Jan | CAHN |
|----|---------------|-------|---------|-----|--------------|-----|------|

CINACALCET HYDROCHLORIDE

TABLET; ORAL

CINACALCET HYDROCHLORIDE

| | | | | | | | |
|----|---------|--------------|---------|-----|--------------|-----|------|
| AB | PIRAMAL | EQ 30MG BASE | A210207 | 001 | Aug 01, 2018 | Jan | CAHN |
| AB | | EQ 60MG BASE | A210207 | 002 | Aug 01, 2018 | Jan | CAHN |
| AB | | EQ 90MG BASE | A210207 | 003 | Aug 01, 2018 | Jan | CAHN |

CISATRACURIUM BESYLATE

INJECTABLE; INJECTION

CISATRACURIUM BESYLATE

| | | | | | | | | |
|-----|----|--|-----------------|---------|-----|--------------|-----|------|
| >D> | AP | HAINAN POLY | EQ 2MG BASE/ML | A216538 | 001 | Mar 08, 2024 | Feb | DISC |
| >A> | | @ | EQ 2MG BASE/ML | A216538 | 001 | Mar 08, 2024 | Feb | DISC |
| >A> | AP | HENGRUI PHARMA | EQ 2MG BASE/ML | A204960 | 003 | Aug 30, 2017 | Feb | CMS1 |
| | | CISATRACURIUM BESYLATE PRESERVATIVE FREE | | | | | | |
| >D> | AP | HAINAN POLY | EQ 2MG BASE/ML | A216539 | 001 | Aug 27, 2024 | Feb | DISC |
| >A> | | @ | EQ 2MG BASE/ML | A216539 | 001 | Aug 27, 2024 | Feb | DISC |
| >D> | AP | | EQ 10MG BASE/ML | A216539 | 002 | Aug 27, 2024 | Feb | DISC |
| >A> | | @ | EQ 10MG BASE/ML | A216539 | 002 | Aug 27, 2024 | Feb | DISC |

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

| | | | | | | | | |
|-----|----|----------|------------------|---------|-----|--------------|-----|------|
| >D> | AP | ALMAJECT | EQ 150MG BASE/ML | A062800 | 001 | Jul 24, 1987 | Feb | DISC |
| >A> | | @ | EQ 150MG BASE/ML | A062800 | 001 | Jul 24, 1987 | Feb | DISC |
| >D> | AP | | EQ 150MG BASE/ML | A062943 | 001 | Sep 29, 1988 | Feb | DISC |
| >A> | | @ | EQ 150MG BASE/ML | A062943 | 001 | Sep 29, 1988 | Feb | DISC |

CLOBAZAM

SUSPENSION; ORAL

CLOBAZAM

@ VISTAPHARM LLC

2.5MG/ML

A210746 001 Jul 10, 2019 Jan CAHN

TABLET; ORAL

CLOBAZAM

| | | | | | | | | |
|-----|----|----------------|------|---------|-----|--------------|-----|------|
| >D> | | @ ALLIED | 5MG | A209308 | 003 | Oct 19, 2021 | Feb | CAHN |
| >D> | AB | | 10MG | A209308 | 001 | Oct 22, 2018 | Feb | CAHN |
| >D> | | @ | 20MG | A209308 | 002 | Oct 22, 2018 | Feb | CAHN |
| >A> | | @ ESJAY PHARMA | 5MG | A209308 | 003 | Oct 19, 2021 | Feb | CAHN |
| >A> | AB | | 10MG | A209308 | 001 | Oct 22, 2018 | Feb | CAHN |
| >A> | | @ | 20MG | A209308 | 002 | Oct 22, 2018 | Feb | CAHN |

CLOBETASOL PROPIONATE

LOTION; TOPICAL

IMPEKLO

+ @ NORVIUM BIOSCIENCE 0.05%

N213691 001 May 19, 2020 Jan CAHN

SUSPENSION/DROPS; OPHTHALMIC

CLOBETASOL PROPIONATE

| | | | | | | | | |
|-----|---|----------|-------|---------|-----|--------------|-----|------|
| >D> | + | EYENOVIA | 0.05% | N218158 | 001 | Mar 04, 2024 | Feb | CAHN |
| >A> | + | FORMOSA | 0.05% | N218158 | 001 | Mar 04, 2024 | Feb | CAHN |

CLONAZEPAM

TABLET, ORALLY DISINTEGRATING; ORAL

CLONAZEPAM

@ SUN PHARM INDS INC

0.125MG

A078654 001 Aug 27, 2014 Jan DISC

@

0.25MG

A078654 002 Aug 27, 2014 Jan DISC

@

0.5MG

A078654 003 Aug 27, 2014 Jan DISC

@

1MG

A078654 004 Aug 27, 2014 Jan DISC

@

2MG

A078654 005 Aug 27, 2014 Jan DISC

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE

| | | | | | | | | |
|-----|----|---------------------------|----------------------|---------|-----|--------------|-----|------|
| >D> | AA | WOCKHARDT BIO AG | 10MG/5ML; 6.25MG/5ML | A088875 | 001 | Dec 17, 1984 | Feb | CAHN |
| >A> | AA | XTTRIUM LABS INC | 10MG/5ML; 6.25MG/5ML | A088875 | 001 | Dec 17, 1984 | Feb | CAHN |
| | | PROMETHAZINE WITH CODEINE | | | | | | |
| | | @ PHARM ASSOC | 10MG/5ML; 6.25MG/5ML | A040650 | 001 | Jan 31, 2006 | Jan | DISC |

COPPER

SYSTEM; INTRAUTERINE
 >A> MIUDELLA
 >A> +! SEBELA WOMENS HLTH N/A N218201 001 Feb 24, 2025 Feb NEWA

COPPER CU-64 DOTATATE

SOLUTION; INTRAVENOUS
 DETECTNET
 +! CURIUM 4mL (1mCi/ML) N213227 001 Sep 03, 2020 Jan CAHN

CROMOLYN SODIUM

CONCENTRATE; ORAL
 GASTROCROM
 >D> AA +! MYLAN SPECIALITY LP 100MG/5ML N020479 001 Feb 29, 1996 Feb CAHN
 >A> AA +! VIATRIS SPECIALTY 100MG/5ML N020479 001 Feb 29, 1996 Feb CAHN

CUPRIC SULFATE

INJECTABLE; INJECTION
 CUPRIC SULFATE
 ! AM REAGENT EQ 0.4MG COPPER/ML A216324 001 Dec 16, 2022 Jan CTEC
 @ APOTEX CORP EQ 0.4MG COPPER/ML A218745 001 Aug 19, 2024 Jan DISC

CYANOCOBALAMIN

INJECTABLE; INJECTION
 DODEX
 @ ACCORD HLTHCARE 1MG/ML A083022 001 Jan DISC

CYCLOSPORINE

SOLUTION; ORAL
 CYCLOSPORINE
 >D> AB1 ABBVIE 100MG/ML A065025 001 Mar 03, 2000 Feb DISC
 >A> @ 100MG/ML A065025 001 Mar 03, 2000 Feb DISC

DABIGATRAN ETEXILATE MESYLATE

CAPSULE; ORAL
 DABIGATRAN ETEXILATE MESYLATE
 AB DR REDDYS EQ 75MG BASE A208048 001 Jan 28, 2025 Jan NEWA
 AB EQ 110MG BASE A208048 002 Jan 28, 2025 Jan NEWA
 AB EQ 150MG BASE A208048 003 Jan 28, 2025 Jan NEWA
 AB MYLAN EQ 75MG BASE A208067 001 Feb 03, 2025 Jan NEWA
 AB EQ 150MG BASE A208067 002 Feb 03, 2025 Jan NEWA

DALFAMPRIDINE

TABLET, EXTENDED RELEASE; ORAL
 AMPYRA
 >A> AB +! MERZ 10MG N022250 001 Jan 22, 2010 Feb CAHN
 >D> AB +! MERZ PHARMS 10MG N022250 001 Jan 22, 2010 Feb CAHN

DAPTOMYCIN

POWDER; INTRAVENOUS
 DAPTOMYCIN
 @ FRESENIUS KABI USA 350MG/VIAL A213396 001 Aug 01, 2024 Jan DISC

DARUNAVIR

TABLET; ORAL
 DARUNAVIR
 AB ANNORA PHARMA 600MG A216168 001 Jan 21, 2025 Jan NEWA
 AB 800MG A216168 002 Jan 21, 2025 Jan NEWA

DASATINIB

TABLET; ORAL
 DASATINIB
 >A> AB BIOCON PHARMA 20MG A217217 001 Mar 03, 2025 Feb NEWA
 >A> AB 50MG A217217 002 Mar 03, 2025 Feb NEWA
 >A> AB 70MG A217217 003 Mar 03, 2025 Feb NEWA
 >A> AB 80MG A217217 004 Mar 03, 2025 Feb NEWA
 >A> AB 100MG A217217 005 Mar 03, 2025 Feb NEWA
 >A> AB 140MG A217217 006 Mar 03, 2025 Feb NEWA
 >A> AB DR REDDYS 20MG A213383 001 Mar 03, 2025 Feb NEWA
 >A> AB 50MG A213383 002 Mar 03, 2025 Feb NEWA
 >A> AB 70MG A213383 003 Mar 03, 2025 Feb NEWA

TABLET;ORAL
DASATINIB

| | | | | | | | | |
|---------|----|--------------|-------|---------|-----|--------------|-----|------|
| >A> | AB | | 80MG | A213383 | 004 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 100MG | A213383 | 005 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 140MG | A213383 | 006 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | ZYDUS PHARMS | 20MG | A218719 | 001 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 50MG | A218719 | 002 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 70MG | A218719 | 003 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 80MG | A218719 | 004 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 100MG | A218719 | 005 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 140MG | A218719 | 006 | Mar 03, 2025 | Feb | NEWA |
| PHYRAGO | | | | | | | | |
| + | | HANDA THERAP | 20MG | N216099 | 001 | Dec 05, 2023 | Jan | CAHN |
| + | | | 50MG | N216099 | 002 | Dec 05, 2023 | Jan | CAHN |
| + | | | 70MG | N216099 | 003 | Dec 05, 2023 | Jan | CAHN |
| + | | | 80MG | N216099 | 004 | Dec 05, 2023 | Jan | CAHN |
| + | ! | | 100MG | N216099 | 005 | Dec 05, 2023 | Jan | CAHN |
| + | | | 140MG | N216099 | 006 | Dec 05, 2023 | Jan | CAHN |

DESLORATADINE

TABLET;ORAL
DESLORATADINE

| | | | | | | | | |
|----|--|---------------|-----|---------|-----|--------------|-----|------|
| AB | | AJENAT PHARMS | 5MG | A078355 | 001 | Apr 19, 2012 | Jan | CAHN |
|----|--|---------------|-----|---------|-----|--------------|-----|------|

DESVENLAFAXINE SUCCINATE

TABLET, EXTENDED RELEASE;ORAL
DESVENLAFAXINE SUCCINATE

| | | | | | | | | |
|-----|----|----------------------|---------------|---------|-----|--------------|-----|------|
| >D> | AB | INTELLIPHARMACEUTICS | EQ 50MG BASE | A204805 | 001 | May 07, 2019 | Feb | CAHN |
| >D> | AB | | EQ 100MG BASE | A204805 | 002 | May 07, 2019 | Feb | CAHN |
| | AB | MACLEODS PHARMS LTD | EQ 50MG BASE | A211427 | 001 | Jan 15, 2025 | Jan | NEWA |
| | AB | | EQ 100MG BASE | A211427 | 002 | Jan 15, 2025 | Jan | NEWA |
| >A> | AB | MEDICAP LABS | EQ 50MG BASE | A204805 | 001 | May 07, 2019 | Feb | CAHN |
| >A> | AB | | EQ 100MG BASE | A204805 | 002 | May 07, 2019 | Feb | CAHN |

DEUTETRABENAZINE

TABLET;ORAL
AUSTEDO

| | | | | | | | | |
|------------------|---|----------------------|------|---------|-----|--------------|-----|------|
| >D> | + | TEVA BRANDED PHARM | 6MG | N208082 | 001 | Apr 03, 2017 | Feb | CAHN |
| >A> | + | | 6MG | N208082 | 001 | Apr 03, 2017 | Feb | CAHN |
| | + | | 6MG | N208082 | 001 | Apr 03, 2017 | Jan | CTEC |
| >D> | + | | 9MG | N208082 | 002 | Apr 03, 2017 | Feb | CAHN |
| >A> | + | | 9MG | N208082 | 002 | Apr 03, 2017 | Feb | CAHN |
| | + | | 9MG | N208082 | 002 | Apr 03, 2017 | Jan | CTEC |
| >D> | + | | 12MG | N208082 | 003 | Apr 03, 2017 | Feb | CAHN |
| >A> | + | | 12MG | N208082 | 003 | Apr 03, 2017 | Feb | CAHN |
| | + | | 12MG | N208082 | 003 | Apr 03, 2017 | Jan | CTEC |
| DEUTETRABENAZINE | | | | | | | | |
| | @ | AUROBINDO PHARMA LTD | 6MG | A215971 | 001 | Dec 26, 2024 | Jan | DISC |
| | @ | | 9MG | A215971 | 002 | Dec 26, 2024 | Jan | DISC |
| | @ | | 12MG | A215971 | 003 | Dec 26, 2024 | Jan | DISC |

DEXCHLORPHENIRAMINE MALEATE

SYRUP;ORAL
POLMON

| | | | | | | | | |
|-----|---|---------------------|---------|---------|-----|--------------|-----|------|
| >D> | ! | CAPELLON PHARMS LLC | 2MG/5ML | A202520 | 001 | Jul 16, 2018 | Feb | CAHN |
| >A> | ! | CARWIN PHARMS | 2MG/5ML | A202520 | 001 | Jul 16, 2018 | Feb | CAHN |

DEXMETHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL
DEXMETHYLPHENIDATE HYDROCHLORIDE

| | | | | | | | | |
|-----|----|----------------------|------|---------|-----|--------------|-----|------|
| >D> | AB | INTELLIPHARMACEUTICS | 5MG | A078992 | 001 | Nov 23, 2021 | Feb | CAHN |
| >D> | AB | | 10MG | A078992 | 002 | Nov 23, 2021 | Feb | CAHN |
| >D> | AB | | 15MG | A078992 | 003 | Nov 18, 2013 | Feb | CAHN |
| >D> | AB | | 30MG | A078992 | 004 | Nov 18, 2013 | Feb | CAHN |
| >D> | AB | | 20MG | A078992 | 005 | Nov 23, 2021 | Feb | CAHN |
| >D> | AB | | 40MG | A078992 | 006 | Nov 23, 2021 | Feb | CAHN |
| >A> | AB | MEDICAP LABS | 5MG | A078992 | 001 | Nov 23, 2021 | Feb | CAHN |
| >A> | AB | | 10MG | A078992 | 002 | Nov 23, 2021 | Feb | CAHN |
| >A> | AB | | 15MG | A078992 | 003 | Nov 18, 2013 | Feb | CAHN |
| >A> | AB | | 30MG | A078992 | 004 | Nov 18, 2013 | Feb | CAHN |
| >A> | AB | | 20MG | A078992 | 005 | Nov 23, 2021 | Feb | CAHN |
| >A> | AB | | 40MG | A078992 | 006 | Nov 23, 2021 | Feb | CAHN |

TABLET;ORAL

DEXMETHYLPHENIDATE HYDROCHLORIDE

@ RHODES PHARMS 2.5MG
 @ 5MG
 @ 10MG

A208756 001 Nov 20, 2017 Jan DISC
 A208756 002 Nov 20, 2017 Jan DISC
 A208756 003 Nov 20, 2017 Jan DISC

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL

PROMETHAZINE W/ DEXTROMETHORPHAN

>D> AA WOCHKHARDT BIO AG 15MG/5ML;6.25MG/5ML
 >A> AA XTTRIUM LABS INC 15MG/5ML;6.25MG/5ML

A088864 001 Jan 04, 1985 Feb CAHN
 A088864 001 Jan 04, 1985 Feb CAHN

DICLOFENAC POTASSIUM

FOR SOLUTION;ORAL

DICLOFENAC POTASSIUM

AB TORRENT 50MG

A215891 001 Jan 22, 2025 Jan NEWA

DIFLUPREDNATE

EMULSION;OPHTHALMIC

DIFLUPREDNATE

AB UPSHER SMITH LABS 0.05%

A218191 001 Feb 11, 2025 Jan NEWA

DIHYDROERGOTAMINE MESYLATE

INJECTABLE;INJECTION

DIHYDROERGOTAMINE MESYLATE

@ CIPLA 1MG/ML

A212334 001 Sep 20, 2024 Jan DISC

SPRAY, METERED;NASAL

DIHYDROERGOTAMINE MESYLATE

>A> AB AGGREGA 0.5MG/SPRAY

A215228 001 Feb 26, 2025 Feb NEWA

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

DILTIAZEM HYDROCHLORIDE

>D> AB3 SUN PHARM 300MG

A203023 004 Jun 08, 2017 Feb DISC

>A> @ 300MG

A203023 004 Jun 08, 2017 Feb DISC

SOLUTION;INTRAVENOUS

DILTIAZEM HYDROCHLORIDE IN 0.72% SODIUM CHLORIDE

>A> +! HQ SPCLT PHARMA 100MG/100ML (1MG/ML)

N218038 001 Feb 21, 2025 Feb NEWA

>A> +! 250MG/250ML (1MG/ML)

N218038 002 Feb 21, 2025 Feb NEWA

DIMETHYL FUMARATE

CAPSULE, DELAYED RELEASE;ORAL

DIMETHYL FUMARATE

>D> AB CIPLA 120MG

A210305 001 Sep 24, 2020 Feb DISC

>A> @ 120MG

A210305 001 Sep 24, 2020 Feb DISC

>D> AB 240MG

A210305 002 Sep 24, 2020 Feb DISC

>A> @ 240MG

A210305 002 Sep 24, 2020 Feb DISC

DIPHENHYDRAMINE HYDROCHLORIDE

INJECTABLE;INJECTION

DIPHENHYDRAMINE HYDROCHLORIDE

>D> AP ! MYLAN INSTITUTIONAL 50MG/ML

A040498 001 Jul 12, 2005 Feb CAHN

>A> AP ! NORVIUM BIOSCIENCE 50MG/ML

A040498 001 Jul 12, 2005 Feb CAHN

DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

MEMANTINE HYDROCHLORIDE AND DONEPEZIL HYDROCHLORIDE

>A> AB AMNEAL 10MG;7MG

A208328 003 Feb 27, 2025 Feb NFTG

>A> AB 10MG;21MG

A208328 004 Feb 27, 2025 Feb NEWA

NAMZARIC

>D> + ABBVIE 10MG;7MG

N206439 003 Jul 18, 2016 Feb CFTG

>A> AB + 10MG;7MG

N206439 003 Jul 18, 2016 Feb CFTG

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE

AT SOMERSET THERAPS LLC EQ 2% BASE

A215004 001 Feb 11, 2025 Jan NEWA

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC
DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE

>A> AT2 IDENTIRX EQ 2% BASE;EQ 0.5% BASE A216308 001 Feb 18, 2025 Feb NEWA

DOXEPIH HYDROCHLORIDE

CAPSULE;ORAL
DOXEPIH HYDROCHLORIDE

@ ADAPTIS EQ 150MG BASE A213796 001 Apr 19, 2022 Jan DISC

DOXYCYCLINE

CAPSULE;ORAL
DOXYCYCLINE

AB PRINSTON INC 40MG A217098 001 Jan 27, 2025 Jan NEWA

DOXYCYCLINE HYCLATE

CAPSULE;ORAL
DOXYCYCLINE HYCLATE

>D> AB HIKMA INTL PHARMS EQ 100MG BASE A062396 001 May 07, 1984 Feb CHRS

>A> AB ! EQ 100MG BASE A062396 001 May 07, 1984 Feb CHRS

VIBRAMYCIN

>D> AB +! PFIZER EQ 100MG BASE N050007 002 Feb DISC

>A> + @ EQ 100MG BASE N050007 002 Feb DISC

INJECTABLE;INJECTION
DOXYCYCLINE HYCLATE

@ AMNEAL EQ 100MG BASE/VIAL A217487 001 Dec 04, 2024 Jan DISC

>A> AP PRECISION DOSE INC EQ 100MG BASE/VIAL A217078 001 Feb 21, 2025 Feb NEWA

EFLORNITHINE HYDROCHLORIDE

CREAM;TOPICAL
VANIQA

>A> + @ ABBVIE 13.9% N021145 001 Jul 27, 2000 Feb CAHN

>D> + @ SKINMEDICA 13.9% N021145 001 Jul 27, 2000 Feb CAHN

ELIGLUSTAT TARTRATE

CAPSULE;ORAL
ELIGLUSTAT TARTRATE

@ APOTEX EQ 84MG BASE A212425 001 Jul 10, 2024 Jan DISC

ELTROMBOPAG OLAMINE

TABLET;ORAL
ELTROMBOPAG OLAMINE

AB HETERO LABS LTD V EQ 12.5MG ACID A206788 001 Jan 17, 2025 Jan NFTG

AB EQ 25MG ACID A206788 002 Jan 17, 2025 Jan NFTG

AB EQ 50MG ACID A206788 003 Jan 17, 2025 Jan NFTG

AB EQ 75MG ACID A206788 004 Jan 17, 2025 Jan NFTG

PROMACTA

AB + NOVARTIS EQ 12.5MG ACID N022291 004 Oct 20, 2011 Jan CFTG

AB + EQ 25MG ACID N022291 001 Nov 20, 2008 Jan CFTG

AB + EQ 50MG ACID N022291 002 Nov 20, 2008 Jan CFTG

AB +! EQ 75MG ACID N022291 003 Sep 08, 2009 Jan CFTG

EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL
EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

>A> AB HETERO LABS LTD III 100MG;150MG A201806 002 Mar 03, 2025 Feb NEWA

>A> AB 133MG;200MG A201806 003 Mar 03, 2025 Feb NEWA

>A> AB 167MG;250MG A201806 004 Mar 03, 2025 Feb NEWA

ENZALUTAMIDE

CAPSULE;ORAL
ENZALUTAMIDE

>D> AB ZYDUS PHARMS 40MG A209667 001 Sep 26, 2024 Feb DISC

>A> @ 40MG A209667 001 Sep 26, 2024 Feb DISC

XTANDI

>D> AB +! ASTELLAS 40MG N203415 001 Aug 31, 2012 Feb CTEC

>A> +! 40MG N203415 001 Aug 31, 2012 Feb CTEC

EPHEDRINE SULFATE

SOLUTION;INTRAVENOUS
EMERPHED

| | | | | | | | |
|-----|----|--------------------|--------------------|---------|-----|--------------|----------|
| AP | + | NEXUS | 50MG/10ML (5MG/ML) | N213407 | 001 | Apr 17, 2020 | Jan CFTG |
| | | EPHEDRINE SULFATE | | | | | |
| >D> | + | ENDO OPERATIONS | 25MG/5ML (5MG/ML) | N213994 | 002 | Apr 22, 2022 | Feb CFTG |
| >A> | AP | + | 25MG/5ML (5MG/ML) | N213994 | 002 | Apr 22, 2022 | Feb CFTG |
| >D> | + | | 50MG/10ML (5MG/ML) | N213994 | 001 | Oct 16, 2020 | Feb CFTG |
| >A> | AP | + | 50MG/10ML (5MG/ML) | N213994 | 001 | Oct 16, 2020 | Feb CFTG |
| >A> | AP | FRESENIUS KABI USA | 25MG/5ML (5MG/ML) | A218271 | 001 | Mar 11, 2025 | Feb NFTG |
| >A> | AP | | 50MG/10ML (5MG/ML) | A218271 | 002 | Mar 11, 2025 | Feb NFTG |
| AP | | GLAND PHARMA LTD | 50MG/10ML (5MG/ML) | A218211 | 001 | Jan 16, 2025 | Jan NFTG |

EPINASTINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC
EPINASTINE HYDROCHLORIDE

| | | | | | | | |
|-----|---|---------------|-------|---------|-----|--------------|----------|
| >D> | @ | BRECKENRIDGE | 0.05% | A090870 | 001 | Mar 14, 2011 | Feb CAHN |
| >A> | @ | RENOVA PHARMS | 0.05% | A090870 | 001 | Mar 14, 2011 | Feb CAHN |

EPINEPHRINE

SOLUTION;INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS
EPINEPHRINE

| | | | | | | | |
|----|---|----------|--------------------|---------|-----|--------------|----------|
| AP | + | BPI LABS | 10MG/10ML (1MG/ML) | N205029 | 002 | Feb 04, 2022 | Jan CFTG |
|----|---|----------|--------------------|---------|-----|--------------|----------|

EPINEPHRINE BITARTRATE

SOLUTION;INTRAVENOUS
EPINEPHRINE BITARTRATE IN 0.9% SODIUM CHLORIDE

| | | | | | | | |
|-----|---|----------------------|---------------------------------------|---------|-----|--------------|----------|
| >A> | + | BAXTER HLTHCARE CORP | EQ 16MG BASE/250ML (EQ 64MCG BASE/ML) | N218475 | 001 | Feb 28, 2025 | Feb NEWA |
|-----|---|----------------------|---------------------------------------|---------|-----|--------------|----------|

ERIBULIN MESYLATE

SOLUTION;INTRAVENOUS
ERIBULIN MESYLATE

| | | | | | | | |
|-----|----|-------------------|--------------------|---------|-----|--------------|----------|
| >A> | AP | CHIA TAI TIANQING | 1MG/2ML (0.5MG/ML) | A218743 | 001 | Mar 04, 2025 | Feb NEWA |
|-----|----|-------------------|--------------------|---------|-----|--------------|----------|

ERLOTINIB HYDROCHLORIDE

TABLET;ORAL
ERLOTINIB HYDROCHLORIDE

| | | | | | | | |
|-----|----|-----------|---------------|---------|-----|--------------|----------|
| | @ | APOTEX | EQ 25MG BASE | A208396 | 001 | Nov 05, 2019 | Jan DISC |
| | @ | | EQ 100MG BASE | A208396 | 002 | Nov 05, 2019 | Jan DISC |
| | @ | | EQ 150MG BASE | A208396 | 003 | Nov 05, 2019 | Jan DISC |
| | @ | SUN PHARM | EQ 25MG BASE | A210300 | 001 | Nov 05, 2019 | Jan DISC |
| >D> | AB | | EQ 100MG BASE | A210300 | 002 | Nov 05, 2019 | Feb DISC |
| >A> | @ | | EQ 100MG BASE | A210300 | 002 | Nov 05, 2019 | Feb DISC |
| | @ | | EQ 150MG BASE | A210300 | 003 | Nov 05, 2019 | Jan DISC |

ERTUGLIFLOZIN

TABLET;ORAL
ERTUGLIFLOZIN

| | | | | | | | |
|-----|----|-------|------|---------|-----|--------------|----------|
| >D> | AB | HIKMA | 5MG | A216842 | 001 | Jan 21, 2025 | Feb DISC |
| >A> | @ | | 5MG | A216842 | 001 | Jan 21, 2025 | Feb DISC |
| | AB | | 5MG | A216842 | 001 | Jan 21, 2025 | Jan NEWA |
| >D> | AB | | 15MG | A216842 | 002 | Jan 21, 2025 | Feb DISC |
| >A> | @ | | 15MG | A216842 | 002 | Jan 21, 2025 | Feb DISC |
| | AB | | 15MG | A216842 | 002 | Jan 21, 2025 | Jan NEWA |

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS;ORAL
ESOMEPRAZOLE MAGNESIUM

| | | | | | | | |
|-----|----|----------------------|--------------|---------|-----|--------------|----------|
| >D> | AB | IVAX SUB TEVA PHARMS | EQ 20MG BASE | A078003 | 001 | Jan 26, 2015 | Feb DISC |
| >A> | @ | | EQ 20MG BASE | A078003 | 001 | Jan 26, 2015 | Feb DISC |
| >D> | AB | | EQ 40MG BASE | A078003 | 002 | Jan 26, 2015 | Feb DISC |
| >A> | @ | | EQ 40MG BASE | A078003 | 002 | Jan 26, 2015 | Feb DISC |

FOR SUSPENSION, DELAYED RELEASE;ORAL
ESOMEPRAZOLE MAGNESIUM

| | | | | | | | |
|-----|----|---------|----------------------|---------|-----|--------------|----------|
| >A> | AB | TORRENT | EQ 2.5MG BASE/PACKET | A212651 | 001 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | EQ 5MG BASE/PACKET | A212651 | 002 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | EQ 10MG BASE/PACKET | A212652 | 001 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | EQ 20MG BASE/PACKET | A212651 | 003 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | EQ 40MG BASE/PACKET | A212651 | 004 | Mar 05, 2025 | Feb NEWA |

ESOMEPRAZOLE MAGNESIUM; NAPROXEN

TABLET, DELAYED RELEASE;ORAL
 NAPROXEN AND ESOMEPRAZOLE MAGNESIUM

| | | | | | | |
|-----|----------------------|--------------------|---------|-----|--------------|----------|
| >D> | @ MYLAN | EQ 20MG BASE;375MG | A204920 | 001 | Jul 20, 2021 | Feb CAHN |
| >D> | @ | EQ 20MG BASE;500MG | A204920 | 002 | Jul 20, 2021 | Feb CAHN |
| >A> | @ NORVIUM BIOSCIENCE | EQ 20MG BASE;375MG | A204920 | 001 | Jul 20, 2021 | Feb CAHN |
| >A> | @ | EQ 20MG BASE;500MG | A204920 | 002 | Jul 20, 2021 | Feb CAHN |

ESOMEPRAZOLE SODIUM

INJECTABLE;INTRAVENOUS
 ESOMEPRAZOLE SODIUM

| | | | | | | |
|----|---------|-------------------|---------|-----|--------------|----------|
| AP | YANGTZE | EQ 40MG BASE/VIAL | A214046 | 001 | Jan 08, 2025 | Jan NEWA |
|----|---------|-------------------|---------|-----|--------------|----------|

ESTRADIOL

CREAM;VAGINAL
 ESTRADIOL

| | | | | | | |
|----|--------|-------|---------|-----|--------------|----------|
| AB | ENCUBE | 0.01% | A209767 | 001 | Mar 05, 2018 | Jan CAHN |
|----|--------|-------|---------|-----|--------------|----------|

GEL;TRANSDERMAL
 ESTRADIOL

| | | | | | | | |
|-----|----|--------|----------------------|---------|-----|--------------|----------|
| >A> | AB | ENCUBE | 0.1% (0.25GM/PACKET) | A218507 | 001 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | 0.1% (0.5GM/PACKET) | A218507 | 002 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | 0.1% (0.75GM/PACKET) | A218507 | 003 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | 0.1% (1.25GM/PACKET) | A218507 | 005 | Mar 05, 2025 | Feb NEWA |
| >A> | AB | | 0.1% (1GM/PACKET) | A218507 | 004 | Mar 05, 2025 | Feb NEWA |

GEL, METERED;TRANSDERMAL
 ELESTRIN

| | | | | | | | |
|-----|---|---------------------|---------------------------|---------|-----|--------------|----------|
| >D> | + | MYLAN SPECIALITY LP | 0.06% (0.87GM/ACTIVATION) | N021813 | 001 | Dec 15, 2006 | Feb CAHN |
| >A> | + | VIATRIS | 0.06% (0.87GM/ACTIVATION) | N021813 | 001 | Dec 15, 2006 | Feb CAHN |

EVEROLIMUS

TABLET, FOR SUSPENSION;ORAL
 EVEROLIMUS

| | | | | | | |
|----|--------|-----|---------|-----|--------------|----------|
| AB | AMNEAL | 2MG | A218863 | 001 | Jan 10, 2025 | Jan NEWA |
| AB | | 3MG | A218863 | 002 | Jan 10, 2025 | Jan NEWA |
| AB | | 5MG | A218863 | 003 | Jan 10, 2025 | Jan NEWA |
| AB | NATCO | 2MG | A217640 | 001 | Jan 28, 2025 | Jan NEWA |
| AB | | 3MG | A217640 | 002 | Jan 28, 2025 | Jan NEWA |
| AB | | 5MG | A217640 | 003 | Jan 28, 2025 | Jan NEWA |

EZETIMIBE; SIMVASTATIN

TABLET;ORAL
 EZETIMIBE AND SIMVASTATIN

| | | | | | | |
|----|---------|-----------|---------|-----|--------------|----------|
| AB | TORRENT | 10MG;10MG | A209461 | 001 | Jan 27, 2025 | Jan NEWA |
| AB | | 10MG;20MG | A209461 | 002 | Jan 27, 2025 | Jan NEWA |
| AB | | 10MG;40MG | A209461 | 003 | Jan 27, 2025 | Jan NEWA |
| AB | | 10MG;80MG | A209461 | 004 | Jan 27, 2025 | Jan NEWA |

FAMOTIDINE; IBUPROFEN

TABLET;ORAL
 FAMOTIDINE AND IBUPROFEN

| | | | | | | |
|-----|--------------------------|--------------|---------|-----|--------------|----------|
| >D> | @ TORRENT | 26.6MG;800MG | A215925 | 001 | Mar 18, 2024 | Feb CTNA |
| >D> | FAMOTIDINE; IBUPROFEN | | | | | |
| >D> | AB ENDO OPERATIONS | 26.6MG;800MG | A203658 | 001 | Mar 22, 2024 | Feb CTNA |
| >A> | IBUPROFEN AND FAMOTIDINE | | | | | |
| >A> | AB ENDO OPERATIONS | 26.6MG;800MG | A203658 | 001 | Mar 22, 2024 | Feb CTNA |
| >A> | @ TORRENT | 26.6MG;800MG | A215925 | 001 | Mar 18, 2024 | Feb CTNA |
| >A> | AB ZYDUS PHARMS | 26.6MG;800MG | A218684 | 001 | Feb 20, 2025 | Feb NEWA |

FEBUXOSTAT

TABLET;ORAL
 FEBUXOSTAT

| | | | | | | |
|----|-----|------|---------|-----|--------------|----------|
| AB | MSN | 40MG | A210461 | 001 | Dec 30, 2019 | Jan CTEC |
| AB | | 80MG | A210461 | 002 | Dec 30, 2019 | Jan CTEC |

FENOFIBRATE

TABLET;ORAL
 FENOFIBRATE

| | | | | | | |
|-----|----------|-------|---------|-----|--------------|----------|
| >D> | AB MYLAN | 54MG | A076520 | 001 | Oct 25, 2007 | Feb DISC |
| >A> | @ | 54MG | A076520 | 001 | Oct 25, 2007 | Feb DISC |
| >D> | AB | 160MG | A076520 | 003 | Oct 25, 2007 | Feb DISC |
| >A> | @ | 160MG | A076520 | 003 | Oct 25, 2007 | Feb DISC |

TABLET;ORAL
FENOFIBRATE
@ SUN PHARM

48MG

A200884 001 Sep 07, 2017 Jan DISC

FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS
FLUDEOXYGLUCOSE F18

>A> AP BAMF 20-400mCi/ML

A216125 001 Mar 11, 2025 Feb NEWA

FLUOCINONIDE

CREAM;TOPICAL
FLUOCINONIDE

>D> @ ENCUBE 0.05%

A211410 001 Oct 16, 2018 Feb CMFD

>A> AB1 0.05%

A211410 001 Oct 16, 2018 Feb CMFD

GEL;TOPICAL
FLUOCINONIDE

>D> @ PADAGIS US 0.05%

A209030 001 Jun 19, 2018 Feb CMFD

>A> AB 0.05%

A209030 001 Jun 19, 2018 Feb CMFD

SOLUTION;TOPICAL
FLUOCINONIDE

>D> @ PAI HOLDINGS PHARM 0.05%

A207554 001 Mar 18, 2019 Feb CAHN

>A> AT QUAGEN 0.05%

A216389 001 Feb 26, 2025 Feb NEWA

>A> @ SAPTALIS PHARMS 0.05%

A207554 001 Mar 18, 2019 Feb CAHN

FLUORODOPA F-18

SOLUTION;INTRAVENOUS
FLUORODOPA F18

>D> +! FEINSTEIN 0.42-8.33mCi/ML

N200655 001 Oct 10, 2019 Feb CPOT

>A> +! 1-40mCi/ML

N200655 001 Oct 10, 2019 Feb CPOT

FLUOROURACIL

CREAM;TOPICAL
FLUOROURACIL

AB ENCUBE 5%

A216942 001 Feb 12, 2025 Jan NEWA

INJECTABLE;INJECTION
FLUOROURACIL

AP KINDOS 5GM/100ML (50MG/ML)

A215699 001 Feb 06, 2025 Jan NEWA

FLUOXETINE HYDROCHLORIDE

TABLET;ORAL
FLUOXETINE HYDROCHLORIDE

>A> @ APPCO EQ 10MG BASE

A211696 001 Jan 30, 2019 Feb CAHN

>A> @ EQ 20MG BASE

A211696 002 Jan 30, 2019 Feb CAHN

>D> @ UPSHER SMITH LABS EQ 10MG BASE

A211696 001 Jan 30, 2019 Feb CAHN

>D> @ EQ 20MG BASE

A211696 002 Jan 30, 2019 Feb CAHN

FLUOXETINE HYDROCHLORIDE; OLANZAPINE

CAPSULE;ORAL
SYMBYAX

>D> AB + LILLY EQ 25MG BASE;EQ 3MG BASE

N021520 001 Apr 09, 2007 Feb DISC

>A> + @ EQ 25MG BASE;EQ 3MG BASE

N021520 001 Apr 09, 2007 Feb DISC

>D> AB + EQ 25MG BASE;EQ 6MG BASE

N021520 002 Dec 24, 2003 Feb DISC

>A> + @ EQ 25MG BASE;EQ 6MG BASE

N021520 002 Dec 24, 2003 Feb DISC

>D> AB + EQ 25MG BASE;EQ 12MG BASE

N021520 004 Dec 24, 2003 Feb DISC

>A> + @ EQ 25MG BASE;EQ 12MG BASE

N021520 004 Dec 24, 2003 Feb DISC

>D> AB +! EQ 50MG BASE;EQ 6MG BASE

N021520 003 Dec 24, 2003 Feb DISC

>A> + @ EQ 50MG BASE;EQ 6MG BASE

N021520 003 Dec 24, 2003 Feb DISC

>D> AB + EQ 50MG BASE;EQ 12MG BASE

N021520 005 Dec 24, 2003 Feb DISC

>A> + @ EQ 50MG BASE;EQ 12MG BASE

N021520 005 Dec 24, 2003 Feb DISC

FLUPHENAZINE HYDROCHLORIDE

TABLET;ORAL
FLUPHENAZINE HYDROCHLORIDE

>D> AB CHARTWELL RX 1MG

A215141 001 Oct 20, 2021 Feb CAHN

>D> AB 2.5MG

A215141 002 Oct 20, 2021 Feb CAHN

>D> AB 5MG

A215141 003 Oct 20, 2021 Feb CAHN

>D> AB 10MG

A215141 004 Oct 20, 2021 Feb CAHN

>A> AB ZAMEER PHARMS 1MG

A215141 001 Oct 20, 2021 Feb CAHN

>A> AB 2.5MG

A215141 002 Oct 20, 2021 Feb CAHN

>A> AB 5MG

A215141 003 Oct 20, 2021 Feb CAHN

>A> AB 10MG

A215141 004 Oct 20, 2021 Feb CAHN

FORMOTEROL FUMARATE

SOLUTION; INHALATION
FORMOTEROL FUMARATE

| | | | | | | | |
|-------------|-----------------|----------------------|------------|---------|--------------|--------------|----------|
| AN | DEVA HOLDING AS | 0.02MG/2ML | A218308 | 001 | Feb 11, 2025 | Jan | NEWA |
| AN | DR REDDYS | 0.02MG/2ML | A215907 | 001 | Jan 30, 2025 | Jan | NEWA |
| PERFOROMIST | | | | | | | |
| >D> | AN | +! MYLAN SPECLT | 0.02MG/2ML | N022007 | 001 | May 11, 2007 | Feb CAHN |
| >A> | AN | +! VIATRIS SPECIALTY | 0.02MG/2ML | N022007 | 001 | May 11, 2007 | Feb CAHN |

FOSAPREPITANT DIMEGLUMINE

POWDER; INTRAVENOUS
FOSAPREPITANT DIMEGLUMINE

@ PRAXGEN EQ 150MG BASE/VIAL

| | | | | |
|---------|-----|--------------|-----|------|
| A213199 | 001 | Oct 04, 2021 | Jan | CAHN |
|---------|-----|--------------|-----|------|

FUROSEMIDE

TABLET; ORAL
FUROSEMIDE

| | | | | | | | |
|-----|----------------------|------|---------|-----|--------------|-----|------|
| >D> | @ MYLAN | 80MG | A070082 | 001 | Oct 29, 1986 | Feb | CAHN |
| >A> | @ NORVIUM BIOSCIENCE | 80MG | A070082 | 001 | Oct 29, 1986 | Feb | CAHN |

GABAPENTIN

SOLUTION; ORAL
GABAPENTIN

AA AJENAT PHARMS 250MG/5ML

| | | | | |
|---------|-----|--------------|-----|------|
| A091286 | 001 | Mar 14, 2016 | Jan | CAHN |
|---------|-----|--------------|-----|------|

GADOTERIDOL

INJECTABLE; INJECTION
GADOTERIDOL

AP HAINAN POLY 279.3MG/ML

| | | | | |
|---------|-----|--------------|-----|------|
| A218749 | 001 | Feb 11, 2025 | Jan | NFTG |
|---------|-----|--------------|-----|------|

AP +! BRACCO 279.3MG/ML

| | | | | |
|---------|-----|--------------|-----|------|
| N020131 | 001 | Nov 16, 1992 | Jan | CFTG |
|---------|-----|--------------|-----|------|

GLIMEPIRIDE

TABLET; ORAL
AMARYL

| | | | | | | | | |
|-----|----|----------------------|-----|---------|-----|--------------|-----|------|
| >D> | AB | +! SANOFI AVENTIS US | 1MG | N020496 | 001 | Nov 30, 1995 | Feb | DISC |
| >A> | | + @ | 1MG | N020496 | 001 | Nov 30, 1995 | Feb | DISC |
| >D> | AB | + | 2MG | N020496 | 002 | Nov 30, 1995 | Feb | DISC |
| >A> | | + @ | 2MG | N020496 | 002 | Nov 30, 1995 | Feb | DISC |
| >D> | AB | + | 4MG | N020496 | 003 | Nov 30, 1995 | Feb | DISC |
| >A> | | + @ | 4MG | N020496 | 003 | Nov 30, 1995 | Feb | DISC |

GLIMEPIRIDE

| | | | | | | | | |
|-----|----|--------------------|-----|---------|-----|--------------|-----|------|
| >D> | AB | DR REDDYS LABS LTD | 1MG | A077091 | 001 | Oct 06, 2005 | Feb | CHRS |
| >A> | AB | ! | 1MG | A077091 | 001 | Oct 06, 2005 | Feb | CHRS |

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE

@ AIPING PHARM INC 5MG
@ 10MG

| | | | | |
|---------|-----|--------------|-----|------|
| A074305 | 001 | Apr 07, 1995 | Jan | CAHN |
| A074305 | 002 | Apr 07, 1995 | Jan | CAHN |

GLYCOPYRROLATE

INJECTABLE; INJECTION
GLYCOPYRROLATE

@ XIROMED 0.2MG/ML

| | | | | |
|---------|-----|--------------|-----|------|
| A212227 | 001 | Mar 04, 2021 | Jan | DISC |
|---------|-----|--------------|-----|------|

TABLET; ORAL
GLYCOPYRROLATE

| | | | | | | | | |
|-----|----|----------------|-----|---------|-----|--------------|-----|------|
| >A> | AA | CHARTWELL RX | 1MG | A040847 | 001 | Mar 21, 2008 | Feb | CAHN |
| >A> | AA | | 2MG | A040847 | 002 | Mar 21, 2008 | Feb | CAHN |
| >D> | AA | INDICUS PHARMA | 1MG | A040847 | 001 | Mar 21, 2008 | Feb | CAHN |
| >D> | AA | | 2MG | A040847 | 002 | Mar 21, 2008 | Feb | CAHN |

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN

| | | | | | | | | |
|-----|----|-----------------|---|---------|-----|--------------|-----|------|
| >D> | AT | NORDIC PHARMA | 0.025MG/ML;EQ 1.75MG BASE/ML;10,000 UNITS/ML | A065187 | 001 | Oct 28, 2005 | Feb | CAHN |
| >A> | AT | SAPTALIS PHARMS | 0.025MG/ML;EQ 1.75MG BASE/ML;10,000 UNITS/ML | A065187 | 001 | Oct 28, 2005 | Feb | CAHN |

GUANFACINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
GUANFACINE HYDROCHLORIDE

| | | | | | | |
|---|---------------|-------------|---------|-----|--------------|----------|
| @ | FOSUN WANBANG | EQ 1MG BASE | A217638 | 001 | Jun 12, 2024 | Jan CAHN |
| @ | | EQ 2MG BASE | A217638 | 002 | Jun 12, 2024 | Jan CAHN |
| @ | | EQ 3MG BASE | A217638 | 003 | Jun 12, 2024 | Jan CAHN |
| @ | | EQ 4MG BASE | A217638 | 004 | Jun 12, 2024 | Jan CAHN |

HALCINONIDE

SOLUTION;TOPICAL
HALCINONIDE

| | | | | | | |
|---|--------|------|---------|-----|--------------|----------|
| @ | ENCUBE | 0.1% | A217671 | 001 | May 29, 2024 | Jan DISC |
|---|--------|------|---------|-----|--------------|----------|

HALOBETASOL PROPIONATE

LOTION;TOPICAL
ULTRAVATE

| | | | | | | |
|---|----------------|-------|---------|-----|--------------|----------|
| + | @ LACER PHARMA | 0.05% | N208183 | 001 | Nov 06, 2015 | Jan CAHN |
|---|----------------|-------|---------|-----|--------------|----------|

HALOPERIDOL

TABLET;ORAL
HALOPERIDOL

| | | | | | | | |
|-----|----|-------------------|-------|---------|-----|--------------|----------|
| >A> | AB | APPCO | 0.5MG | A211061 | 001 | Jan 08, 2020 | Feb CAHN |
| >A> | AB | | 1MG | A211061 | 002 | Jan 08, 2020 | Feb CAHN |
| >A> | AB | | 2MG | A211061 | 003 | Jan 08, 2020 | Feb CAHN |
| >A> | AB | | 5MG | A211061 | 004 | Jan 08, 2020 | Feb CAHN |
| >A> | AB | | 10MG | A211061 | 005 | Jan 08, 2020 | Feb CAHN |
| >A> | AB | | 20MG | A211061 | 006 | Jan 08, 2020 | Feb CAHN |
| >D> | AB | UPSHER SMITH LABS | 0.5MG | A211061 | 001 | Jan 08, 2020 | Feb CAHN |
| >D> | AB | | 1MG | A211061 | 002 | Jan 08, 2020 | Feb CAHN |
| >D> | AB | | 2MG | A211061 | 003 | Jan 08, 2020 | Feb CAHN |
| >D> | AB | | 5MG | A211061 | 004 | Jan 08, 2020 | Feb CAHN |
| >D> | AB | | 10MG | A211061 | 005 | Jan 08, 2020 | Feb CAHN |
| >D> | AB | | 20MG | A211061 | 006 | Jan 08, 2020 | Feb CAHN |

HALOPERIDOL LACTATE

INJECTABLE;INJECTION
HALOPERIDOL

| | | | | | | | |
|-----|----|--------------------|----------------|---------|-----|--------------|----------|
| >D> | AP | FRESENIUS KABI USA | EQ 5MG BASE/ML | A210356 | 001 | Jul 01, 2019 | Feb DISC |
| >A> | | @ | EQ 5MG BASE/ML | A210356 | 001 | Jul 01, 2019 | Feb DISC |

HEPARIN SODIUM

INJECTABLE;INJECTION
HEPARIN SODIUM

| | | | | | | |
|---|---------------------|-------------------|---------|-----|--------------|----------|
| @ | B BRAUN MEDICAL INC | 5,000 UNITS/0.5ML | A208827 | 001 | Nov 19, 2018 | Jan DISC |
| | HIKMA | 5,000 UNITS/0.5ML | N017037 | 013 | Apr 07, 1986 | Jan CTEC |

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP;ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

| | | | | | | | |
|-----|----|------------------|-------------------|---------|-----|--------------|----------|
| >D> | AA | WOCKHARDT BIO AG | 1.5MG/5ML;5MG/5ML | A088008 | 001 | Mar 03, 1983 | Feb CAHN |
| >A> | AA | XTTRIUM LABS INC | 1.5MG/5ML;5MG/5ML | A088008 | 001 | Mar 03, 1983 | Feb CAHN |

HYDROCHLOROTHIAZIDE

FOR SUSPENSION;ORAL
INZIRQO

| | | | | | | | |
|---|---|-----------------|---------|---------|-----|--------------|----------|
| + | ! | NOVITIUM PHARMA | 10MG/ML | N219141 | 001 | Jan 28, 2025 | Jan NEWA |
|---|---|-----------------|---------|---------|-----|--------------|----------|

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET;ORAL

METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

| | | | | | | | |
|----|--|----------------|------------|---------|-----|--------------|----------|
| AB | | SENORES PHARMS | 25MG;50MG | A215789 | 001 | Jan 08, 2025 | Jan NEWA |
| AB | | | 25MG;100MG | A215789 | 002 | Jan 08, 2025 | Jan NEWA |

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET;ORAL

QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

| | | | | | | |
|---|--------|---------------------|---------|-----|--------------|----------|
| @ | APOTEX | 12.5MG;EQ 10MG BASE | A091524 | 001 | Mar 12, 2013 | Jan DISC |
| @ | | 12.5MG;EQ 20MG BASE | A091524 | 002 | Mar 12, 2013 | Jan DISC |
| @ | | 25MG;EQ 20MG BASE | A091524 | 003 | Mar 12, 2013 | Jan DISC |

HYDROCHLOROTHIAZIDE; TELMISARTAN

TABLET; ORAL

TELMISARTAN AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|-----|----|----------------|-------------|---------|-----|--------------|-----|------|
| >A> | AB | MANKIND PHARMA | 12.5MG;40MG | A218406 | 001 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 12.5MG;80MG | A218406 | 002 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 25MG;80MG | A218406 | 003 | Mar 03, 2025 | Feb | NEWA |

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

| | | | | | | | | |
|----|--|---------------------|-------------|---------|-----|--------------|-----|------|
| AB | | MACLEODS PHARMS LTD | 25MG;37.5MG | A214611 | 001 | Jan 28, 2025 | Jan | NEWA |
|----|--|---------------------|-------------|---------|-----|--------------|-----|------|

HYDROCORTISONE ACETATE

AEROSOL, METERED; RECTAL
CORTIFOAM

| | | | | | | | | |
|-----|--|------------------------|-----|---------|-----|--------------|-----|------|
| >D> | | +! MYLAN SPECIALITY LP | 10% | N017351 | 001 | Feb 10, 1982 | Feb | CAHN |
| >A> | | +! VIATRIS | 10% | N017351 | 001 | Feb 10, 1982 | Feb | CAHN |

CREAM; TOPICAL
MICORT-HC

@ LEGACY PHARMA 2%

| | | | | |
|---------|-----|--------------|-----|------|
| A040398 | 001 | Mar 29, 2002 | Jan | CAHN |
|---------|-----|--------------|-----|------|

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

| | | | | | | | | |
|-----|--|-------------------|-------------------------------------|---------|-----|--------------|-----|------|
| >D> | | @ AMRING PHARMS | 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML | A065216 | 001 | Oct 31, 2005 | Feb | CAHN |
| >A> | | @ SAPTALIS PHARMS | 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML | A065216 | 001 | Oct 31, 2005 | Feb | CAHN |

SUSPENSION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

| | | | | | | | | |
|-----|----|-----------------|-------------------------------------|---------|-----|--------------|-----|------|
| >D> | AT | AMRING PHARMS | 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML | A065219 | 001 | May 01, 2006 | Feb | CAHN |
| >A> | AT | SAPTALIS PHARMS | 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML | A065219 | 001 | May 01, 2006 | Feb | CAHN |

ICODEXTRIN

SOLUTION; INTRAPERITONEAL
EXTRANEAL

| | | | | | | | | |
|-----|--|------------------------|-------------|---------|-----|--------------|-----|------|
| >D> | | +! BAXTER HLTHCARE | 7.5GM/100ML | N021321 | 001 | Dec 20, 2002 | Feb | CAHN |
| >A> | | +! VANTIVE US HLTHCARE | 7.5GM/100ML | N021321 | 001 | Dec 20, 2002 | Feb | CAHN |

INDOMETHACIN

SUPPOSITORY; RECTAL
INDOMETHACIN

| | | | | | | | | |
|-----|----|--------|------|---------|-----|--------------|-----|------|
| >A> | AB | AMNEAL | 50MG | A215399 | 001 | Feb 24, 2025 | Feb | NEWA |
|-----|----|--------|------|---------|-----|--------------|-----|------|

IPRATROPIUM BROMIDE

SPRAY, METERED; NASAL
IPRATROPIUM BROMIDE

| | | | | | | | | |
|----|--|---------|---------------|---------|-----|--------------|-----|------|
| AB | | LUPIN | 0.021MG/SPRAY | A217912 | 001 | Feb 07, 2025 | Jan | NEWA |
| AB | | | 0.042MG/SPRAY | A217886 | 001 | Jan 27, 2025 | Jan | NEWA |
| AB | | RUBICON | 0.021MG/SPRAY | A219222 | 001 | Jan 14, 2025 | Jan | NEWA |

ISONIAZID

SYRUP; ORAL
ISONIAZID

| | | | | | | | | |
|-----|----|-------------------|----------|---------|-----|--------------|-----|------|
| >D> | | @ CHARTWELL RX | 50MG/5ML | A081118 | 001 | Jul 21, 1997 | Feb | CMFD |
| >A> | AA | | 50MG/5ML | A081118 | 001 | Jul 21, 1997 | Feb | CMFD |
| >D> | | +! CMP PHARMA INC | 50MG/5ML | A088235 | 001 | Nov 10, 1983 | Feb | CTEC |
| >A> | AA | +! | 50MG/5ML | A088235 | 001 | Nov 10, 1983 | Feb | CTEC |

ITRACONAZOLE

CAPSULE; ORAL
ITRACONAZOLE

| | | | | | | | | |
|-----|----|----------|-------|---------|-----|--------------|-----|------|
| >D> | | @ RISING | 100MG | A205724 | 001 | Dec 13, 2016 | Feb | CMFD |
| >A> | AB | | 100MG | A205724 | 001 | Dec 13, 2016 | Feb | CMFD |

IVERMECTIN

| TABLET; ORAL | | IVERMECTIN | | | | | |
|--------------|---------|------------|---------|-----|--------------|-----|------|
| AB | RUBICON | 3MG | A215922 | 001 | Jan 22, 2025 | Jan | NEWA |
| | | 6MG | A215922 | 002 | Jan 22, 2025 | Jan | NFTG |

KETOCONAZOLE

| SHAMPOO; TOPICAL | | KETOCONAZOLE | | | | | | |
|------------------|----|--------------------|----|---------|-----|--------------|-----|------|
| >A> | AB | ZYDUS LIFESCIENCES | 2% | A218559 | 001 | Mar 07, 2025 | Feb | NEWA |

LACOSAMIDE

| SOLUTION; ORAL | | LACOSAMIDE | | | | | | |
|----------------|----|------------|---------|---------|-----|--------------|-----|------|
| >D> | AA | APOTEX | 10MG/ML | A206355 | 001 | Sep 26, 2022 | Feb | DISC |
| >A> | | @ | 10MG/ML | A206355 | 001 | Sep 26, 2022 | Feb | DISC |

LACTULOSE

| SOLUTION; ORAL | | LACTULOSE | | | | | | |
|----------------|--|------------------|-----------|---------|-----|--------------|-----|------|
| | | @ VISTAPHARM LLC | 10GM/15ML | A074138 | 001 | Sep 30, 1992 | Jan | CAHN |

LAMIVUDINE

| TABLET; ORAL | | LAMIVUDINE | | | | | | |
|--------------|--|----------------------|-------|---------|-----|--------------|-----|------|
| >D> | | @ MYLAN LABS LTD | 150MG | A078545 | 001 | Mar 05, 2019 | Feb | CAHN |
| >D> | | @ | 300MG | A078545 | 002 | Mar 05, 2019 | Feb | CAHN |
| >A> | | @ NORVIUM BIOSCIENCE | 150MG | A078545 | 001 | Mar 05, 2019 | Feb | CAHN |
| >A> | | @ | 300MG | A078545 | 002 | Mar 05, 2019 | Feb | CAHN |

LAMOTRIGINE

| TABLET; ORAL | | LAMOTRIGINE | | | | | | |
|--------------|--|--------------------|-------|---------|-----|--------------|-----|------|
| | | @ AIPING PHARM INC | 25MG | A078645 | 001 | Jan 27, 2009 | Jan | CAHN |
| | | @ | 100MG | A078645 | 002 | Jan 27, 2009 | Jan | CAHN |
| | | @ | 150MG | A078645 | 003 | Jan 27, 2009 | Jan | CAHN |
| | | @ | 200MG | A078645 | 004 | Jan 27, 2009 | Jan | CAHN |

LEFLUNOMIDE

| TABLET; ORAL | | LEFLUNOMIDE | | | | | |
|--------------|---------------|-------------|---------|-----|--------------|-----|------|
| AB | FOSUN WANBANG | 10MG | A077087 | 001 | Sep 13, 2005 | Jan | CAHN |
| AB | | 20MG | A077087 | 002 | Sep 13, 2005 | Jan | CAHN |

LENALIDOMIDE

| CAPSULE; ORAL | | LENALIDOMIDE | | | | | | |
|---------------|--------|---------------|---------|---------|--------------|--------------|------|------|
| AB | AMNEAL | 2.5MG | A216213 | 001 | Jan 31, 2025 | Jan | NEWA | |
| AB | | 5MG | A216213 | 002 | Jan 31, 2025 | Jan | NEWA | |
| AB | | 10MG | A216213 | 003 | Jan 31, 2025 | Jan | NEWA | |
| AB | | 15MG | A216213 | 004 | Jan 31, 2025 | Jan | NEWA | |
| AB | | 20MG | A216213 | 005 | Jan 31, 2025 | Jan | NEWA | |
| AB | | 25MG | A216213 | 006 | Jan 31, 2025 | Jan | NEWA | |
| >A> | AB | BIOCON PHARMA | 2.5MG | A215759 | 001 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 5MG | A215759 | 002 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 10MG | A215759 | 003 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 15MG | A215759 | 004 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 20MG | A215759 | 005 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | 25MG | A215759 | 006 | Mar 03, 2025 | Feb | NEWA |

LEVETIRACETAM

| INJECTABLE; INTRAVENOUS | | LEVETIRACETAM IN SODIUM CHLORIDE | | | | | |
|-------------------------|---------------|----------------------------------|---------|-----|--------------|-----|------|
| AP | CAPLIN | 500MG/100ML (5MG/ML) | A219562 | 001 | Jan 16, 2025 | Jan | NEWA |
| AP | | 1GM/100ML (10MG/ML) | A219562 | 002 | Jan 16, 2025 | Jan | NEWA |
| AP | | 1.5GM/100ML (15MG/ML) | A219562 | 003 | Jan 16, 2025 | Jan | NEWA |
| SOLUTION; ORAL | | LEVETIRACETAM | | | | | |
| AA | AJENAT PHARMS | 100MG/ML | A090461 | 001 | Sep 30, 2010 | Jan | CAHN |

TABLET;ORAL

LEVETIRACETAM

@ CHINA RESOURCES 500MG
 @ 1GM

A205102 004 Dec 16, 2015 Jan CAHN
 A205102 003 Dec 16, 2015 Jan CAHN

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

>A> AB SYNTHON BV 5MG
 >D> AB SYNTHON PHARMS 5MG

A090229 001 Nov 26, 2010 Feb CAHN
 A090229 001 Nov 26, 2010 Feb CAHN

LEVODOPA

POWDER; INHALATION

INBRIJA

>A> +! MERZ 42MG
 >D> +! MERZ PHARMS 42MG

N209184 001 Dec 21, 2018 Feb CAHN
 N209184 001 Dec 21, 2018 Feb CAHN

LEVOTHYROXINE SODIUM

POWDER; INTRAVENOUS

LEVOTHYROXINE SODIUM

>A> AP STERISCIENCE 100MCG/VIAL
 >A> AP 200MCG/VIAL
 >A> AP 500MCG/VIAL

A216729 001 Mar 05, 2025 Feb NEWA
 A216729 002 Mar 05, 2025 Feb NEWA
 A216729 003 Mar 05, 2025 Feb NEWA

LEVOTHYROXINE SODIUM **

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

TABLET;ORAL

LEVOTHYROXINE SODIUM

@ AUROBINDO PHARMA 0.137MG
 @ 0.15MG
 @ 0.175MG
 @ 0.2MG
 @ 0.3MG
 >D> AB1, MACLEODS PHARMS LTD 0.025MG
 AB2
 >A> AB1, 0.025MG
 AB2,
 AB4
 >A> AB1, 0.025MG
 AB2,
 AB3,
 AB4
 >D> AB1, 0.05MG
 AB2
 >A> AB1, 0.05MG
 AB2,
 AB4
 >A> AB1, 0.05MG
 AB2,
 AB3,
 AB4
 >D> AB1, 0.075MG
 AB2
 >A> AB1, 0.075MG
 AB2,
 AB4
 >A> AB1, 0.075MG
 AB2,
 AB3,
 AB4
 >D> AB1, 0.088MG
 AB2
 >A> AB1, 0.088MG
 AB2,
 AB4
 >A> AB1, 0.088MG
 AB2,
 AB3,
 AB4
 >D> AB1, 0.1MG
 AB2
 >A> AB1, 0.1MG
 AB2,
 AB4
 >A> AB1, 0.1MG
 AB2,
 AB3,

A216414 001 Jul 16, 2024 Jan DISC
 A216414 002 Jul 16, 2024 Jan DISC
 A216414 003 Jul 16, 2024 Jan DISC
 A216414 004 Jul 16, 2024 Jan DISC
 A216414 005 Jul 16, 2024 Jan DISC
 A211417 001 Dec 21, 2022 Feb CTEC
 A211417 001 Dec 21, 2022 Feb CTEC
 A211417 001 Dec 21, 2022 Feb CTEC
 A211417 002 Dec 21, 2022 Feb CTEC
 A211417 002 Dec 21, 2022 Feb CTEC
 A211417 002 Dec 21, 2022 Feb CTEC
 A211417 002 Dec 21, 2022 Feb CTEC
 A211417 003 Dec 21, 2022 Feb CTEC
 A211417 003 Dec 21, 2022 Feb CTEC
 A211417 003 Dec 21, 2022 Feb CTEC
 A211417 004 Dec 21, 2022 Feb CTEC
 A211417 004 Dec 21, 2022 Feb CTEC
 A211417 004 Dec 21, 2022 Feb CTEC
 A211417 005 Dec 21, 2022 Feb CTEC
 A211417 005 Dec 21, 2022 Feb CTEC
 A211417 005 Dec 21, 2022 Feb CTEC

TABLET;ORAL
LEVOTHYROXINE SODIUM

| | | | | | | | | |
|-----|------|---------|---------|-----|--------------|-----|------|--|
| AB4 | | | | | | | | |
| >D> | AB1, | 0.112MG | A211417 | 006 | Dec 21, 2022 | Feb | CTEC | |
| | AB2 | | | | | | | |
| >A> | AB1, | 0.112MG | A211417 | 006 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB4 | | | | | | | |
| >A> | AB1, | 0.112MG | A211417 | 006 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB3, | | | | | | | |
| | AB4 | | | | | | | |
| >D> | AB1, | 0.125MG | A211417 | 007 | Dec 21, 2022 | Feb | CTEC | |
| | AB2 | | | | | | | |
| >A> | AB1, | 0.125MG | A211417 | 007 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB4 | | | | | | | |
| >A> | AB1, | 0.125MG | A211417 | 007 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB3, | | | | | | | |
| | AB4 | | | | | | | |
| >D> | AB1, | 0.137MG | A211417 | 008 | Dec 21, 2022 | Feb | CTEC | |
| | AB2 | | | | | | | |
| >A> | AB1, | 0.137MG | A211417 | 008 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB4 | | | | | | | |
| >A> | AB1, | 0.137MG | A211417 | 008 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB3, | | | | | | | |
| | AB4 | | | | | | | |
| >D> | AB1, | 0.15MG | A211417 | 009 | Dec 21, 2022 | Feb | CTEC | |
| | AB2 | | | | | | | |
| >A> | AB1, | 0.15MG | A211417 | 009 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB4 | | | | | | | |
| >A> | AB1, | 0.15MG | A211417 | 009 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB3, | | | | | | | |
| | AB4 | | | | | | | |
| >D> | AB1, | 0.175MG | A211417 | 010 | Dec 21, 2022 | Feb | CTEC | |
| | AB2 | | | | | | | |
| >A> | AB1, | 0.175MG | A211417 | 010 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB4 | | | | | | | |
| >A> | AB1, | 0.175MG | A211417 | 010 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB3, | | | | | | | |
| | AB4 | | | | | | | |
| >D> | AB1, | 0.2MG | A211417 | 011 | Dec 21, 2022 | Feb | CTEC | |
| | AB2 | | | | | | | |
| >A> | AB1, | 0.2MG | A211417 | 011 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB4 | | | | | | | |
| >A> | AB1, | 0.2MG | A211417 | 011 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB3, | | | | | | | |
| | AB4 | | | | | | | |
| >D> | AB1, | 0.3MG | A211417 | 012 | Dec 21, 2022 | Feb | CTEC | |
| | AB2 | | | | | | | |
| >A> | AB1, | 0.3MG | A211417 | 012 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB4 | | | | | | | |
| >A> | AB1, | 0.3MG | A211417 | 012 | Dec 21, 2022 | Feb | CTEC | |
| | AB2, | | | | | | | |
| | AB3, | | | | | | | |
| | AB4 | | | | | | | |

LIDOCAINE HYDROCHLORIDE

SOLUTION;ORAL

LIDOCAINE HYDROCHLORIDE

| | | | | | | | | |
|-----|----|------------------|----|---------|-----|--------------|-----|------|
| >D> | AT | WOCKHARDT BIO AG | 2% | A087872 | 001 | Nov 18, 1982 | Feb | CAHN |
| >A> | AT | XTTRIUM LABS INC | 2% | A087872 | 001 | Nov 18, 1982 | Feb | CAHN |

SOLUTION;TOPICAL

LIDOCAINE HYDROCHLORIDE

| | | | | | | | | |
|-----|----|------------------|----|---------|-----|--------------|-----|------|
| >D> | AT | WOCKHARDT BIO AG | 4% | A087881 | 001 | Nov 18, 1982 | Feb | CAHN |
| >A> | AT | XTTRIUM LABS INC | 4% | A087881 | 001 | Nov 18, 1982 | Feb | CAHN |

LINEZOLID

SOLUTION;INTRAVENOUS
LINEZOLID

| | | | | | | | |
|-----|----|--------------------|----------------------|---------|-----|--------------|----------|
| >D> | AP | MYLAN LABS LTD | 200MG/100ML (2MG/ML) | A205154 | 001 | Dec 06, 2017 | Feb CAHN |
| >D> | AP | | 600MG/300ML (2MG/ML) | A205154 | 002 | Dec 06, 2017 | Feb CAHN |
| >A> | AP | NORVIUM BIOSCIENCE | 200MG/100ML (2MG/ML) | A205154 | 001 | Dec 06, 2017 | Feb CAHN |
| >A> | AP | | 600MG/300ML (2MG/ML) | A205154 | 002 | Dec 06, 2017 | Feb CAHN |

LISDEXAMFETAMINE DIMESYLATE

CAPSULE;ORAL
LISDEXAMFETAMINE DIMESYLATE

| | | | | | | | |
|----|--|----------|------|---------|-----|--------------|----------|
| AB | | GRANULES | 10MG | A218987 | 001 | Jan 29, 2025 | Jan NEWA |
| AB | | | 20MG | A218987 | 002 | Jan 29, 2025 | Jan NEWA |
| AB | | | 30MG | A218987 | 003 | Jan 29, 2025 | Jan NEWA |
| AB | | | 40MG | A218987 | 004 | Jan 29, 2025 | Jan NEWA |
| AB | | | 50MG | A218987 | 005 | Jan 29, 2025 | Jan NEWA |
| AB | | | 60MG | A218987 | 006 | Jan 29, 2025 | Jan NEWA |
| AB | | | 70MG | A218987 | 007 | Jan 29, 2025 | Jan NEWA |
| AB | | SANDOZ | 20MG | A202836 | 001 | Jul 26, 2024 | Jan CMFD |
| AB | | | 30MG | A202836 | 002 | Jul 26, 2024 | Jan CMFD |
| AB | | | 40MG | A202836 | 003 | Jul 26, 2024 | Jan CMFD |
| AB | | | 50MG | A202836 | 004 | Jul 26, 2024 | Jan CMFD |
| AB | | | 60MG | A202836 | 005 | Jul 26, 2024 | Jan CMFD |
| AB | | | 70MG | A202836 | 006 | Jul 26, 2024 | Jan CMFD |

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE;ORAL
LITHIUM CARBONATE

| | | | | | | | |
|-----|----|--------------------|-------|---------|-----|--------------|----------|
| >D> | AB | MYLAN PHARMS INC | 450MG | A202219 | 001 | Aug 08, 2012 | Feb CAHN |
| >A> | AB | NORVIUM BIOSCIENCE | 450MG | A202219 | 001 | Aug 08, 2012 | Feb CAHN |

LOFEXIDINE HYDROCHLORIDE

TABLET;ORAL
LOFEXIDINE HYDROCHLORIDE

| | | | | | | | |
|-----|----|-----|----------------|---------|-----|--------------|----------|
| >A> | AB | MSN | EQ 0.18MG BASE | A218699 | 001 | Feb 24, 2025 | Feb NEWA |
|-----|----|-----|----------------|---------|-----|--------------|----------|

LOSARTAN POTASSIUM

TABLET;ORAL
LOSARTAN POTASSIUM

| | | | | | | | |
|--|--|----------|-------|---------|-----|--------------|----------|
| | | @ APOTEX | 25MG | A218551 | 001 | Jun 04, 2024 | Jan DISC |
| | | @ | 50MG | A218551 | 002 | Jun 04, 2024 | Jan DISC |
| | | @ | 100MG | A218551 | 003 | Jun 04, 2024 | Jan DISC |

LOTEPREDNOL ETABONATE

SUSPENSION/DROPS;OPHTHALMIC
LOTEPREDNOL ETABONATE

| | | | | | | | |
|----|--|------------|------|---------|-----|--------------|----------|
| AB | | PADAGIS US | 0.5% | A215204 | 001 | Jan 29, 2025 | Jan NEWA |
|----|--|------------|------|---------|-----|--------------|----------|

LURASIDONE HYDROCHLORIDE

TABLET;ORAL
LURASIDONE HYDROCHLORIDE

| | | | | | | | |
|----|--|---------|------|---------|-----|--------------|----------|
| AB | | TORRENT | 60MG | A208055 | 005 | Jan 13, 2025 | Jan NEWA |
|----|--|---------|------|---------|-----|--------------|----------|

MEFENAMIC ACID

CAPSULE;ORAL
MEFENAMIC ACID

| | | | | | | | |
|----|--|---------------|-------|---------|-----|--------------|----------|
| AB | | AJENAT PHARMS | 250MG | A091608 | 001 | Jun 02, 2014 | Jan CAHN |
|----|--|---------------|-------|---------|-----|--------------|----------|

MEGESTROL ACETATE

SUSPENSION;ORAL
MEGACE ES

| | | | | | | | | |
|-----|----|-----|-----------------|----------|---------|-----|--------------|----------|
| >D> | AB | +! | ENDO OPERATIONS | 125MG/ML | N021778 | 001 | Jul 05, 2005 | Feb DISC |
| >A> | | + @ | | 125MG/ML | N021778 | 001 | Jul 05, 2005 | Feb DISC |
| >D> | AB | | TWI PHARMS | 125MG/ML | A203139 | 001 | Aug 27, 2014 | Feb CHRS |
| >A> | AB | ! | | 125MG/ML | A203139 | 001 | Aug 27, 2014 | Feb CHRS |
| >A> | | ! | | 125MG/ML | A203139 | 001 | Aug 27, 2014 | Feb CTEC |

MELOXICAMTABLET; ORAL
MELOXICAM

| | | | | | | | |
|-----|----|--------------------|-------|---------|-----|--------------|----------|
| >D> | AB | DR REDDYS LABS INC | 7.5MG | A077931 | 001 | Jul 25, 2006 | Feb CAHN |
| >D> | AB | | 15MG | A077931 | 002 | Jul 25, 2006 | Feb CAHN |
| >A> | AB | GRAVITI PHARMS | 7.5MG | A077931 | 001 | Jul 25, 2006 | Feb CAHN |
| >A> | AB | | 15MG | A077931 | 002 | Jul 25, 2006 | Feb CAHN |

MELOXICAM; RIZATRIPTAN BENZOATETABLET; ORAL
SYMBRAVO

| | | | | | | | |
|---|---|--------|-------------------|---------|-----|--------------|----------|
| + | ! | AXSOME | 20MG;EQ 10MG BASE | N215431 | 001 | Jan 30, 2025 | Jan NEWA |
|---|---|--------|-------------------|---------|-----|--------------|----------|

MERCAPTOPURINESUSPENSION; ORAL
MERCAPTOPURINE

| | | | | | | | |
|-----|----|-------|---------|---------------|-----|--------------|-----------------------------------|
| >A> | AB | HIKMA | 20MG/ML | A216418 | 001 | Feb 26, 2025 | Feb NFTG |
| >D> | | + | ! | NOVA LABS LTD | | 20MG/ML | N205919 001 Apr 28, 2014 Feb CFTG |
| >A> | AB | + | ! | | | 20MG/ML | N205919 001 Apr 28, 2014 Feb CFTG |

MESALAMINETABLET, DELAYED RELEASE; ORAL
MESALAMINE

| | | | | | | | |
|-----|----|--------|-------|---------|-----|--------------|----------|
| >A> | AB | AMNEAL | 800MG | A215067 | 001 | Feb 18, 2025 | Feb NEWA |
|-----|----|--------|-------|---------|-----|--------------|----------|

MESNATABLET; ORAL
MESNA

| | | | | | | | |
|----|--|-----------------|-------|-----------------|-----|--------------|-----------------------------------|
| AB | | RICONPHARMA LLC | 400MG | A218871 | 001 | Jan 13, 2025 | Jan NFTG |
| AB | | + | ! | BAXTER HLTHCARE | | 400MG | N020855 001 Mar 21, 2002 Jan CFTG |

METFORMIN HYDROCHLORIDESOLUTION; ORAL
METFORMIN HYDROCHLORIDE

| | | | | | | | |
|----|--|----------------|-----------|---------|-----|--------------|----------|
| AB | | VISTAPHARM LLC | 500MG/5ML | A212677 | 001 | Aug 19, 2022 | Jan CAHN |
|----|--|----------------|-----------|---------|-----|--------------|----------|

TABLET, EXTENDED RELEASE; ORAL
METFORMIN HYDROCHLORIDE

| | | | | | | | |
|-----|-----|----------------------|-----------|---------|-----|--------------|----------|
| >D> | AB1 | INTELLIPHARMACEUTICS | 500MG | A202306 | 001 | Feb 23, 2017 | Feb CAHN |
| >D> | AB | | 750MG | A202306 | 002 | Feb 23, 2017 | Feb CAHN |
| >A> | AB1 | MEDICAP LABS | 500MG | A202306 | 001 | Feb 23, 2017 | Feb CAHN |
| >A> | AB | | 750MG | A202306 | 002 | Feb 23, 2017 | Feb CAHN |
| | | @ | SUN PHARM | A202917 | 001 | Aug 01, 2016 | Jan DISC |
| | | @ | | A202917 | 002 | Aug 01, 2016 | Jan DISC |

METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDETABLET, EXTENDED RELEASE; ORAL
SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE

| | | | | | | | |
|----|--|-------------------|-------------------|---------|-----|--------------|----------|
| AB | | DR REDDYS LABS SA | 500MG;EQ 5MG BASE | A207678 | 001 | Aug 09, 2023 | Jan CTNA |
| AB | | | 1GM;EQ 2.5MG BASE | A207678 | 002 | Aug 09, 2023 | Jan CTNA |
| AB | | ! | 1GM;EQ 5MG BASE | A207678 | 003 | Aug 09, 2023 | Jan CTNA |

METHADONE HYDROCHLORIDETABLET, FOR SUSPENSION; ORAL
METHADONE HYDROCHLORIDE

| | | | | | | | |
|----|--|----------------|------|---------|-----|--------------|----------|
| AA | | VISTAPHARM LLC | 40MG | A075082 | 001 | Mar 25, 1998 | Jan CAHN |
|----|--|----------------|------|---------|-----|--------------|----------|

METHENAMINE HIPPURATETABLET; ORAL
METHENAMINE HIPPURATE

| | | | | | | | |
|-----|----|--------------------|-----|---------|-----|--------------|----------|
| >A> | AB | ZYDUS LIFESCIENCES | 1GM | A219661 | 001 | Mar 10, 2025 | Feb NEWA |
|-----|----|--------------------|-----|---------|-----|--------------|----------|

METHIMAZOLETABLET; ORAL
METHIMAZOLE

| | | | | | | | |
|----|--|-------------------|------|---------|-----|--------------|----------|
| AB | | SQUARE PHARMS PLC | 5MG | A218830 | 001 | Feb 05, 2025 | Jan NEWA |
| AB | | | 10MG | A218830 | 002 | Feb 05, 2025 | Jan NEWA |

METHYLENE BLUE

| | | | | | | | |
|----|-----------------------|--------------------|---------|-----|--------------|-----|------|
| | SOLUTION; INTRAVENOUS | | | | | | |
| | METHYLENE BLUE | | | | | | |
| AP | HIKMA | 50MG/10ML (5MG/ML) | A216959 | 001 | Dec 17, 2024 | Jan | CAHN |
| AP | MEITHEAL | 50MG/10ML (5MG/ML) | A217380 | 001 | Jan 23, 2025 | Jan | CAHN |
| AP | NANJING KING-FRIEND | 50MG/10ML (5MG/ML) | A217380 | 001 | Jan 23, 2025 | Jan | NEWA |

METHYLPHENIDATE HYDROCHLORIDE

| | | | | | | | |
|-----|-------------------------------|----------|---------|-----|--------------|-----|------|
| | SOLUTION; ORAL | | | | | | |
| | METHYLPHENIDATE HYDROCHLORIDE | | | | | | |
| >D> | @ ALLIED | 5MG/5ML | A201466 | 001 | Nov 12, 2013 | Feb | CAHN |
| >D> | @ | 10MG/5ML | A201466 | 002 | Nov 12, 2013 | Feb | CAHN |
| >A> | @ ESJAY PHARMA | 5MG/5ML | A201466 | 001 | Nov 12, 2013 | Feb | CAHN |
| >A> | @ | 10MG/5ML | A201466 | 002 | Nov 12, 2013 | Feb | CAHN |

METOCLOPRAMIDE HYDROCHLORIDE

| | | | | | | | |
|--|------------------------------|-----------------|---------|-----|--------------|-----|------|
| | SOLUTION; ORAL | | | | | | |
| | METOCLOPRAMIDE HYDROCHLORIDE | | | | | | |
| | @ VISTAPHARM LLC | EQ 5MG BASE/5ML | A075051 | 001 | Jan 26, 2001 | Jan | CAHN |

METOPROLOL TARTRATE

| | | | | | | | |
|----|---------------------|-------|---------|-----|--------------|-----|------|
| | TABLET; ORAL | | | | | | |
| | METOPROLOL TARTRATE | | | | | | |
| AB | SCIEGEN PHARMS INC | 25MG | A208955 | 001 | Feb 05, 2020 | Jan | CAHN |
| AB | | 50MG | A208955 | 002 | Feb 05, 2020 | Jan | CAHN |
| AB | | 100MG | A208955 | 003 | Feb 05, 2020 | Jan | CAHN |

METRONIDAZOLE

| | | | | | | | |
|--|----------------------|------|---------|-----|--------------|-----|------|
| | GEL; VAGINAL | | | | | | |
| | METRONIDAZOLE | | | | | | |
| | @ ENCUBE | 1.3% | A216795 | 001 | Mar 18, 2024 | Jan | DISC |
| | +! CHEMO RESEARCH SL | 1.3% | N205223 | 001 | Mar 24, 2014 | Jan | CTEC |

MIGLUSTAT

| | | | | | | | |
|-----|----------------|-------|---------|-----|--------------|-----|------|
| | CAPSULE; ORAL | | | | | | |
| | MIGLUSTAT | | | | | | |
| >D> | @ BRECKENRIDGE | 100MG | A209325 | 001 | Feb 03, 2022 | Feb | CAHN |
| >A> | @ VERANOVA | 100MG | A209325 | 001 | Feb 03, 2022 | Feb | CAHN |

>A> MIRDAMETINIB

| | | | | | | | |
|-----|------------------------------|-----|---------|-----|--------------|-----|------|
| >A> | CAPSULE; ORAL | | | | | | |
| >A> | GOMEKLI | | | | | | |
| >A> | + SPRINGWORKS | 1MG | N219389 | 001 | Feb 11, 2025 | Feb | NEWA |
| >A> | +! | 2MG | N219389 | 002 | Feb 11, 2025 | Feb | NEWA |
| >A> | TABLET, FOR SUSPENSION; ORAL | | | | | | |
| >A> | GOMEKLI | | | | | | |
| >A> | +! SPRINGWORKS | 1MG | N219379 | 001 | Feb 11, 2025 | Feb | NEWA |

MITOMYCIN

| | | | | | | | |
|----|-----------------------|-----------|---------|-----|--------------|-----|------|
| | INJECTABLE; INJECTION | | | | | | |
| | MITOMYCIN | | | | | | |
| | @ ACCORD HLTHCARE | 20MG/VIAL | A064144 | 002 | Apr 30, 1998 | Jan | DISC |
| AP | ! MEITHEAL | 20MG/VIAL | A214505 | 002 | Sep 08, 2022 | Jan | CHRS |

MODAFINIL

| | | | | | | | |
|----|---------------|-------|---------|-----|--------------|-----|------|
| | TABLET; ORAL | | | | | | |
| | PROVIGIL | | | | | | |
| AB | + NUVO PHARMS | 100MG | N020717 | 001 | Dec 24, 1998 | Jan | CAHN |
| AB | +! | 200MG | N020717 | 002 | Dec 24, 1998 | Jan | CAHN |

MOMETASONE FUROATE

| | | | | | | | |
|-----|-----------------------|------|---------|-----|--------------|-----|------|
| | CREAM; TOPICAL | | | | | | |
| | MOMETASONE FUROATE | | | | | | |
| >D> | @ ANDA REPOSITORY | 0.1% | A076591 | 001 | Apr 18, 2007 | Feb | CAHN |
| >A> | @ CHARTWELL MOLECULAR | 0.1% | A076591 | 001 | Apr 18, 2007 | Feb | CAHN |

MORPHINE SULFATE

SOLUTION;ORAL

MORPHINE SULFATE

| | | | | | | | | | |
|-----|----|---|-----------------|-----------|---------|-----|--------------|-----|------|
| >D> | AA | + | HIKMA | 20MG/5ML | N022195 | 002 | Mar 17, 2008 | Feb | CTEC |
| >A> | | + | | 20MG/5ML | N022195 | 002 | Mar 17, 2008 | Feb | CTEC |
| | | @ | RHODES PHARMS | 10MG/5ML | A206308 | 001 | Jun 22, 2017 | Jan | DISC |
| | | @ | | 20MG/5ML | A206420 | 001 | Jul 12, 2016 | Jan | DISC |
| | | @ | | 100MG/5ML | A206308 | 002 | Jun 22, 2017 | Jan | DISC |
| >D> | AA | | WINDER LABS LLC | 10MG/5ML | A211454 | 001 | Feb 12, 2021 | Feb | DISC |
| >A> | | @ | | 10MG/5ML | A211454 | 001 | Feb 12, 2021 | Feb | DISC |
| >D> | AA | | | 20MG/5ML | A211454 | 002 | Feb 12, 2021 | Feb | DISC |
| >A> | | @ | | 20MG/5ML | A211454 | 002 | Feb 12, 2021 | Feb | DISC |
| >D> | AA | | | 100MG/5ML | A211454 | 003 | Feb 12, 2021 | Feb | DISC |
| >A> | | @ | | 100MG/5ML | A211454 | 003 | Feb 12, 2021 | Feb | DISC |

TABLET, EXTENDED RELEASE;ORAL

MORPHINE SULFATE

| | | | | | | | | | |
|-----|----|---|----------------|-------|---------|-----|--------------|-----|------|
| >D> | AB | | NOVEL LABS INC | 15MG | A203602 | 001 | Dec 16, 2015 | Feb | DISC |
| >A> | | @ | | 15MG | A203602 | 001 | Dec 16, 2015 | Feb | DISC |
| >D> | AB | | | 30MG | A203602 | 002 | Dec 16, 2015 | Feb | DISC |
| >A> | | @ | | 30MG | A203602 | 002 | Dec 16, 2015 | Feb | DISC |
| >D> | AB | | | 60MG | A203602 | 003 | Dec 16, 2015 | Feb | DISC |
| >A> | | @ | | 60MG | A203602 | 003 | Dec 16, 2015 | Feb | DISC |
| >D> | AB | | | 100MG | A203602 | 004 | Dec 16, 2015 | Feb | DISC |
| >A> | | @ | | 100MG | A203602 | 004 | Dec 16, 2015 | Feb | DISC |
| >D> | AB | | | 200MG | A203602 | 005 | Dec 16, 2015 | Feb | DISC |
| >A> | | @ | | 200MG | A203602 | 005 | Dec 16, 2015 | Feb | DISC |

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE

| | | | | | | | | | |
|-----|--|---|--------------------|--------------|---------|-----|--------------|-----|------|
| AT1 | | | MANKIND PHARMA | EQ 0.5% BASE | A217988 | 001 | Jan 27, 2025 | Jan | NEWA |
| >D> | | @ | MYLAN | EQ 0.5% BASE | A206447 | 001 | Mar 30, 2020 | Feb | CAHN |
| >A> | | @ | NORVIUM BIOSCIENCE | EQ 0.5% BASE | A206447 | 001 | Mar 30, 2020 | Feb | CAHN |

MYCOPHENOLATE MOFETIL

FOR SUSPENSION;ORAL

MYCOPHENOLATE MOFETIL

| | | | | | | | | | |
|----|--|--|----------------|----------|---------|-----|--------------|-----|------|
| AB | | | VISTAPHARM LLC | 200MG/ML | A210370 | 001 | Feb 12, 2019 | Jan | CAHN |
|----|--|--|----------------|----------|---------|-----|--------------|-----|------|

MYCOPHENOLIC SODIUM

TABLET, DELAYED RELEASE;ORAL

MYCOPHENOLIC SODIUM

| | | | | | | | | | |
|----|--|--|---------------|---------------|---------|-----|--------------|-----|------|
| AB | | | FOSUN WANBANG | EQ 180MG BASE | A216637 | 001 | May 29, 2024 | Jan | CAHN |
| AB | | | | EQ 360MG BASE | A216637 | 002 | May 29, 2024 | Jan | CAHN |

NALMEFENE HYDROCHLORIDE

SOLUTION;INTRAMUSCULAR, SUBCUTANEOUS

ZURNAI (AUTOINJECTOR)

| | | | | | | | | | | |
|--|--|---|---|------------------|---|---------|-----|--------------|-----|------|
| | | + | @ | PURDUE PHARMA LP | EQ 1.5MG BASE/0.5ML (EQ 1.5MG BASE/0.5ML) | N218590 | 001 | Aug 07, 2024 | Jan | DISC |
|--|--|---|---|------------------|---|---------|-----|--------------|-----|------|

NEBIVOLOL HYDROCHLORIDE

TABLET;ORAL

NEBIVOLOL HYDROCHLORIDE

| | | | | | | | | | |
|----|--|--|---------------------|---------------|---------|-----|--------------|-----|------|
| AB | | | MACLEODS PHARMS LTD | EQ 2.5MG BASE | A212661 | 001 | Jan 28, 2025 | Jan | NEWA |
| AB | | | | EQ 5MG BASE | A212661 | 002 | Jan 28, 2025 | Jan | NEWA |
| AB | | | | EQ 10MG BASE | A212661 | 003 | Jan 28, 2025 | Jan | NEWA |
| AB | | | | EQ 20MG BASE | A212661 | 004 | Jan 28, 2025 | Jan | NEWA |

NICARDIPINE HYDROCHLORIDE

INJECTABLE;INJECTION

NICARDIPINE HYDROCHLORIDE

| | | | | | | | | | |
|--|--|---|--------|----------------------|---------|-----|--------------|-----|------|
| | | @ | AMNEAL | 25MG/10ML (2.5MG/ML) | A215406 | 001 | Oct 31, 2024 | Jan | DISC |
|--|--|---|--------|----------------------|---------|-----|--------------|-----|------|

NILOTINIB D-TARTRATE

CAPSULE;ORAL

NILOTINIB D-TARTRATE

| | | | | | | | | | |
|-----|--|---|-------|---------------|---------|-----|--------------|-----|------|
| >A> | | | | | | | | | |
| >A> | | + | CIPLA | EQ 50MG BASE | N218922 | 001 | Feb 19, 2025 | Feb | NEWA |
| >A> | | + | | EQ 150MG BASE | N218922 | 002 | Feb 19, 2025 | Feb | NEWA |
| >A> | | + | ! | EQ 200MG BASE | N218922 | 003 | Feb 19, 2025 | Feb | NEWA |

NIMODIPINE

| | | | | | | | | |
|----|----------------|--------|---------|-----|--------------|-----|------|--|
| | SOLUTION;ORAL | | | | | | | |
| | NIMODIPINE | | | | | | | |
| AB | ALKEM LABS LTD | 6MG/ML | A213409 | 001 | Jan 22, 2025 | Jan | NFTG | |
| | NYMALIZE | | | | | | | |
| AB | +! AZURITY | 6MG/ML | N203340 | 002 | Apr 08, 2020 | Jan | CFTG | |

NITAZOXANIDE

| | | | | | | | | |
|----|--------------|-------|---------|-----|--------------|-----|------|--|
| | TABLET;ORAL | | | | | | | |
| | NITAZOXANIDE | | | | | | | |
| AB | ! RISING | 500MG | A213820 | 001 | Nov 27, 2020 | Jan | CTEC | |
| AB | ZENARA | 500MG | A214844 | 001 | Feb 03, 2025 | Jan | NEWA | |

NITROFURANTOIN

| | | | | | | | | |
|----|-----------------|----------|---------|-----|--------------|-----|------|--|
| | SUSPENSION;ORAL | | | | | | | |
| | NITROFURANTOIN | | | | | | | |
| AB | APPCO | 25MG/5ML | A208909 | 001 | Jan 14, 2025 | Jan | NEWA | |

NOREPINEPHRINE BITARTRATE

| | | | | | | | | |
|----|---------------------------|----------------|---------|-----|--------------|-----|------|--|
| | INJECTABLE;INJECTION | | | | | | | |
| | NOREPINEPHRINE BITARTRATE | | | | | | | |
| AP | ASPIRO | EQ 1MG BASE/ML | A219163 | 001 | Jan 31, 2025 | Jan | NEWA | |

NYSTATIN

| | | | | | | | | |
|----|------------------|------------------|---------|-----|--------------|-----|------|--|
| | SUSPENSION;ORAL | | | | | | | |
| | NYSTATIN | | | | | | | |
| AA | XTTRIUM LABS INC | 100,000 UNITS/ML | A062512 | 001 | Oct 29, 1984 | Jan | CAHN | |

OFLOXACIN

| | | | | | | | | |
|-----|---------------------------|------|---------|-----|--------------|-----|------|--|
| | SOLUTION/DROPS;OPHTHALMIC | | | | | | | |
| | OFLOXACIN | | | | | | | |
| >D> | AT AMNEAL | 0.3% | A211524 | 001 | Mar 01, 2024 | Feb | DISC | |
| >A> | @ | 0.3% | A211524 | 001 | Mar 01, 2024 | Feb | DISC | |

OLICERIDINE

| | | | | | | | | |
|--|----------------------|------------------|---------|-----|--------------|-----|------|--|
| | SOLUTION;INTRAVENOUS | | | | | | | |
| | OLINVYK | | | | | | | |
| | + @ TREVENA | 1MG/ML (1MG/ML) | N210730 | 001 | Oct 30, 2020 | Jan | DISC | |
| | + @ | 2MG/2ML (1MG/ML) | N210730 | 002 | Oct 30, 2020 | Jan | DISC | |

OMAVELOXOLONE

| | | | | | | | | |
|--|--------------|------|---------|-----|--------------|-----|------|--|
| | CAPSULE;ORAL | | | | | | | |
| | SKYCLARYS | | | | | | | |
| | +! BIOGEN US | 50MG | N216718 | 001 | Feb 28, 2023 | Jan | CAHN | |

OMEGA-3-ACID ETHYL ESTERS

| | | | | | | | | |
|-----|---------------------|--|---------|-----|--------------|-----|------|--|
| | CAPSULE;ORAL | | | | | | | |
| | LOVAZA | | | | | | | |
| >A> | AB +! WAYLIS THERAP | 1GM CONTAINS AT LEAST 900MG OF THE ETHYL ESTERS OF OMEGA-3 FATTY ACIDS | N021654 | 001 | Nov 10, 2004 | Feb | CAHN | |
| >D> | AB +! WOODWARD | 1GM CONTAINS AT LEAST 900MG OF THE ETHYL ESTERS OF OMEGA-3 FATTY ACIDS | N021654 | 001 | Nov 10, 2004 | Feb | CAHN | |

ONDANSETRON

| | | | | | | | | |
|-----|------------------------------------|-----|---------|-----|--------------|-----|------|--|
| | TABLET, ORALLY DISINTEGRATING;ORAL | | | | | | | |
| | ONDANSETRON | | | | | | | |
| >D> | @ MYLAN | 4MG | A078139 | 001 | Jun 25, 2007 | Feb | CAHN | |
| >D> | @ | 8MG | A078139 | 002 | Jun 25, 2007 | Feb | CAHN | |
| >A> | @ NORVIUM BIOSCIENCE | 4MG | A078139 | 001 | Jun 25, 2007 | Feb | CAHN | |
| >A> | @ | 8MG | A078139 | 002 | Jun 25, 2007 | Feb | CAHN | |

OSELTAMIVIR PHOSPHATE

| | | | | | | | | |
|-----|-----------------------|----------------|---------|-----|--------------|-----|------|--|
| | FOR SUSPENSION;ORAL | | | | | | | |
| | OSELTAMIVIR PHOSPHATE | | | | | | | |
| >A> | AB JUBILANT GENERICS | EQ 6MG BASE/ML | A213695 | 001 | Mar 03, 2025 | Feb | NEWA | |

OXALIPLATIN

INJECTABLE; INTRAVENOUS
OXALIPLATIN

| | | | | | | |
|----|--------------------|---------------------|---------|-----|--------------|----------|
| AP | HETERO LABS LTD VI | 50MG/10ML (5MG/ML) | A217925 | 001 | Jan 27, 2025 | Jan NEWA |
| AP | | 100MG/20ML (5MG/ML) | A217925 | 002 | Jan 27, 2025 | Jan NEWA |

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

| | | | | | | | |
|-----|----|---------|------|---------|-----|--------------|----------|
| >A> | AB | LEADING | 10MG | A218261 | 001 | Mar 03, 2025 | Feb NEWA |
| >A> | AB | | 15MG | A218261 | 002 | Mar 03, 2025 | Feb NEWA |
| >A> | AB | | 30MG | A218261 | 003 | Mar 03, 2025 | Feb NEWA |

OXYCODONE HYDROCHLORIDE

SOLUTION; ORAL
OXYCODONE HYDROCHLORIDE
@ VISTAPHARM LLC

| | | | | | | |
|--|--|-----------|---------|-----|--------------|----------|
| | | 100MG/5ML | A202537 | 001 | Jul 30, 2012 | Jan CAHN |
|--|--|-----------|---------|-----|--------------|----------|

TABLET; ORAL
OXYCODONE HYDROCHLORIDE

| | | | | | | | |
|-----|----|----------------|------|---------|-----|--------------|----------|
| >D> | AB | NOVEL LABS INC | 5MG | A204021 | 001 | Jun 12, 2017 | Feb DISC |
| >A> | | @ | 5MG | A204021 | 001 | Jun 12, 2017 | Feb DISC |
| >D> | AB | | 10MG | A204021 | 002 | Jun 12, 2017 | Feb DISC |
| >A> | | @ | 10MG | A204021 | 002 | Jun 12, 2017 | Feb DISC |
| >D> | AB | | 15MG | A204021 | 003 | Jun 12, 2017 | Feb DISC |
| >A> | | @ | 15MG | A204021 | 003 | Jun 12, 2017 | Feb DISC |
| >D> | AB | | 20MG | A204021 | 004 | Jun 12, 2017 | Feb DISC |
| >A> | | @ | 20MG | A204021 | 004 | Jun 12, 2017 | Feb DISC |
| >D> | AB | | 30MG | A204021 | 005 | Jun 12, 2017 | Feb DISC |
| >A> | | @ | 30MG | A204021 | 005 | Jun 12, 2017 | Feb DISC |

PALIPERIDONE

TABLET, EXTENDED RELEASE; ORAL
PALIPERIDONE

| | | | | | | | |
|-----|----|-----------|-----|---------|-----|--------------|----------|
| >A> | AB | DR REDDYS | 3MG | A205559 | 001 | Feb 19, 2025 | Feb NEWA |
| >A> | AB | | 6MG | A205559 | 002 | Feb 19, 2025 | Feb NEWA |
| >A> | AB | | 9MG | A205559 | 003 | Feb 19, 2025 | Feb NEWA |

PANTOPRAZOLE SODIUM

POWDER; INTRAVENOUS
PANTOPRAZOLE SODIUM

| | | | | | | | |
|-----|----|--------------------|-------------------|---------|-----|--------------|----------|
| >D> | AP | FRESENIUS KABI USA | EQ 40MG BASE/VIAL | A216021 | 001 | Aug 01, 2024 | Feb DISC |
| >A> | | @ | EQ 40MG BASE/VIAL | A216021 | 001 | Aug 01, 2024 | Feb DISC |
| >D> | AP | +! HIKMA | EQ 40MG BASE/VIAL | N209463 | 001 | Jun 30, 2017 | Feb CTEC |
| >A> | | +! | EQ 40MG BASE/VIAL | N209463 | 001 | Jun 30, 2017 | Feb CTEC |

TABLET, DELAYED RELEASE; ORAL
PANTOPRAZOLE SODIUM

| | | | | | | |
|----|----------------------|--------------|---------|-----|--------------|----------|
| AB | GRAVITI PHARMS | EQ 20MG BASE | A219087 | 001 | Jan 16, 2025 | Jan NEWA |
| AB | | EQ 40MG BASE | A219087 | 002 | Jan 16, 2025 | Jan NEWA |
| | @ INGENUS PHARMS LLC | EQ 40MG BASE | A211368 | 001 | Mar 01, 2019 | Jan DISC |

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION; INTRAVENOUS
BIORPHEN

| | | | | | | | |
|-----|----|----------------------|-----------------------------|---------|-----|--------------|----------|
| >D> | +! | DR REDDYS LABS SA | 0.5MG/5ML (0.1MG/ML) | N212909 | 001 | Oct 21, 2019 | Feb CFTG |
| >A> | AP | +! | 0.5MG/5ML (0.1MG/ML) | N212909 | 001 | Oct 21, 2019 | Feb CFTG |
| >A> | AP | | PHENYLEPHRINE HYDROCHLORIDE | | | | |
| >A> | AP | SOMERSET THERAPS LLC | 0.5MG/5ML (0.1MG/ML) | A215617 | 001 | Feb 14, 2025 | Feb NFTG |

PHENYTOIN

SUSPENSION; ORAL
PHENYTOIN

| | | | | | | |
|--|------------------|-----------|---------|-----|--------------|----------|
| | @ VISTAPHARM LLC | 125MG/5ML | A040342 | 001 | Jan 31, 2001 | Jan CAHN |
| | @ | 125MG/5ML | A040342 | 002 | Aug 18, 2005 | Jan CAHN |

PHYTONADIONE

TABLET; ORAL
PHYTONADIONE

| | | | | | | | |
|-----|----|-------|-----|---------|-----|--------------|----------|
| >D> | AB | HIKMA | 5MG | A212112 | 001 | Dec 19, 2024 | Feb DISC |
| >A> | | @ | 5MG | A212112 | 001 | Dec 19, 2024 | Feb DISC |

PITOLISANT HYDROCHLORIDE

TABLET;ORAL
WAKIX

| | | | | | | | |
|-----|---|---------|----------------|---------|-----|--------------|----------|
| >D> | + | HARMONY | EQ 4.45MG BASE | N211150 | 001 | Aug 14, 2019 | Feb CAHN |
| >A> | + | | EQ 4.45MG BASE | N211150 | 001 | Aug 14, 2019 | Feb CAHN |
| >D> | + | ! | EQ 17.8MG BASE | N211150 | 002 | Aug 14, 2019 | Feb CAHN |
| >A> | + | ! | EQ 17.8MG BASE | N211150 | 002 | Aug 14, 2019 | Feb CAHN |

POMALIDOMIDE

CAPSULE;ORAL
POMALIDOMIDE
@ APOTEX
@
@
@

| | | | | | | |
|--|--|-----|---------|-----|--------------|----------|
| | | 1MG | A210164 | 001 | Jun 11, 2024 | Jan DISC |
| | | 2MG | A210164 | 002 | Jun 11, 2024 | Jan DISC |
| | | 3MG | A210164 | 003 | Jun 11, 2024 | Jan DISC |
| | | 4MG | A210164 | 004 | Jun 11, 2024 | Jan DISC |

POSACONAZOLE

TABLET, DELAYED RELEASE;ORAL
POSACONAZOLE

| | | | | | | | |
|-----|----|-----|-------|---------|-----|--------------|----------|
| >A> | AB | MSN | 100MG | A218434 | 001 | Feb 24, 2025 | Feb NEWA |
|-----|----|-----|-------|---------|-----|--------------|----------|

POTASSIUM CHLORIDE

FOR SOLUTION;ORAL
POTASSIUM CHLORIDE
AJENAT PHARMS
+! GENUS
+ @
SOLUTION;ORAL
POTASSIUM CHLORIDE

| | | | | | | | |
|----|---|---------------|------------|---------|-----|--------------|----------|
| AA | | AJENAT PHARMS | 20MEQ | A212183 | 001 | May 06, 2019 | Jan CAHN |
| AA | + | ! | GENUS | N208019 | 001 | Aug 19, 2015 | Jan CHRS |
| | + | @ | | N208019 | 003 | Aug 25, 2023 | Jan DISC |
| AA | | AJENAT PHARMS | 20MEQ/15ML | A216156 | 001 | Mar 07, 2023 | Jan CAHN |
| AA | | | 40MEQ/15ML | A216156 | 002 | Mar 07, 2023 | Jan CAHN |

POTASSIUM PHOSPHATE, DIBASIC; POTASSIUM PHOSPHATE, MONOBASIC

SOLUTION;INTRAVENOUS
POTASSIUM PHOSPHATES

| | | | | | | | |
|----|--|-------|---|---------|-----|--------------|----------|
| AP | | CIPLA | 1.18GM/5ML (236MG/ML);1.12GM/5ML (224MG/ML) | A217892 | 001 | Jan 24, 2025 | Jan NEWA |
| AP | | | 3.54GM/15ML (236MG/ML);3.36GM/15ML (224MG/ML) | A217892 | 002 | Jan 24, 2025 | Jan NEWA |
| AP | | | 11.8GM/50ML (236MG/ML);11.2GM/50ML (224MG/ML) | A217892 | 003 | Jan 24, 2025 | Jan NEWA |

PRALATREXATE

SOLUTION;INTRAVENOUS
FOLOTYN

| | | | | | | | |
|-----|----|--------------------|--------------------|---------|-----|--------------|----------|
| >D> | + | ACROTECH BIOPHARMA | 20MG/ML (20MG/ML) | N022468 | 001 | Sep 24, 2009 | Feb CFTG |
| >A> | AP | + | 20MG/ML (20MG/ML) | N022468 | 001 | Sep 24, 2009 | Feb CFTG |
| >D> | + | ! | 40MG/2ML (20MG/ML) | N022468 | 002 | Sep 24, 2009 | Feb CFTG |
| >A> | AP | + | 40MG/2ML (20MG/ML) | N022468 | 002 | Sep 24, 2009 | Feb CFTG |
| >A> | AP | | DR REDDYS | A206183 | 001 | Mar 10, 2025 | Feb NFTG |
| >A> | AP | | | A206183 | 002 | Mar 10, 2025 | Feb NFTG |

PREDNISONE

TABLET;ORAL
PREDNISONE
@ AIPING PHARM INC

| | | | | | | |
|--|--|-----|---------|-----|--|----------|
| | | 5MG | A080336 | 002 | | Jan CAHN |
|--|--|-----|---------|-----|--|----------|

PREGABALIN

CAPSULE;ORAL
PREGABALIN

| | | | | | | | |
|-----|----|----------|-------|---------|-----|--------------|----------|
| >A> | AB | HLTHCARE | 25MG | A091222 | 001 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 50MG | A091222 | 002 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 75MG | A091222 | 003 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 100MG | A091222 | 004 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 150MG | A091222 | 005 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 200MG | A091222 | 006 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 225MG | A091222 | 007 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 300MG | A091222 | 008 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | TORRENT | 25MG | A206942 | 001 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 50MG | A206942 | 002 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 75MG | A206942 | 003 | Feb 21, 2025 | Feb NEWA |

CAPSULE;ORAL
PREGABALIN

| | | | | | | | |
|-----|----|--|-------|---------|-----|--------------|----------|
| >A> | AB | | 100MG | A206942 | 004 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 150MG | A206942 | 005 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 200MG | A206942 | 006 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 225MG | A206942 | 007 | Feb 21, 2025 | Feb NEWA |
| >A> | AB | | 300MG | A206942 | 008 | Feb 21, 2025 | Feb NEWA |

TABLET, EXTENDED RELEASE;ORAL
PREGABALIN

| | | | | | | | |
|-----|----|-----------|--------|---------|-----|--------------|----------|
| >D> | AB | ALVOGEN | 82.5MG | A211593 | 001 | Apr 13, 2021 | Feb DISC |
| >A> | | @ | 82.5MG | A211593 | 001 | Apr 13, 2021 | Feb DISC |
| >D> | AB | | 165MG | A211593 | 002 | Apr 13, 2021 | Feb DISC |
| >A> | | @ | 165MG | A211593 | 002 | Apr 13, 2021 | Feb DISC |
| >D> | AB | | 330MG | A211593 | 003 | Apr 13, 2021 | Feb DISC |
| >A> | | @ | 330MG | A211593 | 003 | Apr 13, 2021 | Feb DISC |
| | | @ APOTEX | 165MG | A213313 | 001 | Apr 13, 2021 | Jan DISC |
| | | @ | 330MG | A213313 | 002 | Apr 13, 2021 | Jan DISC |
| | AB | HQ PHARMA | 330MG | A217857 | 001 | Jan 28, 2025 | Jan NEWA |

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINAMIDE HYDROCHLORIDE

| | | | | | | | |
|----|--|--------|----------|---------|-----|--------------|----------|
| AP | | CAPLIN | 100MG/ML | A218674 | 001 | Feb 04, 2025 | Jan NEWA |
| AP | | | 500MG/ML | A218674 | 002 | Feb 04, 2025 | Jan NEWA |

PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL
PROMETHAZINE PLAIN

| | | | | | | | |
|-----|----|------------------|------------|---------|-----|--------------|----------|
| >D> | AA | WOCKHARDT BIO AG | 6.25MG/5ML | A087953 | 001 | Nov 15, 1982 | Feb CAHN |
| >A> | AA | XTTRIUM LABS INC | 6.25MG/5ML | A087953 | 001 | Nov 15, 1982 | Feb CAHN |

QUETIAPINE FUMARATE

TABLET;ORAL
QUETIAPINE FUMARATE

| | | | | | | | |
|-----|----|--------------------|---------------|---------|-----|--------------|----------|
| >D> | AB | DR REDDYS LABS LTD | EQ 25MG BASE | A077380 | 001 | Mar 27, 2012 | Feb CAHN |
| >D> | AB | | EQ 50MG BASE | A077380 | 002 | Mar 27, 2012 | Feb CAHN |
| >D> | AB | | EQ 100MG BASE | A077380 | 003 | Mar 27, 2012 | Feb CAHN |
| >D> | AB | | EQ 150MG BASE | A077380 | 004 | Mar 27, 2012 | Feb CAHN |
| >D> | AB | | EQ 200MG BASE | A077380 | 005 | Mar 27, 2012 | Feb CAHN |
| >D> | AB | | EQ 300MG BASE | A077380 | 006 | Mar 27, 2012 | Feb CAHN |
| >D> | AB | | EQ 400MG BASE | A077380 | 007 | Mar 27, 2012 | Feb CAHN |
| >A> | AB | GRAVITI PHARMS | EQ 25MG BASE | A077380 | 001 | Mar 27, 2012 | Feb CAHN |
| >A> | AB | | EQ 50MG BASE | A077380 | 002 | Mar 27, 2012 | Feb CAHN |
| >A> | AB | | EQ 100MG BASE | A077380 | 003 | Mar 27, 2012 | Feb CAHN |
| >A> | AB | | EQ 150MG BASE | A077380 | 004 | Mar 27, 2012 | Feb CAHN |
| >A> | AB | | EQ 200MG BASE | A077380 | 005 | Mar 27, 2012 | Feb CAHN |
| >A> | AB | | EQ 300MG BASE | A077380 | 006 | Mar 27, 2012 | Feb CAHN |
| >A> | AB | | EQ 400MG BASE | A077380 | 007 | Mar 27, 2012 | Feb CAHN |

TABLET, EXTENDED RELEASE;ORAL
QUETIAPINE FUMARATE

| | | | | | | | |
|-----|----|----------------------|---------------|---------|-----|--------------|----------|
| >D> | AB | INTELLIPHARMACEUTICS | EQ 50MG BASE | A202939 | 001 | May 09, 2017 | Feb CAHN |
| >D> | AB | | EQ 150MG BASE | A202939 | 002 | May 09, 2017 | Feb CAHN |
| >D> | AB | | EQ 200MG BASE | A202939 | 003 | May 09, 2017 | Feb CAHN |
| >D> | AB | | EQ 300MG BASE | A202939 | 004 | May 09, 2017 | Feb CAHN |
| >D> | AB | | EQ 400MG BASE | A202939 | 005 | May 09, 2017 | Feb CAHN |
| >A> | AB | MEDICAP LABS | EQ 50MG BASE | A202939 | 001 | May 09, 2017 | Feb CAHN |
| >A> | AB | | EQ 150MG BASE | A202939 | 002 | May 09, 2017 | Feb CAHN |
| >A> | AB | | EQ 200MG BASE | A202939 | 003 | May 09, 2017 | Feb CAHN |
| >A> | AB | | EQ 300MG BASE | A202939 | 004 | May 09, 2017 | Feb CAHN |
| >A> | AB | | EQ 400MG BASE | A202939 | 005 | May 09, 2017 | Feb CAHN |

RALTEGRAVIR POTASSIUM

TABLET;ORAL
ISENTRESS

| | | | | | | | |
|---|---------------|-----------------------|---------------|---------|-----|--------------|----------|
| + | MSD SUB MERCK | | EQ 400MG BASE | N022145 | 001 | Oct 12, 2007 | Jan CTEC |
| | | RALTEGRAVIR POTASSIUM | | | | | |
| | | @ HETERO LABS LTD III | EQ 400MG BASE | A203540 | 001 | Dec 19, 2024 | Jan DISC |

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL
RANOLAZINE

| | | | | | | |
|----|------------|-------|---------|-----|--------------|----------|
| AB | ARTHUR GRP | 500MG | A212781 | 001 | Mar 23, 2020 | Jan CAHN |
| AB | | 1GM | A212781 | 002 | Mar 23, 2020 | Jan CAHN |
| AB | TORRENT | 500MG | A210407 | 001 | Feb 04, 2025 | Jan NEWA |
| AB | | 1GM | A210407 | 002 | Feb 04, 2025 | Jan NEWA |

REGORAFENIB

TABLET;ORAL
REGORAFENIB

| | | | | | | |
|----|-------------------|------|---------|-----|--------------|----------|
| AB | ACTAVIS LABS FL | 40MG | A209728 | 001 | Jan 13, 2025 | Jan NFTG |
| AB | +! BAYER HLTHCARE | 40MG | N203085 | 001 | Sep 27, 2012 | Jan CFTG |

REPAGLINIDE

TABLET;ORAL
REPAGLINIDE

| | | | | | | | |
|-----|----|--------------------|-----|---------|-----|--------------|----------|
| >D> | AB | SUN PHARM INDS INC | 1MG | A077571 | 002 | Jul 11, 2013 | Feb DISC |
| >A> | | @ | 1MG | A077571 | 002 | Jul 11, 2013 | Feb DISC |
| >D> | AB | | 2MG | A077571 | 003 | Jul 11, 2013 | Feb DISC |
| >A> | | @ | 2MG | A077571 | 003 | Jul 11, 2013 | Feb DISC |

RILUZOLE

TABLET;ORAL
RILUZOLE

| | | | | | | | |
|-----|----|--------------------|------|---------|-----|--------------|----------|
| >D> | AB | MYLAN PHARMS INC | 50MG | A203042 | 001 | Jul 01, 2013 | Feb CAHN |
| >A> | AB | NORVIUM BIOSCIENCE | 50MG | A203042 | 001 | Jul 01, 2013 | Feb CAHN |

RISDIPLAM

| | | | | | | | |
|-----|----|---------------|-----|---------|-----|--------------|----------|
| >A> | | TABLET;ORAL | | | | | |
| >A> | | EVRYSDI | | | | | |
| >A> | +! | GENENTECH INC | 5MG | N219285 | 001 | Feb 11, 2025 | Feb NEWA |

RISPERIDONE

SOLUTION;ORAL
RISPERIDONE

| | | | | | | | |
|-----|----|----------------|--------|---------|-----|--------------|----------|
| >D> | AA | LANNETT CO INC | 1MG/ML | A079158 | 001 | Dec 03, 2010 | Feb DISC |
| >A> | | @ | 1MG/ML | A079158 | 001 | Dec 03, 2010 | Feb DISC |

RIVAROXABAN

TABLET;ORAL
RIVAROXABAN

| | | | | | | | |
|-----|----|----------------|-------|---------|-----|--------------|----------|
| >A> | | RIVAROXABAN | | | | | |
| >A> | AB | LUPIN LTD | 2.5MG | A208555 | 001 | Mar 03, 2025 | Feb NFTG |
| >A> | AB | TARO | 2.5MG | A208557 | 001 | Mar 03, 2025 | Feb NFTG |
| >D> | | XARELTO | | | | | |
| >D> | + | JANSSEN PHARMS | 2.5MG | N022406 | 004 | Oct 11, 2018 | Feb CFTG |
| >A> | AB | + | 2.5MG | N022406 | 004 | Oct 11, 2018 | Feb CFTG |

RIZATRIPTAN BENZOATE

TABLET;ORAL
RIZATRIPTAN BENZOATE

| | | | | | | | |
|-----|----|--------------------|--------------|---------|-----|--------------|----------|
| >D> | AB | MYLAN PHARMS INC | EQ 5MG BASE | A201993 | 001 | Dec 31, 2012 | Feb CAHN |
| >D> | AB | | EQ 10MG BASE | A201993 | 002 | Dec 31, 2012 | Feb CAHN |
| >A> | AB | NORVIUM BIOSCIENCE | EQ 5MG BASE | A201993 | 001 | Dec 31, 2012 | Feb CAHN |
| >A> | AB | | EQ 10MG BASE | A201993 | 002 | Dec 31, 2012 | Feb CAHN |

ROFLUMILAST

TABLET;ORAL
ROFLUMILAST

| | | | | | | | |
|-----|----------------------|----------------|---------|---------|--------------|--------------|----------|
| AB | AUROBINDO PHARMA LTD | 250MCG | A213298 | 002 | Jan 31, 2025 | Jan NEWA | |
| >D> | @ | BRECKENRIDGE | 250MCG | A208236 | 002 | Oct 19, 2023 | Feb CAHN |
| >D> | @ | | 500MCG | A208236 | 001 | Oct 03, 2018 | Feb CAHN |
| >A> | @ | SENORES PHARMS | 250MCG | A208236 | 002 | Oct 19, 2023 | Feb CAHN |
| >A> | @ | | 500MCG | A208236 | 001 | Oct 03, 2018 | Feb CAHN |

ROSUVASTATIN CALCIUM

TABLET; ORAL

CRESTOR

| | | | | | | | |
|----|---|-------------|--------------|---------|-----|--------------|----------|
| AB | + | ASTRAZENECA | EQ 5MG BASE | N021366 | 002 | Aug 12, 2003 | Jan CAHN |
| AB | + | | EQ 10MG BASE | N021366 | 003 | Aug 12, 2003 | Jan CAHN |
| AB | + | | EQ 20MG BASE | N021366 | 004 | Aug 12, 2003 | Jan CAHN |
| AB | + | | EQ 40MG BASE | N021366 | 005 | Aug 12, 2003 | Jan CAHN |

SACUBITRIL; VALSARTAN

TABLET; ORAL

SACUBITRIL AND VALSARTAN

| | | | | | | | |
|----|--|-----------|------------|---------|-----|--------------|----------|
| AB | | DR REDDYS | 24MG;26MG | A213627 | 001 | Jan 13, 2025 | Jan NEWA |
| AB | | | 49MG;51MG | A213627 | 002 | Jan 13, 2025 | Jan NEWA |
| AB | | | 97MG;103MG | A213627 | 003 | Jan 13, 2025 | Jan NEWA |
| AB | | LUPIN | 24MG;26MG | A213808 | 001 | Jan 08, 2025 | Jan NEWA |
| AB | | | 49MG;51MG | A213808 | 002 | Jan 08, 2025 | Jan NEWA |
| AB | | | 97MG;103MG | A213808 | 003 | Jan 08, 2025 | Jan NEWA |

SELENIOS ACID

SOLUTION; INTRAVENOUS

SELENIOS ACID

| | | | | | | | | |
|-----|----|---|--------------------|--|---------|-----|--------------|----------|
| >D> | AP | + | AM REGENT | EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML) | N209379 | 002 | Jan 25, 2021 | Feb CTEC |
| >A> | | + | | EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML) | N209379 | 002 | Jan 25, 2021 | Feb CTEC |
| | AP | + | | EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML) | N209379 | 002 | Jan 25, 2021 | Jan CFTG |
| >D> | | + | | EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML) | N209379 | 001 | Apr 30, 2019 | Feb CFTG |
| >A> | AP | + | | EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML) | N209379 | 001 | Apr 30, 2019 | Feb CFTG |
| >D> | AP | | FRESENIUS KABI USA | EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML) | A218779 | 001 | Feb 10, 2025 | Feb CMS1 |
| | AP | | | EQ 60MCG SELENIUM/ML (EQ 60MCG SELENIUM/ML) | A218779 | 001 | Feb 10, 2025 | Jan NFTG |
| >A> | AP | | | EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML) | A218779 | 001 | Feb 10, 2025 | Feb CMS1 |
| >A> | AP | | SUN PHARM | EQ 600MCG SELENIUM/10ML (EQ 60MCG SELENIUM/ML) | A219547 | 001 | Feb 20, 2025 | Feb NEWA |

SELPERCATINIB

CAPSULE; ORAL

RETEVMO

+ ELI LILLY AND CO

+! 80MG

| | | | |
|---------|-----|--------------|----------|
| N213246 | 001 | May 08, 2020 | Jan CAHN |
| N213246 | 002 | May 08, 2020 | Jan CAHN |

TABLET; ORAL

RETEVMO

+ ELI LILLY AND CO

+ 40MG
 + 80MG
 + 120MG
 +! 160MG

| | | | |
|---------|-----|--------------|----------|
| N218160 | 001 | Apr 10, 2024 | Jan CAHN |
| N218160 | 002 | Apr 10, 2024 | Jan CAHN |
| N218160 | 003 | Apr 10, 2024 | Jan CAHN |
| N218160 | 004 | Apr 10, 2024 | Jan CAHN |

SEVELAMER CARBONATE

FOR SUSPENSION; ORAL

SEVELAMER CARBONATE

@ INVAGEN PHARMS

@ 800MG/PACKET

@ 2.4GM/PACKET

| | | | | | | | | |
|-----|----|--|---------|--------------|---------|-----|--------------|----------|
| >A> | AB | | TORRENT | 800MG/PACKET | A215909 | 001 | Feb 27, 2025 | Feb NEWA |
|-----|----|--|---------|--------------|---------|-----|--------------|----------|

| | | | | | | | | |
|-----|----|--|--|--------------|---------|-----|--------------|----------|
| >A> | AB | | | 2.4GM/PACKET | A215909 | 002 | Feb 27, 2025 | Feb NEWA |
|-----|----|--|--|--------------|---------|-----|--------------|----------|

SEVELAMER HYDROCHLORIDE

TABLET; ORAL

SEVELAMER HYDROCHLORIDE

| | | | | | | | |
|----|--|-------------|-------|---------|-----|--------------|----------|
| AB | | NAVINTA LLC | 800MG | A218966 | 001 | Feb 03, 2025 | Jan NEWA |
|----|--|-------------|-------|---------|-----|--------------|----------|

SILDENAFIL CITRATE

FOR SUSPENSION; ORAL

SILDENAFIL CITRATE

| | | | | | | | | |
|-----|----|--|----------------------|-----------------|---------|-----|--------------|----------|
| >A> | AB | | APPCO | EQ 10MG BASE/ML | A213814 | 001 | Apr 29, 2021 | Feb CAHN |
| >A> | AB | | CHARTWELL RX | EQ 10MG BASE/ML | A213814 | 001 | Apr 29, 2021 | Feb CAHN |
| >D> | AB | | SOMERSET THERAPS LLC | EQ 10MG BASE/ML | A213814 | 001 | Apr 29, 2021 | Feb CAHN |

| | | | | | | | |
|---|----|---------------------|---------------------|---------|-----|--------------|----------|
| <p>TABLET;ORAL SILDENAFIL CITRATE</p> | | | | | | | |
| >A> | AB | JUBILANT GENERICS | EQ 20MG BASE | A202954 | 001 | Mar 06, 2025 | Feb NEWA |
| <p><u>SILODOSIN</u></p> | | | | | | | |
| <p>CAPSULE;ORAL SILODOSIN</p> | | | | | | | |
| | AB | TORRENT | 4MG | A210396 | 001 | Feb 10, 2025 | Jan NEWA |
| | AB | | 8MG | A210396 | 002 | Feb 10, 2025 | Jan NEWA |
| <p><u>SIMVASTATIN</u></p> | | | | | | | |
| <p>TABLET;ORAL SIMVASTATIN</p> | | | | | | | |
| >D> | AB | DR REDDYS LABS INC | 5MG | A077752 | 005 | Jan 23, 2008 | Feb CAHN |
| >D> | AB | | 10MG | A077752 | 001 | Dec 20, 2006 | Feb CAHN |
| >D> | AB | | 20MG | A077752 | 002 | Dec 20, 2006 | Feb CAHN |
| >D> | AB | | 40MG | A077752 | 003 | Dec 20, 2006 | Feb CAHN |
| >D> | AB | | 80MG | A077752 | 004 | Dec 20, 2006 | Feb CAHN |
| >A> | AB | GRAVITI PHARMS | 5MG | A077752 | 005 | Jan 23, 2008 | Feb CAHN |
| >A> | AB | | 10MG | A077752 | 001 | Dec 20, 2006 | Feb CAHN |
| >A> | AB | | 20MG | A077752 | 002 | Dec 20, 2006 | Feb CAHN |
| >A> | AB | | 40MG | A077752 | 003 | Dec 20, 2006 | Feb CAHN |
| >A> | AB | | 80MG | A077752 | 004 | Dec 20, 2006 | Feb CAHN |
| <p><u>SITAGLIPTIN HYDROCHLORIDE</u></p> | | | | | | | |
| <p>SOLUTION;ORAL BRYNOVIN</p> | | | | | | | |
| | + | ! AZURITY | EQ 25MG BASE/ML | N219122 | 001 | Jan 16, 2025 | Jan NEWA |
| <p><u>SODIUM NITROPRUSSIDE</u></p> | | | | | | | |
| <p>INJECTABLE;INJECTION SODIUM NITROPRUSSIDE</p> | | | | | | | |
| | @ | XIROMED | 25MG/ML | A211277 | 001 | Oct 29, 2020 | Jan DISC |
| <p><u>SODIUM POLYSTYRENE SULFONATE</u></p> | | | | | | | |
| <p>POWDER;ORAL, RECTAL SODIUM POLYSTYRENE SULFONATE</p> | | | | | | | |
| AA | | AJENAT PHARMS | 454GM/BOT | A205727 | 001 | Feb 23, 2016 | Jan CAHN |
| <p><u>SOLIFENACIN SUCCINATE</u></p> | | | | | | | |
| <p>TABLET;ORAL SOLIFENACIN SUCCINATE</p> | | | | | | | |
| >A> | AB | TORRENT | 5MG | A209424 | 001 | Mar 04, 2025 | Feb NEWA |
| >A> | AB | | 10MG | A209424 | 002 | Mar 04, 2025 | Feb NEWA |
| <p><u>SPIRONOLACTONE</u></p> | | | | | | | |
| <p>SUSPENSION;ORAL SPIRONOLACTONE</p> | | | | | | | |
| >A> | AB | HETERO LABS LTD III | 25MG/5ML | A218085 | 001 | Feb 21, 2025 | Feb NEWA |
| <p>TABLET;ORAL SPIRONOLACTONE</p> | | | | | | | |
| | AB | GRAVITI PHARMS | 25MG | A219494 | 001 | Jan 23, 2025 | Jan NEWA |
| | AB | | 50MG | A219494 | 002 | Jan 23, 2025 | Jan NEWA |
| | AB | | 100MG | A219494 | 003 | Jan 23, 2025 | Jan NEWA |
| <p><u>STREPTOZOCIN</u></p> | | | | | | | |
| <p>INJECTABLE;INJECTION ZANOSAR</p> | | | | | | | |
| >D> | | + | ! TEVA PHARMS USA | N050577 | 001 | May 07, 1982 | Feb DISC |
| >A> | | + | @ | N050577 | 001 | May 07, 1982 | Feb DISC |
| <p><u>SUCCINYLCHOLINE CHLORIDE</u></p> | | | | | | | |
| <p>INJECTABLE;INJECTION SUCCINYLCHOLINE CHLORIDE</p> | | | | | | | |
| >A> | AP | FRESENIUS KABI USA | 20MG/ML | A217885 | 001 | Feb 21, 2025 | Feb NEWA |
| <p>SOLUTION;INTRAMUSCULAR, INTRAVENOUS SUCCINYLCHOLINE CHLORIDE</p> | | | | | | | |
| AP | | FRESENIUS KABI USA | 100MG/5ML (20MG/ML) | A217884 | 001 | Feb 11, 2025 | Jan NEWA |

SUNITINIB MALATE

CAPSULE;ORAL
SUNITINIB MALATE

| | | | | | | |
|-----|---------------|----------------|---------|-----|--------------|----------|
| AB | FOSUN WANBANG | EQ 12.5MG BASE | A218012 | 001 | Aug 21, 2023 | Jan CAHN |
| AB | | EQ 25MG BASE | A218012 | 002 | Aug 21, 2023 | Jan CAHN |
| AB | | EQ 37.5MG BASE | A218012 | 003 | Aug 21, 2023 | Jan CAHN |
| AB | | EQ 50MG BASE | A218012 | 004 | Aug 21, 2023 | Jan CAHN |
| >A> | MSN | EQ 12.5MG BASE | A214824 | 001 | Feb 14, 2025 | Feb NEWA |
| >A> | | EQ 25MG BASE | A214824 | 002 | Feb 14, 2025 | Feb NEWA |
| >A> | | EQ 37.5MG BASE | A214824 | 003 | Feb 14, 2025 | Feb NEWA |
| >A> | | EQ 50MG BASE | A214824 | 004 | Feb 14, 2025 | Feb NEWA |

SUZETRIGINE

TABLET;ORAL
JOURNAVX

| | | | | | | |
|---|-------------------|------|---------|-----|--------------|----------|
| + | VERTEX PHARMS INC | 50MG | N219209 | 001 | Jan 30, 2025 | Jan NEWA |
|---|-------------------|------|---------|-----|--------------|----------|

TACROLIMUS

CAPSULE;ORAL
TACROLIMUS

| | | | | | | |
|----|---------------|---------------|---------|-----|--------------|----------|
| AB | AJENAT PHARMS | EQ 0.5MG BASE | A206651 | 001 | Nov 30, 2017 | Jan CAHN |
| AB | | EQ 1MG BASE | A206651 | 002 | Nov 30, 2017 | Jan CAHN |
| AB | | EQ 5MG BASE | A206651 | 003 | Nov 30, 2017 | Jan CAHN |

INJECTABLE;INJECTION
PROGRAF

| | | | | | | | |
|----|---|------------|----------------|---------|-----|--------------|----------|
| AP | + | ASTELLAS | EQ 5MG BASE/ML | N050709 | 001 | Apr 08, 1994 | Jan CFTG |
| AP | | TACROLIMUS | | | | | |
| AP | | NEXUS | EQ 5MG BASE/ML | A217108 | 001 | Feb 12, 2025 | Jan NFTG |

TALAZOPARIB TOSYLATE

CAPSULE;ORAL
TALZENNA

| | | | | | | | |
|-----|---|--------|----------------|---------|-----|--------------|----------|
| >D> | + | PFIZER | EQ 0.1MG BASE | N211651 | 005 | Jun 20, 2023 | Feb DISC |
| >A> | + | @ | EQ 0.1MG BASE | N211651 | 005 | Jun 20, 2023 | Feb DISC |
| >D> | + | | EQ 0.25MG BASE | N211651 | 001 | Oct 16, 2018 | Feb DISC |
| >A> | + | @ | EQ 0.25MG BASE | N211651 | 001 | Oct 16, 2018 | Feb DISC |
| >D> | + | | EQ 0.35MG BASE | N211651 | 006 | Jun 20, 2023 | Feb DISC |
| >A> | + | @ | EQ 0.35MG BASE | N211651 | 006 | Jun 20, 2023 | Feb DISC |
| >D> | + | | EQ 0.5MG BASE | N211651 | 003 | Sep 20, 2021 | Feb DISC |
| >A> | + | @ | EQ 0.5MG BASE | N211651 | 003 | Sep 20, 2021 | Feb DISC |
| >D> | + | | EQ 0.75MG BASE | N211651 | 004 | Sep 20, 2021 | Feb DISC |
| >A> | + | @ | EQ 0.75MG BASE | N211651 | 004 | Sep 20, 2021 | Feb DISC |
| >D> | + | ! | EQ 1MG BASE | N211651 | 002 | Oct 16, 2018 | Feb DISC |
| >A> | + | @ | EQ 1MG BASE | N211651 | 002 | Oct 16, 2018 | Feb DISC |

TAMSULOSIN HYDROCHLORIDE

CAPSULE;ORAL
FLOMAX

| | | | | | | | | |
|-----|----|---|--------|-------|---------|-----|--------------|----------|
| >D> | AB | + | SANOFI | 0.4MG | N020579 | 001 | Apr 15, 1997 | Feb DISC |
| >A> | | + | @ | 0.4MG | N020579 | 001 | Apr 15, 1997 | Feb DISC |

TAMSULOSIN HYDROCHLORIDE

| | | | | | | | | |
|-----|----|---|----------------------|-------|---------|-----|--------------|----------|
| >D> | | @ | ASCENT PHARMS INC | 0.4MG | A214730 | 001 | May 04, 2022 | Feb CMFD |
| >A> | AB | | | 0.4MG | A214730 | 001 | May 04, 2022 | Feb CMFD |
| >D> | AB | | ZYDUS PHARMS USA INC | 0.4MG | A078225 | 001 | Apr 27, 2010 | Feb CHRS |
| >A> | AB | ! | | 0.4MG | A078225 | 001 | Apr 27, 2010 | Feb CHRS |

TAZAROTENE

CREAM;TOPICAL
TAZAROTENE

| | | | | | | | | |
|-----|----|--|---------|-------|---------|-----|--------------|----------|
| >A> | AB | | COSETTE | 0.05% | A208662 | 002 | Mar 10, 2025 | Feb NEWA |
|-----|----|--|---------|-------|---------|-----|--------------|----------|

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE;INJECTION
OSTEOLITE

| | | | | | | | | |
|-----|--|---|--------------------|-----|---------|-----|--|----------|
| >D> | | @ | PHARMALUCENCE | N/A | N017972 | 001 | | Feb CAHN |
| >A> | | @ | SUN PHARM INDS INC | N/A | N017972 | 001 | | Feb CAHN |

TELMISARTANTABLET; ORAL
MICARDIS

| | | | | | | | | | |
|-------------|----|---|----------------------|------|---------|-----|--------------|-----|------|
| >D> | AB | + | BOEHRINGER INGELHEIM | 80MG | N020850 | 002 | Nov 10, 1998 | Feb | CHRS |
| >A> | AB | + | | 80MG | N020850 | 002 | Nov 10, 1998 | Feb | CHRS |
| TELMISARTAN | | | | | | | | | |
| >D> | AB | | INVENTIA | 80MG | A205150 | 003 | Oct 30, 2015 | Feb | CHRS |
| >A> | AB | ! | | 80MG | A205150 | 003 | Oct 30, 2015 | Feb | CHRS |
| | AB | | MACLEODS PHARMS LTD | 20MG | A203986 | 001 | Jan 15, 2025 | Jan | NEWA |
| | AB | | | 40MG | A203986 | 002 | Jan 15, 2025 | Jan | NEWA |
| | AB | | | 80MG | A203986 | 003 | Jan 15, 2025 | Jan | NEWA |

TERIFLUNOMIDETABLET; ORAL
TERIFLUNOMIDE

| | | | | | | | | | |
|-----|----|---|--------|------|---------|-----|--------------|-----|------|
| >D> | AB | | APOTEX | 7MG | A209601 | 001 | Nov 02, 2018 | Feb | DISC |
| >A> | | @ | | 7MG | A209601 | 001 | Nov 02, 2018 | Feb | DISC |
| >D> | AB | | | 14MG | A209601 | 002 | Nov 02, 2018 | Feb | DISC |
| >A> | | @ | | 14MG | A209601 | 002 | Nov 02, 2018 | Feb | DISC |

TERIPARATIDESOLUTION; SUBCUTANEOUS
BONSITY

| | | | | | | | | | |
|--------------|----|---|-----------------|---------------------------|---------|-----|--------------|-----|------|
| >A> | | | ALVOGEN | 0.56MG/2.24ML (0.25MG/ML) | N211939 | 001 | Oct 04, 2019 | Feb | CPOT |
| >D> | | | | 0.62MG/2.48ML (0.25MG/ML) | N211939 | 001 | Oct 04, 2019 | Feb | CPOT |
| FORTEO | | | | | | | | | |
| >A> | AP | + | LILLY | 0.56MG/2.24ML (0.25MG/ML) | N021318 | 002 | Jun 25, 2008 | Feb | CPOT |
| >D> | AP | + | | 0.6MG/2.4ML (0.25MG/ML) | N021318 | 002 | Jun 25, 2008 | Feb | CPOT |
| TERIPARATIDE | | | | | | | | | |
| >A> | AP | + | ALMAJECT | 0.56MG/2.24ML (0.25MG/ML) | N218771 | 001 | Jun 04, 2024 | Feb | CPOT |
| >D> | | + | | 0.6MG/2.4ML (0.25MG/ML) | N218771 | 001 | Jun 04, 2024 | Feb | CTEC |
| >A> | AP | + | | 0.6MG/2.4ML (0.25MG/ML) | N218771 | 001 | Jun 04, 2024 | Feb | CTEC |
| >A> | AP | | APOTEX | 0.56MG/2.24ML (0.25MG/ML) | A211097 | 001 | Nov 16, 2023 | Feb | CPOT |
| >D> | AP | | | 0.6MG/2.4ML (0.25MG/ML) | A211097 | 001 | Nov 16, 2023 | Feb | CPOT |
| >A> | AP | | TEVA PHARMS USA | 0.56MG/2.24ML (0.25MG/ML) | A208569 | 001 | Nov 16, 2023 | Feb | CPOT |
| >D> | AP | | | 0.6MG/2.4ML (0.25MG/ML) | A208569 | 001 | Nov 16, 2023 | Feb | CPOT |

TESTOSTERONESOLUTION, METERED; TRANSDERMAL
TESTOSTERONE

| | | | | | | | |
|---|--------|----------------------|---------|-----|--------------|-----|------|
| @ | ENCUBE | 30MG/1.5ML ACTUATION | A212301 | 001 | Jan 11, 2021 | Jan | DISC |
|---|--------|----------------------|---------|-----|--------------|-----|------|

THEOPHYLLINETABLET, EXTENDED RELEASE; ORAL
THEOPHYLLINE

| | | | | | | | | | |
|----|--|---|-------------------|-------|---------|-----|--------------|-----|------|
| AB | | | AJANTA PHARMA LTD | 450MG | A218401 | 001 | Jan 13, 2025 | Jan | NEWA |
| | | @ | RHODES PHARMS | 300MG | A214113 | 001 | May 11, 2023 | Jan | DISC |

THIAMINE HYDROCHLORIDEINJECTABLE; INJECTION
THIAMINE HYDROCHLORIDE

| | | | | | | | | | |
|-----|----|--|------------------|----------|---------|-----|--------------|-----|------|
| >A> | AP | | GLAND PHARMA LTD | 100MG/ML | A217800 | 001 | Feb 24, 2025 | Feb | NEWA |
|-----|----|--|------------------|----------|---------|-----|--------------|-----|------|

TICAGRELORTABLET; ORAL
TICAGRELOR

| | | | | | | | | | |
|-----|--|---|---------------------|------|---------|-----|--------------|-----|------|
| >A> | | @ | MSN | 90MG | A208596 | 001 | Apr 07, 2020 | Feb | CAHN |
| >D> | | @ | SIGMAPHARM LABS LLC | 90MG | A208596 | 001 | Apr 07, 2020 | Feb | CAHN |

TOBRAMYCINPOWDER; INHALATION
TOBI PODHALER

| | | | | | | | | | |
|-----|--|---|---------------------|------|---------|-----|--------------|-----|------|
| >D> | | + | MYLAN SPECIALITY LP | 28MG | N201688 | 001 | Mar 22, 2013 | Feb | CAHN |
| >A> | | + | VIATRIS | 28MG | N201688 | 001 | Mar 22, 2013 | Feb | CAHN |

SOLUTION; INHALATION
TOBI

| | | | | | | | | | |
|-----|----|---|---------------------|-----------|---------|-----|--------------|-----|------|
| >D> | AN | + | MYLAN SPECIALITY LP | 300MG/5ML | N050753 | 001 | Dec 22, 1997 | Feb | CAHN |
| >A> | AN | + | VIATRIS | 300MG/5ML | N050753 | 001 | Dec 22, 1997 | Feb | CAHN |

TRAMADOL HYDROCHLORIDE

TABLET;ORAL

TRAMADOL HYDROCHLORIDE

| | | | | | | | |
|-----|----|----------------------|------|---------|-----|--------------|----------|
| >A> | AB | APDM PHARMS | 50MG | A090404 | 001 | Jan 31, 2011 | Feb CAHN |
| >D> | AB | MERRO PHARM USA | 50MG | A206706 | 001 | Jul 02, 2019 | Feb DISC |
| >A> | | @ | 50MG | A206706 | 001 | Jul 02, 2019 | Feb DISC |
| >D> | AB | ZYDUS PHARMS USA INC | 50MG | A090404 | 001 | Jan 31, 2011 | Feb CAHN |

TABLET, EXTENDED RELEASE;ORAL

TRAMADOL HYDROCHLORIDE

| | | | | | | | |
|-----|---|---------------------|-------|---------|-----|--------------|----------|
| AB1 | ! | LUPIN LTD | 100MG | A200503 | 001 | Aug 29, 2011 | Jan CTEC |
| AB1 | | | 200MG | A200503 | 002 | Aug 29, 2011 | Jan CTEC |
| AB1 | | | 300MG | A200503 | 003 | Aug 29, 2011 | Jan CTEC |
| AB1 | | MACLEODS PHARMS LTD | 100MG | A209404 | 001 | Jan 31, 2025 | Jan NEWA |
| AB1 | | | 200MG | A209404 | 002 | Jan 31, 2025 | Jan NEWA |
| AB1 | | | 300MG | A209404 | 003 | Jan 31, 2025 | Jan NEWA |

TRAMETINIB DIMETHYL SULFOXIDE

TABLET;ORAL

TRAMETINIB DIMETHYL SULFOXIDE

| | | | | | | | |
|-----|--|-----------|----------|---------|-----|--------------|----------|
| >A> | | @ HIKMA | EQ 0.5MG | A219002 | 001 | Aug 06, 2024 | Feb CAHN |
| >A> | | @ | EQ 2MG | A219002 | 002 | Aug 06, 2024 | Feb CAHN |
| >D> | | @ NOVUGEN | EQ 0.5MG | A219002 | 001 | Aug 06, 2024 | Feb CAHN |
| >D> | | @ | EQ 2MG | A219002 | 002 | Aug 06, 2024 | Feb CAHN |

TRANEXAMIC ACID

INJECTABLE;INJECTION

TRANEXAMIC ACID

| | | | | | | | |
|--|--|----------------------|----------|---------|-----|--------------|----------|
| | | @ FRESENIUS KABI USA | 100MG/ML | A091596 | 001 | Mar 02, 2012 | Jan DISC |
|--|--|----------------------|----------|---------|-----|--------------|----------|

TRAVOPROST

SOLUTION/DROPS;OPHTHALMIC

TRAVATAN Z

| | | | | | | | | |
|-----|-----|---|----------------------|--------|---------|-----|--------------|----------|
| >D> | AT | + | SANDOZ | 0.004% | N021994 | 001 | Sep 21, 2006 | Feb CTEC |
| >A> | AT2 | + | | 0.004% | N021994 | 001 | Sep 21, 2006 | Feb CTEC |
| | | | TRAVOPROST | | | | | |
| >D> | AT1 | | ALEMBIC | 0.004% | A210458 | 001 | Dec 20, 2019 | Feb DISC |
| >A> | | @ | | 0.004% | A210458 | 001 | Dec 20, 2019 | Feb DISC |
| >D> | AT | | APOTEX | 0.004% | A203431 | 001 | Jul 10, 2015 | Feb CTEC |
| >A> | AT2 | | | 0.004% | A203431 | 001 | Jul 10, 2015 | Feb CTEC |
| >D> | AT1 | ! | CHARTWELL RX | 0.004% | A091340 | 001 | Mar 01, 2013 | Feb CTEC |
| >A> | | ! | | 0.004% | A091340 | 001 | Mar 01, 2013 | Feb CTEC |
| >D> | AT | | GLAND PHARMA LTD | 0.004% | A218159 | 001 | Jul 12, 2024 | Feb CTEC |
| >A> | AT2 | | | 0.004% | A218159 | 001 | Jul 12, 2024 | Feb CTEC |
| >D> | AT | | MICRO LABS | 0.004% | A203767 | 001 | Mar 19, 2021 | Feb CTEC |
| >A> | AT2 | | | 0.004% | A203767 | 001 | Mar 19, 2021 | Feb CTEC |
| >D> | AT | | MYLAN | 0.004% | A205050 | 001 | Jul 07, 2017 | Feb CTEC |
| >A> | AT2 | | | 0.004% | A205050 | 001 | Jul 07, 2017 | Feb CTEC |
| >D> | AT | | SOMERSET THERAPS LLC | 0.004% | A217228 | 001 | Sep 23, 2024 | Feb CTEC |
| >A> | AT2 | | | 0.004% | A217228 | 001 | Sep 23, 2024 | Feb CTEC |

TREOSULFAN

POWDER;INTRAVENOUS

GRAFAPEX

| | | | | | | | |
|---|---|---------|----------|---------|-----|--------------|----------|
| + | ! | MEDEXUS | 1GM/VIAL | N214759 | 001 | Jan 21, 2025 | Jan CAHN |
| + | ! | | 5GM/VIAL | N214759 | 002 | Jan 21, 2025 | Jan CAHN |
| + | ! | MGFKSMB | 1GM/VIAL | N214759 | 001 | Jan 21, 2025 | Jan NEWA |
| + | ! | | 5GM/VIAL | N214759 | 002 | Jan 21, 2025 | Jan NEWA |

TREPROSTINIL

POWDER;INHALATION

TYVASO DPI

| | | | | | | | |
|---|---|---------------|-------------|---------|-----|--------------|----------|
| + | ! | UNITED THERAP | 0.032MG/INH | N214324 | 002 | May 23, 2022 | Jan CHRS |
| + | ! | | 0.048MG/INH | N214324 | 003 | May 23, 2022 | Jan CHRS |
| + | ! | | 0.08MG/INH | N214324 | 005 | Oct 24, 2024 | Jan CHRS |

TRETINOIN

CAPSULE;ORAL

TRETINOIN

| | | | | | | | | |
|-----|----|---|-----------------|------|---------|-----|--------------|----------|
| >D> | AB | ! | BARR LABS INC | 10MG | A077684 | 001 | Jun 22, 2007 | Feb DISC |
| >A> | | @ | | 10MG | A077684 | 001 | Jun 22, 2007 | Feb DISC |
| >D> | AB | | ENDO OPERATIONS | 10MG | A201687 | 001 | Oct 24, 2012 | Feb CHRS |

| | | | | | | | | | |
|-----|----|--------------|----------------------|--------|---------|-----|--------------|-----|------|
| | | CAPSULE;ORAL | | | | | | | |
| | | TRETINOIN | | | | | | | |
| >A> | AB | ! | 10MG | | A201687 | 001 | Oct 24, 2012 | Feb | CHRS |
| | | GEL;TOPICAL | | | | | | | |
| | | RETIN-A | | | | | | | |
| | AB | +! | BAUSCH | 0.01% | N017955 | 001 | | Jan | CAHN |
| | | TRETINOIN | | | | | | | |
| | AB | | AUROBINDO PHARMA LTD | 0.01% | A218246 | 001 | Jan 13, 2025 | Jan | NEWA |
| >A> | AB | | | 0.025% | A218245 | 001 | Feb 27, 2025 | Feb | NEWA |
| >A> | AB | | ENCUBE | 0.01% | A217588 | 001 | Mar 03, 2025 | Feb | NEWA |
| >A> | AB | | | 0.025% | A217587 | 001 | Mar 03, 2025 | Feb | NEWA |

TRIAMCINOLONE ACETONIDE

| | | | | | | | | | |
|-----|----|-------------------------|------------------|---------|---------|-----|--------------|-----|------|
| | | GEL;TOPICAL | | | | | | | |
| | | ARISTOGEL | | | | | | | |
| >D> | | @ | ASTELLAS | 0.1% | A083380 | 001 | | Feb | CRLD |
| >A> | | + @ | | 0.1% | A083380 | 001 | | Feb | CRLD |
| | | INJECTABLE;INJECTION | | | | | | | |
| | | KENALOG-10 | | | | | | | |
| >D> | | + | APOTHECON | 10MG/ML | N012041 | 001 | | Feb | CTEC |
| >A> | AB | + | | 10MG/ML | N012041 | 001 | | Feb | CTEC |
| | | TRIAMCINOLONE ACETONIDE | | | | | | | |
| >A> | AB | | DR REDDYS | 10MG/ML | A218773 | 001 | Mar 12, 2025 | Feb | NEWA |
| | | LOTION;TOPICAL | | | | | | | |
| | | TRIAMCINOLONE ACETONIDE | | | | | | | |
| >D> | AT | ! | WOCKHARDT BIO AG | 0.025% | A088450 | 001 | Apr 01, 1985 | Feb | CAHN |
| >D> | AT | ! | | 0.1% | A088451 | 001 | Apr 03, 1985 | Feb | CAHN |
| >A> | AT | ! | XTTRIUM LABS INC | 0.025% | A088450 | 001 | Apr 01, 1985 | Feb | CAHN |
| >A> | AT | ! | | 0.1% | A088451 | 001 | Apr 03, 1985 | Feb | CAHN |

TROSPIMUM CHLORIDE

| | | | | | | | | | |
|-----|----|--------------------|---------------|------|---------|-----|--------------|-----|------|
| | | TABLET;ORAL | | | | | | | |
| | | TROSPIMUM CHLORIDE | | | | | | | |
| >D> | AB | | CHARTWELL RX | 20MG | A215781 | 001 | Feb 16, 2022 | Feb | CAHN |
| >A> | AB | | ZAMEER PHARMS | 20MG | A215781 | 001 | Feb 16, 2022 | Feb | CAHN |

VALBENAZINE TOSYLATE

| | | | | | | | | | |
|-----|----|----------------------|--------------------|--------------|---------|-----|--------------|-----|------|
| | | CAPSULE;ORAL | | | | | | | |
| | | INGREZZA | | | | | | | |
| >D> | AB | + | NEUROCRINE | EQ 60MG BASE | N209241 | 003 | Apr 23, 2021 | Feb | CTEC |
| >A> | | + | | EQ 60MG BASE | N209241 | 003 | Apr 23, 2021 | Feb | CTEC |
| | | VALBENAZINE TOSYLATE | | | | | | | |
| >D> | AB | | ZYDUS LIFESCIENCES | EQ 40MG BASE | A216137 | 001 | Aug 07, 2024 | Feb | DISC |
| >A> | | @ | | EQ 40MG BASE | A216137 | 001 | Aug 07, 2024 | Feb | DISC |
| >D> | AB | | | EQ 60MG BASE | A216137 | 002 | Aug 07, 2024 | Feb | DISC |
| >A> | | @ | | EQ 60MG BASE | A216137 | 002 | Aug 07, 2024 | Feb | DISC |
| >D> | AB | | | EQ 80MG BASE | A216137 | 003 | Aug 07, 2024 | Feb | DISC |
| >A> | | @ | | EQ 80MG BASE | A216137 | 003 | Aug 07, 2024 | Feb | DISC |

VALSARTAN

| | | | | | | | | | |
|-----|----|-------------|--------|-------|---------|-----|--------------|-----|------|
| | | TABLET;ORAL | | | | | | | |
| | | VALSARTAN | | | | | | | |
| >D> | AB | | RENATA | 40MG | A218169 | 001 | Aug 05, 2024 | Feb | DISC |
| >A> | | @ | | 40MG | A218169 | 001 | Aug 05, 2024 | Feb | DISC |
| | AB | | | 40MG | A218169 | 001 | Aug 05, 2024 | Jan | CAHN |
| >D> | AB | | | 80MG | A218169 | 002 | Aug 05, 2024 | Feb | DISC |
| >A> | | @ | | 80MG | A218169 | 002 | Aug 05, 2024 | Feb | DISC |
| | AB | | | 80MG | A218169 | 002 | Aug 05, 2024 | Jan | CAHN |
| >D> | AB | | | 160MG | A218169 | 003 | Aug 05, 2024 | Feb | DISC |
| >A> | | @ | | 160MG | A218169 | 003 | Aug 05, 2024 | Feb | DISC |
| | AB | | | 160MG | A218169 | 003 | Aug 05, 2024 | Jan | CAHN |
| >D> | AB | | | 320MG | A218169 | 004 | Aug 05, 2024 | Feb | DISC |
| >A> | | @ | | 320MG | A218169 | 004 | Aug 05, 2024 | Feb | DISC |
| | AB | | | 320MG | A218169 | 004 | Aug 05, 2024 | Jan | CAHN |

VANCOMYCIN HYDROCHLORIDE

| | | | | | | | | | |
|----|--|--------------------------|--------------------|--------------------|---------|-----|--------------|-----|------|
| | | INJECTABLE;INJECTION | | | | | | | |
| | | VANCOMYCIN HYDROCHLORIDE | | | | | | | |
| AP | | | MEDIMETRIKS PHARMS | EQ 500MG BASE/VIAL | A065401 | 001 | Jun 30, 2008 | Jan | CMFD |
| AP | | | | EQ 1GM BASE/VIAL | A065401 | 002 | Jun 30, 2008 | Jan | CMFD |

VARENICLINE TARTRATE

TABLET;ORAL

VARENICLINE TARTRATE

| | | | | | | | |
|-----|----|---------|---------------|---------|-----|--------------|----------|
| >D> | AB | PIRAMAL | EQ 0.5MG BASE | A217115 | 001 | Jul 23, 2024 | Feb DISC |
| >A> | | @ | EQ 0.5MG BASE | A217115 | 001 | Jul 23, 2024 | Feb DISC |
| >D> | AB | | EQ 1MG BASE | A217115 | 002 | Jul 23, 2024 | Feb DISC |
| >A> | | @ | EQ 1MG BASE | A217115 | 002 | Jul 23, 2024 | Feb DISC |

VENLAFAXINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL

VENLAFAXINE HYDROCHLORIDE

| | | | | | | | |
|-----|----|----------------------|----------------|---------|-----|--------------|----------|
| >D> | AB | INTELLIPHARMACEUTICS | EQ 37.5MG BASE | A201272 | 001 | Nov 23, 2018 | Feb CAHN |
| >D> | AB | | EQ 75MG BASE | A201272 | 002 | Nov 23, 2018 | Feb CAHN |
| >D> | AB | | EQ 150MG BASE | A201272 | 003 | Nov 23, 2018 | Feb CAHN |
| >A> | AB | MEDICAP LABS | EQ 37.5MG BASE | A201272 | 001 | Nov 23, 2018 | Feb CAHN |
| >A> | AB | | EQ 75MG BASE | A201272 | 002 | Nov 23, 2018 | Feb CAHN |
| >A> | AB | | EQ 150MG BASE | A201272 | 003 | Nov 23, 2018 | Feb CAHN |

TABLET, EXTENDED RELEASE;ORAL

VENLAFAXINE HYDROCHLORIDE

| | | | | | | | |
|----|--|-----------------|----------------|---------|-----|--------------|----------|
| AB | | ABON PHARMS LLC | EQ 150MG BASE | A217841 | 001 | Feb 07, 2025 | Jan NEWA |
| AB | | | EQ 225MG BASE | A217841 | 002 | Feb 07, 2025 | Jan NEWA |
| AB | | TORRENT | EQ 37.5MG BASE | A218180 | 001 | Jan 28, 2025 | Jan NEWA |
| AB | | | EQ 75MG BASE | A218180 | 002 | Jan 28, 2025 | Jan NEWA |
| AB | | | EQ 150MG BASE | A218180 | 003 | Jan 28, 2025 | Jan NEWA |
| AB | | | EQ 225MG BASE | A218180 | 004 | Jan 28, 2025 | Jan NEWA |

VIGABATRIN

TABLET;ORAL

VIGABATRIN

| | | | | | | | |
|-----|----|---------------|-------|---------|-----|--------------|----------|
| >D> | AB | AMNEAL PHARMS | 500MG | A210042 | 001 | Jun 22, 2022 | Feb DISC |
| >A> | | @ | 500MG | A210042 | 001 | Jun 22, 2022 | Feb DISC |
| | | @ RYAN LABS | 500MG | A215519 | 001 | Apr 28, 2023 | Jan DISC |

>A> VIMSELTINIB

CAPSULE;ORAL

ROMVIMZA

| | | | | | | | |
|-----|---|------------------|------|---------|-----|--------------|----------|
| >A> | + | DECIPHERA PHARMS | 14MG | N219304 | 001 | Feb 14, 2025 | Feb NEWA |
| >A> | + | | 20MG | N219304 | 002 | Feb 14, 2025 | Feb NEWA |
| >A> | + | ! | 30MG | N219304 | 003 | Feb 14, 2025 | Feb NEWA |

ZINC ACETATE

CAPSULE;ORAL

GALZIN

| | | | | | | |
|---|------|--------------|---------|-----|--------------|----------|
| + | ETON | EQ 25MG ZINC | N020458 | 001 | Jan 28, 1997 | Jan CAHN |
| + | ! | EQ 50MG ZINC | N020458 | 002 | Jan 28, 1997 | Jan CAHN |

ZOLPIDEM TARTRATE

TABLET;ORAL

AMBIEN

| | | | | | | | |
|----|---|---------|------|---------|-----|--------------|----------|
| AB | + | COSETTE | 5MG | N019908 | 001 | Dec 16, 1992 | Jan CAHN |
| AB | + | ! | 10MG | N019908 | 002 | Dec 16, 1992 | Jan CAHN |

TABLET;SUBLINGUAL

EDLUAR

| | | | | | | | | |
|-----|----|---|---------------------|------|---------|-----|--------------|----------|
| >D> | AB | + | MYLAN SPECIALITY LP | 5MG | N021997 | 001 | Mar 13, 2009 | Feb CAHN |
| >D> | AB | + | ! | 10MG | N021997 | 002 | Mar 13, 2009 | Feb CAHN |
| >A> | AB | + | VIATRIS | 5MG | N021997 | 001 | Mar 13, 2009 | Feb CAHN |
| >A> | AB | + | ! | 10MG | N021997 | 002 | Mar 13, 2009 | Feb CAHN |

TABLET, EXTENDED RELEASE;ORAL

AMBIEN CR

| | | | | | | | |
|----|---|---------|--------|---------|-----|--------------|----------|
| AB | + | COSETTE | 6.25MG | N021774 | 002 | Sep 02, 2005 | Jan CAHN |
| AB | + | ! | 12.5MG | N021774 | 001 | Sep 02, 2005 | Jan CAHN |

ACETAMINOPHEN; IBUPROFEN

TABLET;ORAL

ACETAMINOPHEN AND IBUPROFEN

STRIDES PHARMA

250MG;125MG

A217241 001 Jan 17, 2025 Jan NEWA

AZELASTINE HYDROCHLORIDE

SPRAY, METERED;NASAL

AZELASTINE HYDROCHLORIDE ALLERGY

AUROBINDO PHARMA

0.2055MG/SPRAY

A216561 001 Jan 27, 2025 Jan NEWA

FEXOFENADINE HYDROCHLORIDE

TABLET;ORAL

FEXOFENADINE HYDROCHLORIDE

>A>

CONTRACT PHARMACAL

60MG

A219032 001 Feb 28, 2025 Feb NEWA

>A>

180MG

A219032 002 Feb 28, 2025 Feb NEWA

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET;ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

@ APOTEX

5MG

A211443 001 Apr 21, 2021 Jan DISC

LOPERAMIDE HYDROCHLORIDE

SOLUTION;ORAL

LOPERAMIDE HYDROCHLORIDE

>A>

@ PAI HOLDINGS

1MG/5ML

A074352 001 Nov 17, 1995 Feb CAHN

>D>

@ SCIEGEN PHARMS INC

1MG/5ML

A074352 001 Nov 17, 1995 Feb CAHN

LORATADINE

CAPSULE;ORAL

LORATADINE

>A>

CATALENT PHARMA

10MG

A215127 001 Feb 28, 2025 Feb NEWA

OLOPATADINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

OLOPATADINE HYDROCHLORIDE

>D>

@ BAUSCH AND LOMB INC

EQ 0.2% BASE

A206087 001 Dec 05, 2017 Feb CMFD

>A>

EQ 0.2% BASE

A206087 001 Dec 05, 2017 Feb CMFD

>A>

GLENMARK PHARMS INC

EQ 0.2% BASE

A219557 001 Feb 28, 2025 Feb NEWA

OMEPRAZOLE

TABLET, DELAYED RELEASE;ORAL

OMEPRAZOLE

@ APOTEX

20MG

A210070 001 Feb 11, 2019 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 2 FEBRUARY 2025

NO FEBRUARY 2025 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 FEBRUARY 2025 APPROVALS

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2025

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE (S) | EXCLUSIVITY EXPIRATION DATE |
|---|--------------|------------------------|--------------|-------------------------|----------------------|-----------------------------|
| <u>ACALABRUTINIB - CALOQUENCE</u> | | | | | | |
| N 210259 001 | >A> 10167291 | Jul 01, 2036 | DP U-2145 | | >A> I-960 | Jan 16, 2028 |
| | >A> 10167291 | Jul 01, 2036 | DP U-2519 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2666 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2667 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2668 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2669 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2670 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2671 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2682 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2683 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2684 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2685 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2686 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-2687 | | | |
| | >A> 10167291 | Jul 01, 2036 | DP U-4109 | | | |
| | 10272083 | Jan 21, 2035 | U-2519 | | | |
| | 10272083 | Jan 21, 2035 | U-2682 | | | |
| | 10272083 | Jan 21, 2035 | U-2683 | | | |
| | 10272083 | Jan 21, 2035 | U-2684 | | | |
| | 10272083 | Jan 21, 2035 | U-2685 | | | |
| | 10272083 | Jan 21, 2035 | U-2686 | | | |
| | 10272083 | Jan 21, 2035 | U-2687 | | | |
| | 10272083 | Jan 21, 2035 | U-4109 | | | |
| | >A> 9758524 | Jul 11, 2032 | U-2145 | | | |
| | >A> 9758524 | Jul 11, 2032 | U-4108 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-2145 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-2666 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-2667 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-2668 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-2669 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-2670 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-2671 | | | |
| | 9796721 | Jul 01, 2036 | DS DP U-4108 | | | |
| <u>ACALABRUTINIB MALEATE - CALOQUENCE</u> | | | | | | |
| N 216387 001 | 10272083 | Jan 21, 2035 | U-2519 | | >A> I-960 | Jan 16, 2028 |
| | 10272083 | Jan 21, 2035 | U-2682 | | | |
| | 10272083 | Jan 21, 2035 | U-2683 | | | |
| | 10272083 | Jan 21, 2035 | U-2684 | | | |
| | 10272083 | Jan 21, 2035 | U-2685 | | | |
| | 10272083 | Jan 21, 2035 | U-2686 | | | |
| | 10272083 | Jan 21, 2035 | U-2687 | | | |
| | 10272083 | Jan 21, 2035 | U-4109 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-2145 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-2666 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-2667 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-2668 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-2669 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-2670 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-2671 | | | |
| | 11059829 | Jul 01, 2036 | DS DP U-4108 | | | |
| | >A> 9758524 | Jul 11, 2032 | U-2145 | | | |
| | >A> 9758524 | Jul 11, 2032 | U-4108 | | | |
| <u>ACORAMIDIS HYDROCHLORIDE - ATTRUBY</u> | | | | | | |
| N 216540 001 | 9913826 | May 05, 2031 | U-4046 | | ODE-506 | Nov 22, 2031 |
| <u>AMIKACIN SULFATE - ARIKAYCE KIT</u> | | | | | | |
| N 207356 001 | 12168021 | May 15, 2035 | U-2414 | | | |
| | 12168022 | May 15, 2035 | U-2414 | | | |
| <u>AMISULPRIDE - BARHEMSYS</u> | | | | | | |
| N 209510 001 | 12005042 | Feb 09, 2038 | U-1744 | | | |
| | 12005042 | Feb 09, 2038 | U-2754 | | | |
| | 12005042 | Feb 09, 2038 | U-3467 | | | |

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2025

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|---|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>AMISULPRIDE - BARHEMSYS</u> | | | | | | |
| N 209510 001 | 12194022 | Mar 10, 2031 | U-1744 | | | |
| | 12194022 | Mar 10, 2031 | U-3467 | | | |
| <u>AMISULPRIDE - BARHEMSYS</u> | | | | | | |
| N 209510 002 | 12005042 | Feb 09, 2038 | U-1744 | | | |
| | 12005042 | Feb 09, 2038 | U-2754 | | | |
| | 12005042 | Feb 09, 2038 | U-3467 | | | |
| | 12194022 | Mar 10, 2031 | U-1744 | | | |
| | 12194022 | Mar 10, 2031 | U-3467 | | | |
| <u>AMLODIPINE BESYLATE - NORLIOVA</u> | | | | | | |
| N 214439 001 | >A> 12005141 | Feb 24, 2041 | DP U-3309 | | | |
| | >A> 12005141 | Feb 24, 2041 | DP U-3310 | | | |
| | >A> 12005141 | Feb 24, 2041 | DP U-3311 | | | |
| | >A> 12226528 | Feb 24, 2041 | DP U-3309 | | | |
| | >A> 12226528 | Feb 24, 2041 | DP U-3310 | | | |
| | >A> 12226528 | Feb 24, 2041 | DP U-3311 | | | |
| <u>AVACINCAPTAD PEGOL SODIUM - IZERVAY</u> | | | | | | |
| N 217225 001 | >A> 7579456 | Feb 14, 2026 | DS | | | |
| | >A> 9617546 | Feb 14, 2026 | DS | | U-3673 | |
| <u>AVIBACTAM SODIUM; AZTREONAM - EMBLAVEO</u> | | | | | | |
| N 217906 001 | >A> 7112592 | Jan 07, 2026 | DS DP U-4147 | | | |
| | >A> 7612087 | Nov 12, 2026 | DP | | | |
| | >A> 8471025 | Aug 12, 2031 | DS | | | |
| | >A> 8835455 | Oct 08, 2030 | DP | | | |
| | >A> 8969566 | Jun 15, 2032 | DS | | | |
| | >A> 9284314 | Jun 15, 2032 | DS | | | |
| | >A> 9695122 | Jun 15, 2032 | DS DP | | | |
| <u>BACLOFEN - BACLOFEN</u> | | | | | | |
| A 214445 001 | | | | | PC | Jul 14, 2025 |
| <u>BALOXAVIR MARBOXIL - XOFLUZA</u> | | | | | | |
| N 210854 001 | | | | >A> M-187 | | Dec 19, 2027 |
| <u>BALOXAVIR MARBOXIL - XOFLUZA</u> | | | | | | |
| N 210854 002 | | | | >A> M-187 | | Dec 19, 2027 |
| <u>BALOXAVIR MARBOXIL - XOFLUZA</u> | | | | | | |
| N 210854 003 | | | | >A> M-187 | | Dec 19, 2027 |
| <u>BALOXAVIR MARBOXIL - XOFLUZA</u> | | | | | | |
| N 214410 001 | | | | >A> M-187 | | Dec 19, 2027 |
| <u>BENDAMUSTINE HYDROCHLORIDE - BELRAPZO</u> | | | | | | |
| N 205580 001 | 12138248 | Jan 28, 2031 | DP | | | |
| <u>BENDAMUSTINE HYDROCHLORIDE - BENDEKA</u> | | | | | | |
| N 208194 001 | 12138248 | Jan 28, 2031 | DP | | | |
| <u>BENDAMUSTINE HYDROCHLORIDE - VIVIMUSTA</u> | | | | | | |
| N 212209 001 | 12208086 | Jul 29, 2042 | DP | | | |
| <u>BENZGALANTAMINE GLUCONATE - ZUNVEYL</u> | | | | | | |
| N 218549 001 | >A> 12208176 | Feb 26, 2044 | DP U-713 | | | |
| <u>BENZGALANTAMINE GLUCONATE - ZUNVEYL</u> | | | | | | |
| N 218549 002 | >A> 12208176 | Feb 26, 2044 | DP U-713 | | | |

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2025

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|---|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>BENZGALANTAMINE GLUCONATE - ZUNVEYL</u> | | | | | | |
| N 218549 003 | >A> 12208176 | Feb 26, 2044 | DP U-713 | | | |
| <u>BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - BIKTARVY</u> | | | | | | |
| N 210251 001 | 7390791 | Jan 07, 2025 | DS DP | | | |
| | 7390791*PED | Jul 07, 2025 | | | | |
| <u>BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - BIKTARVY</u> | | | | | | |
| N 210251 002 | 7390791 | Jan 07, 2025 | DS DP | | | |
| | 7390791*PED | Jul 07, 2025 | | | | |
| <u>BUDESONIDE - TARPEYO</u> | | | | | | |
| N 215935 001 | 12171882 | Jan 23, 2043 | U-4085 | | | |
| | 12171882 | Jan 23, 2043 | U-4086 | | | |
| | 12171883 | Jan 23, 2043 | DP | | | |
| <u>BUPRENORPHINE - BRIXADI</u> | | | | | | |
| N 210136 001 | 12161640 | Jul 26, 2032 | DP U-4100 | | | |
| <u>BUPRENORPHINE - BRIXADI</u> | | | | | | |
| N 210136 002 | 12161640 | Jul 26, 2032 | DP U-4100 | | | |
| <u>BUPRENORPHINE - BRIXADI</u> | | | | | | |
| N 210136 003 | 12161640 | Jul 26, 2032 | DP U-4100 | | | |
| <u>BUPRENORPHINE - BRIXADI</u> | | | | | | |
| N 210136 004 | 12161640 | Jul 26, 2032 | DP U-4100 | | | |
| <u>BUPRENORPHINE - BRIXADI</u> | | | | | | |
| N 210136 005 | 12161640 | Jul 26, 2032 | DP U-4100 | | | |
| <u>BUPRENORPHINE - BRIXADI</u> | | | | | | |
| N 210136 006 | 12161640 | Jul 26, 2032 | DP U-4100 | | | |
| <u>BUPRENORPHINE - BRIXADI</u> | | | | | | |
| N 210136 007 | 12161640 | Jul 26, 2032 | DP U-4100 | | | |
| <u>CABOTEGRAVIR; RILPIVIRINE - CABENUVA KIT</u> | | | | | | |
| N 212888 001 | 12178815 | Jul 18, 2038 | U-3348 | | | |
| <u>CABOTEGRAVIR; RILPIVIRINE - CABENUVA KIT</u> | | | | | | |
| N 212888 002 | 12178815 | Jul 18, 2038 | U-3348 | | | |
| <u>CANAGLIFLOZIN - INVOKANA</u> | | | | | | |
| N 204042 001 | | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN - INVOKANA</u> | | | | | | |
| N 204042 002 | | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u> | | | | | | |
| N 204353 001 | | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u> | | | | | | |
| N 204353 002 | | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u> | | | | | | |
| N 204353 003 | | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 02 - February 2025

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|--|-----------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u> | | | | | | |
| N 204353 | 003 | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET</u> | | | | | | |
| N 204353 | 004 | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u> | | | | | | |
| N 205879 | 001 | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u> | | | | | | |
| N 205879 | 002 | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u> | | | | | | |
| N 205879 | 003 | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE - INVOKAMET XR</u> | | | | | | |
| N 205879 | 004 | | | | NPP PED | Dec 18, 2027 Jun 18, 2028 |
| <u>CAPMATINIB HYDROCHLORIDE - TABRECTA</u> | | | | | | |
| N 213591 | 001 | 10596178 | Jul 22, 2035 | DP | | |
| | | 12208101 | Jul 22, 2035 | DP | | |
| <u>CAPMATINIB HYDROCHLORIDE - TABRECTA</u> | | | | | | |
| N 213591 | 002 | 10596178 | Jul 22, 2035 | DP | | |
| | | 12208101 | Jul 22, 2035 | DP | | |
| <u>CARBIDOPA; LEVODOPA - CREXONT</u> | | | | | | |
| N 217186 | 001 | 12194150 | Dec 21, 2041 | U-219 | | |
| | | 12201596 | Dec 21, 2041 | U-1649 | | |
| | | 12201596 | Dec 21, 2041 | U-4004 | | |
| | | 12201596 | Dec 21, 2041 | U-4005 | | |
| <u>CARBIDOPA; LEVODOPA - CREXONT</u> | | | | | | |
| N 217186 | 002 | 12194150 | Dec 21, 2041 | U-219 | | |
| | | 12201596 | Dec 21, 2041 | U-1649 | | |
| | | 12201596 | Dec 21, 2041 | U-4004 | | |
| | | 12201596 | Dec 21, 2041 | U-4005 | | |
| <u>CARBIDOPA; LEVODOPA - CREXONT</u> | | | | | | |
| N 217186 | 003 | 12194150 | Dec 21, 2041 | U-219 | | |
| | | 12201596 | Dec 21, 2041 | U-1649 | | |
| | | 12201596 | Dec 21, 2041 | U-4004 | | |
| | | 12201596 | Dec 21, 2041 | U-4005 | | |
| <u>CARBIDOPA; LEVODOPA - CREXONT</u> | | | | | | |
| N 217186 | 004 | 12194150 | Dec 21, 2041 | U-219 | | |
| | | 12201596 | Dec 21, 2041 | U-1649 | | |
| | | 12201596 | Dec 21, 2041 | U-4004 | | |
| | | 12201596 | Dec 21, 2041 | U-4005 | | |
| <u>CEDAZURIDINE; DECITABINE - INOOVI</u> | | | | | | |
| N 212576 | 001 | 12195496 | Oct 07, 2040 | DP | | |
| <u>CHLOROPROCAINE HYDROCHLORIDE - IHEEZO</u> | | | | | | |
| N 216227 | 001 | 11969403 | May 14, 2039 | DP | | |

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| <u>COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - GENVOYA</u> | | | | | | |
| N 207561 001 | 7390791 | Jan 07, 2025 | DS DP | | | |
| | 7390791*PED | Jul 07, 2025 | | | | |
| <u>COLCHICINE - LODOCO</u> | | | | | | |
| N 215727 001 >A> | 12233035 | Nov 01, 2033 | U-4132 | | | |
| <u>COPPER CU-64 DOTATATE - DETECTNET</u> | | | | | | |
| N 213227 001 >A> | 10383961 | Jul 02, 2033 | U-2951 | | | |
| <u>CORTICOTROPIN - PURIFIED CORTROPHIN GEL</u> | | | | | | |
| N 008975 002 >A> | 12233105 | Oct 27, 2043 | U-3904 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3905 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3906 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3907 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3908 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3909 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3910 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3911 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3912 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3913 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3914 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3915 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3916 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3917 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3918 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3919 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3920 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3921 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3922 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3923 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3924 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3925 | | | |
| | >A> 12233105 | Oct 27, 2043 | U-3926 | | | |
| <u>CRINECERFONT - CRENESSITY</u> | | | | | | |
| N 218808 001 | 10905690 | Jan 21, 2035 | U-4049 | | NCE | Dec 13, 2029 |
| | 11311544 | Jan 21, 2035 | U-4049 | | | |
| | 11730739 | Jan 21, 2035 | U-4049 | | | |
| | 12128033 | Jun 09, 2041 | DS U-4049 | | | |
| <u>CRINECERFONT - CRENESSITY</u> | | | | | | |
| N 218808 002 | 10905690 | Jan 21, 2035 | U-4049 | | NCE | Dec 13, 2029 |
| | 11311544 | Jan 21, 2035 | U-4049 | | | |
| | 11730739 | Jan 21, 2035 | U-4049 | | | |
| | 12128033 | Jun 09, 2041 | DS U-4049 | | | |
| <u>CRINECERFONT - CRENESSITY</u> | | | | | | |
| N 218808 003 | 10905690 | Jan 21, 2035 | U-4049 | | NCE | Dec 13, 2029 |
| | 11311544 | Jan 21, 2035 | U-4049 | | | |
| | 11730739 | Jan 21, 2035 | U-4049 | | | |
| | 12128033 | Jun 09, 2041 | DS U-4049 | | | |
| <u>CRINECERFONT - CRENESSITY</u> | | | | | | |
| N 218820 001 | 10905690 | Jan 21, 2035 | U-4049 | | NCE | Dec 13, 2029 |
| | 11311544 | Jan 21, 2035 | U-4049 | | | |
| | 11730739 | Jan 21, 2035 | U-4049 | | | |
| | 12128033 | Jun 09, 2041 | DS U-4049 | | | |
| <u>DAPAGLIFLOZIN - FARXIGA</u> | | | | | | |
| N 202293 002 >A> | 12213988 | Apr 01, 2041 | U-4140 | | | |
| <u>DARIDOREXANT HYDROCHLORIDE - QUVIVIO</u> | | | | | | |
| N 214985 001 | | | | | M-200 | Sep 30, 2027 |

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| <u>DARIDOREXANT HYDROCHLORIDE - QUVIVIO</u> | | | | | | |
| N 214985 | 002 | | | | M-200 | Sep 30, 2027 |
| <u>DEOXYCHOLIC ACID - KYBELLA</u> | | | | | | |
| N 206333 | 001 | 12161653 | Feb 17, 2032 | U-1940 | | |
| <u>DEUTIVACAFTOR; TEZACAFTOR; VANZACAFTOR CALCIUM - ALYFTREK</u> | | | | | | |
| N 218730 | 001 | 10022352 | Apr 09, 2027 | DP U-4081 | NCE | Dec 20, 2029 |
| | | 10047053 | May 17, 2032 | DS | | |
| | | 10081621 | Mar 25, 2031 | DP U-4087 | | |
| | | 10239867 | Apr 09, 2027 | DS DP U-4090 | | |
| | | 10646481 | Aug 13, 2029 | DP | | |
| | | 11066417 | Feb 14, 2039 | DS DP | | |
| | | 11564916 | Aug 13, 2029 | U-4095 | | |
| | | 11578062 | Mar 25, 2031 | DP U-4096 | | |
| | | 11639347 | Apr 09, 2027 | DS DP U-4090 | | |
| | | 11866450 | Feb 14, 2039 | U-4082 | | |
| | | 11873300 | Aug 13, 2040 | DS DP U-4083 | | |
| | | 7495103 | May 20, 2027 | DS DP | | |
| | | 7645789 | May 01, 2027 | DS DP | | |
| | | 7776905 | Jun 03, 2027 | DS DP | | |
| | | 8324242 | Aug 05, 2027 | U-4090 | | |
| | | 8354427 | Jul 06, 2026 | U-4091 | | |
| | | 8410274 | Dec 28, 2026 | DP | | |
| | | 8415387 | Nov 12, 2027 | U-4082 | | |
| | | 8598181 | May 01, 2027 | U-4090 | | |
| | | 8623905 | May 01, 2027 | DS DP | | |
| | | 8629162 | Jun 24, 2025 | U-4084 | | |
| | | 8754224 | Dec 28, 2026 | DS DP | | |
| | | 8865902 | May 17, 2032 | DS DP | | |
| | | 9181192 | May 17, 2032 | DS DP U-4094 | | |
| | | 9512079 | May 17, 2032 | DS DP U-4098 | | |
| | | 9670163 | Dec 28, 2026 | DP U-4080 | | |
| | | 9931334 | Dec 28, 2026 | DP U-4080 | | |
| | | 9974781 | Apr 09, 2027 | DP U-4082 | | |
| <u>DEUTIVACAFTOR; TEZACAFTOR; VANZACAFTOR CALCIUM - ALYFTREK</u> | | | | | | |
| N 218730 | 002 | 10022352 | Apr 09, 2027 | DP U-4081 | NCE | Dec 20, 2029 |
| | | 10047053 | May 17, 2032 | DS | | |
| | | 10058546 | Jul 15, 2033 | U-4093 | | |
| | | 10081621 | Mar 25, 2031 | DP U-4087 | | |
| | | 10206877 | Apr 14, 2035 | DP U-4092 | | |
| | | 10239867 | Apr 09, 2027 | DS DP U-4090 | | |
| | | 10646481 | Aug 13, 2029 | DP | | |
| | | 11066417 | Feb 14, 2039 | DS DP | | |
| | | 11564916 | Aug 13, 2029 | U-4095 | | |
| | | 11578062 | Mar 25, 2031 | DP U-4096 | | |
| | | 11639347 | Apr 09, 2027 | DS DP U-4090 | | |
| | | 11866450 | Feb 14, 2039 | U-4082 | | |
| | | 11873300 | Aug 13, 2040 | DS DP U-4083 | | |
| | | 11951212 | Apr 14, 2035 | DP U-4089 | | |
| | | 12186306 | Jan 10, 2043 | U-4088 | | |
| | | 7495103 | May 20, 2027 | DS DP | | |
| | | 7645789 | May 01, 2027 | DS DP | | |
| | | 7776905 | Jun 03, 2027 | DS DP | | |
| | | 8324242 | Aug 05, 2027 | U-4090 | | |
| | | 8354427 | Jul 06, 2026 | U-4091 | | |
| | | 8410274 | Dec 28, 2026 | DP | | |
| | | 8415387 | Nov 12, 2027 | U-4082 | | |
| | | 8598181 | May 01, 2027 | U-4090 | | |
| | | 8623905 | May 01, 2027 | DS DP | | |
| | | 8629162 | Jun 24, 2025 | U-4084 | | |
| | | 8754224 | Dec 28, 2026 | DS DP | | |
| | | 8865902 | May 17, 2032 | DS DP | | |
| | | 9012496 | Jul 15, 2033 | U-4097 | | |
| | | 9181192 | May 17, 2032 | DS DP U-4094 | | |
| | | 9512079 | May 17, 2032 | DS DP U-4098 | | |
| | | 9670163 | Dec 28, 2026 | DP U-4080 | | |

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| <u>DEUTIVACAFTOR; TEZACAFTOR; VANZACAFTOR CALCIUM - ALYFTREK</u> | | | | | | |
| N 218730 002 | 9931334 | Dec 28, 2026 | DP U-4080 | | | |
| | 9974781 | Apr 09, 2027 | DP U-4082 | | | |
| <u>DONEPEZIL HYDROCHLORIDE - ADLARITY</u> | | | | | | |
| N 212304 001 | 12161767 | Dec 30, 2036 | DS DP U-3334 | | | |
| | 12168075 | Dec 30, 2036 | U-3334 | | | |
| <u>DONEPEZIL HYDROCHLORIDE - ADLARITY</u> | | | | | | |
| N 212304 002 | 12161767 | Dec 30, 2036 | DS DP U-3334 | | | |
| | 12168075 | Dec 30, 2036 | U-3334 | | | |
| <u>DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - MEMANTINE HYDROCHLORIDE AND DONEPEZIL HYDROCHLORIDE</u> | | | | | | |
| A 208328 001 | | | | | PC | Jul 15, 2025 |
| <u>DONEPEZIL HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE - MEMANTINE HYDROCHLORIDE AND DONEPEZIL HYDROCHLORIDE</u> | | | | | | |
| A 208328 002 | | | | | PC | Jul 15, 2025 |
| <u>DROSPIRENONE; ESTETROL - NEXTSTELLIS</u> | | | | | | |
| N 214154 001 | >A> 12233074 | Feb 09, 2043 | DP U-3152 | | | |
| <u>DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE</u> | | | | | | |
| N 212516 001 | 12171742 | Apr 13, 2037 | DP | | | |
| <u>DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE</u> | | | | | | |
| N 212516 002 | 12171742 | Apr 13, 2037 | DP | | | |
| <u>DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE</u> | | | | | | |
| N 212516 003 | 12171742 | Apr 13, 2037 | DP | | | |
| <u>DULOXETINE HYDROCHLORIDE - DRIZALMA SPRINKLE</u> | | | | | | |
| N 212516 004 | 12171742 | Apr 13, 2037 | DP | | | |
| <u>DUVELISIB - COPIKTRA</u> | | | | | | |
| N 211155 001 | >A> 12213983 | Apr 26, 2035 | U-2412 | | | |
| <u>DUVELISIB - COPIKTRA</u> | | | | | | |
| N 211155 002 | >A> 12213983 | Apr 26, 2035 | U-2412 | | | |
| <u>EDARAVONE - RADICAVA ORS</u> | | | | | | |
| N 215446 001 | 12194025 | Nov 12, 2041 | U-4111 | | | |
| <u>ELAFIBRANOR - IQIRVO</u> | | | | | | |
| N 218860 001 | >A> 12233038 | Mar 30, 2037 | U-1854 | | | |
| <u>ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)</u> | | | | | | |
| N 212273 001 | 10081621 | Mar 25, 2031 | DP U-3032 | | >A> M-313 | Dec 20, 2027 |
| | 10081621 | Mar 25, 2031 | DP U-3157 | | | |
| | 10081621 | Mar 25, 2031 | DP U-4075 | | | |
| | >A> 10239867 | Apr 09, 2027 | DS DP U-3033 | | | |
| | >A> 10239867 | Apr 09, 2027 | DS DP U-3158 | | | |
| | >A> 10239867 | Apr 09, 2027 | DS DP U-4056 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-3028 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-3144 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-4073 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-3028 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-3144 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-4073 | | | |
| | 11179367 | Dec 08, 2037 | DP U-3253 | | | |
| | 11179367 | Dec 08, 2037 | DP U-4071 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-3425 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-4070 | | | |
| | 11517564 | Dec 08, 2037 | DP U-3498 | | | |
| | 11517564 | Dec 08, 2037 | DP U-4067 | | | |

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| <u>ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)</u> | | | | | | |
| N 212273 001 | 11564916 | Aug 13, 2029 | U-3525 | | | |
| | 11564916 | Aug 13, 2029 | U-4063 | | | |
| | 11578062 | Mar 25, 2031 | DP U-3544 | | | |
| | 11578062 | Mar 25, 2031 | DP U-4054 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-3587 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-4056 | | | |
| | 8324242 | Aug 05, 2027 | U-3028 | | | |
| | 8324242 | Aug 05, 2027 | U-3144 | | | |
| | 8324242 | Aug 05, 2027 | U-4073 | | | |
| | 8415387 | Nov 12, 2027 | U-3028 | | | |
| | 8415387 | Nov 12, 2027 | U-3144 | | | |
| | 8415387 | Nov 12, 2027 | U-4073 | | | |
| | 8598181 | May 01, 2027 | U-3028 | | | |
| | 8598181 | May 01, 2027 | U-3144 | | | |
| | 8598181 | May 01, 2027 | U-4056 | | | |
| | 8629162 | Jun 24, 2025 | U-3030 | | | |
| | 8629162 | Jun 24, 2025 | U-3146 | | | |
| | 8629162 | Jun 24, 2025 | U-4079 | | | |
| | 9670163 | Dec 28, 2026 | DP U-3031 | | | |
| | 9670163 | Dec 28, 2026 | DP U-3155 | | | |
| | 9670163 | Dec 28, 2026 | DP U-4078 | | | |
| | 9931334 | Dec 28, 2026 | DP U-3031 | | | |
| | 9931334 | Dec 28, 2026 | DP U-3155 | | | |
| | 9931334 | Dec 28, 2026 | DP U-4078 | | | |
| | 9974781 | Apr 09, 2027 | DP U-3028 | | | |
| | 9974781 | Apr 09, 2027 | DP U-3144 | | | |
| | 9974781 | Apr 09, 2027 | DP U-4073 | | | |
| <u>ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)</u> | | | | | | |
| N 212273 002 | 10081621 | Mar 25, 2031 | DP U-3157 | | >A> M-313 | Dec 20, 2027 |
| | 10081621 | Mar 25, 2031 | DP U-4075 | | | |
| | 10239867 | Apr 09, 2027 | DS DP U-3158 | | | |
| | 10239867 | Apr 09, 2027 | DS DP U-4056 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-3144 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-4073 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-3144 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-4073 | | | |
| | 11179367 | Dec 08, 2037 | DP U-3253 | | | |
| | 11179367 | Dec 08, 2037 | DP U-4071 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-3425 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-4070 | | | |
| | 11517564 | Dec 08, 2037 | DP U-3498 | | | |
| | 11517564 | Dec 08, 2037 | DP U-4069 | | | |
| | 11564916 | Aug 13, 2029 | U-3525 | | | |
| | 11564916 | Aug 13, 2029 | U-4063 | | | |
| | 11578062 | Mar 25, 2031 | DP U-3544 | | | |
| | 11578062 | Mar 25, 2031 | DP U-4054 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-3587 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-4056 | | | |
| | 8324242 | Aug 05, 2027 | U-3144 | | | |
| | 8324242 | Aug 05, 2027 | U-4073 | | | |
| | 8415387 | Nov 12, 2027 | U-3144 | | | |
| | 8415387 | Nov 12, 2027 | U-4073 | | | |
| | 8598181 | May 01, 2027 | U-3144 | | | |
| | 8598181 | May 01, 2027 | U-4056 | | | |
| | 8629162 | Jun 24, 2025 | U-3146 | | | |
| | 8629162 | Jun 24, 2025 | U-4079 | | | |
| | 9670163 | Dec 28, 2026 | DP U-3155 | | | |
| | 9670163 | Dec 28, 2026 | DP U-4078 | | | |
| | 9931334 | Dec 28, 2026 | DP U-3155 | | | |
| | 9931334 | Dec 28, 2026 | DP U-4078 | | | |
| | 9974781 | Apr 09, 2027 | DP U-3144 | | | |
| | 9974781 | Apr 09, 2027 | DP U-4073 | | | |
| <u>ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)</u> | | | | | | |
| N 217660 001 | 10081621 | Mar 25, 2031 | DP U-3600 | | >A> M-313 | Dec 20, 2027 |
| | 10081621 | Mar 25, 2031 | DP U-4065 | | | |
| | 10239867 | Apr 09, 2027 | DS DP U-3590 | | | |

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| <u>ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)</u> | | | | | | |
| N 217660 001 | 10239867 | Apr 09, 2027 | DS DP U-4053 | | | |
| | 10272046 | Feb 27, 2033 | DP U-3599 | | | |
| | 10272046 | Feb 27, 2033 | DP U-4062 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-3589 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-4066 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-3588 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-4066 | | | |
| | 11147770 | Feb 27, 2033 | DP U-3598 | | | |
| | 11147770 | Feb 27, 2033 | DP U-4060 | | | |
| | 11179367 | Dec 08, 2037 | DP U-3597 | | | |
| | 11179367 | Dec 08, 2037 | DP U-4059 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-3595 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-4058 | | | |
| | 11517564 | Dec 08, 2037 | DP U-3586 | | | |
| | 11517564 | Dec 08, 2037 | DP U-4057 | | | |
| | 11564916 | Aug 13, 2029 | U-3585 | | | |
| | 11564916 | Aug 13, 2029 | U-4055 | | | |
| | 11578062 | Mar 25, 2031 | DP U-3584 | | | |
| | 11578062 | Mar 25, 2031 | DP U-4054 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-3583 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-4053 | | | |
| | 11752106 | Feb 27, 2033 | DP U-3696 | | | |
| | 11752106 | Feb 27, 2033 | DP U-4052 | | | |
| >A> | 12214083 | Feb 27, 2033 | DP U-4141 | | | |
| | 8324242 | Aug 05, 2027 | U-3589 | | | |
| | 8324242 | Aug 05, 2027 | U-4066 | | | |
| | 8415387 | Nov 12, 2027 | U-3589 | | | |
| | 8415387 | Nov 12, 2027 | U-4066 | | | |
| | 8598181 | May 01, 2027 | U-3589 | | | |
| | 8598181 | May 01, 2027 | U-4066 | | | |
| | 8629162 | Jun 24, 2025 | U-3592 | | | |
| | 8629162 | Jun 24, 2025 | U-4072 | | | |
| | 9670163 | Dec 28, 2026 | DP U-3591 | | | |
| | 9670163 | Dec 28, 2026 | DP U-4068 | | | |
| | 9931334 | Dec 28, 2026 | DP U-3591 | | | |
| | 9931334 | Dec 28, 2026 | DP U-4068 | | | |
| | 9974781 | Apr 09, 2027 | DP U-3589 | | | |
| | 9974781 | Apr 09, 2027 | DP U-4066 | | | |
| <u>ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)</u> | | | | | | |
| N 217660 002 | 10081621 | Mar 25, 2031 | DP U-3600 | | | |
| | 10081621 | Mar 25, 2031 | DP U-4065 | | | |
| | 10239867 | Apr 09, 2027 | DS DP U-3590 | | | |
| | 10239867 | Apr 09, 2027 | DS DP U-4053 | | | |
| | 10272046 | Feb 27, 2033 | DP U-3599 | | | |
| | 10272046 | Feb 27, 2033 | DP U-4062 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-3589 | | | |
| | 10758534 | Oct 06, 2035 | DS DP U-4066 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-3588 | | | |
| | 10793547 | Dec 08, 2037 | DS DP U-4066 | | | |
| | 11147770 | Feb 27, 2033 | DP U-3598 | | | |
| | 11147770 | Feb 27, 2033 | DP U-4060 | | | |
| | 11179367 | Dec 08, 2037 | DP U-3597 | | | |
| | 11179367 | Dec 08, 2037 | DP U-4059 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-3595 | | | |
| | 11426407 | Oct 06, 2035 | DS DP U-4058 | | | |
| | 11517564 | Dec 08, 2037 | DP U-3586 | | | |
| | 11517564 | Dec 08, 2037 | DP U-4057 | | | |
| | 11564916 | Aug 13, 2029 | U-3585 | | | |
| | 11564916 | Aug 13, 2029 | U-4055 | | | |
| | 11578062 | Mar 25, 2031 | DP U-3584 | | | |
| | 11578062 | Mar 25, 2031 | DP U-4054 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-3583 | | | |
| | 11639347 | Apr 09, 2027 | DS DP U-4053 | | | |
| | 11752106 | Feb 27, 2033 | DP U-3696 | | | |
| | 11752106 | Feb 27, 2033 | DP U-4052 | | | |
| >A> | 12214083 | Feb 27, 2033 | DP U-4141 | | | |
| | 8324242 | Aug 05, 2027 | U-3589 | | | |

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|---|-------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>ELEXACAFTOR, IVACAFTOR, TEZACAFTOR; IVACAFTOR - TRIKAFTA (COPACKAGED)</u> | | | | | | |
| N 217660 002 | 8324242 | Aug 05, 2027 | U-4066 | | | |
| | 8415387 | Nov 12, 2027 | U-3589 | | | |
| | 8415387 | Nov 12, 2027 | U-4066 | | | |
| | 8598181 | May 01, 2027 | U-3589 | | | |
| | 8598181 | May 01, 2027 | U-4066 | | | |
| | 8629162 | Jun 24, 2025 | U-3592 | | | |
| | 8629162 | Jun 24, 2025 | U-4072 | | | |
| | 9670163 | Dec 28, 2026 | DP U-3591 | | | |
| | 9670163 | Dec 28, 2026 | DP U-4068 | | | |
| | 9931334 | Dec 28, 2026 | DP U-3591 | | | |
| | 9931334 | Dec 28, 2026 | DP U-4068 | | | |
| | 9974781 | Apr 09, 2027 | DP U-3589 | | | |
| | 9974781 | Apr 09, 2027 | DP U-4066 | | | |
| <u>EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI</u> | | | | | | |
| N 206073 001 | 12178819 | May 04, 2027 | DP | | | |
| <u>EMPAGLIFLOZIN; LINAGLIPTIN - GLYXAMBI</u> | | | | | | |
| N 206073 002 | 12178819 | May 04, 2027 | DP | | | |
| <u>EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR ALAFENAMIDE FUMARATE - ODEFSEY</u> | | | | | | |
| N 208351 001 | 7390791 | Jan 07, 2025 | DS DP | | | |
| | 7390791*PED | Jul 07, 2025 | | | | |
| <u>EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - DESCOVY</u> | | | | | | |
| N 208215 001 | 7390791 | Jan 07, 2025 | DS DP | | | |
| | 7390791*PED | Jul 07, 2025 | | | | |
| <u>EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE - DESCOVY</u> | | | | | | |
| N 208215 002 | 7390791 | Jan 07, 2025 | DS DP | | | |
| | 7390791*PED | Jul 07, 2025 | | | | |
| <u>ENCORAFENIB - BRAFTOVI</u> | | | | | | |
| N 210496 001 | | | | | >A> I-957 | Dec 20, 2027 |
| <u>ENCORAFENIB - BRAFTOVI</u> | | | | | | |
| N 210496 002 | 10005761 | Aug 27, 2030 | U-2335 | | >A> I-957 | Dec 20, 2027 |
| | 10005761 | Aug 27, 2030 | U-2802 | | | |
| | 10005761 | Aug 27, 2030 | U-2803 | | | |
| | 10005761 | Aug 27, 2030 | U-3738 | | | |
| | 10005761 | Aug 27, 2030 | U-4051 | | | |
| | 10258622 | Nov 21, 2032 | U-2802 | | | |
| | 10258622 | Nov 21, 2032 | U-4051 | | | |
| | 8541575 | Feb 26, 2030 | DS DP U-2335 | | | |
| | 8541575 | Feb 26, 2030 | DS DP U-2802 | | | |
| | 8541575 | Feb 26, 2030 | DS DP U-2803 | | | |
| | 8541575 | Feb 26, 2030 | DS DP U-3738 | | | |
| | 8541575 | Feb 26, 2030 | DS DP U-4051 | | | |
| | 9314464 | Jul 04, 2031 | U-2336 | | | |
| | 9314464 | Jul 04, 2031 | U-2802 | | | |
| | 9314464 | Jul 04, 2031 | U-2803 | | | |
| | 9314464 | Jul 04, 2031 | U-3738 | | | |
| | 9314464 | Jul 04, 2031 | U-4051 | | | |
| | 9474754 | Aug 05, 2033 | U-2802 | | | |
| | 9474754 | Aug 05, 2033 | U-4051 | | | |
| | 9850230 | Aug 27, 2030 | U-2334 | | | |
| | 9850230 | Aug 27, 2030 | U-2802 | | | |
| | 9850230 | Aug 27, 2030 | U-2803 | | | |
| | 9850230 | Aug 27, 2030 | U-3738 | | | |
| | 9850230 | Aug 27, 2030 | U-4051 | | | |
| <u>ENSARTINIB HYDROCHLORIDE - ENSACOVE</u> | | | | | | |
| N 218171 001 | 10899744 | Jun 01, 2037 | DS U-4099 | | NCE | Dec 18, 2029 |
| | 8551995 | Feb 09, 2029 | DS | | | |
| | 9126947 | Nov 29, 2031 | DS | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>ENSARTINIB HYDROCHLORIDE - ENSACOVE</u> | | | | | | |
| N 218171 001 | 9296724 | Jun 18, 2029 | DS U-4099 | | | |
| <u>ENSARTINIB HYDROCHLORIDE - ENSACOVE</u> | | | | | | |
| N 218171 002 | 10899744 | Jun 01, 2037 | DS U-4099 | | NCE | Dec 18, 2029 |
| | 8551995 | Feb 09, 2029 | DS | | | |
| | 9126947 | Nov 29, 2031 | DS | | | |
| | 9296724 | Jun 18, 2029 | DS U-4099 | | | |
| <u>ENTRECTINIB - ROZLYTREK</u> | | | | | | |
| N 218550 001 | | | | | >A> ODE* | Aug 15, 2026 |
| | | | | | >A> ODE* | Aug 15, 2026 |
| <u>ENZALUTAMIDE - XTANDI</u> | | | | | | |
| N 203415 001 | 12161628 | Feb 23, 2037 | U-4101 | | | |
| | 12161628 | Feb 23, 2037 | U-4102 | | | |
| | 12161628 | Feb 23, 2037 | U-4103 | | | |
| | 12161628 | Feb 23, 2037 | U-4104 | | | |
| <u>ENZALUTAMIDE - XTANDI</u> | | | | | | |
| N 213674 001 | 12161628 | Feb 23, 2037 | U-4101 | | | |
| | 12161628 | Feb 23, 2037 | U-4102 | | | |
| | 12161628 | Feb 23, 2037 | U-4103 | | | |
| | 12161628 | Feb 23, 2037 | U-4104 | | | |
| <u>ENZALUTAMIDE - XTANDI</u> | | | | | | |
| N 213674 002 | 12161628 | Feb 23, 2037 | U-4101 | | | |
| | 12161628 | Feb 23, 2037 | U-4102 | | | |
| | 12161628 | Feb 23, 2037 | U-4103 | | | |
| | 12161628 | Feb 23, 2037 | U-4104 | | | |
| <u>ESKETAMINE HYDROCHLORIDE - SPRAVATO</u> | | | | | | |
| N 211243 001 | 10869844 | Sep 10, 2035 | U-3034 | | >A> I-959 | Jan 17, 2028 |
| | 10869844 | Sep 10, 2035 | U-3035 | | | |
| | 10869844 | Sep 10, 2035 | U-3036 | | | |
| | 10869844 | Sep 10, 2035 | U-4113 | | | |
| | 10869844 | Sep 10, 2035 | U-4114 | | | |
| | 11173134 | Sep 10, 2035 | U-3257 | | | |
| | 11173134 | Sep 10, 2035 | U-3536 | | | |
| | 11173134 | Sep 10, 2035 | U-4115 | | | |
| | 11311500 | Sep 10, 2035 | U-3034 | | | |
| | 11311500 | Sep 10, 2035 | U-3035 | | | |
| | 11311500 | Sep 10, 2035 | U-3036 | | | |
| | 11311500 | Sep 10, 2035 | U-4116 | | | |
| | 11311500 | Sep 10, 2035 | U-4117 | | | |
| | 11446260 | Mar 14, 2034 | U-3444 | | | |
| | 11446260 | Mar 14, 2034 | U-3445 | | | |
| | 11446260 | Mar 14, 2034 | U-3446 | | | |
| | 11446260 | Mar 14, 2034 | U-4118 | | | |
| | 11446260 | Mar 14, 2034 | U-4119 | | | |
| | 11883526 | Feb 18, 2040 | U-3812 | | | |
| | 11883526 | Feb 18, 2040 | U-3813 | | | |
| | 11883526 | Feb 18, 2040 | U-4120 | | | |
| | 8785500 | Mar 05, 2033 | U-2502 | | | |
| | 8785500 | Mar 05, 2033 | U-4112 | | | |
| | 9592207 | Mar 20, 2027 | U-2502 | | | |
| | 9592207 | Mar 20, 2027 | U-4112 | | | |
| <u>ETHINYL ESTRADIOL; NORETHINDRONE ACETATE - FEMLYV</u> | | | | | | |
| N 218718 001 | 12178824 | Jun 24, 2041 | DP | | | |
| <u>FERRIC CARBOXYMALTOSSE - INJECTAFER</u> | | | | | | |
| N 203565 001 | >A> 7612109 | Feb 05, 2026 | DS DP | | | |

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|---|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>FERRIC CARBOXYMALTOSE - INJECTAFER</u> | | | | | | |
| N 203565 002 | >A> 7612109 | Feb 05, 2026 | DS DP | | | |
| <u>FERRIC CARBOXYMALTOSE - INJECTAFER</u> | | | | | | |
| N 203565 003 | >A> 7612109 | Feb 05, 2026 | DS DP | | | |
| <u>FERRIC CARBOXYMALTOSE - INJECTAFER</u> | | | | | | |
| N 203565 004 | >A> 7612109 | Feb 05, 2026 | DS DP | | | |
| <u>FOSCARBIDOPA; FOSLEVODOPA - VYALEV</u> | | | | | | |
| N 216962 001 | | | | | NP | Oct 16, 2027 |
| <u>FOSNETUPITANT CHLORIDE HYDROCHLORIDE; PALONOSETRON HYDROCHLORIDE - AKYNZEO</u> | | | | | | |
| N 210493 001 | >A> 12208109 | Jun 02, 2037 | DP | | | |
| <u>FOSNETUPITANT CHLORIDE HYDROCHLORIDE; PALONOSETRON HYDROCHLORIDE - AKYNZEO</u> | | | | | | |
| N 210493 002 | >A> 12208109 | Jun 02, 2037 | DP | | | |
| <u>HYDROCHLOROTHIAZIDE - INZIROQ</u> | | | | | | |
| N 219141 001 | >A> 11878022 | Jan 23, 2044 | DP U-4138 | | | |
| | >A> 11878022 | Jan 23, 2044 | DP U-4139 | | | |
| <u>IBRUTINIB - IMBRUVICA</u> | | | | | | |
| N 205552 001 | 8476284 | Dec 28, 2026 | U-1650 | | | |
| | 8476284 | Dec 28, 2026 | U-1946 | | | |
| | 8476284*PED | Jun 28, 2027 | | | | |
| | 8497277 | Dec 28, 2026 | U-1491 | | | |
| | 8497277 | Dec 28, 2026 | U-1650 | | | |
| | 8497277 | Dec 28, 2026 | U-1946 | | | |
| | 8497277 | Dec 28, 2026 | U-2241 | | | |
| | 8497277 | Dec 28, 2026 | U-2242 | | | |
| | 8497277 | Dec 28, 2026 | U-3422 | | | |
| | 8497277*PED | Jun 28, 2027 | | | | |
| | 9540382 | Aug 18, 2033 | U-1650 | | | |
| | 9540382 | Aug 18, 2033 | U-1684 | | | |
| | 9540382 | Aug 18, 2033 | U-1946 | | | |
| | 9540382*PED | Feb 18, 2034 | | | | |
| <u>IBRUTINIB - IMBRUVICA</u> | | | | | | |
| N 205552 002 | 8476284 | Dec 28, 2026 | U-1650 | | | |
| | 8476284 | Dec 28, 2026 | U-1946 | | | |
| | 8476284*PED | Jun 28, 2027 | | | | |
| | 8497277 | Dec 28, 2026 | U-1491 | | | |
| | 8497277 | Dec 28, 2026 | U-1650 | | | |
| | 8497277 | Dec 28, 2026 | U-1946 | | | |
| | 8497277 | Dec 28, 2026 | U-2241 | | | |
| | 8497277 | Dec 28, 2026 | U-2242 | | | |
| | 8497277 | Dec 28, 2026 | U-3422 | | | |
| | 8497277*PED | Jun 28, 2027 | | | | |
| | 9540382 | Aug 18, 2033 | U-1491 | | | |
| | 9540382 | Aug 18, 2033 | U-1650 | | | |
| | 9540382 | Aug 18, 2033 | U-1946 | | | |
| | 9540382*PED | Feb 18, 2034 | | | | |
| <u>IBRUTINIB - IMBRUVICA</u> | | | | | | |
| N 217003 001 | >A> 12201690 | Jun 14, 2039 | DP | | | |
| <u>ICOSAPENT ETHYL - VASCEPA</u> | | | | | | |
| N 202057 001 | 12171738 | Feb 09, 2030 | U-4105 | | | |
| <u>ICOSAPENT ETHYL - VASCEPA</u> | | | | | | |
| N 202057 002 | 12171738 | Feb 09, 2030 | U-4105 | | | |

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| <u>IMETELSTAT SODIUM - RYTELO</u> | | | | | | |
| N 217779 001 | 12171778 | Jun 16, 2039 | U-3956 | | | |
| | >A> 9388415 | Sep 09, 2025 | U-3956 | | | |
| | >A> 9388416 | Sep 09, 2025 | U-3956 | | | |
| <u>IMETELSTAT SODIUM - RYTELO</u> | | | | | | |
| N 217779 002 | 12171778 | Jun 16, 2039 | U-3956 | | | |
| | >A> 9388415 | Sep 09, 2025 | U-3956 | | | |
| | >A> 9388416 | Sep 09, 2025 | U-3956 | | | |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 001 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 002 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 003 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 004 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 005 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 006 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 007 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 008 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 009 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 010 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 011 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 012 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216016 013 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 001 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 002 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 003 | | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 004 | | | | | NCE | Nov 27, 2029 |

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|--|-----------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 005 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 006 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 007 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 008 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 009 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 010 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 011 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 012 | | | | NCE | Nov 27, 2029 |
| <u>IOMEPROL - IOMERVU</u> | | | | | | |
| N 216017 | 013 | | | | NCE | Nov 27, 2029 |
| <u>IVABRADINE HYDROCHLORIDE - IVABRADINE HYDROCHLORIDE</u> | | | | | | |
| A 214051 | 001 | | | | PC | Jan 11, 2025 |
| <u>IVABRADINE HYDROCHLORIDE - IVABRADINE HYDROCHLORIDE</u> | | | | | | |
| A 214051 | 002 | | | | PC | Jan 11, 2025 |
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 203188 | 001 | >A> 10646481 | Aug 13, 2029 | DP | | |
| | | >A> 10646481*PED | Feb 13, 2030 | | | |
| | | >A> 11564916 | Aug 13, 2029 | | U-3530 | |
| | | >A> 11564916*PED | Feb 13, 2030 | | | |
| | | 8410274 | Dec 28, 2026 | DP | | |
| | | 8410274*PED | Jun 28, 2027 | | | |
| | | >A> 8754224 | Dec 28, 2026 | DS DP | | |
| | | >A> 8754224*PED | Jun 28, 2027 | | | |
| | | >A> 9670163 | Dec 28, 2026 | DP | U-1311 | |
| | | >A> 9670163*PED | Jun 28, 2027 | | | |
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 207925 | 001 | >A> 10646481 | Aug 13, 2029 | DP | | |
| | | >A> 10646481*PED | Feb 13, 2030 | | | |
| | | >A> 11564916 | Aug 13, 2029 | | U-3528 | |
| | | >A> 11564916*PED | Feb 13, 2030 | | | |
| | | >A> 12214083 | Feb 27, 2033 | DP | U-4126 | |
| | | >A> 7495103 | May 20, 2027 | DS DP | | |
| | | >A> 7495103*PED | Nov 20, 2027 | | | |
| | | >A> 8324242 | Aug 05, 2027 | | U-1311 | |
| | | >A> 8324242 | Aug 05, 2027 | | U-1906 | |
| | | >A> 8324242 | Aug 05, 2027 | | U-2527 | |
| | | >A> 8324242*PED | Feb 05, 2028 | | | |
| | | >A> 8410274 | Dec 28, 2026 | DP | | |
| | | >A> 8410274*PED | Jun 28, 2027 | | | |
| | | >A> 8754224 | Dec 28, 2026 | DS DP | | |
| | | >A> 8754224*PED | Jun 28, 2027 | | | |
| | | >A> 9670163 | Dec 28, 2026 | DP | U-1311 | |
| | | >A> 9670163 | Dec 28, 2026 | DP | U-2530 | |
| | | >A> 9670163*PED | Jun 28, 2027 | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE (S) | EXCLUSIVITY EXPIRATION DATE |
|-----------------------------|------------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 207925 001 | >A> 10646481 | Aug 13, 2029 | DP | | | |
| | >A> 10646481*PED | Feb 13, 2030 | | | | |
| | >A> 11564916 | Aug 13, 2029 | | | U-3528 | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12214083 | Feb 27, 2033 | DP | | U-4126 | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | | | U-1311 | |
| | >A> 8324242 | Aug 05, 2027 | | | U-1906 | |
| | >A> 8324242 | Aug 05, 2027 | | | U-2527 | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP | | U-1311 | |
| | >A> 9670163 | Dec 28, 2026 | DP | | U-2530 | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 207925 002 | >A> 10646481 | Aug 13, 2029 | DP | | | |
| | >A> 10646481*PED | Feb 13, 2030 | | | | |
| | >A> 11564916 | Aug 13, 2029 | | | U-3528 | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12214083 | Feb 27, 2033 | DP | | U-4126 | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | | | U-1311 | |
| | >A> 8324242 | Aug 05, 2027 | | | U-1906 | |
| | >A> 8324242 | Aug 05, 2027 | | | U-2527 | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP | | U-1311 | |
| | >A> 9670163 | Dec 28, 2026 | DP | | U-2530 | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 207925 003 | >A> 10646481 | Aug 13, 2029 | DP | | | |
| | >A> 10646481*PED | Feb 13, 2030 | | | | |
| | >A> 11564916 | Aug 13, 2029 | | | U-3528 | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12214083 | Feb 27, 2033 | DP | | U-4128 | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | | | U-1311 | |
| | >A> 8324242 | Aug 05, 2027 | | | U-1906 | |
| | >A> 8324242 | Aug 05, 2027 | | | U-2963 | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP | | U-1311 | |
| | >A> 9670163 | Dec 28, 2026 | DP | | U-2966 | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 207925 004 | >A> 10646481 | Aug 13, 2029 | DP | | | |
| | >A> 10646481*PED | Feb 13, 2030 | | | | |
| | >A> 11564916 | Aug 13, 2029 | | | U-3603 | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12214083 | Feb 27, 2033 | DP | | U-4127 | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE (S) | EXCLUSIVITY EXPIRATION DATE |
|--|------------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 207925 004 | >A> 8324242 | Aug 05, 2027 | U-3609 | | | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP U-3606 | | | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR - KALYDECO</u> | | | | | | |
| N 207925 005 | >A> 10646481 | Aug 13, 2029 | DP | | | |
| | >A> 10646481*PED | Feb 13, 2030 | | | | |
| | >A> 11564916 | Aug 13, 2029 | U-3603 | | | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12214083 | Feb 27, 2033 | DP U-4127 | | | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | U-3609 | | | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP U-3606 | | | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u> | | | | | | |
| N 206038 001 | >A> 10076513 | Dec 04, 2028 | DP U-2411 | | | |
| | >A> 10076513*PED | Jun 04, 2029 | | | | |
| | >A> 10597384 | Dec 04, 2028 | DS DP U-2777 | | | |
| | >A> 10597384*PED | Jun 04, 2029 | | | | |
| | >A> 10646481 | Aug 13, 2029 | DP | | | |
| | >A> 10646481*PED | Feb 13, 2030 | | | | |
| | >A> 11052075 | Dec 04, 2028 | DP U-3181 | | | |
| | >A> 11052075*PED | Jun 04, 2029 | | | | |
| | >A> 11564916 | Aug 13, 2029 | U-3529 | | | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12065432 | Dec 04, 2028 | U-3984 | | | |
| | >A> 12065432*PED | Jun 04, 2029 | | | | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 7973038 | Nov 08, 2026 | U-1973 | | | |
| | >A> 7973038*PED | May 08, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | U-1311 | | | |
| | >A> 8324242 | Aug 05, 2027 | U-1911 | | | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8507534 | Sep 20, 2030 | DS DP | | | |
| | >A> 8507534*PED | Mar 20, 2031 | | | | |
| | >A> 8653103 | Dec 04, 2028 | DP | | | |
| | >A> 8653103*PED | Jun 04, 2029 | | | | |
| | >A> 8716338 | Sep 20, 2030 | DP U-1718 | | | |
| | >A> 8716338 | Sep 20, 2030 | DP U-1910 | | | |
| | >A> 8716338*PED | Mar 20, 2031 | | | | |
| | >A> 8741933 | Nov 08, 2026 | U-1717 | | | |
| | >A> 8741933 | Nov 08, 2026 | U-1909 | | | |
| | >A> 8741933*PED | May 08, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 8846718 | Jul 02, 2029 | U-1717 | | | |
| | >A> 8846718 | Jul 02, 2029 | U-1908 | | | |
| | >A> 8846718*PED | Jan 02, 2030 | | | | |
| | >A> 8993600 | Dec 11, 2030 | DP | | | |
| | >A> 8993600*PED | Jun 11, 2031 | | | | |
| | >A> 9150552 | Dec 04, 2028 | U-1908 | | | |
| | >A> 9150552*PED | Jun 04, 2029 | | | | |
| | >A> 9192606 | Sep 29, 2029 | DP U-1912 | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE (S) | EXCLUSIVITY EXPIRATION DATE |
|---|------------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>IVACAFTOR; LUMACAF TOR - ORKAMBI</u> | | | | | | |
| N 206038 001 | >A> 9192606*PED | Mar 29, 2030 | | | | |
| | >A> 9216969 | Nov 08, 2026 | DS DP | | | |
| | >A> 9216969*PED | May 08, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP U-1911 | | | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| | >A> 9931334 | Dec 28, 2026 | DP U-2276 | | | |
| | >A> 9931334*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR; LUMACAF TOR - ORKAMBI</u> | | | | | | |
| N 206038 002 | >A> 10597384 | Dec 04, 2028 | DS DP U-2777 | | | |
| | >A> 10597384*PED | Jun 04, 2029 | | | | |
| | >A> 10646481 | Aug 13, 2029 | DP | | | |
| | >A> 10646481*PED | Feb 13, 2030 | | | | |
| | >A> 11052075 | Dec 04, 2028 | DP U-3181 | | | |
| | >A> 11052075*PED | Jun 04, 2029 | | | | |
| | >A> 11564916 | Aug 13, 2029 | U-3529 | | | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12065432 | Dec 04, 2028 | U-3984 | | | |
| | >A> 12065432*PED | Jun 04, 2029 | | | | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 7973038 | Nov 08, 2026 | U-1973 | | | |
| | >A> 7973038*PED | May 08, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | U-1911 | | | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8507534 | Sep 20, 2030 | DS DP | | | |
| | >A> 8507534*PED | Mar 20, 2031 | | | | |
| | >A> 8653103 | Dec 04, 2028 | DP | | | |
| | >A> 8653103*PED | Jun 04, 2029 | | | | |
| | >A> 8716338 | Sep 20, 2030 | DP U-1910 | | | |
| | >A> 8716338*PED | Mar 20, 2031 | | | | |
| | >A> 8741933 | Nov 08, 2026 | U-1909 | | | |
| | >A> 8741933*PED | May 08, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 8846718 | Jul 02, 2029 | U-1908 | | | |
| | >A> 8846718*PED | Jan 02, 2030 | | | | |
| | >A> 8993600 | Dec 11, 2030 | DP | | | |
| | >A> 8993600*PED | Jun 11, 2031 | | | | |
| | >A> 9150552 | Dec 04, 2028 | U-1908 | | | |
| | >A> 9150552*PED | Jun 04, 2029 | | | | |
| | >A> 9192606 | Sep 29, 2029 | DP U-1912 | | | |
| | >A> 9192606*PED | Mar 29, 2030 | | | | |
| | >A> 9216969 | Nov 08, 2026 | DP | | | |
| | >A> 9216969*PED | May 08, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP U-1911 | | | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| | >A> 9931334 | Dec 28, 2026 | DP U-2276 | | | |
| | >A> 9931334*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR; LUMACAF TOR - ORKAMBI</u> | | | | | | |
| N 211358 001 | >A> 10597384 | Dec 04, 2028 | DS DP U-2778 | | M-14 | Dec 13, 2027 |
| | >A> 10597384*PED | Jun 04, 2029 | | | >A> ODE-408 | Sep 02, 2029 |
| | >A> 10646481 | Aug 13, 2029 | DP | | PED | Jun 13, 2028 |
| | >A> 10646481*PED | Feb 13, 2030 | | | >A> PED | Mar 02, 2030 |
| | >A> 11564916 | Aug 13, 2029 | U-3526 | | | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12065432 | Dec 04, 2028 | U-3983 | | | |
| | >A> 12065432*PED | Jun 04, 2029 | | | | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 7973038 | Nov 08, 2026 | U-2374 | | | |
| | >A> 7973038*PED | May 08, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | U-2374 | | | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |

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|--|------------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u> | | | | | | |
| N 211358 001 | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8507534 | Sep 20, 2030 | DS DP | | | |
| | >A> 8507534*PED | Mar 20, 2031 | | | | |
| | >A> 8653103 | Dec 04, 2028 | DP | | | |
| | >A> 8653103*PED | Jun 04, 2029 | | | | |
| | >A> 8716338 | Sep 20, 2030 | DP U-2396 | | | |
| | >A> 8716338*PED | Mar 20, 2031 | | | | |
| | >A> 8741933 | Nov 08, 2026 | | | U-2374 | |
| | >A> 8741933*PED | May 08, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 8846718 | Jul 02, 2029 | | | U-2375 | |
| | >A> 8846718*PED | Jan 02, 2030 | | | | |
| | >A> 8993600 | Dec 11, 2030 | DP | | | |
| | >A> 8993600*PED | Jun 11, 2031 | | | | |
| | >A> 9150552 | Dec 04, 2028 | | | U-2375 | |
| | >A> 9150552*PED | Jun 04, 2029 | | | | |
| | >A> 9192606 | Sep 29, 2029 | DP U-2397 | | | |
| | >A> 9192606*PED | Mar 29, 2030 | | | | |
| | >A> 9216969 | Nov 08, 2026 | DP | | | |
| | >A> 9216969*PED | May 08, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP U-2376 | | | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| | >A> 9931334 | Dec 28, 2026 | DP U-2376 | | | |
| | >A> 9931334*PED | Jun 28, 2027 | | | | |
| <u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u> | | | | | | |
| N 211358 002 | >A> 10597384 | Dec 04, 2028 | DS DP U-2778 | | M-14 | Dec 13, 2027 |
| | >A> 10597384*PED | Jun 04, 2029 | | | >A> ODE-408 | Sep 02, 2029 |
| | >A> 10646481 | Aug 13, 2029 | DP | | PED | Jun 13, 2028 |
| | >A> 10646481*PED | Feb 13, 2030 | | | >A> PED | Mar 02, 2030 |
| | >A> 11564916 | Aug 13, 2029 | | | U-3526 | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12065432 | Dec 04, 2028 | | | U-3983 | |
| | >A> 12065432*PED | Jun 04, 2029 | | | | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 7973038 | Nov 08, 2026 | | | U-2374 | |
| | >A> 7973038*PED | May 08, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | | | U-2374 | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8507534 | Sep 20, 2030 | DS DP | | | |
| | >A> 8507534*PED | Mar 20, 2031 | | | | |
| | >A> 8653103 | Dec 04, 2028 | DP | | | |
| | >A> 8653103*PED | Jun 04, 2029 | | | | |
| | >A> 8716338 | Sep 20, 2030 | DP U-2396 | | | |
| | >A> 8716338*PED | Mar 20, 2031 | | | | |
| | >A> 8741933 | Nov 08, 2026 | | | U-2374 | |
| | >A> 8741933*PED | May 08, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 8846718 | Jul 02, 2029 | | | U-2375 | |
| | >A> 8846718*PED | Jan 02, 2030 | | | | |
| | >A> 8993600 | Dec 11, 2030 | DP | | | |
| | >A> 8993600*PED | Jun 11, 2031 | | | | |
| | >A> 9150552 | Dec 04, 2028 | | | U-2375 | |
| | >A> 9150552*PED | Jun 04, 2029 | | | | |
| | >A> 9192606 | Sep 29, 2029 | DP U-2397 | | | |
| | >A> 9192606*PED | Mar 29, 2030 | | | | |
| | >A> 9216969 | Nov 08, 2026 | DP | | | |
| | >A> 9216969*PED | May 08, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP U-2376 | | | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| | >A> 9931334 | Dec 28, 2026 | DP U-2376 | | | |
| | >A> 9931334*PED | Jun 28, 2027 | | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE (S) | EXCLUSIVITY EXPIRATION DATE |
|---|------------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>IVACAFTOR; LUMACAFTOR - ORKAMBI</u> | | | | | | |
| N 211358 003 | >A> 10597384 | Dec 04, 2028 | DS DP U-3430 | | M-14 | Dec 13, 2027 |
| | >A> 10597384*PED | Jun 04, 2029 | | | >A> ODE-408 | Sep 02, 2029 |
| | >A> 10646481 | Aug 13, 2029 | DP | | PED | Jun 13, 2028 |
| | >A> 10646481*PED | Feb 13, 2030 | | | >A> PED | Mar 02, 2030 |
| | >A> 11564916 | Aug 13, 2029 | U-3526 | | | |
| | >A> 11564916*PED | Feb 13, 2030 | | | | |
| | >A> 12065432 | Dec 04, 2028 | U-3983 | | | |
| | >A> 12065432*PED | Jun 04, 2029 | | | | |
| | >A> 7495103 | May 20, 2027 | DS DP | | | |
| | >A> 7495103*PED | Nov 20, 2027 | | | | |
| | >A> 7973038 | Nov 08, 2026 | U-3424 | | | |
| | >A> 7973038*PED | May 08, 2027 | | | | |
| | >A> 8324242 | Aug 05, 2027 | U-3424 | | | |
| | >A> 8324242*PED | Feb 05, 2028 | | | | |
| | >A> 8410274 | Dec 28, 2026 | DP | | | |
| | >A> 8410274*PED | Jun 28, 2027 | | | | |
| | >A> 8507534 | Sep 20, 2030 | DS DP | | | |
| | >A> 8507534*PED | Mar 20, 2031 | | | | |
| | >A> 8653103 | Dec 04, 2028 | DP | | | |
| | >A> 8653103*PED | Jun 04, 2029 | | | | |
| | >A> 8716338 | Sep 20, 2030 | DP U-3426 | | | |
| | >A> 8716338*PED | Mar 20, 2031 | | | | |
| | >A> 8741933 | Nov 08, 2026 | U-3424 | | | |
| | >A> 8741933*PED | May 08, 2027 | | | | |
| | >A> 8754224 | Dec 28, 2026 | DS DP | | | |
| | >A> 8754224*PED | Jun 28, 2027 | | | | |
| | >A> 8846718 | Jul 02, 2029 | U-3427 | | | |
| | >A> 8846718*PED | Jan 02, 2030 | | | | |
| | >A> 8993600 | Dec 11, 2030 | DP | | | |
| | >A> 8993600*PED | Jun 11, 2031 | | | | |
| | >A> 9150552 | Dec 04, 2028 | U-3427 | | | |
| | >A> 9150552*PED | Jun 04, 2029 | | | | |
| | >A> 9192606 | Sep 29, 2029 | DP U-3428 | | | |
| | >A> 9192606*PED | Mar 29, 2030 | | | | |
| | >A> 9216969 | Nov 08, 2026 | DP | | | |
| | >A> 9216969*PED | May 08, 2027 | | | | |
| | >A> 9670163 | Dec 28, 2026 | DP U-3429 | | | |
| | >A> 9670163*PED | Jun 28, 2027 | | | | |
| | >A> 9931334 | Dec 28, 2026 | DP U-3429 | | | |
| | >A> 9931334*PED | Jun 28, 2027 | | | | |
| <u>LAROTRECTINIB SULFATE - VITRAKVI</u> | | | | | | |
| N 210861 001 | >A> 11337967 | May 16, 2037 | U-4123 | | | |
| | >A> 11974998 | May 16, 2037 | U-4124 | | | |
| <u>LAROTRECTINIB SULFATE - VITRAKVI</u> | | | | | | |
| N 210861 002 | >A> 11337967 | May 16, 2037 | U-4123 | | | |
| | >A> 11974998 | May 16, 2037 | U-4124 | | | |
| <u>LAROTRECTINIB SULFATE - VITRAKVI</u> | | | | | | |
| N 211710 001 | >A> 11337967 | May 16, 2037 | U-4123 | | | |
| | >A> 11974998 | May 16, 2037 | U-4124 | | | |
| <u>LAZERTINIB MESYLATE - LAZCLUZE</u> | | | | | | |
| N 219008 001 | >A> 12138351 | Apr 13, 2041 | DP | | | |
| <u>LAZERTINIB MESYLATE - LAZCLUZE</u> | | | | | | |
| N 219008 002 | >A> 12138351 | Apr 13, 2041 | DP | | | |
| <u>LENVATINIB MESYLATE - LENVIMA</u> | | | | | | |
| N 206947 001 | >A> 12226409 | May 15, 2038 | U-4146 | | | |
| <u>LENVATINIB MESYLATE - LENVIMA</u> | | | | | | |
| N 206947 002 | >A> 12226409 | May 15, 2038 | U-4146 | | | |

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|---|-----------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>LEVOKETOCONAZOLE - RECORLEV</u> | | | | | | |
| N 214133 | 001 | | | | NCE* | Dec 30, 2026 |
| <u>LINAGLIPTIN - TRADJENTA</u> | | | | | | |
| N 201280 | 001 | 12178819 | May 04, 2027 | DP | | |
| <u>LISINOPRIL - OBRELIS</u> | | | | | | |
| N 208401 | 001 | 12186360 | Nov 06, 2035 | DP | | |
| <u>LOTILANER - XDEMVY</u> | | | | | | |
| N 217603 | 001 | 12171750 | Dec 14, 2038 | U-3674 | | |
| | >A> | 12213964 | Dec 14, 2038 | DP | | |
| <u>LUTETIUM LU-177 VIPIVOTIDE TETRAXETAN - PLUVICTO</u> | | | | | | |
| N 215833 | 001 | >A> 12208102 | Sep 18, 2041 | U-3345 | | |
| <u>MAGNESIUM SULFATE; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM SULFATE - SUFLAVE</u> | | | | | | |
| N 215344 | 001 | >A> 12239659 | Jun 14, 2044 | U-4143 | | |
| <u>MARIBAVIR - LIVTENCITY</u> | | | | | | |
| N 215596 | 001 | >A> 12213989 | Nov 18, 2042 | U-4137 | | |
| <u>MELOXICAM; RIZATRIPTAN BENZOATE - SYMBRAVO</u> | | | | | | |
| N 215431 | 001 | >A> 10029010 | Apr 11, 2036 | U-4133 | >A> NP | Jan 30, 2028 |
| | | >A> 10058614 | Apr 11, 2036 | DP | | |
| | | >A> 10137131 | Apr 11, 2036 | DP U-1719 | | |
| | | >A> 10195278 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10265324 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10363312 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10369224 | Apr 11, 2036 | U-4134 | | |
| | | >A> 10426839 | Apr 11, 2036 | U-4135 | | |
| | | >A> 10463736 | Apr 11, 2036 | DP | | |
| | | >A> 10471014 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10471069 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10512692 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10512693 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10517950 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10532101 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10537642 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10561664 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10583144 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10653777 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10688102 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10688185 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10695429 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10695430 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10702535 | Apr 11, 2036 | U-4136 | | |
| | | >A> 10702602 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10722583 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10729696 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10729697 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10729773 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10758617 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10758618 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10780165 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10780166 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10799588 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10821181 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10821182 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10894053 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10905693 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10918722 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10933136 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10933137 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10940153 | Apr 11, 2036 | U-1719 | | |
| | | >A> 10987358 | Apr 11, 2036 | U-1719 | | |
| | | >A> 11013805 | Apr 11, 2036 | U-1719 | | |

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|---|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>MELOXICAM; RIZATRIPTAN BENZOATE - SYMBRAVO</u> | | | | | | |
| N 215431 001 | >A> 11013806 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11020483 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11045549 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11135295 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11207328 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11219626 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11285213 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11331323 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11369684 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11426414 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11471464 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11471465 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11504429 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11510927 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11571428 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11602563 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11607456 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11617755 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11617756 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11617791 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11628173 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11712441 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11738085 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11759522 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11801250 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11806354 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11826370 | Apr 11, 2036 | U-1719 | | | |
| | >A> 11865117 | Apr 11, 2036 | U-1719 | | | |
| | >A> 12128052 | May 28, 2040 | U-1719 | | | |
| | >A> 9821075 | Apr 11, 2036 | DP U-1719 | | | |
| <u>MERCAPTOPYRINE - MERCAPTOPYRINE</u> | | | | | | |
| A 216418 001 | | | | >A> CGT | | Aug 25, 2025 |
| <u>MESNA - MESNA</u> | | | | | | |
| A 218871 001 | | | | CGT | | Jul 13, 2025 |
| <u>METOCLOPRAMIDE HYDROCHLORIDE - GIMOTI</u> | | | | | | |
| N 209388 001 | 12194008 | Dec 22, 2029 | U-2843 | | | |
| | 12194009 | Dec 22, 2029 | U-2843 | | | |
| <u>MIRDAMETINIB - GOMEKLI</u> | | | | | | |
| N 219379 001 | >A> 11066358 | Feb 17, 2041 | DS | >A> NCE | | Feb 11, 2030 |
| | >A> 11084780 | Feb 17, 2041 | DS | | | |
| | >A> 11453641 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11571402 | Feb 17, 2041 | DP | | | |
| | >A> 11806321 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11806322 | Mar 16, 2043 | U-4130 | | | |
| | >A> 11819487 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11839595 | Mar 16, 2043 | U-4130 | | | |
| | >A> 11883375 | Mar 16, 2043 | U-4130 | | | |
| | >A> 12011424 | Feb 17, 2041 | U-4130 | | | |
| | >A> 12029711 | Mar 15, 2044 | DP U-4130 | | | |
| | >A> 12037306 | Feb 17, 2041 | U-4130 | | | |
| | >A> 12090128 | Feb 17, 2041 | DP U-4130 | | | |
| | >A> 12220390 | Mar 16, 2043 | U-4130 | | | |
| <u>MIRDAMETINIB - GOMEKLI</u> | | | | | | |
| N 219389 001 | >A> 11066358 | Feb 17, 2041 | DS | >A> NCE | | Feb 11, 2030 |
| | >A> 11084780 | Feb 17, 2041 | DS | | | |
| | >A> 11453641 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11806321 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11806322 | Mar 16, 2043 | U-4130 | | | |
| | >A> 11819487 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11839595 | Mar 16, 2043 | U-4130 | | | |
| | >A> 11883375 | Mar 16, 2043 | U-4131 | | | |
| | >A> 12011424 | Feb 17, 2041 | U-4130 | | | |

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|--|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>MIRDAMETINIB - GOMEKLI</u> | | | | | | |
| N 219389 001 | >A> 12029711 | Mar 15, 2044 | DP U-4130 | | | |
| | >A> 12037306 | Feb 17, 2041 | U-4130 | | | |
| | >A> 12220390 | Mar 16, 2043 | U-4130 | | | |
| <u>MIRDAMETINIB - GOMEKLI</u> | | | | | | |
| N 219389 002 | >A> 11066358 | Feb 17, 2041 | DS | | >A> NCE | Feb 11, 2030 |
| | >A> 11084780 | Feb 17, 2041 | DS | | | |
| | >A> 11453641 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11806321 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11806322 | Mar 16, 2043 | U-4130 | | | |
| | >A> 11819487 | Feb 17, 2041 | U-4130 | | | |
| | >A> 11839595 | Mar 16, 2043 | U-4130 | | | |
| | >A> 11883375 | Mar 16, 2043 | U-4131 | | | |
| | >A> 12029711 | Mar 15, 2044 | DP U-4130 | | | |
| | >A> 12037306 | Feb 17, 2041 | U-4130 | | | |
| | >A> 12220390 | Mar 16, 2043 | U-4130 | | | |
| <u>MYCOPHENOLATE MOFETIL - MYHIBBIN</u> | | | | | | |
| N 216482 001 | 12194143 | Aug 16, 2039 | DP U-1752 | | | |
| | >A> 12226526 | Aug 16, 2039 | DP U-1752 | | | |
| <u>NIMODIPINE - NYMALIZE</u> | | | | | | |
| N 203340 002 | 12186308 | Apr 16, 2038 | DP U-2804 | | | |
| <u>NIRAPARIB TOSYLATE - ZEJULA</u> | | | | | | |
| N 214876 001 | 11730725 | Jan 25, 2039 | DP | | | |
| <u>NIRAPARIB TOSYLATE - ZEJULA</u> | | | | | | |
| N 214876 002 | 11730725 | Jan 25, 2039 | DP | | | |
| <u>NIRAPARIB TOSYLATE - ZEJULA</u> | | | | | | |
| N 214876 003 | 11730725 | Jan 25, 2039 | DP | | | |
| <u>NIRMATRELVIR; RITONAVIR - PAXLOVID (COPACKAGED)</u> | | | | | | |
| N 217188 001 | | | | | >A> D-195 | Jan 31, 2028 |
| <u>ODEVIXIBAT - BYLVAY</u> | | | | | | |
| N 215498 001 | 12187812 | Nov 08, 2031 | U-3186 | | | |
| | 12187812 | Nov 08, 2031 | U-3648 | | | |
| <u>ODEVIXIBAT - BYLVAY</u> | | | | | | |
| N 215498 002 | 12187812 | Nov 08, 2031 | U-3186 | | | |
| | 12187812 | Nov 08, 2031 | U-3648 | | | |
| <u>ODEVIXIBAT - BYLVAY</u> | | | | | | |
| N 215498 003 | 12187812 | Nov 08, 2031 | U-3186 | | | |
| | 12187812 | Nov 08, 2031 | U-3648 | | | |
| <u>ODEVIXIBAT - BYLVAY</u> | | | | | | |
| N 215498 004 | 12187812 | Nov 08, 2031 | U-3186 | | | |
| | 12187812 | Nov 08, 2031 | U-3648 | | | |
| <u>OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI</u> | | | | | | |
| N 213378 001 | 12194035 | Aug 23, 2031 | U-3141 | | | |
| <u>OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI</u> | | | | | | |
| N 213378 002 | 12194035 | Aug 23, 2031 | U-3141 | | | |
| <u>OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI</u> | | | | | | |
| N 213378 003 | 12194035 | Aug 23, 2031 | U-3141 | | | |

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| <u>OLANZAPINE; SAMIDORPHAN L-MALATE - LYBALVI</u> | | | | | | |
| N 213378 004 | 12194035 | Aug 23, 2031 | U-3141 | | | |
| <u>OLAPARIB - LYNPARZA</u> | | | | | | |
| N 208558 001 | 12178816 | Oct 07, 2029 | DP | | | |
| <u>OLAPARIB - LYNPARZA</u> | | | | | | |
| N 208558 002 | 12178816 | Oct 07, 2029 | DP | | | |
| <u>OLEZARSEN SODIUM - TRYNGOLZA (AUTOINJECTOR)</u> | | | | | | |
| N 218614 001 | 9127276 | May 01, 2034 | DS | | | |
| | 9157082 | Apr 27, 2032 | U-4050 | | | |
| | 9163239 | May 01, 2034 | DS | | | |
| | 9181549 | May 01, 2034 | DS | | | |
| | 9593333 | Feb 14, 2034 | U-4050 | | | |
| <u>OMADACYCLINE TOSYLATE - NUZYRA</u> | | | | | | |
| N 209816 001 | >A> 9265740 | Oct 24, 2030 | DP U-1569 | | | |
| <u>OMADACYCLINE TOSYLATE - NUZYRA</u> | | | | | | |
| N 209817 001 | >A> 9265740 | Oct 24, 2030 | DP | | | |
| <u>OMAVELOXOLONE - SKYCLARYS</u> | | | | | | |
| N 216718 001 | | | | >A> M-270 | | Dec 20, 2027 |
| <u>PALIPERIDONE PALMITATE - INVEGA HAFYERA</u> | | | | | | |
| N 207946 005 | 12208100 | May 07, 2041 | U-3359 | | | |
| | 12208100 | May 07, 2041 | U-4110 | | | |
| <u>PALIPERIDONE PALMITATE - INVEGA HAFYERA</u> | | | | | | |
| N 207946 006 | 12208100 | May 07, 2041 | U-3359 | | | |
| | 12208100 | May 07, 2041 | U-4110 | | | |
| <u>PALOPEGTERIPARATIDE - YORVIPATH</u> | | | | | | |
| N 216490 001 | | | | | NCE | Aug 09, 2029 |
| <u>PALOPEGTERIPARATIDE - YORVIPATH</u> | | | | | | |
| N 216490 002 | | | | | NCE | Aug 09, 2029 |
| <u>PALOPEGTERIPARATIDE - YORVIPATH</u> | | | | | | |
| N 216490 003 | | | | | NCE | Aug 09, 2029 |
| <u>PALOVAROTENE - SOHONOS</u> | | | | | | |
| N 215559 001 | >A> 12201614 | Jun 08, 2037 | U-4031 | | | |
| <u>PALOVAROTENE - SOHONOS</u> | | | | | | |
| N 215559 002 | >A> 12201614 | Jun 08, 2037 | U-4031 | | | |
| <u>PALOVAROTENE - SOHONOS</u> | | | | | | |
| N 215559 003 | >A> 12201614 | Jun 08, 2037 | U-4031 | | | |
| <u>PALOVAROTENE - SOHONOS</u> | | | | | | |
| N 215559 004 | >A> 12201614 | Jun 08, 2037 | U-4031 | | | |
| <u>PALOVAROTENE - SOHONOS</u> | | | | | | |
| N 215559 005 | >A> 12201614 | Jun 08, 2037 | U-4031 | | | |
| <u>PATISIRAN SODIUM - ONPATRO</u> | | | | | | |
| N 210922 001 | 8168775 | Aug 10, 2032 | DS DP U-2378 | | | |

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|--|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>PEGULICIANINE ACETATE - LUMISIGHT</u> | | | | | | |
| N 214511 001 | 11592396 | Sep 01, 2030 | DS | | | |
| <u>PHENTOLAMINE MESYLATE - RYZUMVI</u> | | | | | | |
| N 217064 001 | 12201615 | Dec 25, 2039 | U-3804 | | | |
| | 12201616 | Oct 25, 2039 | U-3804 | | | |
| <u>PHYTONADIONE - PHYTONADIONE</u> | | | | | | |
| A 214966 001 | | | | | >A> CGT | Sep 06, 2025 |
| <u>PIRTOBRUTINIB - JAYPIRCA</u> | | | | | | |
| N 216059 001 | >A> 12220401 | Dec 16, 2036 | DS DP U-3518 | | | |
| | >A> 12220401 | Dec 16, 2036 | DS DP U-4144 | | | |
| <u>PIRTOBRUTINIB - JAYPIRCA</u> | | | | | | |
| N 216059 002 | >A> 12220401 | Dec 16, 2036 | DS DP U-3518 | | | |
| | >A> 12220401 | Dec 16, 2036 | DS DP U-4144 | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 001 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 002 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 003 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 004 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 005 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 006 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 007 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 008 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 009 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>PONESIMOD - PONVORY</u> | | | | | | |
| N 213498 010 | >A> RE43728 | Nov 16, 2029 | DS DP | | | |
| <u>REPOTRECTINIB - AUGTYRO</u> | | | | | | |
| N 218213 001 | >A> 12187739 | Jul 05, 2036 | DP | | >A> ODE-483 | Jun 13, 2031 |
| <u>REPOTRECTINIB - AUGTYRO</u> | | | | | | |
| N 218213 002 | >A> 12187739 | Jul 05, 2036 | DP | | >A> ODE-483 | Jun 13, 2031 |
| <u>REVUMENIB CITRATE - REVUFORJ</u> | | | | | | |
| N 218944 001 | | | | | ODE-504 | Nov 15, 2031 |
| | | | | | ODE-505 | Nov 15, 2031 |
| <u>REVUMENIB CITRATE - REVUFORJ</u> | | | | | | |
| N 218944 002 | | | | | ODE-504 | Nov 15, 2031 |
| | | | | | ODE-505 | Nov 15, 2031 |

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|---------------------------------------|-----------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>REVUMENIB CITRATE - REVUFORJ</u> | | | | | | |
| N 218944 | 003 | | | | ODE-504 ODE-505 | Nov 15, 2031 Nov 15, 2031 |
| <u>RIFAXIMIN - XIFAXAN</u> | | | | | | |
| N 021361 | 002 | 8309569 | Jul 18, 2029 | U-1707 | Y | |
| | | 8309569 | Jul 18, 2029 | U-1708 | Y | |
| <u>RIPRETINIB - QINLOCK</u> | | | | | | |
| N 213973 | 001 | 12213967 | Dec 30, 2040 | DP | | |
| | | 12213968 | Dec 30, 2040 | DP | | |
| | >A> | 12226406 | Dec 30, 2040 | DP | | |
| <u>RISDIPLAM - EVRYSDI</u> | | | | | | |
| N 219285 | 001 | >A> 11534444 | Oct 04, 2038 | U-1943 | >A> M-270 | Oct 03, 2026 |
| | | >A> 11827646 | Jan 25, 2036 | U-1943 | >A> NCE | Aug 07, 2025 |
| | | >A> 12122789 | Apr 15, 2041 | DS DP | | |
| | | >A> 9586955 | Feb 08, 2033 | DS DP | | |
| | | >A> 9969754 | May 11, 2035 | DS DP U-1943 | | |
| <u>ROFLUMILAST - ZORYVE</u> | | | | | | |
| N 215985 | 001 | >A> 12220409 | Jun 07, 2037 | DP | | |
| <u>ROFLUMILAST - ZORYVE</u> | | | | | | |
| N 215985 | 002 | >A> 12220409 | Jun 07, 2037 | DP | | |
| <u>ROFLUMILAST - ZORYVE</u> | | | | | | |
| N 217242 | 001 | >A> 12220409 | Jun 07, 2037 | DP | | |
| <u>SELPERCATINIB - RETEVMO</u> | | | | | | |
| N 213246 | 001 | | | | M-311 M-312 | Sep 27, 2027 Sep 27, 2027 |
| <u>SELPERCATINIB - RETEVMO</u> | | | | | | |
| N 213246 | 002 | | | | M-311 M-312 | Sep 27, 2027 Sep 27, 2027 |
| <u>SELPERCATINIB - RETEVMO</u> | | | | | | |
| N 218160 | 001 | | | | M-311 M-312 | Sep 27, 2027 Sep 27, 2027 |
| <u>SELPERCATINIB - RETEVMO</u> | | | | | | |
| N 218160 | 002 | | | | M-311 M-312 | Sep 27, 2027 Sep 27, 2027 |
| <u>SELPERCATINIB - RETEVMO</u> | | | | | | |
| N 218160 | 003 | | | | M-311 M-312 | Sep 27, 2027 Sep 27, 2027 |
| <u>SELPERCATINIB - RETEVMO</u> | | | | | | |
| N 218160 | 004 | | | | M-311 M-312 | Sep 27, 2027 Sep 27, 2027 |
| <u>SELUMETINIB SULFATE - KOSELUGO</u> | | | | | | |
| N 213756 | 001 | >A> 12220403 | Mar 26, 2029 | DP | | |
| | | 7425637 | Mar 13, 2026 | DS | | |
| <u>SELUMETINIB SULFATE - KOSELUGO</u> | | | | | | |
| N 213756 | 002 | >A> 12220403 | Mar 26, 2029 | DP | | |
| | | 7425637 | Mar 13, 2026 | DS | | |

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|---|-----------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>SEMAGLUTIDE - OZEMPIC</u> | | | | | | |
| N 209637 | 001 | | | | >A> I-961 | Jan 28, 2028 |
| <u>SEMAGLUTIDE - OZEMPIC</u> | | | | | | |
| N 209637 | 002 | | | | >A> I-961 | Jan 28, 2028 |
| <u>SEMAGLUTIDE - OZEMPIC</u> | | | | | | |
| N 209637 | 003 | | | | >A> I-961 | Jan 28, 2028 |
| <u>SEMAGLUTIDE - OZEMPIC</u> | | | | | | |
| N 209637 | 004 | | | | >A> I-961 | Jan 28, 2028 |
| <u>SEMAGLUTIDE - RYBELSUS</u> | | | | | | |
| N 213051 | 001 | >A> 10278923 | May 02, 2034 | U-2628 | | |
| | | >A> 9278123 | Dec 16, 2031 | DP U-2628 | | |
| <u>SEMAGLUTIDE - RYBELSUS</u> | | | | | | |
| N 213051 | 002 | >A> 10278923 | May 02, 2034 | U-2628 | | |
| | | >A> 9278123 | Dec 16, 2031 | DP U-2628 | | |
| <u>SEMAGLUTIDE - RYBELSUS</u> | | | | | | |
| N 213051 | 003 | >A> 10278923 | May 02, 2034 | U-2628 | | |
| | | >A> 9278123 | Dec 16, 2031 | DP U-2628 | | |
| <u>SEMAGLUTIDE - RYBELSUS</u> | | | | | | |
| N 213051 | 004 | >A> 10278923 | May 02, 2034 | DS DP U-2628 | | |
| | | >A> 11382957 | Dec 16, 2031 | DS DP | | |
| <u>SEMAGLUTIDE - RYBELSUS</u> | | | | | | |
| N 213051 | 005 | >A> 10278923 | May 02, 2034 | DS DP U-2628 | | |
| | | >A> 11382957 | Dec 16, 2031 | DS DP | | |
| <u>SEMAGLUTIDE - RYBELSUS</u> | | | | | | |
| N 213051 | 006 | >A> 10278923 | May 02, 2034 | DS DP U-2628 | | |
| | | >A> 11382957 | Dec 16, 2031 | DS DP | | |
| | | >A> 9278123 | Dec 16, 2031 | DS DP U-2628 | | |
| <u>SEMAGLUTIDE - WEGOVY</u> | | | | | | |
| N 215256 | 001 | >A> 12214017 | Aug 24, 2038 | DP U-3162 | | |
| <u>SEMAGLUTIDE - WEGOVY</u> | | | | | | |
| N 215256 | 002 | >A> 12214017 | Aug 24, 2038 | DP U-3162 | | |
| <u>SEMAGLUTIDE - WEGOVY</u> | | | | | | |
| N 215256 | 003 | >A> 12214017 | Aug 24, 2038 | DP U-3162 | | |
| <u>SEMAGLUTIDE - WEGOVY</u> | | | | | | |
| N 215256 | 004 | >A> 12214017 | Aug 24, 2038 | DP U-3162 | | |
| <u>SEMAGLUTIDE - WEGOVY</u> | | | | | | |
| N 215256 | 005 | >A> 12214017 | Aug 24, 2038 | DP U-3162 | | |
| <u>SETMELANOTIDE ACETATE - IMCIVREE</u> | | | | | | |
| N 213793 | 001 | | | | NPP | Dec 20, 2027 |
| <u>SILDENAFIL CITRATE - LIOREV</u> | | | | | | |
| N 214952 | 001 | 12186321 | Dec 24, 2038 | DP U-3582 | | |
| <u>SITAGLIPTIN HYDROCHLORIDE - BRYNOVIN</u> | | | | | | |
| N 219122 | 001 | >A> 11944621 | Oct 23, 2040 | DP | | |

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|--|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>SODIUM OXYBATE - LUMRYZ</u> | | | | | | |
| N 214755 001 | >A> 12226377 | Jul 21, 2037 | DP | | | |
| <u>SODIUM OXYBATE - LUMRYZ</u> | | | | | | |
| N 214755 002 | >A> 12226377 | Jul 21, 2037 | DP | | | |
| <u>SODIUM OXYBATE - LUMRYZ</u> | | | | | | |
| N 214755 003 | >A> 12226377 | Jul 21, 2037 | DP | | | |
| <u>SODIUM OXYBATE - LUMRYZ</u> | | | | | | |
| N 214755 004 | >A> 12226377 | Jul 21, 2037 | DP | | | |
| <u>SOLRIAMFETOL HYDROCHLORIDE - SUNOSI</u> | | | | | | |
| N 211230 001 | 12194016 | Mar 19, 2040 | U-4106 | | | |
| | >A> 12209059 | Jun 07, 2026 | U-2548 | | | |
| <u>SOLRIAMFETOL HYDROCHLORIDE - SUNOSI</u> | | | | | | |
| N 211230 002 | 12194016 | Mar 19, 2040 | U-4106 | | | |
| | >A> 12209059 | Jun 07, 2026 | U-2548 | | | |
| <u>SOTORASIB - LUMAKRAS</u> | | | | | | |
| N 214665 001 | 11236091 | May 20, 2040 | DS DP U-3306 | | >A> I-962 | Jan 16, 2028 |
| | 11236091 | May 20, 2040 | DS DP U-4107 | | | |
| | 11426404 | Sep 15, 2040 | U-3306 | | | |
| | 11426404 | Sep 15, 2040 | U-4107 | | | |
| | 11827635 | May 20, 2040 | DS DP U-3306 | | | |
| | 11827635 | May 20, 2040 | DS DP U-4107 | | | |
| <u>SOTORASIB - LUMAKRAS</u> | | | | | | |
| N 214665 002 | 11236091 | May 20, 2040 | DS DP U-3306 | | >A> I-962 | Jan 16, 2028 |
| | 11236091 | May 20, 2040 | DS DP U-4107 | | | |
| | 11426404 | Sep 15, 2040 | U-3306 | | | |
| | 11426404 | Sep 15, 2040 | U-4107 | | | |
| | 11827635 | May 20, 2040 | DS DP U-3306 | | | |
| | 11827635 | May 20, 2040 | DS DP U-4107 | | | |
| <u>SOTORASIB - LUMAKRAS</u> | | | | | | |
| N 214665 003 | 11236091 | May 20, 2040 | DS DP U-3306 | | >A> I-962 | Jan 16, 2028 |
| | 11236091 | May 20, 2040 | DS DP U-4107 | | | |
| | 11426404 | Sep 15, 2040 | U-3306 | | | |
| | 11426404 | Sep 15, 2040 | U-4107 | | | |
| | 11827635 | May 20, 2040 | DS DP U-3306 | | | |
| | 11827635 | May 20, 2040 | DS DP U-4107 | | | |
| <u>SUGAMMADEX SODIUM - BRIDION</u> | | | | | | |
| N 022225 001 | | | | | NPP PED | Dec 12, 2027 Jun 12, 2028 |
| <u>SUGAMMADEX SODIUM - BRIDION</u> | | | | | | |
| N 022225 002 | | | | | NPP PED | Dec 12, 2027 Jun 12, 2028 |
| <u>SUZETRIGINE - JOURNAVX</u> | | | | | | |
| N 219209 001 | >A> 11834441 | Dec 04, 2040 | DS DP U-4125 | | >A> NCE | Jan 30, 2030 |
| <u>TADALAFIL - TADLIQ</u> | | | | | | |
| N 214522 001 | 12186322 | Dec 24, 2038 | DP U-3397 | | | |
| <u>TAPINAROF - VTAMA</u> | | | | | | |
| N 215272 001 | 10426743 | May 19, 2036 | U-2625 | | I-956 | Dec 12, 2027 |
| | 10426743 | May 19, 2036 | U-4048 | | | |
| | 11497718 | Nov 13, 2039 | U-4048 | | | |
| | 11612573 | May 19, 2036 | U-2625 | | | |
| | 11612573 | May 19, 2036 | U-4048 | | | |

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|--|--------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>TAPINAROF - VTAMA</u> | | | | | | |
| N 215272 001 | 11938099 | Nov 13, 2039 | U-4048 | | | |
| <u>TASIMELTEON - HETLIOZ</u> | | | | | | |
| N 205677 001 | >A> 12201604 | Jan 25, 2033 | U-3003 | | | |
| | >A> 12201604 | Jan 25, 2033 | U-3865 | | | |
| <u>TASIMELTEON - HETLIOZ LO</u> | | | | | | |
| N 214517 001 | >A> 12201604 | Jan 25, 2033 | U-3003 | | | |
| <u>TAZEMETOSTAT HYDROBROMIDE - TAZVERIK</u> | | | | | | |
| N 211723 001 | 12161645 | Sep 12, 2031 | U-2853 | | | |
| | 12162865 | May 21, 2034 | U-2736 | | | |
| | 12168014 | May 03, 2038 | U-2736 | | | |
| | 12168014 | May 03, 2038 | U-2852 | | | |
| | 12168014 | May 03, 2038 | U-2853 | | | |
| | 12168015 | Sep 12, 2031 | DS DP | | | |
| | 12168016 | Sep 12, 2031 | U-2736 | | | |
| | 12168016 | Sep 12, 2031 | U-2853 | | | |
| <u>TENOFOVIR ALAFENAMIDE FUMARATE - VEMLIDY</u> | | | | | | |
| N 208464 001 | 7390791 | Jan 07, 2025 | DS DP | | | |
| | 7390791*PED | Jul 07, 2025 | | | | |
| <u>TETRACAINE HYDROCHLORIDE - TETRACAINE HYDROCHLORIDE</u> | | | | | | |
| A 217227 001 | | | | | CGT | Jun 25, 2025 |
| <u>THIOTEPA - TEPYLUTE</u> | | | | | | |
| N 216984 002 | >A> 11975013 | Aug 16, 2041 | DP | | | |
| <u>TIRZEPATIDE - ZEPBOUND (AUTOINJECTOR)</u> | | | | | | |
| N 217806 001 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND (AUTOINJECTOR)</u> | | | | | | |
| N 217806 002 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND (AUTOINJECTOR)</u> | | | | | | |
| N 217806 003 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND (AUTOINJECTOR)</u> | | | | | | |
| N 217806 004 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND (AUTOINJECTOR)</u> | | | | | | |
| N 217806 005 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND (AUTOINJECTOR)</u> | | | | | | |
| N 217806 006 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND</u> | | | | | | |
| N 217806 007 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND</u> | | | | | | |
| N 217806 008 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND</u> | | | | | | |
| N 217806 009 | | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND</u> | | | | | | |
| N 217806 010 | | | | | >A> I-958 | Dec 20, 2027 |

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|---|-----------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>TIRZEPATIDE - ZEPBOUND</u> | | | | | | |
| N 217806 | 011 | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIRZEPATIDE - ZEPBOUND</u> | | | | | | |
| N 217806 | 012 | | | | >A> I-958 | Dec 20, 2027 |
| <u>TIVOZANIB HYDROCHLORIDE - FOTIVDA</u> | | | | | | |
| N 212904 | 001 | >A> 7166722 | Nov 16, 2028 | DS DP | | |
| <u>TIVOZANIB HYDROCHLORIDE - FOTIVDA</u> | | | | | | |
| N 212904 | 002 | >A> 7166722 | Nov 16, 2028 | DS DP | | |
| <u>TOFACITINIB CITRATE - XELJANZ</u> | | | | | | |
| N 203214 | 001 | >A> RE41783 | Dec 08, 2025 | DS | | |
| | | >A> RE41783*PED | Jun 08, 2026 | | | |
| <u>TOFACITINIB CITRATE - XELJANZ</u> | | | | | | |
| N 203214 | 002 | >A> RE41783 | Dec 08, 2025 | DS | | |
| | | >A> RE41783*PED | Jun 08, 2026 | | | |
| <u>TOFACITINIB CITRATE - XELJANZ XR</u> | | | | | | |
| N 208246 | 001 | >A> 11253523 | Mar 14, 2034 | | U-3326 | |
| | | >A> 11253523 | Mar 14, 2034 | | U-3327 | |
| | | >A> 11253523 | Mar 14, 2034 | | U-3328 | |
| | | >A> 11253523 | Mar 14, 2034 | | U-3329 | |
| | | >A> 11253523*PED | Sep 14, 2034 | | | |
| | | >A> 9937181 | Mar 14, 2034 | DP | | |
| | | >A> 9937181*PED | Sep 14, 2034 | | | |
| | | >A> RE41783 | Dec 08, 2025 | DS | | |
| | | >A> RE41783*PED | Jun 08, 2026 | | | |
| <u>TOFACITINIB CITRATE - XELJANZ XR</u> | | | | | | |
| N 208246 | 002 | >A> 10639309 | Mar 14, 2034 | DP | | |
| | | >A> 10639309*PED | Sep 14, 2034 | | | |
| | | >A> 11253523 | Mar 14, 2034 | | U-3326 | |
| | | >A> 11253523 | Mar 14, 2034 | | U-3327 | |
| | | >A> 11253523 | Mar 14, 2034 | | U-3328 | |
| | | >A> 11253523 | Mar 14, 2034 | | U-3329 | |
| | | >A> 11253523*PED | Sep 14, 2034 | | | |
| | | >A> RE41783 | Dec 08, 2025 | DS | | |
| | | >A> RE41783*PED | Jun 08, 2026 | | | |
| <u>TOFACITINIB CITRATE - XELJANZ</u> | | | | | | |
| N 213082 | 001 | >A> RE41783 | Dec 08, 2025 | DS | | |
| | | >A> RE41783*PED | Jun 08, 2026 | | | |
| <u>TRAVOPROST - IDOSE TR</u> | | | | | | |
| N 218010 | 001 | >A> 12201555 | Feb 14, 2031 | DS DP | | |
| | | >A> 12201557 | Jun 18, 2030 | DS DP | U-4129 | |
| <u>TREOSULFAN - GRAFAPEX</u> | | | | | | |
| N 214759 | 001 | >A> 7199162 | Oct 12, 2025 | U-4142 | >A> NCE | Jan 21, 2030 |
| <u>TREOSULFAN - GRAFAPEX</u> | | | | | | |
| N 214759 | 002 | >A> 7199162 | Oct 12, 2025 | U-4142 | >A> NCE | Jan 21, 2030 |
| <u>TRILACICLIB DIHYDROCHLORIDE - COSELA</u> | | | | | | |
| N 214200 | 001 | 12168666 | Nov 13, 2040 | DS DP | | |
| <u>UBROGEPANT - UBRELVY</u> | | | | | | |
| N 211765 | 001 | 12168004 | Jan 30, 2035 | DP | | |
| | | 12194030 | Dec 22, 2041 | | U-4121 | |
| | | 12194030 | Dec 22, 2041 | | U-4122 | |

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| <u>UBROGEPANT - UBRELVY</u> | | | | | | |
| N 211765 002 | 12168004 | Jan 30, 2035 | DP | | | |
| <u>VAMOROLONE - AGAMREE</u> | | | | | | |
| N 215239 001 >A> | 12201639 | Mar 17, 2040 | DS DP U-3747 | | | |
| <u>VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE</u> | | | | | | |
| N 211962 001 | 12161690 | Nov 06, 2035 | DP | | | |
| <u>VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE</u> | | | | | | |
| N 211962 002 | 12161690 | Nov 06, 2035 | DP | | | |
| <u>VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE</u> | | | | | | |
| N 211962 003 | 12161690 | Nov 06, 2035 | DP | | | |
| <u>VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE</u> | | | | | | |
| N 211962 004 | 12161690 | Nov 06, 2035 | DP | | | |
| <u>VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE</u> | | | | | | |
| N 211962 005 | 12161690 | Nov 06, 2035 | DP | | | |
| <u>VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE</u> | | | | | | |
| N 211962 006 | 12161690 | Nov 06, 2035 | DP | | | |
| <u>VANCOMYCIN HYDROCHLORIDE - VANCOMYCIN HYDROCHLORIDE</u> | | | | | | |
| N 211962 007 | 12161690 | Nov 06, 2035 | DP | | | |
| <u>VASOPRESSIN - VASOSTRICT</u> | | | | | | |
| N 204485 005 | 12186362 | Jan 30, 2035 | DP | | | |
| <u>VIBEGRON - GEMTESA</u> | | | | | | |
| N 213006 001 | 12180219 | Mar 12, 2034 | DS DP | | I-955 | Dec 18, 2027 |
| <u>VILOXAZINE HYDROCHLORIDE - QELBREE</u> | | | | | | |
| N 211964 001 >A> | 9662338 | Apr 02, 2035 | DP | | | |
| <u>VILOXAZINE HYDROCHLORIDE - QELBREE</u> | | | | | | |
| N 211964 002 >A> | 9662338 | Apr 02, 2035 | DP | | | |
| <u>VILOXAZINE HYDROCHLORIDE - QELBREE</u> | | | | | | |
| N 211964 003 >A> | 9662338 | Apr 02, 2035 | DP | | | |
| <u>VIMSELTINIB - ROMVIMZA</u> | | | | | | |
| N 219304 001 >A> | 11103507 | Feb 03, 2040 | U-4145 | | >A> NCE | Feb 14, 2030 |
| | >A> 11679110 | Feb 03, 2040 | U-4145 | | | |
| | >A> 9181223 | Mar 14, 2034 | DS DP | | | |
| <u>VIMSELTINIB - ROMVIMZA</u> | | | | | | |
| N 219304 002 >A> | 11103507 | Feb 03, 2040 | U-4145 | | >A> NCE | Feb 14, 2030 |
| | >A> 11679110 | Feb 03, 2040 | U-4145 | | | |
| | >A> 9181223 | Mar 14, 2034 | DS DP | | | |
| <u>VIMSELTINIB - ROMVIMZA</u> | | | | | | |
| N 219304 003 >A> | 11103507 | Feb 03, 2040 | U-4145 | | >A> NCE | Feb 14, 2030 |
| | >A> 11679110 | Feb 03, 2040 | U-4145 | | | |
| | >A> 9181223 | Mar 14, 2034 | DS DP | | | |
| <u>ZURANOLONE - ZURZUVAE</u> | | | | | | |
| N 217369 001 | 11884696 | Aug 23, 2037 | U-2552 | | | |

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| <u>ZURANOLONE - ZURZUVAE</u> | | | | | | |
| N 217369 002 | 11884696 | Aug 23, 2037 | U-2552 | | | |
| <u>ZURANOLONE - ZURZUVAE</u> | | | | | | |
| N 217369 003 | 11884696 | Aug 23, 2037 | U-2552 | | | |

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, 45TH Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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