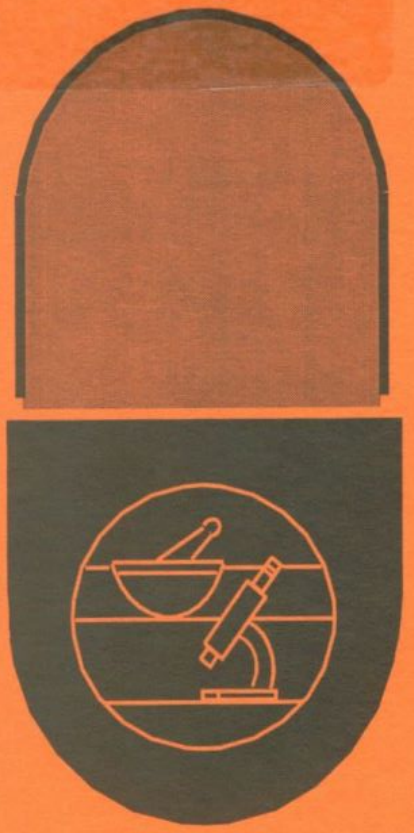
CUMULATIVE
SUPPLEMENT 10
OCTOBER 2000



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT AND SERVICES

2000

Prepared By
Division of Data Management and Services
Office of Information Technology
Center for Drug Evaluation and Research
Food and Drug Administration

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*See Subscription Form Inside Back Cover*

**APPROVED DRUG PRODUCTS**
**with**
**THERAPEUTIC EQUIVALENCE EVALUATIONS**

**20TH EDITION**

**Cumulative Supplement 10**

**October 2000**

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# APPROVED DRUG PRODUCTS
# with
# THERAPEUTIC EQUIVALENCE EVALUATIONS

## 20TH EDITION

## CUMULATIVE SUPPLEMENT 10
## OCTOBER 2000

## 1.0 INTRODUCTION

### 1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 20th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. 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. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

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 place an asterisk (*) 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. [Strength(s) which already exist in the List will not be repeated for context.]

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.)

New additions to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol **>ADD>** to the left of the line on which new information exists. The **>ADD>** 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 **>DLT>** (DELETE) to the left of the line. The **>DLT>** symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition.

Products that have never been marketed, have been discontinued from marketing 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 the 20h Edition List will then be added to the "Discontinued Drug Product List" appearing in the 21st Edition.

## 1.2 APPLICANT NAME CHANGES

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

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When

this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

## APPLICANT NAME CHANGES

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|
| GALDERMA LABS INC (GALDERMA) | GALDERMA LABORATORIES LP (GALDERMA LABS LP) |
| GLOBAL PHARMACEUTICAL CORP (GLOBAL PHARM) | IMPAX LABORATORIES INC (IMPAX LABS) |
| HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL) | AVENTIS PHARMACEUTICALS INC (AVENTIS PHARMS) |
| RHONE POULENC RORER PHARMACEUTICALS INC (RHONE POULENCE RORER) | AVENTIS PHARMACEUTICALS PRODUCTS INC (AVENTIS PHARM PROD) |
| ROCHE GLOBAL DEVELOPMENT (ROCHE GLOBAL) | ROCHE GLOBAL A DIVISION OF SYNTEX (USA) LLC (ROCHE GLOBAL DEV) |
| SYNTEX (USA) INC (SYNTEX) | SYNTEX (USA) LLC (SYNTEX (USA) LLC) |
| SYNTEX FP INC (SYNTEX) | SYNTEX (USA) LLC (SYNTEX (USA) LLC) |
| SYNTEX LABORATORIES INC SUB SYNTEX CORP (SYNTEX) | SYNTEX (USA) LLC (SYNTEX (USA) LLC) |
| SYNTEX USA INC (SYNTEX) | SYNTEX (USA) LLC (SYNTEX (USA) LLC) |
| TAP HOLDINGS INC (TAP HOLDINGS) | TAP PHARMACEUTICAL PRODUCTS INC (TAP PHARM) |
| ZENECA INC (ZENECA) | ASTRAZENECA PHARMACEUTICALS LP (ASTRAZENECA PHARMS) |
| ZENECA LTD (ZENECA) | ASTRAZENECA UK LTD (ASTRAZENECA UK) |
| ZENECA PHARMACEUTICALS DIV ZENECA INC (ZENECA) | ASTRAZENECA PHARMACEUTICALS LP (ASTRAZENECA PHARMS) |

## 1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

Two NDAs have been approved for diclofenac sodium ophthalmic solution 0.1% (DSOS), (1) Ciba's NDA 20-037 for Voltaren and (2) Falcon Pharms' (Alcon) NDA 20-809 for DSOS. Alcon was required to do a study comparing their DSOS to Voltaren and to a placebo control in post cataract surgical inflammation. This study was necessary to demonstrate that the different formulation of the Alcon drug product did not affect the safety and/or effectiveness of the proposed drug product for this indication. Prior to the approval of Alcon's DSOS Ciba did clinical studies and was approved for two additional indications for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery. Three years of Waxman-Hatch marketing exclusivity was granted to Ciba for these two new uses.

Since the treatment of pain has a different site of action than the anti-inflammatory or photophobia indications the Agency did not have information to support a recommendation that the Alcon and Ciba DSOS are therapeutically equivalent for the treatment of pain. The designation of therapeutic equivalence at this time applies only to the anti-inflammatory indication. The therapeutic equivalence designation will apply to the photophobia indication upon expiration of Ciba's marketing exclusivity.

## 1.4 AVAILABILITY OF THE EDITION

The 20th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is $101.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at http://www.fda.gov/cder/ob. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant 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. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at
http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the hard copy monthly supplement is at
http://www.fda.gov/cder/orange/supplement/cspreface.htm. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product data at http://www.fda.gov/cder/orange/obreadme.htm. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 20th annual edition of the 1999 Orange Book Patent and Exclusivity List is at http://www.fda.gov/cder/orange/20bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at http://www.fda.gov/cder/orange/supplement/patents.pdf.

The Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:
http://www.fda.gov/cder/orange/patdecl.pdf
http://www.fda.gov/cder/orange/patdecl.html

The current listing of the Orphan Product Designations and Approvals is available at http://www.fda.gov/orphan/designat/list.htm.

## 1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

### DESCRIPTION OF REPORT

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

The baseline column (Dec 1999) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### DEFINITIONS

#### Drug Product

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

#### New Molecular Entity

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

## REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

### COUNTS CUMULATIVE BY QUARTER

| CATEGORIES COUNTED | DEC 1999 | MAR 2000 | JUN 2000 | SEP 2000 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 10045 | 10082 | 10186 | 10332 |
| SINGLE SOURCE | 2599 (25.9%) | 2596 (25.7%) | 2617 (25.7%) | 2662 (25.8%) |
| MULTISOURCE | 7335 (73.0%) | 7375 (73.2%) | 7458 (73.2%) | 7560 (73.2%) |
| THERAPEUTICALLY EQUIVALENT | 6986 (69.5%) | 7040 (69.8%) | 7132 (70.0%) | 7238 (70.1%) |
| NOT THERAPEUTICALLY EQUIVALENT | 349 (3.5%) | 335 (3.3%) | 326 (3.2%) | 322 (3.1%) |
| EXCEPTIONS[1] | 111 (1.1%) | 111 (1.1%) | 111 (1.1%) | 110 (1.1%) |
| NEW MOLECULAR ENTITIES APPROVED | 0 | 6 | 11 | 7 |
| NUMBER OF APPLICANTS | 576 | 575 | 580 | 587 |

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

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| | | **PHRENILIN FORTE** | | | | |
| AB | + | AMARIN PHARMS | 650MG;50MG | N88831 001<br>JUN 19, 1985 | | |
| AB | + | CARNRICK | 650MG;50MG | N88831 001<br>JUN 19, 1985 | > ADD > | |

TABLET; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| | | **PHRENILIN** | | | | |
| AB | + | AMARIN PHARMS | 325MG;50MG | N87811 001<br>JUN 19, 1985 | | |
| AB | + | CARNRICK | 325MG;50MG | N87811 001<br>JUN 19, 1985 | | |

ACETAMINOPHEN; CODEINE PHOSPHATE

SUSPENSION; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| | | **ACETAMINOPHEN AND CODEINE PHOSPHATE** | | | | |
| AA | | AMARIN PHARMS | 120MG/5ML;12MG/5ML | N86024 001 | | |
| AA | | CARNRICK | 120MG/5ML;12MG/5ML | N86024 001 | | |

TABLET; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| > DLT > | | **ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 4** | | | | |
| > DLT > | AA | ROXANE | 300MG;60MG | N84667 001 | | |
| > ADD > | | @ | 300MG;60MG | N84667 001 | > ADD > | |
| > DLT > | | **ACETAMINOPHEN W/ CODEINE NO. 2** | | | > ADD > | |
| > DLT > | AA | ROXANE | 300MG;15MG | N84659 001 | > DLT > | |
| > ADD > | | @ | 300MG;15MG | N84659 001 | > DLT > | |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| | | **HYDROCODONE BITARTRATE AND ACETAMINOPHEN** | | | | |
| AA | | BARR | 500MG;2.5MG | N40307 001<br>JUL 26, 2000 | | |
| AA | | | 500MG;5MG | N40308 001<br>JUL 26, 2000 | | |
| AA | | | 500MG;7.5MG | N40307 002<br>JUL 26, 2000 | > ADD > | |
| AA | | | 500MG;10MG | N40309 001<br>JUL 26, 2000 | > ADD > | |
| AA | | | 650MG;7.5MG | N40307 003<br>JUL 26, 2000 | | |
| AA | | | 650MG;10MG | N40307 004<br>JUL 26, 2000 | | |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| | | **HYDROCODONE BITARTRATE AND ACETAMINOPHEN** | | | | |
| AA | | BARR | 750MG;7.5MG | N40308 002<br>JUL 26, 2000 | | |
| AA | | MALLINCKRODT | 325MG;5MG | N40409 001<br>OCT 20, 2000 | > ADD > | |
| AA | | | 325MG;7.5MG | N40405 001<br>SEP 08, 2000 | | |
| AA | | | 325MG;10MG | N40400 001<br>JUL 26, 2000 | | |
| AA | + | UCB | 325MG;7.5MG | N40248 001<br>APR 28, 2000 | | |
| AA | | | 325MG;10MG | N40248 002<br>APR 28, 2000 | | |
| | + | | 325MG;7.5MG | N40248 001<br>APR 28, 2000 | | |
| AA | | VINTAGE PHARMS | 325MG;10MG | N40355 001<br>MAY 31, 2000 | | |
| AA | | | 500MG;10MG | N40356 001<br>MAY 31, 2000 | | |
| AA | | | 660MG;10MG | N40358 001<br>MAY 31, 2000 | | |
| AA | | WATSON LABS | 660MG;10MG | N40094 003<br>AUG 08, 2000 | | |
| | | **LORTAB** | | | | |
| AA | + | UCB | 325MG;5MG | N40099 001<br>JUN 25, 1997 | | |
| | + | | 325MG;5MG | N40099 001<br>JUN 25, 1997 | | |
| | | **NORCO** | | | | |
| AA | + | WATSON LABS | 325MG;10MG | N40148 001<br>FEB 14, 1997 | | |
| | + | | 325MG;10MG | N40148 001<br>FEB 14, 1997 | | |

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| | | **OXYCODONE AND ACETAMINOPHEN** | | | | |
| AA | | BARR | 500MG;5MG | N40304 001<br>OCT 02, 2000 | > ADD > | |

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **PENTAZOCINE HCL AND ACETAMINOPHEN** | | | |
| AB | WATSON LABS | 650MG;EQ 25MG BASE | N74699 001 | MAR 24, 2000 |
| | **TALACEN** | | | |
| AB | + SANOFI SYNTHELABO | 650MG;EQ 25MG BASE | N18458 001 | SEP 23, 1982 |
| | + | 650MG;EQ 25MG BASE | N18458 001 | SEP 23, 1982 |

ACETOHEXAMIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **ACETOHEXAMIDE** | | | |
| AB | BARR | 500MG | N70870 001 | FEB 09, 1987 |
| AB | + | 500MG | N70870 001 | FEB 09, 1987 |
| | **DYMELOR** | | | |
| AB | LILLY | 250MG | N13378 002 | |
| AB | + | 500MG | N13378 001 | |
| | @ | 250MG | N13378 002 | |
| | @ | 500MG | N13378 001 | |

ACYCLOVIR

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | **ACYCLOVIR** | | | |
| AB | ROXANE | 200MG | N74570 002 | APR 22, 1997 |
| | @ | 200MG | N74570 002 | APR 22, 1997 |

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **ACYCLOVIR SODIUM** | | | |
| AP | APOTHECON | EQ 500MG BASE/VIAL | N74897 001 | FEB 27, 1998 |
| AP | | EQ 1GM BASE/VIAL | N74897 002 | FEB 27, 1998 |
| | @ | EQ 500MG BASE/VIAL | N74897 001 | FEB 27, 1998 |

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **ACYCLOVIR SODIUM** | | | |
| | @ APOTHECON | EQ 1GM BASE/VIAL | N74897 002 | FEB 27, 1998 |

ADAPALENE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | DIFFERIN | | | |
| | + GALDERMA LABS LP | 0.1% | N20748 001 | MAY 26, 2000 |

ALBUMIN HUMAN

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | OPTISON | | | |
| | + MALLINCKRODT | 10MG/ML | N20899 001 | DEC 31, 1997 |
| | + MOLECULAR BIOSYSTEMS | 10MG/ML | N20899 001 | DEC 31, 1997 |

ALBUTEROL

AEROSOL, METERED; INHALATION

| | | | | |
|---|---|---|---|---|
| | **ALBUTEROL** | | | |
| AB | MEDISOL | 0.09MG/INH | N74072 001 | AUG 01, 1996 |
| AB | SIDMAK LABS CA | 0.09MG/INH | N74072 001 | AUG 01, 1996 |

ALBUTEROL SULFATE

SOLUTION; INHALATION

| | | | | |
|---|---|---|---|---|
| | **ALBUTEROL SULFATE** | | | |
| AN | BAUSCH AND LOMB | EQ 0.083% BASE | N75358 001 | MAR 29, 2000 |

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | **ALBUTEROL SULFATE** | | | |
| AA | WATSON LABS | EQ 2MG BASE/5ML | N73165 001 | APR 29, 1993 |
| | @ | EQ 2MG BASE/5ML | N73165 001 | APR 29, 1993 |

> DLT >
> DLT >
> ADD >
> ADD >

ALBUTEROL SULFATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **ALBUTEROL SULFATE** | | | |
| **AB** | **MD PHARM** | **EQ 2MG BASE** | **N73120 001** | **SEP 29, 1992** |
| **AB** | | **EQ 4MG BASE** | **N73121 001** | **SEP 29, 1992** |
| | @ MEDEVA PHARMS CA | EQ 2MG BASE | N73120 001 | SEP 29, 1992 |
| | @ | EQ 4MG BASE | N73121 001 | SEP 29, 1992 |

ALENDRONATE SODIUM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | FOSAMAX | | | |
| > DLT > | + MERCK | EQ 40MG BASE | N20560 002 | SEP 29, 1995 |
| > DLT > | | EQ 35MG BASE | N20560 004 | OCT 20, 2000 |
| > ADD > | | EQ 40MG BASE | N20560 002 | SEP 29, 1995 |
| > ADD > | + | EQ 70MG BASE | N20560 005 | OCT 20, 2000 |

ALOSETRON HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | LOTRONEX | | | |
| > ADD > | + GLAXO WELLCOME | EQ 1MG BASE | N21107 001 | FEB 09, 2000 |

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

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | MULTI-12 | | | |
| > ADD > | + SABEX | 2 IU/ML;20MG/ML;12 UGM/ML;40 IU/ML; 1 UGM/ML;3MG/ML;80 UGM/ML;8MG/ML; 0.8MG/ML;0.72MG/ML;0.6MG/ML; 600 IU/ML | N21163 001 | MAY 18, 2000 |

ALPRAZOLAM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **ALPRAZOLAM** | | | |
| **AB** | **ROXANE** | **0.25MG** | **N74199 001** | **OCT 19, 1993** |
| **AB** | | **0.5MG** | **N74199 002** | **OCT 19, 1993** |
| **AB** | | **1MG** | **N74199 003** | **OCT 19, 1993** |
| | @ | 0.25MG | N74199 001 | OCT 19, 1993 |
| | @ | 0.5MG | N74199 002 | OCT 19, 1993 |
| | @ | 1MG | N74199 003 | OCT 19, 1993 |

ALTRETAMINE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | HEXALEN | | | |
| | + MEDIMMUNE ONCOLOGY | 50MG | N19926 001 | DEC 26, 1990 |
| | + US BIOSCIENCE | 50MG | N19926 001 | DEC 26, 1990 |

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | **AMANTADINE HCL** | | | |
| **AB** | **GENEVA PHARMS TECH** | **100MG** | **N71293 001** | **FEB 18, 1987** |
| **AB** | **INVAMED** | **100MG** | **N71293 001** | **FEB 18, 1987** |

AMIFOSTINE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | ETHYOL | | | |
| | + MEDIMMUNE ONCOLOGY | 500MG/VIAL | N20221 001 | DEC 08, 1995 |
| | + US BIOSCIENCE | 500MG/VIAL | N20221 001 | DEC 08, 1995 |

## AMIKACIN SULFATE

INJECTABLE; INJECTION

**AMIKACIN SULFATE**

| | | | | |
|---|---|---|---|---|
| > DLT > | AP | ASTRAZENECA | **EQ 50MG BASE/ML** | **N63167 001** |
| > DLT > | | | | DEC 14, 1995 |
| > DLT > | AP | | **EQ 250MG BASE/ML** | **N63169 001** |
| > DLT > | | | | DEC 14, 1995 |
| > ADD > | @ | | EQ 50MG BASE/ML | N63167 001 |
| > ADD > | | | | DEC 14, 1995 |
| > ADD > | @ | | EQ 250MG BASE/ML | N63169 001 |
| > ADD > | | | | DEC 14, 1995 |

## AMINO ACIDS

INJECTABLE; INJECTION

NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | | BAXTER HLTHCARE | 15% | N20107 001 |
| | | | | FEB 05, 1993 |
| | @ | | 15% | N20107 001 |
| | | | | FEB 05, 1993 |
| | | TROPHAMINE | | |
| | | B BRAUN | 6% | N19018 001 |
| | | | | JUL 20, 1984 |
| | + | | 6% | N19018 001 |
| | | | | JUL 20, 1984 |
| | | TROPHAMINE 10% | | |
| | | B BRAUN | 10% | N19018 003 |
| | | | | SEP 07, 1988 |
| | + | | 10% | N19018 003 |
| | | | | SEP 07, 1988 |

## AMINOPHYLLINE

TABLET; ORAL

**AMINOPHYLLINE**

| | | | | |
|---|---|---|---|---|
| AB | | GLOBAL PHARM | **100MG** | **N84574 001** |
| AB | | | **200MG** | **N84576 001** |
| | @ | IMPAX LABS | 100MG | N84574 001 |
| | @ | | 200MG | N84576 001 |

## AMIODARONE HYDROCHLORIDE

TABLET; ORAL

AMIODARONE HCL

| | | | | |
|---|---|---|---|---|
| | + | EON | 400MG | N75315 002 |
| | | | | JUN 30, 2000 |

## AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

**AMITRIPTYLINE HCL**

| | | | | |
|---|---|---|---|---|
| > DLT > | AB | MD PHARM | **10MG** | **N85864 001** |
| > DLT > | AB | | **25MG** | **N85935 001** |
| > DLT > | AB | | **50MG** | **N85936 001** |
| > DLT > | AB | | **75MG** | **N86337 001** |
| > DLT > | AB | | **100MG** | **N86336 001** |
| > DLT > | AB | | **150MG** | **N86335 001** |
| > ADD > | @ | MEDEVA PHARMS CA | 10MG | N85864 001 |
| > ADD > | @ | | 25MG | N85935 001 |
| > ADD > | @ | | 50MG | N85936 001 |
| > ADD > | @ | | 75MG | N86337 001 |
| > ADD > | @ | | 100MG | N86336 001 |
| > ADD > | @ | | 150MG | N86335 001 |
| > DLT > | AB | PUREPAC PHARM | **10MG** | **N88075 001** |
| > DLT > | | | | SEP 16, 1983 |
| > DLT > | AB | | **25MG** | **N88076 001** |
| > DLT > | | | | MAY 20, 1983 |
| > DLT > | AB | | **50MG** | **N88077 001** |
| > DLT > | | | | SEP 16, 1983 |
| > DLT > | AB | | **75MG** | **N88078 001** |
| > DLT > | | | | SEP 16, 1983 |
| > DLT > | AB | | **100MG** | **N88079 001** |
| > ADD > | @ | | 10MG | SEP 16, 1983 |
| > ADD > | | | | N88075 001 |
| > ADD > | @ | | 25MG | SEP 16, 1983 |
| > ADD > | | | | N88076 001 |
| > ADD > | @ | | 50MG | MAY 20, 1983 |
| > ADD > | | | | N88077 001 |
| > ADD > | @ | | 75MG | SEP 16, 1983 |
| > ADD > | | | | N88078 001 |
| > ADD > | @ | | 100MG | SEP 16, 1983 |
| > ADD > | | | | N88079 001 |
| > DLT > | AB | ROXANE | **10MG** | SEP 16, 1983 |
| > DLT > | AB | | **25MG** | **N86002 001** |
| > DLT > | AB | | **50MG** | **N85944 001** |
| > DLT > | AB | | **75MG** | **N85945 001** |
| > DLT > | AB | | **100MG** | **N86004 001** |
| > ADD > | @ | | 10MG | **N86003 001** |
| > ADD > | @ | | 25MG | N86002 001 |
| > ADD > | @ | | 50MG | N85944 001 |
| > ADD > | @ | | 75MG | N85945 001 |
| > ADD > | @ | | 100MG | N86004 001 |
| | | | | N86003 001 |

AMOXAPINE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | **AMOXAPINE** | | | |
| > DLT > | **AB** | **WATSON LABS** | **150MG** | **N72421 001** | |
| > DLT > | | | | MAY 11, 1989 | |
| > ADD > | **AB** | + | **150MG** | **N72421 001** | |
| > ADD > | | | | MAY 11, 1989 | |
| > DLT > | | **ASENDIN** | | | |
| > DLT > | **AB** | **LEDERLE** | **25MG** | **N18021 001** | |
| > DLT > | **AB** | | **50MG** | **N18021 002** | |
| > DLT > | **AB** | | **100MG** | **N18021 003** | |
| > DLT > | **AB** | + | **150MG** | **N18021 004** | |
| > ADD > | | @ | 25MG | N18021 001 | |
| > ADD > | | @ | 50MG | N18021 002 | |
| > ADD > | | @ | 100MG | N18021 003 | |
| > ADD > | | @ | 150MG | N18021 004 | |

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | **AMOXICILLIN** | | | |
| > DLT > | **AB** | **MYLAN** | **125MG/5ML** | **N62090 001** | |
| > DLT > | **AB** | | **250MG/5ML** | **N62090 002** | |
| > ADD > | | @ | 125MG/5ML | N62090 001 | |
| > ADD > | | @ | 250MG/5ML | N62090 002 | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **AMOXICILLIN** | | | |
| **AB** | TEVA | **500MG** | **N65056 001** | |
| | | | SEP 18, 2000 | |
| **AB** | | **875MG** | **N65056 002** | |
| | | | SEP 18, 2000 | |
| | **AMOXIL** | | | |
| **AB** | SMITHKLINE BEECHAM | **500MG** | **N50754 002** | |
| | | | JUL 10, 1998 | |
| **AB** | + | **875MG** | **N50754 001** | |
| | | | JUL 10, 1998 | |
| | | 500MG | N50754 002 | |
| | | | JUL 10, 1998 | |
| | + | 875MG | N50754 001 | |
| | | | JUL 10, 1998 | |

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | AUGMENTIN '500' | | | |
| + | SMITHKLINE BEECHAM | 500MG;EQ 125MG BASE | N50564 002 | |
| | | | AUG 06, 1984 | |
| | | 500MG;EQ 125MG BASE | N50564 002 | |
| | | | AUG 06, 1984 | |

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | ADDERALL 12.5 | | |
| | SHIRE LABS | 3.125MG;3.125MG;3.125MG; 3.125MG | N11522 012 |
| | | | AUG 31, 2000 |
| | ADDERALL 15 | | |
| | SHIRE LABS | 3.75MG;3.75MG;3.75MG; 3.75MG | N11522 013 |
| | | | AUG 31, 2000 |
| | ADDERALL 7.5 | | |
| + | SHIRE LABS | 1.875MG;1.875MG;1.875MG; 1.875MG | N11522 011 |
| | | | AUG 31, 2000 |

AMPICILLIN SODIUM

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | **TOTACILLIN-N** | | | |
| > DLT > | **AP** | **SMITHKLINE BEECHAM** | **EQ 1GM BASE/VIAL** | **N62727 001** | |
| > DLT > | | | | DEC 19, 1986 | |
| > DLT > | **AP** | | **EQ 2GM BASE/VIAL** | **N62727 002** | |
| > DLT > | | | | DEC 19, 1986 | |
| > ADD > | | @ | EQ 1GM BASE/VIAL | N62727 001 | |
| > ADD > | | | | DEC 19, 1986 | |
| > ADD > | | @ | EQ 2GM BASE/VIAL | N62727 002 | |
| > ADD > | | | | DEC 19, 1986 | |

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **AMPICILLIN TRIHYDRATE** | | |
| > DLT > | **AB** | **MYLAN** | **EQ 250MG BASE** | **N61755 001** |
| > DLT > | **AB** | | **EQ 500MG BASE** | **N61755 002** |
| > ADD > | | @ | EQ 250MG BASE | N61755 001 |

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
> ADD > **AMPICILLIN TRIHYDRATE**
@ MYLAN — EQ 500MG BASE — N61755 002

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL
AGRYLIN
ROBERTS LABS — EQ 0.5MG BASE — N20333 001 MAR 14, 1997
\+ — EQ 1MG BASE — N20333 002 MAR 14, 1997
SHIRE LABS — EQ 0.5MG BASE — N20333 001 MAR 14, 1997
\+ — EQ 1MG BASE — N20333 002 MAR 14, 1997

ARDEPARIN SODIUM

INJECTABLE; INJECTION
NORMIFLO
\+ WYETH AYERST — 5,000 UNITS/0.5ML — N20227 002 MAY 23, 1997
\+ — 10,000 UNITS/0.5ML — N20227 001 MAY 23, 1997
\+ — 5,000 UNITS/0.5ML — N20227 002 MAY 23, 1997
\+ — 10,000 UNITS/0.5ML — N20227 001 MAY 23, 1997

ARGATROBAN

INJECTABLE; INJECTION
ACOVA
\+ TX BIOTECH — 100MG/ML — N20883 001 JUN 30, 2000 — > DLT > > DLT > > ADD > > ADD >

ARSENIC TRIOXIDE

INJECTABLE; INJECTION
TRISENOX
\+ CELL THERAP — 1MG/ML — N21248 001 SEP 25, 2000 — > DLT > > DLT > > DLT >

ARTICAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION
SEPTOCAINE
\+ DEPROCO — 4%;EQ 0.01MG BASE/ML — N20971 001 APR 03, 2000

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E

INJECTABLE; INJECTION
KABIVITE PED F + W KIT
\+ FRESENIUS KABI — N/A,80MG/VIAL;N/A,0.02MG/VIAL;N/A, 0.001MG/VIAL;400 IU/10ML,N/A;N/A, 0.14MG/VIAL;N/A,17MG/VIAL;N/A, 5MG/VIAL;0.2MG/10ML,N/A;N/A, 1MG/VIAL;N/A,1.4MG/VIAL;N/A, 1.2MG/VIAL;EQ 2,300 UNITS BASE/10ML, N/A;7 IU/10ML,N/A — N20176 001 DEC 29, 1993

VITAPED
@ FRESENIUS KABI — N/A,80MG/VIAL;N/A,0.02MG/VIAL;N/A, 0.001MG/VIAL;400 IU/10ML,N/A;N/A, 0.14MG/VIAL;N/A,17MG/VIAL;N/A, 5MG/VIAL;0.2MG/10ML,N/A;N/A, 1MG/VIAL;N/A,1.4MG/VIAL;N/A, 1.2MG/VIAL;EQ 2,300 UNITS BASE/10ML, N/A;7 IU/10ML,N/A — N20176 001 DEC 29, 1993

ASPIRIN; METHOCARBAMOL

TABLET; ORAL
**METHOCARBAMOL AND ASPIRIN**
> DLT > > DLT > > ADD > > ADD > **AB** MCNEIL — **325MG;400MG** — **N89193 001 FEB 12, 1986**
@ — 325MG;400MG — N89193 001 FEB 12, 1986

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL
**OXYCODONE AND ASPIRIN (HALF-STRENGTH)**
> DLT > > DLT > > DLT > **AA** ROXANE — **325MG;2.25MG;0.19MG** — **N87742 001 JUN 04, 1982**

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL
OXYCODONE AND ASPIRIN (HALF-STRENGTH)

| | | | | |
|---|---|---|---|---|
| > ADD > | | @ ROXANE | 325MG;2.25MG;0.19MG | N87742 001 |
| > ADD > | | | | JUN 04, 1982 |

ATENOLOL

TABLET; ORAL
ATENOLOL

| | | | | |
|---|---|---|---|---|
| > ADD > | AB | GENEVA PHARMS TECH | 25MG | N74265 001 |
| > ADD > | | | | FEB 28, 1994 |
| > ADD > | AB | | 50MG | N74265 002 |
| > ADD > | | | | FEB 28, 1994 |
| > ADD > | AB | | 100MG | N74265 003 |
| > ADD > | | | | FEB 28, 1994 |
| > DLT > | AB | INVAMED | 25MG | N74265 001 |
| > DLT > | | | | FEB 28, 1994 |
| > DLT > | AB | | 50MG | N74265 002 |
| > DLT > | | | | FEB 28, 1994 |
| > DLT > | AB | | 100MG | N74265 003 |
| > DLT > | | | | FEB 28, 1994 |

ATORVASTATIN CALCIUM

TABLET; ORAL
LIPITOR

| | | | | |
|---|---|---|---|---|
| > ADD > | | PFIZER IRELAND PHARM | EQ 40MG BASE | N20702 003 |
| > ADD > | | | | DEC 17, 1996 |
| > ADD > | + | | EQ 80MG BASE | N20702 004 |
| > ADD > | | | | APR 07, 2000 |
| > DLT > | + | WARNER LAMBERT EXPOR | EQ 40MG BASE | N20702 003 |
| > DLT > | | | | DEC 17, 1996 |

ATOVAQUONE; PROGUANIL HYDROCHLORIDE

TABLET; ORAL
MALARONE

| | | | |
|---|---|---|---|
| + | GLAXO WELLCOME | 250MG;100MG | N21078 001 |
| | | | JUL 14, 2000 |

MALARONE PEDIATRIC

| | | | |
|---|---|---|---|
| + | GLAXO WELLCOME | 62.5MG;25MG | N21078 002 |
| | | | JUL 14, 2000 |

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL
MOTOFEN

| | | | |
|---|---|---|---|
| + | AMARIN PHARMS | 0.025MG;1MG | N17744 002 |
| + | CARNRICK | 0.025MG;1MG | N17744 002 |

MOTOFEN HALF-STRENGTH

| | | | |
|---|---|---|---|
| @ | AMARIN PHARMS | 0.025MG;0.5MG | N17744 001 |
| @ | CARNRICK | 0.025MG;0.5MG | N17744 001 |

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE

| | | | | |
|---|---|---|---|---|
| AA | | PAR PHARM | 0.025MG;2.5MG | N40357 001 |
| | | | | MAY 02, 2000 |

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
ENLON-PLUS

| | | | |
|---|---|---|---|
| + | BAXTER PHARM PROD | 0.14MG/ML;10MG/ML | N19677 001 |
| | | | NOV 06, 1991 |
| + | | 0.14MG/ML;10MG/ML | N19678 001 |
| | | | NOV 06, 1991 |
| + | OHMEDA | 0.14MG/ML;10MG/ML | N19677 001 |
| | | | NOV 06, 1991 |
| + | | 0.14MG/ML;10MG/ML | N19678 001 |
| | | | NOV 06, 1991 |

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OPTIVAR

| | | | |
|---|---|---|---|
| + | ASTA | 0.05% | N21127 001 |
| | | | MAY 22, 2000 |

BALSALAZIDE DISODIUM

CAPSULE; ORAL
COLAZAL

| | | | |
|---|---|---|---|
| + | SALIX | 750MG | N20610 001 |
| | | | JUL 18, 2000 |

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

| | | | | |
|---|---|---|---|---|
| | QVAR 40 | | | |
| + | 3M | 0.04MG/INH | N20911 002 | SEP 15, 2000 |
| | QVAR 80 | | | |
| + | 3M | 0.08MG/INH | N20911 001 | SEP 15, 2000 |

BENZTROPINE MESYLATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **BENZTROPINE MESYLATE** | | | |
| AA | GENEVA PHARMS TECH | 0.5MG | N72264 001 | FEB 27, 1989 |
| AA | | 1MG | N72265 001 | FEB 27, 1989 |
| AA | | 2MG | N72266 001 | FEB 27, 1989 |
| AA | INVAMED | 0.5MG | N72264 001 | FEB 27, 1989 |
| AA | | 1MG | N72265 001 | FEB 27, 1989 |
| AA | | 2MG | N72266 001 | FEB 27, 1989 |

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | **BETAXOLOL** | | | |
| AT | AKORN | EQ 0.5% BASE | N75386 001 | JUN 30, 2000 |
| AT | NOVEX | EQ 0.5% BASE | N75446 001 | SEP 28, 2000 |
| | **BETOPTIC** | | | |
| AT + | ALCON | EQ 0.5% BASE | N19270 001 | AUG 30, 1985 |
| + | | EQ 0.5% BASE | N19270 001 | AUG 30, 1985 |

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | URECHOLINE | | | |
| + | MERCK | 5MG/ML | N06536 001 | |

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | URECHOLINE | | | |
| @ | MERCK | 5MG/ML | N06536 001 | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **BETHANECHOL CHLORIDE** | | | |
| AA | DANBURY PHARMA | 10MG | N84408 001 | |
| AA | | 25MG | N84441 001 | |
| AA | | 50MG | N87444 001 | |
| @ | | 10MG | N84408 001 | |
| @ | | 25MG | N84441 001 | |
| @ | | 50MG | N87444 001 | |
| | **DUVOID** | | | |
| AA | ROBERTS LABS | 10MG | N86262 001 | |
| AA | | 25MG | N86263 001 | |
| AA | | 50MG | N85882 003 | |
| @ | | 10MG | N86262 001 | |
| @ | | 25MG | N86263 001 | |
| @ | | 50MG | N85882 003 | |
| | **MYOTONACHOL** | | | |
| AA | GLENWOOD | 5MG | N84188 001 | |
| AA | | 10MG | N84188 003 | |
| AA | | 25MG | N84188 004 | |
| @ | | 5MG | N84188 001 | |
| @ | | 10MG | N84188 003 | |
| @ | | 25MG | N84188 004 | |
| | **URECHOLINE** | | | |
| AA + | MERCK | 5MG | N06536 003 | |
| AA + | | 10MG | N06536 002 | |
| AA + | | 25MG | N06536 004 | |
| AA + | | 50MG | N06536 005 | |
| @ | | 5MG | N06536 003 | |
| @ | | 10MG | N06536 002 | |
| @ | | 25MG | N06536 004 | |
| @ | | 50MG | N06536 005 | |
| + | ODYSSEY PHARMS | 5MG | N89095 001 | DEC 19, 1985 |
| + | | 10MG | N88440 001 | MAY 29, 1984 |
| + | | 25MG | N88441 001 | MAY 29, 1984 |
| + | | 50MG | N89096 001 | DEC 19, 1985 |
| AA + | SIDMAK LABS NJ | 5MG | N89095 001 | DEC 19, 1985 |
| AA + | | 10MG | N88440 001 | MAY 29, 1984 |



BETHANECHOL CHLORIDE

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

BETHANECHOL CHLORIDE

TABLET; ORAL
**URECHOLINE**

| | | | | |
|---|---|---|---|---|
| AA | + | SIDMAK LABS NJ | 25MG | N88441 001<br>MAY 29, 1984 |
| AA | + | | 50MG | N89096 001<br>DEC 19, 1985 |

BEXAROTENE

GEL; TOPICAL
TARGRETIN

| | | | | |
|---|---|---|---|---|
| | + | LIGAND | 1% | N21056 001<br>JUN 28, 2000 |

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
**BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE**

| | | | |
|---|---|---|---|
| AB | CHELSEA LABS | 2.5MG;6.25MG | N75469 001<br>SEP 25, 2000 |
| AB | | 5MG;6.25MG | N75469 002<br>SEP 25, 2000 |
| AB | | 10MG;6.25MG | N75469 003<br>SEP 25, 2000 |
| AB | EON | 2.5MG;6.25MG | N75579 001<br>SEP 25, 2000 |
| AB | | 5MG;6.25MG | N75579 002<br>SEP 25, 2000 |
| AB | | 10MG;6.25MG | N75579 003<br>SEP 25, 2000 |
| AB | INVAMED | 2.5MG;6.25MG | N75527 001<br>SEP 25, 2000 |
| AB | | 5MG;6.25MG | N75527 003<br>SEP 25, 2000 |
| AB | | 10MG;6.25MG | N75527 002<br>SEP 25, 2000 |
| AB | MYLAN | 2.5MG;6.25MG | N75768 001<br>SEP 25, 2000 |
| AB | | 5MG;6.25MG | N75768 002<br>SEP 25, 2000 |
| AB | | 10MG;6.25MG | N75768 003<br>SEP 25, 2000 |
| AB | PUREPAC PHARM | 2.5MG;6.25MG | N75672 001<br>SEP 25, 2000 |

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
**BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE**

| | | | |
|---|---|---|---|
| AB | PUREPAC PHARM | 5MG;6.25MG | N75672 002<br>SEP 25, 2000 |
| AB | | 10MG;6.25MG | N75672 003<br>SEP 25, 2000 |
| AB | ZENITH GOLDLINE | 2.5MG;6.25MG | N75632 001<br>SEP 27, 2000 |
| AB | | 5MG;6.25MG | N75632 002<br>SEP 27, 2000 |
| AB | | 10MG;6.25MG | N75632 003<br>SEP 27, 2000 |

**ZIAC**

| | | | |
|---|---|---|---|
| AB | LEDERLE | 2.5MG;6.25MG | N20186 003<br>MAR 26, 1993 |
| AB | | 5MG;6.25MG | N20186 001<br>MAR 26, 1993 |
| AB | + | 10MG;6.25MG | N20186 002<br>MAR 26, 1993 |
| | | 2.5MG;6.25MG | N20186 003<br>MAR 26, 1993 |
| | | 5MG;6.25MG | N20186 001<br>MAR 26, 1993 |
| | + | 10MG;6.25MG | N20186 002<br>MAR 26, 1993 |

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
**BLEOMYCIN**

| | | | |
|---|---|---|---|
| AP | FAULDING | EQ 15 UNITS BASE/VIAL | N65031 001<br>MAR 10, 2000 |
| AP | | EQ 30 UNITS BASE/VIAL | N65031 002<br>MAR 10, 2000 |
| AP | GENSIA SICOR PHARMS | EQ 15 UNITS BASE/VIAL | N65033 001<br>JUN 27, 2000 |
| AP | | EQ 30 UNITS BASE/VIAL | N65033 002<br>JUN 27, 2000 |

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
**BRETYLIUM TOSYLATE**

| | | | |
|---|---|---|---|
| AP | ASTRAZENECA | 50MG/ML | N71151 001<br>AUG 10, 1987 |

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
**BRETYLIUM TOSYLATE**
@ ASTRAZENECA 50MG/ML N71151 001 AUG 10, 1987

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL
**DIMETANE-DC**
AA + ROBINS AH **2MG/5ML;10MG/5ML; 12.5MG/5ML** N11694 006 MAR 29, 1984
@ 2MG/5ML;10MG/5ML; 12.5MG/5ML N11694 006 MAR 29, 1984
**MYPHETANE DC**
AA MORTON GROVE **2MG/5ML;10MG/5ML; 12.5MG/5ML** N88904 001 FEB 21, 1985
AA + **2MG/5ML;10MG/5ML; 12.5MG/5ML** N88904 001 FEB 21, 1985

BUDESONIDE

SUSPENSION; INHALATION
PULMICORT RESPULES
ASTRAZENECA PHARMS 0.25MG/2ML N20929 001 AUG 08, 2000
+ 0.5MG/2ML N20929 002 AUG 08, 2000
@ 1MG/2ML N20929 003 AUG 08, 2000

BUPROPION HYDROCHLORIDE

TABLET; ORAL
**BUPROPION HCL**
> ADD > AB EON **75MG** N75613 002 OCT 10, 2000
> ADD > AB **100MG** N75613 001 OCT 10, 2000

BUPROPION HYDROCHLORIDE

TABLET; ORAL
**BUPROPION HCL**
> ADD > AB GENEVA PHARMS TECH **75MG** N75584 001 FEB 07, 2000
> ADD > AB **100MG** N75584 002 FEB 07, 2000
> DLT > AB INVAMED **75MG** N75584 001 FEB 07, 2000
> DLT > AB **100MG** N75584 002 FEB 07, 2000
> DLT > AB MYLAN **75MG** N75491 001 APR 17, 2000
> DLT > AB **100MG** N75491 002 APR 17, 2000

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL
BUSPAR
+ BRISTOL MYERS SQUIBB 15MG N18731 003 APR 22, 1996
@ 30MG N18731 004 APR 22, 1996
15MG N18731 003 APR 22, 1996
+ 30MG N18731 004 APR 22, 1996

BUTABARBITAL SODIUM

ELIXIR; ORAL
**BUTABARB**
> DLT > AA ALPHARMA **30MG/5ML** N85873 001
> DLT > @ 30MG/5ML N85873 001
> ADD >
**BUTISOL SODIUM**
> DLT > AA + WALLACE LABS **30MG/5ML** N85380 001
> ADD > + 30MG/5ML N85380 001

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION
**BUTORPHANOL TARTRATE**
AP ABBOTT **1MG/ML** N75559 001 MAR 20, 2000

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION
**BUTORPHANOL TARTRATE**

| | | | | | |
|---|---|---|---|---|---|
| **AP** | | ABBOTT | **2MG/ML** | **N75559 002** | |
| | | | | MAR 20, 2000 | |

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL
CAFERGOT

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | BR | + | NOVARTIS | 100MG;2MG | N09000 002 |
| > ADD > | | + | | 100MG;2MG | N09000 002 |
| > DLT > | | | MIGERGOT | | |
| > DLT > | BR | | G AND W LABS | 100MG;2MG | N86557 001 |
| > DLT > | | | | | OCT 04, 1983 |
| > ADD > | | @ | | 100MG;2MG | N86557 001 |
| > ADD > | | | | | OCT 04, 1983 |

CALCIUM CHLORIDE

INJECTABLE; INJECTION
CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | + | ABBOTT | 100MG/ML | N21117 001 |
| | | | | JAN 28, 2000 |

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERFUSION, CARDIAC
**CARDIOPLEGIC IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| **AT** | | BAXTER HLTHCARE | **17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML** | **N75323 001** |
| | | | | APR 21, 2000 |

**PLEGISOL IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| **AT** | + | ABBOTT | **17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML** | **N18608 001** |
| | | | | FEB 26, 1982 |
| | + | | 17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML | N18608 001 |
| | | | | FEB 26, 1982 |

CALCIUM GLUCEPTATE

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | INJECTABLE; INJECTION | | | | |
| > DLT > | CALCIUM GLUCEPTATE | | | | |
| > DLT > | + | ABBOTT | EQ 90MG CALCIUM/5ML | N80001 001 | |
| > ADD > | @ | | EQ 90MG CALCIUM/5ML | N80001 001 | |

CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL
ATACAND HCT

| | | | | |
|---|---|---|---|---|
| | ASTRAZENECA PHARMS | 16MG;12.5MG | N21093 001 | |
| | | | SEP 05, 2000 | |
| + | | 32MG;12.5MG | N21093 002 | |
| | | | SEP 05, 2000 | |

CANDICIDIN

OINTMENT; VAGINAL
VANOBID

| | | | |
|---|---|---|---|
| @ | AVENTIS PHARMS | 0.6MG/GM | N61596 001 |
| + | HOECHST MARION RSSL | 0.6MG/GM | N61596 001 |

TABLET; VAGINAL
VANOBID

| | | | |
|---|---|---|---|
| @ | AVENTIS PHARMS | 3MG | N61613 001 |
| + | HOECHST MARION RSSL | 3MG | N61613 001 |

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL
**CAPTOPRIL AND HYDROCHLOROTHIAZIDE**

| | | | | |
|---|---|---|---|---|
| **AB** | | DANBURY PHARMA | **50MG;25MG** | **N74832 001** |
| | | | | DEC 29, 1997 |
| | @ | | 50MG;25MG | N74832 001 |
| | | | | DEC 29, 1997 |

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL
**CARBAMAZEPINE**

| | | | | |
|---|---|---|---|---|
| > ADD > | **AB** | TARO PHARM INDS | **100MG** | **N75687 001** |
| > ADD > | | | | OCT 24, 2000 |

## CARBIDOPA; LEVODOPA

TABLET; ORAL

**CARBIDOPA AND LEVODOPA**

| | | | | |
|---|---|---|---|---|
| > DLT > | **AB** | WATSON LABS | **10MG;100MG** | **N73381 001** SEP 28, 1993 |
| > DLT > | **AB** | | **25MG;100MG** | **N73382 001** SEP 28, 1993 |
| > DLT > | **AB** | | **25MG;250MG** | **N73383 001** SEP 28, 1993 |
| > ADD > | @ | | 10MG;100MG | N73381 001 SEP 28, 1993 |
| > ADD > | @ | | 25MG;100MG | N73382 001 SEP 28, 1993 |
| > ADD > | @ | | 25MG;250MG | N73383 001 SEP 28, 1993 |

TABLET, EXTENDED RELEASE; ORAL

**CARBIDOPA AND LEVODOPA**

| | | | |
|---|---|---|---|
| **AB** | MYLAN | **25MG;100MG** | **N75091 002** APR 21, 2000 |

**SINEMET CR**

| | | | |
|---|---|---|---|
| **AB** | DUPONT PHARMS | **25MG;100MG** | **N19856 002** DEC 24, 1992 |
| | | 25MG;100MG | N19856 002 DEC 24, 1992 |

## CARISOPRODOL

TABLET; ORAL

**CARISOPRODOL**

| | | | |
|---|---|---|---|
| **AA** | COREPHARMA | **350MG** | **N40397 001** SEP 21, 2000 |

## CARMUSTINE

IMPLANT; INTRACRANIAL

GLIADEL

| | | | |
|---|---|---|---|
| > DLT > | + AVENTIS | 7.7MG | N20637 001 SEP 23, 1996 |
| > ADD > | + GUILFORD PHARMS | 7.7MG | N20637 001 SEP 23, 1996 |

## CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

**CARTEOLOL HCL**

| | | | |
|---|---|---|---|
| **AT** | ALCON | **1%** | **N75476 001** JAN 03, 2000 |
| **AT** | BAUSCH AND LOMB | **1%** | **N75546 001** JAN 20, 2000 |

**OCUPRESS**

| | | | |
|---|---|---|---|
| **AT** | + CIBA | **1%** | **N19972 001** MAY 23, 1990 |
| | * | 1% | N19972 001 MAY 23, 1990 |

## CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN AND DEXTROSE

| | | | |
|---|---|---|---|
| | + B BRAUN | EQ 500MG BASE/VIAL | N50779 001 JUL 27, 2000 |
| | + | EQ 1GM BASE/VIAL | N50779 002 JUL 27, 2000 |

**CEFAZOLIN SODIUM**

| | | | |
|---|---|---|---|
| **AP** | AM PHARM PARTNERS | **EQ 1MG BASE/VIAL** | **N64169 002** AUG 14, 1998 |
| **AP** | | **EQ 1GM BASE/VIAL** | **N64169 002** AUG 14, 1998 |

## CEFDINIR

CAPSULE; ORAL

OMNICEF

| | | | |
|---|---|---|---|
| | + ABBOTT | 300MG | N50739 001 DEC 04, 1997 |
| | + PARKE DAVIS | 300MG | N50739 001 DEC 04, 1997 |

POWDER FOR RECONSTITUTION; ORAL

OMNICEF

| | | | |
|---|---|---|---|
| | + ABBOTT | 125MG/5ML | N50749 001 DEC 04, 1997 |
| | + PARKE DAVIS | 125MG/5ML | N50749 001 DEC 04, 1997 |

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | CEFOTAXIME | | | |
| AP | AM PHARM PARTNERS | EQ 500MG BASE/VIAL | N64200 001 | MAR 24, 2000 |
| AP | | EQ 1GM BASE/VIAL | N64200 002 | MAR 24, 2000 |
| AP | | EQ 2GM BASE/VIAL | N64200 003 | MAR 24, 2000 |
| AP | | EQ 10GM BASE/VIAL | N64201 001 | MAR 24, 2000 |
| + | | EQ 20GM BASE/VIAL | N64201 002 | MAR 24, 2000 |
| | CLAFORAN | | | |
| AP | + AVENTIS PHARMS | EQ 500MG BASE/VIAL | N50547 001 | |
| AP | + | EQ 1GM BASE/VIAL | N50547 002 | |
| AP | + | EQ 2GM BASE/VIAL | N50547 003 | |
| AP | + | EQ 10GM BASE/VIAL | N50547 004 | DEC 29, 1983 |
| + | HOECHST MARION RSSL | EQ 500MG BASE/VIAL | N50547 001 | |
| + | | EQ 1GM BASE/VIAL | N50547 002 | |
| + | | EQ 2GM BASE/VIAL | N50547 003 | |
| + | | EQ 10GM BASE/VIAL | N50547 004 | DEC 29, 1983 |

CEFOXITIN SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | CEFOXITIN | | | |
| AP | AM PHARM PARTNERS | EQ 1GM BASE/VIAL | N65012 001 | JUL 03, 2000 |
| AP | | EQ 2GM BASE/2VIAL | N65012 002 | JUL 03, 2000 |
| AP | | EQ 10GM BASE/VIAL | N65011 001 | JUL 03, 2000 |
| AP | ESI LEDERLE | EQ 1GM BASE/VIAL | N65051 001 | SEP 11, 2000 |
| AP | | EQ 2GM BASE/VIAL | N65051 002 | SEP 11, 2000 |
| AP | | EQ 10GM BASE/VIAL | N65050 001 | SEP 11, 2000 |
| | MEFOXIN | | | |
| AP | + MERCK | EQ 1GM BASE/VIAL | N50517 001 | |
| AP | | EQ 1GM BASE/VIAL | N62757 001 | JAN 08, 1987 |
| AP | + | EQ 2GM BASE/VIAL | N50517 002 | |

CEFOXITIN SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | MEFOXIN | | | |
| AP | MERCK | EQ 2GM BASE/VIAL | N62757 002 | JAN 08, 1987 |
| AP | + | EQ 10GM BASE/VIAL | N50517 003 | |
| + | | EQ 1GM BASE/VIAL | N50517 001 | |
| | | EQ 1GM BASE/VIAL | N62757 001 | JAN 08, 1987 |
| + | | EQ 2GM BASE/VIAL | N50517 002 | |
| | | EQ 2GM BASE/VIAL | N62757 002 | JAN 08, 1987 |
| + | | EQ 10GM BASE/VIAL | N50517 003 | |

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | CEDAX | | | |
| + | DJ PHARMA | EQ 400MG BASE | N50685 002 | DEC 20, 1995 |
| + | SCHERING PLOUGH | EQ 400MG BASE | N50685 002 | DEC 20, 1995 |

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | CEDAX | | | |
| | DJ PHARMA | EQ 90MG BASE/5ML | N50686 001 | DEC 20, 1995 |
| + | | EQ 180MG BASE/5ML | N50686 002 | DEC 20, 1995 |
| + | SCHERING PLOUGH | EQ 90MG BASE/5ML | N50686 001 | DEC 20, 1995 |
| + | | EQ 180MG BASE/5ML | N50686 002 | DEC 20, 1995 |

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | ROCEPHIN | | | |
| + | HLR | EQ 250MG BASE/VIAL | N50585 001 | DEC 21, 1984 |
| | | EQ 250MG BASE/VIAL | N63239 001 | AUG 13, 1993 |
| + | | EQ 500MG BASE/VIAL | N50585 002 | DEC 21, 1984 |
| | | EQ 500MG BASE/VIAL | N63239 002 | AUG 13, 1993 |

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN

| | | | |
|---|---|---|---|
| + | HLR | EQ 1GM BASE/VIAL | N50585 003<br>DEC 21, 1984 |
| | | EQ 1GM BASE/VIAL | N62654 002<br>APR 30, 1987 |
| | | EQ 1GM BASE/VIAL | N63239 003<br>AUG 13, 1993 |
| + | | EQ 2GM BASE/VIAL | N50585 004<br>DEC 21, 1984 |
| | | EQ 2GM BASE/VIAL | N62654 003<br>APR 30, 1987 |
| + | | EQ 10GM BASE/VIAL | N50585 005<br>DEC 21, 1984 |
| + | ROCHE | EQ 250MG BASE/VIAL | N50585 001<br>DEC 21, 1984 |
| | | EQ 250MG BASE/VIAL | N63239 001<br>AUG 13, 1993 |
| + | | EQ 500MG BASE/VIAL | N50585 002<br>DEC 21, 1984 |
| | | EQ 500MG BASE/VIAL | N63239 002<br>AUG 13, 1993 |
| + | | EQ 1GM BASE/VIAL | N50585 003<br>DEC 21, 1984 |
| | | EQ 1GM BASE/VIAL | N62654 002<br>APR 30, 1987 |
| | | EQ 1GM BASE/VIAL | N63239 003<br>AUG 13, 1993 |
| + | | EQ 2GM BASE/VIAL | N50585 004<br>DEC 21, 1984 |
| | | EQ 2GM BASE/VIAL | N62654 003<br>APR 30, 1987 |
| + | | EQ 10GM BASE/VIAL | N50585 005<br>DEC 21, 1984 |

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| @ | HLR | EQ 10MG BASE/ML | N50624 001<br>FEB 11, 1987 |
| + | | EQ 20MG BASE/ML | N50624 002<br>FEB 11, 1987 |
| + | | EQ 40MG BASE/ML | N50624 003<br>FEB 11, 1987 |
| @ | ROCHE | EQ 10MG BASE/ML | N50624 001<br>FEB 11, 1987 |
| + | | EQ 20MG BASE/ML | N50624 002<br>FEB 11, 1987 |
| + | | EQ 40MG BASE/ML | N50624 003<br>FEB 11, 1987 |

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION
ROCEPHIN KIT

| | | | |
|---|---|---|---|
| + | HLR | EQ 1GM BASE/VIAL,N/A;N/A,<br>1% | N50585 006<br>MAY 08, 1996 |
| + | | EQ 500MG BASE/VIAL,N/A;N/A,<br>1% | N50585 007<br>MAY 08, 1996 |
| + | ROCHE | EQ 1GM BASE/VIAL,N/A;N/A,<br>1% | N50585 006<br>MAY 08, 1996 |
| + | | EQ 500MG BASE/VIAL,N/A;N/A,<br>1% | N50585 007<br>MAY 08, 1996 |

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL
**KEFLEX**

| | | | | |
|---|---|---|---|---|
| **AB** | + | LILLY | **EQ 125MG BASE/5ML** | **N50406 001** |
| **AB** | + | | **EQ 250MG BASE/5ML** | **N50406 002** |
| **AB** | | | **EQ 250MG BASE/5ML** | **N62117 003** |
| **AB** | + | | **EQ 250MG BASE/5ML** | **N62117 003** |
| | @ | | EQ 125MG BASE/5ML | N50406 001 |
| | @ | | EQ 250MG BASE/5ML | N50406 002 |

CERIVASTATIN SODIUM

TABLET; ORAL
BAYCOL

| | | | |
|---|---|---|---|
| + | BAYER | 0.4MG | N20740 005<br>MAY 24, 1999 |
| | | 0.4MG | N20740 005<br>MAY 24, 1999 |
| + | | 0.8MG | N20740 006<br>JUL 24, 2000 |

CETRORELIX

INJECTABLE; INJECTION
CETROTIDE

| | | | |
|---|---|---|---|
| + | ASTA | EQ 0.25MG BASE/ML | N21197 001<br>AUG 11, 2000 |

CETRORELIX

INJECTABLE; INJECTION
CETROTIDE
+ ASTA — EQ 3MG BASE/ML — N21197 002 AUG 11, 2000
+ SERONO INC — EQ 0.25MG BASE/ML — N21197 001 AUG 11, 2000
+ — EQ 3MG BASE/ML — N21197 002 AUG 11, 2000

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL
EVOXAC
+ SNOWBRAND — EQ 30MG BASE — N20989 002 JAN 11, 2000

CHENODIOL

TABLET; ORAL
CHENIX
@ AXCAN — 250MG — N18513 002 JUL 28, 1983
@ AXCAN SCANDIPHARM — 250MG — N18513 002 JUL 28, 1983

CHLORAMPHENICOL

SOLUTION/DROPS; OPHTHALMIC
OPHTHOCHLOR
> DLT > > DLT > AT PARKEDALE — 0.5% — N61220 001
> ADD > @ — 0.5% — N61220 001

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
AA GLOBAL PHARM — 4MG — N80809 001
@ IMPAX LABS — 4MG — N80809 001

CICLOPIROX

CREAM; TOPICAL
LOPROX
+ AVENTIS PHARMS — 0.77% — N18748 001 DEC 30, 1982

LOTION; TOPICAL
LOPROX
+ AVENTIS PHARMS — 0.77% — N19824 001 DEC 30, 1988

CICLOPIROX OLAMINE

CREAM; TOPICAL
LOPROX
+ HOECHST MARION RSSL — 1% — N18748 001 DEC 30, 1982

LOTION; TOPICAL
LOPROX
+ HOECHST MARION RSSL — 1% — N19824 001 DEC 30, 1988

CIMETIDINE

TABLET; ORAL
CIMETIDINE
> DLT > AB ROXANE — 300MG — N74361 001 DEC 23, 1994
> DLT > > DLT > AB — 400MG — N74361 002 DEC 23, 1994
> DLT > > DLT > AB — 800MG — N74371 001 DEC 23, 1994
> DLT > > ADD > @ — 300MG — N74361 001 DEC 23, 1994
> ADD > > ADD > @ — 400MG — N74361 002 DEC 23, 1994
> ADD > > ADD > @ — 800MG — N74371 001 DEC 23, 1994
> ADD >

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL
CIMETIDINE HCL
AA NOVEX — EQ 300MG BASE/5ML — N75560 001 MAR 15, 2000

CISAPRIDE MONOHYDRATE

SUSPENSION; ORAL
PROPULSID
+ JANSSEN — EQ 1MG BASE/ML — N20398 001 SEP 15, 1995
@ — EQ 1MG BASE/ML — N20398 001 SEP 15, 1995

TABLET; ORAL
PROPULSID
JANSSEN — EQ 10MG BASE — N20210 001 JUL 29, 1993
+ — EQ 20MG BASE — N20210 002 DEC 23, 1993
@ — EQ 10MG BASE — N20210 001 JUL 29, 1993
@ — EQ 20MG BASE — N20210 002 DEC 23, 1993

CISPLATIN

INJECTABLE; INJECTION
**CISPLATIN**
AP GENSIA SICOR PHARMS — **1MG/ML** — **N74814 001** MAY 16, 2000
AP PHARMACHEMIE — **1MG/ML** — **N74656 001** MAY 16, 2000

CITALOPRAM HYDROBROMIDE

TABLET; ORAL
CELEXA
FOREST LABS — EQ 40MG BASE — N20822 003 JUL 17, 1998
+ — EQ 60MG BASE — N20822 004 JUL 17, 1998 > DLT >
EQ 10MG BASE — N20822 001 APR 27, 2000 > ADD >
+ — EQ 40MG BASE — N20822 003 JUL 17, 1998 > DLT >
@ — EQ 60MG BASE — N20822 004 JUL 17, 1998 > ADD >

CLADRIBINE

INJECTABLE; INJECTION
**CLADRIBINE**
AP BEDFORD — **1MG/ML** — **N75405 001** FEB 28, 2000

CLARITHROMYCIN

TABLET; ORAL
BIAXIN
ABBOTT — 250MG — N50662 001 OCT 31, 1991
+ — 250MG — N50662 001 OCT 31, 1991

TABLET, EXTENDED RELEASE; ORAL
BIAXIN XL
+ ABBOTT — 500MG — N50775 001 MAR 03, 2000

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
**CLEOCIN T**
AB + PHARMACIA AND UPJOHN — **EQ 1% BASE** — **N50615 001** JAN 07, 1987
+ — EQ 1% BASE — N50615 001 JAN 07, 1987

**CLINDAMYCIN PHOSPHATE**
AB ALTANA — **EQ 1% BASE** — **N64160 001** JAN 28, 2000

INJECTABLE; INJECTION
**CLINDAMYCIN PHOSPHATE**
AP ASTRAZENECA — **EQ 150MG BASE/ML** — **N62928 001** FEB 13, 1989
@ — EQ 150MG BASE/ML — N62928 001 FEB 13, 1989

SOLUTION; TOPICAL
**CLINDAMYCIN PHOSPHATE**
AT CLAY PARK — **EQ 1% BASE** — **N65049 001** MAY 25, 2000

CLOBETASOL PROPIONATE

AEROSOL; TOPICAL
OLUX FOAM
+ CONNETICS — 0.05% — N21142 001 MAY 26, 2000

CREAM; TOPICAL
CLOBETASOL PROPIONATE
AB2 TARO — 0.05% — N75633 001 MAY 17, 2000

GEL; TOPICAL
CLOBETASOL PROPIONATE
AB ALTANA — 0.05% — N75368 001 FEB 15, 2000

CLONAZEPAM

TABLET; ORAL
CLONAZEPAM
> ADD > AB TORPHARM — 0.5MG — N75468 001 OCT 06, 2000
> ADD > AB — 1MG — N75468 002 OCT 06, 2000
> ADD > AB — 2MG — N75468 003 OCT 06, 2000

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM
AB TARO — 3.75MG — N75731 003 APR 27, 2000
AB — 7.5MG — N75731 002 APR 27, 2000
AB — 15MG — N75731 001 APR 27, 2000

CLOTRIMAZOLE

TABLET; VAGINAL
MYCELEX-G
+ BAYER — 500MG — N19069 001 APR 19, 1985

CLOTRIMAZOLE

TABLET; VAGINAL
MYCELEX-G
@ BAYER — 500MG — N19069 001 APR 19, 1985

CLOXACILLIN SODIUM

CAPSULE; ORAL
CLOXACILLIN SODIUM
AB + APOTHECON — EQ 250MG BASE — N61452 001
AB + — EQ 500MG BASE — N61452 002
@ — EQ 250MG BASE — N61452 001
@ — EQ 500MG BASE — N61452 002
CLOXAPEN
AB SMITHKLINE BEECHAM — EQ 500MG BASE — N61806 002
AB + — EQ 500MG BASE — N61806 002

CLOZAPINE

TABLET; ORAL
CLOZAPINE
> DLT > > DLT > > DLT > > DLT > > ADD > > ADD > > ADD > > ADD > AB GENEVA PHARMS — 25MG — N74546 001 AUG 30, 1996
> DLT > > DLT > > DLT > > DLT > > ADD > > ADD > > ADD > > ADD > AB — 100MG — N74546 002 AUG 30, 1996
@ — 25MG — N74546 001 AUG 30, 1996
@ — 100MG — N74546 002 AUG 30, 1996

COLESEVELAM HYDROCHLORIDE

CAPSULE; ORAL
WELCHOL
+ GELTEX — 375MG — N21141 001 MAY 26, 2000
+ SANKYO — 375MG — N21141 001 MAY 26, 2000

TABLET; ORAL
WELCHOL
+ GELTEX — 625MG — N21176 001 MAY 26, 2000

COLESEVELAM HYDROCHLORIDE

TABLET; ORAL
WELCHOL
+ SANKYO 625MG N21176 001 MAY 26, 2000

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE
BP GLOBAL PHARM 25MG N09458 001
@ IMPAX LABS 25MG N09458 001

CROMOLYN SODIUM

CONCENTRATE; ORAL
GASTROCROM
+ MEDEVA 100MG/5ML N20479 001 FEB 29, 1996

SOLUTION; INHALATION
**CROMOLYN SODIUM**
AN STERIPAK **10MG/ML** **N75271 001** JAN 18, 2000
AN WARRICK PHARMS **10MG/ML** **N75437 001** APR 21, 2000

SOLUTION, CONCENTRATE; ORAL
GASTROCROM
+ MEDEVA 100MG/5ML N20479 001 FEB 29, 1996

CYANOCOBALAMIN

INJECTABLE; INJECTION
**CYANOCOBALAMIN**
@ AVENTIS PHARMS 1MG/ML N80564 001
AP HOECHST MARION RSSL **1MG/ML** **N80564 001**

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
**CYCLOBENZAPRINE HCL**
>ADD> >ADD> AB GENEVA PHARMS TECH **10MG** **N73683 001** FEB 26, 1993

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
**CYCLOBENZAPRINE HCL**
>DLT> >DLT> AB INVAMED **10MG** **N73683 001** FEB 26, 1993

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
**CYCLOPENTOLATE HCL**
AT ALCON UNIVERSAL 1% **N89162 001** JAN 24, 1991
AT STERIS **1%** **N89162 001** JAN 24, 1991

CYCLOSPORINE

CAPSULE; ORAL
**CYCLOSPORINE**
AB ABBOTT **25MG** **N65003 001** MAY 12, 2000
>DLT> >DLT> AB **50MG** **N65003 002** MAY 12, 2000
AB **100MG** **N65003 003** MAY 12, 2000
>ADD> >ADD> 50MG N65003 002 MAY 12, 2000
AB EON **25MG** **N65017 002** JAN 13, 2000
AB **100MG** **N65017 001** JAN 13, 2000

**NEORAL**
AB NOVARTIS **25MG** **N50715 001** JUL 14, 1995
>DLT> >DLT> AB **50MG** **N50715 003** JUL 14, 1995
AB + **100MG** **N50715 002** JUL 14, 1995
BX **25MG** N50715 001 JUL 14, 1995
BX + **100MG** N50715 002 JUL 14, 1995
>ADD> >ADD> @ 50MG N50715 003 JUL 14, 1995

CYCLOSPORINE

SOLUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | **CYCLOSPORINE** | | | |
| AB | ABBOTT | **100MG/ML** | **N65025 001** | |
| | | | MAR 03, 2000 | |
| | **SANGCYA** | | | |
| AB | SANGSTAT MEDCL | **100MG/ML** | **N64195 001** | |
| | | | OCT 31, 1998 | |
| | @ | 100MG/ML | N64195 001 | |
| | | | OCT 31, 1998 | |

DACARBAZINE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **DACARBAZINE** | | | |
| AP | GENSIA SICOR PHARMS | **500MG/VIAL** | **N75259 001** | |
| | | | SEP 22, 2000 | |

DAUNORUBICIN CITRATE

INJECTABLE, LIPOSOMAL; INJECTION

| | | | | |
|---|---|---|---|---|
| | DAUNOXOME | | | |
| + | GILEAD | EQ 2MG BASE/ML | N50704 002 | |
| | | | APR 08, 1996 | |
| + | NEXSTAR | EQ 2MG BASE/ML | N50704 002 | |
| | | | APR 08, 1996 | |

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | **DAUNORUBICIN HCL** | | | |
| AP | + BEDFORD | **EQ 5MG BASE/ML** | **N50731 001** | | |
| | | | JAN 30, 1998 | | |
| | + | EQ 5MG BASE/ML | N50731 001 | | |
| | | | JAN 30, 1998 | | |
| AP | GENSIA SICOR PHARMS | **EQ 5MG BASE/ML** | **N65035 001** | | |
| | | | JAN 24, 2000 | | |
| | + | EQ 50MG BASE/VIAL | N64212 002 | > DLT > | |
| | | | MAY 03, 1999 | > ADD > | |
| | | | | > DLT > | |
| | | | | > DLT > | |
| | | | | > ADD > | |

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | DECLOMYCIN | | |
| + | LEDERLE | 150MG | N50262 001 |

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | DECLOMYCIN | | |
| @ | LEDERLE | 150MG | N50262 001 |

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **DESMOPRESSIN ACETATE** | | |
| AP | ABBOTT | **0.004MG/ML** | **N75220 001** |
| | | | AUG 28, 2000 |
| AP | BEDFORD | **0.004MG/ML** | **N74575 001** |
| | | | FEB 18, 2000 |
| | **DESMOPRESSIN ACETATE PRESERVATIVE FREE** | | |
| AP | BEDFORD | **0.004MG/ML** | **N74574 001** |
| | | | FEB 18, 2000 |

SPRAY, METERED; NASAL

| | | | |
|---|---|---|---|
| | STIMATE | | |
| + | AVENTIS BEHRING | 0.15MG/SPRAY | N20355 001 |
| | | | MAR 07, 1994 |
| + | CENTEON | 0.15MG/SPRAY | N20355 001 |
| | | | MAR 07, 1994 |

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

| | | | |
|---|---|---|---|
| | MIRCETTE | | |
| + | ORGANON | 0.15MG;0.02MG | N20713 001 |
| | | | APR 22, 1998 |
| + | | 0.15MG,N/A;0.02MG,0.01MG | N20713 001 |
| | | | APR 22, 1998 |

DEXAMETHASONE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | DEXAMETHASONE | | | |
| BP | GLOBAL PHARM | 0.75MG | N85376 001 | |
| @ | IMPAX LABS | 0.75MG | N85376 001 | |
| | DEXONE 1.5 | | | |
| BP | SOLVAY | 1.5MG | N84990 001 | |
| @ | | 1.5MG | N84990 001 | |

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
**NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE**

| | | | |
|---|---|---|---|
| AT | ALCON UNIVERSAL | 0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62721 001 NOV 17, 1986 |
| AT | STERIS | 0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62721 001 NOV 17, 1986 |

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC, OTIC
**DEXAMETHASONE SODIUM PHOSPHATE**

| | | | |
|---|---|---|---|
| AT | ALCON UNIVERSAL | EQ 0.1% PHOSPHATE | N88771 001 JAN 16, 1985 |

SOLUTION/DROPS; OPHTHALMIC, OTIC
**DEXAMETHASONE SODIUM PHOSPHATE**

| | | | |
|---|---|---|---|
| AT | STERIS | EQ 0.1% PHOSPHATE | N88771 001 JAN 16, 1985 |

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
**NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE**

| | | | |
|---|---|---|---|
| AT | ALCON UNIVERSAL | EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML | N62714 001 JUL 21, 1986 |
| AT | STERIS | EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML | N62714 001 JUL 21, 1986 |

DEZOCINE

INJECTABLE; INJECTION
DALGAN

| | | | |
|---|---|---|---|
| + | ASTRAZENECA | 5MG/ML | N19082 001 DEC 29, 1989 |
| + | | 10MG/ML | N19082 002 DEC 29, 1989 |
| + | | 15MG/ML | N19082 003 DEC 29, 1989 |
| @ | | 5MG/ML | N19082 001 DEC 29, 1989 |

DEZOCINE

INJECTABLE; INJECTION
DALGAN

| | | | |
|---|---|---|---|
| @ | ASTRAZENECA | 10MG/ML | N19082 002 DEC 29, 1989 |
| @ | | 15MG/ML | N19082 003 DEC 29, 1989 |

DIAZEPAM

INJECTABLE; INJECTION
DIZAC

| | | | |
|---|---|---|---|
| @ | PHARMACIA AND UPJOHN | 5MG/ML | N19287 001 JUN 18, 1993 |

INJECTABLE; INTRAVENOUS
DIZAC

| | | | |
|---|---|---|---|
| + | PHARMACIA AND UPJOHN | 5MG/ML | N19287 001 JUN 18, 1993 |

TABLET; ORAL
**DIAZEPAM**

| | | | | |
|---|---|---|---|---|
| > DLT > | AB | ROXANE | 2MG | N70356 001 JUN 17, 1986 |
| > DLT > | AB | | 5MG | N70357 001 JUN 17, 1986 |
| > DLT > | AB | | 10MG | N70358 001 JUN 17, 1986 |
| > ADD > | @ | | 2MG | N70356 001 JUN 17, 1986 |
| > ADD > | @ | | 5MG | N70357 001 JUN 17, 1986 |
| > ADD > | @ | | 10MG | N70358 001 JUN 17, 1986 |

DICLOFENAC POTASSIUM

TABLET; ORAL
**DICLOFENAC POTASSIUM**

| | | | | |
|---|---|---|---|---|
| AB | GENEVA PHARMS TECH | 50MG | N75229 001 NOV 20, 1998 |
| AB | INVAMED | 50MG | N75229 001 NOV 20, 1998 |

DICLOFENAC SODIUM

> ADD > GEL; TOPICAL
> ADD > SOLARAZE
> ADD > + SKYEPHARMA 3% N21005 001
> ADD > OCT 16, 2000

SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM †
AB FALCON PHARMS 0.1% N20809 001
MAY 04, 1998
@ 0.1% N20809 001
MAY 04, 1998

VOLTAREN
AB * CIBA 0.1% N20037 001
MAR 28, 1991
+ 0.1% N20037 001
MAR 28, 1991

TABLET, EXTENDED RELEASE; ORAL
DICLOFENAC SODIUM
AB BIOVAIL 100MG N75492 001
FEB 11, 2000

VOLTAREN-XR
AB + NOVARTIS 100MG N20254 001
MAR 08, 1996
* 100MG N20254 001
MAR 08, 1996

DIDANOSINE

> ADD > CAPSULE, DELAYED REL PELLETS; ORAL
> ADD > VIDEX EC
> ADD > + BRISTOL MYERS SQUIBB 125MG N21183 001
> ADD > OCT 31, 2000
> ADD > + 200MG N21183 002
> ADD > OCT 31, 2000
> ADD > + 250MG N21183 003
> ADD > OCT 31, 2000
> ADD > + 400MG N21183 004
> ADD > OCT 31, 2000

DIENESTROL

SUPPOSITORY; VAGINAL
DV
@ AVENTIS PHARMS 0.7MG N83517 001

DIENESTROL

SUPPOSITORY; VAGINAL
DV
* HOECHST MARION RSSL 0.7MG N83517 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL
AA MD PHARM 25MG N85544 001
@ MEDEVA PHARMS CA 25MG N85544 001

DIETHYLSTILBESTROL DIPHOSPHATE

INJECTABLE; INJECTION
STILPHOSTROL
* BAYER 250MG/5ML N10010 001
@ 250MG/5ML N10010 001

TABLET; ORAL
STILPHOSTROL
* BAYER 50MG N10010 002
@ 50MG N10010 002

DIFLORASONE DIACETATE

CREAM; TOPICAL
DIFLORASONE DIACETATE
AB TARO 0.05% N75508 001
APR 24, 2000

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HCL
AB3 BIOVAIL 120MG N20939 001
JAN 28, 2000
AB3 180MG N20939 002
JAN 28, 2000
AB3 240MG N20939 003
JAN 28, 2000
AB3 300MG N20939 004
JAN 28, 2000

† SEE SECTION 1.3 OF INTRODUCTION

## DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION
**DILTIAZEM HCL**

| | | | |
|---|---|---|---|
| **AP** | ABBOTT | **5MG/ML** | **N75004 001** FEB 16, 2000 |

## DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL
TIAMATE

| | | | |
|---|---|---|---|
| + | HOECHST MARION RSSL | EQ 120MG HCL | N20506 001 OCT 04, 1996 |
| + | | EQ 180MG HCL | N20506 002 OCT 04, 1996 |
| + | | EQ 240MG HCL | N20506 003 OCT 04, 1996 |
| + | MERCK | EQ 120MG HCL | N20506 001 OCT 04, 1996 |
| + | | EQ 180MG HCL | N20506 002 OCT 04, 1996 |
| + | | EQ 240MG HCL | N20506 003 OCT 04, 1996 |

## DILTIAZEM MALATE; ENALAPRIL MALEATE

TABLET, EXTENDED RELEASE; ORAL
TECZEM

| | | | | |
|---|---|---|---|---|
| >DLT> >DLT> | + | AVENTIS PHARMS | EQ 180MG HCL;5MG | N20507 001 OCT 04, 1996 |
| >ADD> >ADD> | + | MERCK | EQ 180MG HCL;5MG | N20507 001 OCT 04, 1996 |

## DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
**DIPHENHYDRAMINE HCL**

| | | | |
|---|---|---|---|
| **AA** | GLOBAL PHARM | **25MG** | **N80807 001** |
| **AA** | | **50MG** | **N80807 002** |
| | IMPAX LABS | 25MG | N80807 001 |
| @ | | 50MG | N80807 002 |

## DIPYRIDAMOLE

TABLET; ORAL
**DIPYRIDAMOLE**

| | | | | |
|---|---|---|---|---|
| >DLT> >DLT> | **AB** | PUREPAC PHARM | **75MG** | **N89427 001 JUL 12, 1990** |
| >ADD> >ADD> | @ | | 75MG | N89427 001 JUL 12, 1990 |

## DIVALPROEX SODIUM

TABLET, EXTENDED RELEASE; ORAL
DEPAKOTE ER

| | | | |
|---|---|---|---|
| + | ABBOTT | EQ 500MG VALPROIC ACID | N21168 001 AUG 04, 2000 |

## DOXAZOSIN MESYLATE

TABLET; ORAL
**CARDURA**

| | | | | |
|---|---|---|---|---|
| >ADD> >ADD> | **AB** | + PFIZER | **EQ 1MG BASE** | **N19668 001 NOV 02, 1990** |
| >ADD> >ADD> | **AB** | | **EQ 2MG BASE** | **N19668 002 NOV 02, 1990** |
| >ADD> >ADD> | **AB** | | **EQ 4MG BASE** | **N19668 003 NOV 02, 1990** |
| >ADD> >ADD> | **AB** | | **EQ 8MG BASE** | **N19668 004 NOV 02, 1990** |
| >DLT> >DLT> | | + | EQ 1MG BASE | N19668 001 NOV 02, 1990 |
| >DLT> >DLT> | | | EQ 2MG BASE | N19668 002 NOV 02, 1990 |
| >DLT> >DLT> | | | EQ 4MG BASE | N19668 003 NOV 02, 1990 |
| >DLT> >DLT> | | | EQ 8MG BASE | N19668 004 NOV 02, 1990 |
| >ADD> | | **DOXAZOSIN MESYLATE** | | |
| >ADD> >ADD> | **AB** | CHELSEA LABS | **EQ 1MG BASE** | **N75426 001 OCT 18, 2000** |
| >ADD> >ADD> | **AB** | | **EQ 2MG BASE** | **N75426 002 OCT 18, 2000** |
| >ADD> >ADD> | **AB** | | **EQ 4MG BASE** | **N75426 003 OCT 18, 2000** |
| >ADD> >ADD> | **AB** | | **EQ 8MG BASE** | **N75426 004 OCT 18, 2000** |
| >ADD> >ADD> | **AB** | EON | **EQ 1MG BASE** | **N75646 001 OCT 18, 2000** |

DOXAZOSIN MESYLATE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| ADD | | **DOXAZOSIN MESYLATE** | | | |
| ADD | AB | EON | EQ 2MG BASE | N75646 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75646 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75646 004 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | GENPHARM | EQ 1MG BASE | N75466 001 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75466 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75466 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75466 004 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | INVAMED | EQ 1MG BASE | N75432 001 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75432 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75432 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75432 004 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | KV PHARM | EQ 1MG BASE | N75609 001 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75609 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75609 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75609 004 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | MYLAN | EQ 1MG BASE | N75509 001 | OCT 19, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75509 002 | OCT 19, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75509 003 | OCT 19, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75509 004 | OCT 19, 2000 |
| ADD | | | | | |
| ADD | AB | PUREPAC PHARM | EQ 1MG BASE | N75574 001 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75574 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75574 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75574 004 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | TEVA | EQ 1MG BASE | N75536 001 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75536 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75536 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75536 004 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | TORPHARM | EQ 1MG BASE | N75580 001 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75580 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75580 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75580 004 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | ZENITH GOLDLINE | EQ 1MG BASE | N75453 001 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 2MG BASE | N75453 002 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 4MG BASE | N75453 003 | OCT 18, 2000 |
| ADD | | | | | |
| ADD | AB | | EQ 8MG BASE | N75453 004 | OCT 18, 2000 |
| ADD | | | | | |

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

| | | | |
|---|---|---|---|
| | ZONALON | | |
| + | BIOGLAN PHAR | 5% | N20126 001 APR 01, 1994 |
| + | MEDICIS | 5% | N20126 001 APR 01, 1994 |

DOXERCALCIFEROL

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | HECTOROL | | |
| + | BONE CARE | 2 UGM/ML | N21027 001 APR 06, 2000 |

DOXYCYCLINE

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | **DOXYCYCLINE** | | | |
| AB | | EON | EQ 50MG BASE | N65032 001 | JUN 30, 2000 |
| AB | | | EQ 100MG BASE | N65032 002 | JUN 30, 2000 |
| AB | | HALSEY | EQ 50MG BASE | N65041 001 | APR 28, 2000 |
| AB | | | EQ 100MG BASE | N65041 002 | APR 28, 2000 |
| | | **MONODOX** | | | |
| AB | | OCLASSEN | EQ 50MG BASE | N50641 002 | FEB 10, 1992 |
| AB | + | | EQ 100MG BASE | N50641 001 | DEC 29, 1989 |
| | | | EQ 50MG BASE | N50641 002 | FEB 10, 1992 |
| | + | | EQ 100MG BASE | N50641 001 | DEC 29, 1989 |

DROPERIDOL

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | **DROPERIDOL** | | | |
| > DLT > | AP | ASTRAZENECA | 2.5MG/ML | N72018 001 | OCT 20, 1988 |
| > DLT > | AP | | 2.5MG/ML | N72019 001 | OCT 19, 1988 |
| > DLT > | AP | | 2.5MG/ML | N72021 001 | OCT 19, 1988 |
| > ADD > | | @ | 2.5MG/ML | N72018 001 | OCT 20, 1988 |
| > ADD > | | @ | 2.5MG/ML | N72019 001 | OCT 19, 1988 |
| > ADD > | | @ | 2.5MG/ML | N72021 001 | OCT 19, 1988 |

EFLORNITHINE HYDROCHLORIDE

CREAM; TOPICAL

| | | | | | |
|---|---|---|---|---|---|
| | | VANIQA | | | |
| | + | WESTWOOD SQUIBB CLTN | 13.9% | N21145 001 | JUL 27, 2000 |

ENALAPRIL MALEATE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | **ENALAPRIL MALEATE** | | | |
| AB | | APOTHECON | 2.5MG | N75583 001 | AUG 22, 2000 |
| AB | | | 5MG | N75583 002 | AUG 22, 2000 |
| AB | | | 10MG | N75583 003 | AUG 22, 2000 |
| AB | | | 20MG | N75583 004 | AUG 22, 2000 |
| AB | | CHELSEA LABS | 2.5MG | N75501 001 | AUG 22, 2000 |
| AB | | | 5MG | N75501 002 | AUG 22, 2000 |
| AB | | | 10MG | N75501 003 | AUG 22, 2000 |
| AB | | | 20MG | N75501 004 | AUG 22, 2000 |
| AB | | EON | 2.5MG | N75621 001 | AUG 22, 2000 |
| AB | | | 5MG | N75621 002 | AUG 22, 2000 |
| AB | | | 10MG | N75621 003 | AUG 22, 2000 |
| AB | | | 20MG | N75621 004 | AUG 22, 2000 |
| AB | | GENEVA PHARMS | 2.5MG | N75048 001 | AUG 22, 2000 |
| AB | | | 5MG | N75048 002 | AUG 22, 2000 |
| AB | | | 10MG | N75048 003 | AUG 22, 2000 |
| AB | | | 20MG | N75048 004 | AUG 22, 2000 |
| AB | | GENPHARM | 2.5MG | N75472 001 | AUG 22, 2000 |
| AB | | | 5MG | N75472 002 | AUG 22, 2000 |
| AB | | | 10MG | N75472 003 | AUG 22, 2000 |
| AB | | | 20MG | N75472 004 | AUG 22, 2000 |
| AB | | KRKA DD NOVO MESTO | 2.5MG | N75370 001 | AUG 22, 2000 |
| AB | | | 5MG | N75370 002 | AUG 22, 2000 |

ENALAPRIL MALEATE

TABLET; ORAL

**ENALAPRIL MALEATE**

| | | | | |
|---|---|---|---|---|
| AB | KRKA DD NOVO MESTO | 10MG | N75369 001 | AUG 22, 2000 |
| AB | | 20MG | N75369 002 | AUG 22, 2000 |
| AB | LEK PHARM | 2.5MG | N75496 001 | AUG 22, 2000 |
| AB | | 5MG | N75496 002 | AUG 22, 2000 |
| AB | | 10MG | N75459 001 | AUG 22, 2000 |
| AB | | 20MG | N75459 002 | AUG 22, 2000 |
| AB | MYLAN | 2.5MG | N75480 001 | AUG 22, 2000 |
| AB | | 5MG | N75480 002 | AUG 22, 2000 |
| AB | | 10MG | N75480 003 | AUG 22, 2000 |
| AB | | 20MG | N75480 004 | AUG 22, 2000 |
| AB | RANBAXY | 2.5MG | N75556 001 | AUG 22, 2000 |
| AB | | 5MG | N75556 002 | AUG 22, 2000 |
| AB | | 10MG | N75556 003 | AUG 22, 2000 |
| AB | | 20MG | N75556 004 | AUG 22, 2000 |
| AB | TEVA | 2.5MG | N75479 001 | AUG 22, 2000 |
| AB | | 5MG | N75479 002 | AUG 22, 2000 |
| AB | | 10MG | N75479 003 | AUG 22, 2000 |
| AB | | 20MG | N75479 004 | AUG 22, 2000 |
| AB | WOCKHARDT | 2.5MG | N75483 001 | AUG 22, 2000 |
| AB | | 5MG | N75483 002 | AUG 22, 2000 |
| AB | | 10MG | N75483 003 | AUG 22, 2000 |
| AB | | 20MG | N75483 004 | AUG 22, 2000 |

ENALAPRIL MALEATE

TABLET; ORAL

**ENALAPRIL MALEATE**

| | | | | |
|---|---|---|---|---|
| AB | ZENITH GOLDLINE | 2.5MG | N75482 001 | AUG 22, 2000 |
| AB | | 5MG | N75482 002 | AUG 22, 2000 |
| AB | | 10MG | N75482 003 | AUG 22, 2000 |
| AB | | 20MG | N75482 004 | AUG 22, 2000 |

**VASOTEC**

| | | | | |
|---|---|---|---|---|
| AB | MERCK | 2.5MG | N18998 005 | JUL 26, 1988 |
| AB | | 5MG | N18998 001 | DEC 24, 1985 |
| AB | | 10MG | N18998 002 | DEC 24, 1985 |
| AB | + | 20MG | N18998 003 | DEC 24, 1985 |
| | | 2.5MG | N18998 005 | JUL 26, 1988 |
| | | 5MG | N18998 001 | DEC 24, 1985 |
| | | 10MG | N18998 002 | DEC 24, 1985 |
| | + | 20MG | N18998 003 | DEC 24, 1985 |

ENALAPRILAT

INJECTABLE; INJECTION

**ENALAPRILAT**

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT | 1.25MG/ML | N75456 001 | AUG 22, 2000 |
| AP | | 1.25MG/ML | N75458 001 | AUG 22, 2000 |
| AP | BEDFORD | 1.25MG/ML | N75634 001 | AUG 22, 2000 |
| AP | FAULDING | 1.25MG/ML | N75571 001 | AUG 22, 2000 |
| AP | GENSIA SICOR PHARMS | 1.25MG/ML | N75578 001 | AUG 22, 2000 |

**VASOTEC**

| | | | | |
|---|---|---|---|---|
| AP | + MERCK | 1.25MG/ML | N19309 001 | FEB 09, 1988 |

ENALAPRILAT

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **VASOTEC** | | |
| | + | MERCK | 1.25MG/ML | N19309 001<br>FEB 09, 1988 |

ENFLURANE

LIQUID; INHALATION

| | | | | |
|---|---|---|---|---|
| | | **ETHRANE** | | |
| **AN** | + | BAXTER PHARM PROD | **99.9%** | **N17087 001** |
| **AN** | + | OHMEDA | **99.9%** | **N17087 001** |

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

| | | | | |
|---|---|---|---|---|
| | | **ERGOMAR** | | |
| **AA** | | LOTUS BIOCHEM | **2MG** | **N87693 001**<br>FEB 24, 1983 |
| | + | | 2MG | N87693 001<br>FEB 24, 1983 |
| | | **ERGOSTAT** | | |
| **AA** | | PARKE DAVIS | **2MG** | **N88337 001**<br>JUN 08, 1984 |
| | @ | | 2MG | N88337 001<br>JUN 08, 1984 |
| | | **WIGRETTES** | | |
| **AA** | + | ORGANON | **2MG** | **N86750 001**<br>JUL 29, 1982 |
| | @ | | 2MG | N86750 001<br>JUL 29, 1982 |

ERYTHROMYCIN

SOLUTION; TOPICAL

| | | | | | |
|---|---|---|---|---|---|
| | | | **ERYTHROMYCIN** | | |
| > DLT > | **AT** | | ALPHARMA | **1.5%** | **N62328 001**<br>APR 19, 1982 |
| > DLT > | | @ | | 1.5% | N62328 001<br>APR 19, 1982 |
| > ADD > | | | **SANSAC** | | |
| > ADD > | **AT** | | GALDERMA LABS | **2%** | **N62522 001**<br>JAN 24, 1985 |
| | **AT** | | HEALTHPOINT | **2%** | **N62522 001**<br>JAN 24, 1985 |

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **PEDIAMYCIN** | | |
| **AB** | | ROSS LABS | **EQ 200MG BASE/5ML** | **N62305 001** |
| | @ | | EQ 200MG BASE/5ML | N62305 001 |

SUSPENSION/DROPS; ORAL

| | | | | |
|---|---|---|---|---|
| | | PEDIAMYCIN | | |
| | + | ROSS LABS | EQ 100MG BASE/2.5ML | N62305 002 |
| | @ | | EQ 100MG BASE/2.5ML | N62305 002 |

TABLET, CHEWABLE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **PEDIAMYCIN** | | |
| **AB** | | ROSS LABS | **EQ 200MG BASE** | **N62306 001** |
| | @ | | EQ 200MG BASE | N62306 001 |

ESTRADIOL

CREAM; VAGINAL

| | | | | |
|---|---|---|---|---|
| | | ESTRACE | | |
| | + | BRISTOL MYERS SQUIBB | 0.01% | N86069 001<br>JAN 31, 1984 |
| | + | WARNER CHILCOTT | 0.01% | N86069 001<br>JAN 31, 1984 |

FILM, EXTENDED RELEASE; TRANSDERMAL

| | | | | |
|---|---|---|---|---|
| | | **CLIMARA** | | |
| **AB** | + | BERLEX LABS | **0.05MG/24HR** | **N20375 001**<br>DEC 22, 1994 |
| **AB** | + | | **0.1MG/24HR** | **N20375 002**<br>DEC 22, 1994 |
| BX | + | | 0.05MG/24HR | N20375 001<br>DEC 22, 1994 |
| BX | + | | 0.1MG/24HR | N20375 002<br>DEC 22, 1994 |
| | | **ESTRADIOL** | | |
| BX | | CYGNUS CA | 0.05MG/24HR | N21048 001<br>SEP 20, 1999 |
| BX | | | 0.075MG/24HR | N21048 002<br>SEP 20, 1999 |
| BX | | | 0.1MG/24HR | N21048 003<br>SEP 20, 1999 |
| | @ | JOHNSON RW | 0.05MG/24HR | N21048 001<br>SEP 20, 1999 |
| | @ | | 0.075MG/24HR | N21048 002<br>SEP 20, 1999 |

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

| | | | | |
|---|---|---|---|---|
| | ESTRADIOL | | | |
| | @ JOHNSON RW | | 0.1MG/24HR | N21048 003<br>SEP 20, 1999 |
| AB | MYLAN TECHNOLOGIES | | 0.05MG/24HR | N75233 001<br>FEB 24, 2000 |
| AB | | | 0.1MG/24HR | N75182 001<br>FEB 24, 2000 |
| | VIVELLE | | | |
| | + NOVARTIS | | 0.025MG/24HR | N20323 005<br>AUG 16, 2000 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ESTRADIOL | | | |
| AB | APPLIED ANAL | | 0.5MG | N40138 001<br>JAN 30, 1998 |
| AB | | | 1MG | N40138 002<br>JAN 30, 1998 |
| AB | | | 2MG | N40138 003<br>JAN 30, 1998 |
| AB | ENDEAVOR | | 0.5MG | N40138 001<br>JAN 30, 1998 |
| AB | | | 1MG | N40138 002<br>JAN 30, 1998 |
| AB | | | 2MG | N40138 003<br>JAN 30, 1998 |

> ADD > ESTRADIOL CYPIONATE; MEDROXYPROGESTERONE ACETATE

> ADD > INJECTABLE; INTRAMUSCULAR

| | | | | |
|---|---|---|---|---|
| > ADD > | | LUNELLE | | |
| > ADD > | | + PHARMACIA AND UPJOHN | 5MG/0.5ML;25MG/0.5ML | N20874 001<br>OCT 05, 2000 |
| > ADD > | | | | |

ESTROGENS, ESTERIFIED

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | ESTRATAB | | |
| > DLT > | BP | + SOLVAY | 2.5MG | N83857 001 |
| > ADD > | | @ | 2.5MG | N83857 001 |
| | | MENEST | | |
| > DLT > | BP | MONARCH PHARMS | 2.5MG | N84949 001 |
| > ADD > | | + | 2.5MG | N84949 001 |

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | ETHAMOLIN | | |
| + | CYPROS | 50MG/ML | N19357 001<br>DEC 22, 1988 |
| + | QUESTCOR PHARM | 50MG/ML | N19357 001<br>DEC 22, 1988 |

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

| | | | | |
|---|---|---|---|---|
| | | TRIVORA-21 | | |
| AB | | SEARLE | 0.03MG,0.04MG,0.03MG;0.05MG,0.075MG,0.125MG | N74538 001<br>DEC 18, 1997 |
| AB | | WATSON LABS | 0.03MG,0.04MG,0.03MG;0.05MG,0.075MG,0.125MG | N74538 001<br>DEC 18, 1997 |

TABLET; ORAL-28

| | | | | |
|---|---|---|---|---|
| | | TRIVORA-28 | | |
| AB | | SEARLE | 0.03MG,0.04MG,0.03MG;0.05MG,0.075MG,0.125MG | N74538 002<br>DEC 18, 1997 |
| AB | | WATSON LABS | 0.03MG,0.04MG,0.03MG;0.05MG,0.075MG,0.125MG | N74538 002<br>DEC 18, 1997 |

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

| | | | |
|---|---|---|---|
| | OVCON-35 | | |
| + | BRISTOL MYERS SQUIBB | 0.035MG;0.4MG | N18127 001 |
| + | WARNER CHILCOTT | 0.035MG;0.4MG | N18127 001 |
| | OVCON-50 | | |
| @ | BRISTOL MYERS SQUIBB | 0.05MG;1MG | N18128 001 |
| @ | WARNER CHILCOTT | 0.05MG;1MG | N18128 001 |

TABLET; ORAL-28

| | | | |
|---|---|---|---|
| | OVCON-35 | | |
| | BRISTOL MYERS SQUIBB | 0.035MG;0.4MG | N17716 001 |
| | WARNER CHILCOTT | 0.035MG;0.4MG | N17716 001 |
| | OVCON-50 | | |
| | BRISTOL MYERS SQUIBB | 0.05MG;1MG | N17576 001 |
| | WARNER CHILCOTT | 0.05MG;1MG | N17576 001 |

ETODOLAC

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | ETODOLAC | | | |
| | AB | TORPHARM | 200MG | N75419 001 | JUL 28, 2000 |
| | AB | | 300MG | N75419 002 | JUL 28, 2000 |

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | ETODOLAC | | | |
| > ADD > | AB | GENEVA PHARMS TECH | 400MG | N74846 001 | FEB 28, 1997 |
| > ADD > | | | | | |
| > DLT > | AB | INVAMED | 400MG | N74846 001 | FEB 28, 1997 |
| > DLT > | | | | | |
| | AB | TARO PHARM INDS | 500MG | N75074 002 | APR 25, 2000 |

TABLET, EXTENDED RELEASE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | ETODOLAC | | | |
| | AB | TEVA | 500MG | N75665 002 | JUL 31, 2000 |
| | AB | | 600MG | N75665 001 | JUL 31, 2000 |
| | AB | WHITNEY PHARMS | 400MG | N75696 001 | JUL 31, 2000 |
| | | LODINE XL | | | |
| | AB + | WYETH AYERST | 400MG | N20584 001 | OCT 25, 1996 |
| | AB + | | 500MG | N20584 003 | JAN 20, 1998 |
| | AB + | | 600MG | N20584 002 | OCT 25, 1996 |
| | + | | 400MG | N20584 001 | OCT 25, 1996 |
| | + | | 500MG | N20584 003 | JAN 20, 1998 |
| | + | | 600MG | N20584 002 | OCT 25, 1996 |

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | CORLOPAM | | | |
| | + | ABBOTT | EQ 10MG BASE/ML | N19922 001 | SEP 23, 1997 |
| | + | ELAN PHARMA | EQ 10MG BASE/ML | N19922 001 | SEP 23, 1997 |

FENOPROFEN CALCIUM

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | FENOPROFEN CALCIUM | | | |
| > DLT > | AB | WATSON LABS | EQ 200MG BASE | N72294 001 | AUG 17, 1988 |
| > DLT > | | | | | |
| > DLT > | AB | | EQ 300MG BASE | N72293 001 | AUG 17, 1988 |
| > DLT > | | | | | |
| > ADD > | @ | | EQ 200MG BASE | N72294 001 | AUG 17, 1988 |
| > ADD > | | | | | |
| > ADD > | @ | | EQ 300MG BASE | N72293 001 | AUG 17, 1988 |
| > ADD > | | | | | |

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | FENOPROFEN CALCIUM | | | |
| > DLT > | AB | WATSON LABS | EQ 600MG BASE | N72165 001 | AUG 17, 1988 |
| > DLT > | | | | | |
| > ADD > | @ | | EQ 600MG BASE | N72165 001 | AUG 17, 1988 |
| > ADD > | | | | | |

FENTANYL CITRATE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | SUBLIMAZE PRESERVATIVE FREE | | | |
| AP | + | AKORN MFG | EQ 0.05MG BASE/ML | N16619 001 | |
| AP | + | JANSSEN | EQ 0.05MG BASE/ML | N16619 001 | |

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | ALLEGRA | | | |
| | | AVENTIS PHARMS | 30MG | N20872 001 | FEB 25, 2000 |
| | | | 60MG | N20872 002 | FEB 25, 2000 |
| | + | | 180MG | N20872 004 | FEB 25, 2000 |

FLOXURIDINE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | FLOXURIDINE | | | |
| AP | | BEDFORD | 500MG/VIAL | N75387 001 | APR 16, 2000 |
| | | FUDR | | | |
| AP | + | ROCHE | 500MG/VIAL | N16929 001 | |

FLOXURIDINE

INJECTABLE; INJECTION
FUDR
+ ROCHE 500MG/VIAL N16929 001

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN
PFIZER 150MG N20322 001 JUN 30, 1994
150MG N19949 004 JUN 30, 1994

FLUMAZENIL

INJECTABLE; INJECTION
ROMAZICON
+ HLR 0.1MG/ML N20073 001 DEC 20, 1991
+ ROCHE 0.1MG/ML N20073 001 DEC 20, 1991

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUONID
AT ALLERGAN HERBERT 0.025% N87156 002 SEP 06, 1984
@ 0.025% N87156 002 SEP 06, 1984

OINTMENT; TOPICAL
FLUONID
AT ALLERGAN HERBERT 0.025% N87157 001 SEP 06, 1984
@ 0.025% N87157 001 SEP 06, 1984

FLUOROURACIL

CREAM; TOPICAL
FLUOROURACIL
+ DERMIK LABS 0.5% N20985 001 OCT 27, 2000

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
AP GENSIA SICOR PHARMS 50MG/ML N40333 001 JAN 27, 2000
AP 50MG/ML N40334 001 FEB 25, 2000

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
SARAFEM
LILLY EQ 10MG BASE N18936 007 JUL 06, 2000
+ EQ 20MG BASE N18936 008 JUL 06, 2000

FLURANDRENOLIDE

LOTION; TOPICAL
FLURANDRENOLIDE
AT ALPHARMA 0.05% N87203 001 APR 29, 1982
@ 0.05% N87203 001 APR 29, 1982

FLUTICASONE PROPIONATE

POWDER; INHALATION
FLOVENT DISKUS 100
+ GLAXO 0.1MG/INH N20833 002 SEP 29, 2000
FLOVENT DISKUS 250
+ GLAXO 0.25MG/INH N20833 003 SEP 29, 2000
FLOVENT DISKUS 50
+ GLAXO 0.05MG/INH N20833 001 SEP 29, 2000

FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE

POWDER; INHALATION
ADVAIR DISKUS 100/50
+ GLAXO WELLCOME — 0.1MG/INH; EQ 0.05MG BASE/INH — N21077 001 AUG 24, 2000
ADVAIR DISKUS 250/50
+ GLAXO WELLCOME — 0.25MG/INH; EQ 0.05MG BASE/INH — N21077 002 AUG 24, 2000
ADVAIR DISKUS 500/50
+ GLAXO WELLCOME — 0.5MG/INH; EQ 0.05MG BASE/INH — N21077 003 AUG 24, 2000

FLUVASTATIN SODIUM

> ADD > TABLET, EXTENDED RELEASE; ORAL
> ADD > LESCOL XL
> ADD > + NOVARTIS — 80MG — N21192 001 OCT 06, 2000
> ADD >

FOLLITROPIN ALFA/BETA

INJECTABLE; INJECTION
GONAL-F
SERONO — 37.5 IU/VIAL — N20378 003 MAY 25, 2000

FURAZOLIDONE

SUSPENSION; ORAL
FUROXONE
+ ROBERTS LABS — 50MG/15ML — N11323 002
+ SHIRE LABS — 50MG/15ML — N11323 002

TABLET; ORAL
FUROXONE
+ ROBERTS LABS — 100MG — N11270 002
+ SHIRE LABS — 100MG — N11270 002

FUROSEMIDE

INJECTABLE; INJECTION
**FUROSEMIDE**
> DLT > > DLT > **AP** ASTRAZENECA — **10MG/ML** — **N70095 001 SEP 09, 1985**
> DLT > > DLT > **AP** — **10MG/ML** — **N70096 001 SEP 09, 1985**
> ADD > > ADD > @ — 10MG/ML — N70095 001 SEP 09, 1985
> ADD > > ADD > @ — 10MG/ML — N70096 001 SEP 09, 1985

GABAPENTIN

SOLUTION; ORAL
NEURONTIN
> DLT > > DLT > + PARKE DAVIS — 250MG/5ML — N21129 001 MAR 02, 2000
> ADD > > ADD > @ — 250MG/5ML — N21129 001 MAR 02, 2000

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION
MAGNEVIST
+ BERLEX LABS — 469.01MG/ML — N21037 001 MAR 10, 2000

GEMFIBROZIL

TABLET; ORAL
**GEMFIBROZIL**
> DLT > > DLT > **AB** WATSON LABS — **600MG** — **N74156 001 OCT 24, 1994**
> ADD > > ADD > @ — 600MG — N74156 001 OCT 24, 1994

GEMTUZUMAB OZOGAMICIN

INJECTABLE; INJECTION
MYLOTARG
+ WYETH AYERST — 5MG/VIAL — N21174 001 MAY 17, 2000

GENTAMICIN SULFATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | GARAMYCIN | | | |
| AP | + SCHERING | EQ 10MG BASE/ML | N61739 001 | |
| | @ | EQ 10MG BASE/ML | N61739 001 | |
| | GENTAMICIN SULFATE | | | |
| AP | ELKINS SINN | EQ 10MG BASE/ML | N62251 002 | |
| AP | + | EQ 10MG BASE/ML | N62251 002 | |

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | GENTAMICIN SULFATE | | | |
| AT | ALCON UNIVERSAL | EQ 0.3% BASE | N62523 001 | NOV 25, 1985 |
| AT | STERIS | EQ 0.3% BASE | N62523 001 | NOV 25, 1985 |

GLUTETHIMIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | GLUTETHIMIDE | | | |
| | @ MD PHARM | 500MG | N85171 001 | |
| | @ MEDEVA PHARMS CA | 500MG | N85171 001 | |

GLYBURIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | GLYBURIDE (MICRONIZED) | | | |
| AB | AVENTIS PHARMS | 6MG | N20055 003 | MAR 08, 2000 |

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | GLUCOVANCE | | | |
| | BRISTOL MYERS SQUIBB | 1.25MG;250MG | N21178 001 | JUL 31, 2000 |
| | | 2.5MG;500MG | N21178 002 | JUL 31, 2000 |
| | + | 5MG;500MG | N21178 003 | JUL 31, 2000 |

GONADOTROPIN CHORIONIC RECOMBINANT HUMAN

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | OVIDREL | | | |
| | + SERONO | 0.25MG/VIAL | N21149 001 | SEP 20, 2000 |

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN | | | |
| AT | IPHARM | 0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML | N62818 001 | OCT 11, 1988 |
| | @ | 0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML | N62818 001 | OCT 11, 1988 |

GREPAFLOXACIN HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | RAXAR | | | |
| | GLAXO WELLCOME | EQ 200MG BASE | N20695 001 | NOV 06, 1997 |
| | | EQ 400MG BASE | N20695 002 | MAY 14, 1998 |
| | + | EQ 600MG BASE | N20695 003 | MAY 14, 1998 |
| | OTSUKA | EQ 200MG BASE | N20695 001 | NOV 06, 1997 |
| | | EQ 400MG BASE | N20695 002 | MAY 14, 1998 |
| | + | EQ 600MG BASE | N20695 003 | MAY 14, 1998 |

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | GRIFULVIN V | | | |
| AB | J AND J | 250MG | N60618 002 | |
| AB | | 500MG | N60618 003 | |
| > DLT > | | 125MG | N60618 001 | |
| > DLT > | @ | 125MG | N60618 001 | |
| > ADD > | @ | 250MG | N60618 002 | |
| > ADD > | @ | 500MG | N60618 003 | |
| > ADD > | | | | |

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL
GRIS-PEG

| | | | | |
|---|---|---|---|---|
| AB | ALLERGAN HERBERT | 125MG | N50475 001 | |
| AB | | 250MG | N50475 002 | |
| AB | PEDINOL | 125MG | N50475 001 | |
| AB | | 250MG | N50475 002 | |

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

| | | | | |
|---|---|---|---|---|
| AO | APOTEX | EQ 50MG BASE/ML | N75440 001 FEB 28, 2000 | |
| AO | | EQ 100MG BASE/ML | N75440 002 FEB 28, 2000 | |
| AO | KING PHARMS | EQ 50MG BASE/ML | N75176 001 FEB 09, 2000 | |
| AO | | EQ 100MG BASE/ML | N75176 002 FEB 09, 2000 | |

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

| | | | | |
|---|---|---|---|---|
| AP | SMITH AND NEPHEW | 10 UNITS/ML | N87904 001 APR 20, 1983 | |
| AP | | 100 UNITS/ML | N87906 001 APR 20, 1983 | |
| @ | | 10 UNITS/ML | N87904 001 APR 20, 1983 | |
| @ | | 100 UNITS/ML | N87906 001 APR 20, 1983 | |
| @ | STERIS | 100 UNITS/ML | N17064 001 | |
| @ | | 100 UNITS/ML | N17064 001 | |

HEPARIN SODIUM

| | | | | |
|---|---|---|---|---|
| AP | STERIS | 5,000 UNITS/ML | N17064 003 | |
| AP | | 10,000 UNITS/ML | N17064 004 | |
| AP | | 20,000 UNITS/ML | N17064 005 | |
| AP | | 40,000 UNITS/ML | N17064 006 | > DLT > |
| @ | | 5,000 UNITS/ML | N17064 003 | > ADD > |
| @ | | 10,000 UNITS/ML | N17064 004 | |
| @ | | 20,000 UNITS/ML | N17064 005 | |
| @ | | 40,000 UNITS/ML | N17064 006 | |

HEXACHLOROPHENE

AEROSOL; TOPICAL
SEPTISOL

| | | | |
|---|---|---|---|
| @ | VESTAL LABS | 0.23% | N17424 001 |

DISC; TOPICAL
SEPTISOL

| | | | |
|---|---|---|---|
| + | VESTAL LABS | 0.23% | N17424 001 |

HISTRELIN ACETATE

INJECTABLE; INJECTION
SUPPRELIN

| | | | |
|---|---|---|---|
| + | ROBERTS LABS | EQ 0.2MG BASE/ML | N19836 001 DEC 24, 1991 |
| + | | EQ 0.5MG BASE/ML | N19836 002 DEC 24, 1991 |
| + | | EQ 1MG BASE/ML | N19836 003 DEC 24, 1991 |
| + | SHIRE LABS | EQ 0.2MG BASE/ML | N19836 001 DEC 24, 1991 |
| + | | EQ 0.5MG BASE/ML | N19836 002 DEC 24, 1991 |
| + | | EQ 1MG BASE/ML | N19836 003 DEC 24, 1991 |

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL

| | | | | |
|---|---|---|---|---|
| AP | GENSIA SICOR PHARMS | 20MG/ML | N40373 001 FEB 23, 2000 | |
| AP | + LUITPOLD | 20MG/ML | N40136 001 JUN 30, 1997 | |
| + | | 20MG/ML | N40136 001 JUN 30, 1997 | |

TABLET; ORAL
HYDRALAZINE HCL

| | | | | |
|---|---|---|---|---|
| AA | GLOBAL PHARM | 25MG | N84922 001 | |
| @ | IMPAX LABS | 25MG | N84922 001 | |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | **APRESAZIDE** | | | |
| > DLT > | AB | + NOVARTIS | 100MG;50MG | N84811 001 | |
| > ADD > | | @ | 100MG;50MG | N84811 001 | |
| | | **HYDRA-ZIDE** | | | |
| > DLT > | AB | PAR PHARM | 100MG;50MG | N88961 001 | |
| > DLT > | | | | OCT 21, 1985 | |
| > ADD > | | + | 100MG;50MG | N88961 001 | |
| > ADD > | | | | OCT 21, 1985 | |

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **HYDROCHLOROTHIAZIDE** | | |
| AB | | MYLAN | 12.5MG | N75640 001 |
| | | | | JAN 28, 2000 |
| | | **MICROZIDE** | | |
| AB | | + WATSON LABS | 12.5MG | N20504 001 |
| | | | | DEC 27, 1996 |
| | | + | 12.5MG | N20504 001 |
| | | | | DEC 27, 1996 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **HYDROCHLOROTHIAZIDE** | | |
| AB | | GLOBAL PHARM | 100MG | N85098 001 |
| | | @ IMPAX LABS | 100MG | N85098 001 |

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | HYZAAR | | |
| | | + MERCK | 12.5MG;50MG | N20387 001 |
| | | | | APR 28, 1995 |
| | | | 12.5MG;50MG | N20387 001 |
| | | | | APR 28, 1995 |
| | | + | 25MG;100MG | N20387 002 |
| | | | | NOV 10, 1998 |

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **METHYLDOPA AND HYDROCHLOROTHIAZIDE** | | |
| > DLT > | AB | WATSON LABS | 15MG;250MG | N71920 001 |
| > DLT > | | | | AUG 29, 1988 |

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **METHYLDOPA AND HYDROCHLOROTHIAZIDE** | | |
| > DLT > | AB | WATSON LABS | 25MG;250MG | N71921 001 |
| > DLT > | | | | AUG 29, 1988 |
| > DLT > | AB | | 30MG;500MG | N71922 001 |
| > DLT > | | | | AUG 29, 1988 |
| > DLT > | AB | | 50MG;500MG | N71923 001 |
| > DLT > | | | | AUG 29, 1988 |
| > ADD > | | @ | 15MG;250MG | N71920 001 |
| > ADD > | | | | AUG 29, 1988 |
| > ADD > | | @ | 25MG;250MG | N71921 001 |
| > ADD > | | | | AUG 29, 1988 |
| > ADD > | | @ | 30MG;500MG | N71922 001 |
| > ADD > | | | | AUG 29, 1988 |
| > ADD > | | @ | 50MG;500MG | N71923 001 |
| > ADD > | | | | AUG 29, 1988 |

HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | | **CODAMINE** | | |
| AA | | ALPHARMA | 5MG/5ML;25MG/5ML | N75103 001 |
| | | | | SEP 29, 2000 |
| | | **HYCOMINE** | | |
| AA | | + ENDO PHARMS | 5MG/5ML;25MG/5ML | N19410 001 |
| | | | | AUG 17, 1990 |
| | | + | 5MG/5ML;25MG/5ML | N19410 001 |
| | | | | AUG 17, 1990 |

HYDROCORTISONE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **HYDROCORTISONE** | | |
| AT | | ZENITH GOLDLINE | 1% | N85733 001 |
| | | @ | 1% | N85733 001 |
| | | **NOGENIC HC** | | |
| AT | | ZENITH GOLDLINE | 1% | N87427 001 |
| | | | | APR 04, 1988 |
| | | @ | 1% | N87427 001 |
| | | | | APR 04, 1988 |
| | | **NUTRACORT** | | |
| AT | | GALDERMA LABS | 0.5% | N80442 002 |
| AT | | | 1% | N80442 003 |
| AT | | HEALTHPOINT | 1% | N80442 003 |
| | | @ | 0.5% | N80442 002 |

HYDROCORTISONE

GEL; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | NUTRACORT | | |
| | | @ GALDERMA LABS | 1% | N84698 001 |
| | | @ HEALTHPOINT | 1% | N84698 001 |
| > DLT > | | PENECORT | | |
| > DLT > | | + ALLERGAN HERBERT | 1% | N88215 001 |
| > DLT > | | | | JUN 06, 1984 |
| > ADD > | | @ | 1% | N88215 001 |
| > ADD > | | | | JUN 06, 1984 |

LOTION; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **HYDROCORTISONE** | | |
| AT | | ALTANA | 2.5% | N40351 001 |
| | | | | JUL 25, 2000 |
| | | **NUTRACORT** | | |
| AT | | GALDERMA LABS | 0.5% | N80443 002 |
| AT | | | 1% | N80443 003 |
| AT | | | 2.5% | N87644 001 |
| | | | | AUG 24, 1982 |
| AT | | HEALTHPOINT | 1% | N80443 003 |
| AT | | | 2.5% | N87644 001 |
| | | | | AUG 24, 1982 |
| | | @ | 0.5% | N80443 002 |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| > DLT > | | **HYTONE** | | |
| > DLT > | AT | + DERMIK LABS | 1% | N80474 003 |
| > DLT > | AT | + | 2.5% | N80474 004 |
| > ADD > | | @ | 1% | N80474 003 |
| > ADD > | | @ | 2.5% | N80474 004 |

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

| | | | |
|---|---|---|---|
| | **NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE** | | |
| AT | ALCON UNIVERSAL | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62874 001 |
| | | | MAY 11, 1988 |
| AT | STERIS | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62874 001 |
| | | | MAY 11, 1988 |

SUSPENSION/DROPS; OTIC

| | | | |
|---|---|---|---|
| | **NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE** | | |
| AT | ALCON UNIVERSAL | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62488 001 |
| | | | NOV 06, 1985 |

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OTIC

| | | | |
|---|---|---|---|
| | **NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE** | | |
| AT | STERIS | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62488 001 |
| | | | NOV 06, 1985 |

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL

| | | | |
|---|---|---|---|
| | EPIFOAM | | |
| BX | SCHWARZ PHARMA | 1%;1% | N86457 001 |
| | PROCTOFOAM HC | | |
| BX | SCHWARZ PHARMA | 1%;1% | N86195 001 |

DISC; TOPICAL

| | | | |
|---|---|---|---|
| | EPIFOAM | | |
| BX | SCHWARZ PHARMA | 1%;1% | N86457 001 |
| | PROCTOFOAM HC | | |
| BX | SCHWARZ PHARMA | 1%;1% | N86195 001 |

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

| | | | |
|---|---|---|---|
| | LOCOID | | |
| | @ GALDERMA LABS | 0.1% | N18795 001 |
| | | | JAN 07, 1983 |
| | @ YAMANOUCHI | 0.1% | N18795 001 |
| | | | JAN 07, 1983 |
| | LOCOID LIPOCREAM | | |
| | YAMANOUCHI | 0.1% | N20769 001 |
| | | | SEP 08, 1997 |
| | + | 0.1% | N20769 001 |
| | | | SEP 08, 1997 |

OINTMENT; TOPICAL

| | | | |
|---|---|---|---|
| | LOCOID | | |
| | @ GALDERMA LABS | 0.1% | N19106 001 |
| | | | JUL 03, 1984 |
| | @ YAMANOUCHI | 0.1% | N19106 001 |
| | | | JUL 03, 1984 |

SOLUTION; TOPICAL

| | | | |
|---|---|---|---|
| | LOCOID | | |
| | @ GALDERMA LABS | 0.1% | N19819 001 |
| | | | SEP 15, 1988 |

HYDROCORTISONE BUTYRATE

SOLUTION; TOPICAL
LOCOID

| | | | | |
|---|---|---|---|---|
| @ | YAMANOUCHI | 0.1% | N19819 001 | SEP 15, 1988 |

HYDROCORTISONE VALERATE

CREAM; TOPICAL
**HYDROCORTISONE VALERATE**

| | | | | |
|---|---|---|---|---|
| **AB** | CLAY PARK | **0.2%** | **N75666 001** | MAY 24, 2000 |

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL
**HYDROXYCHLOROQUINE SULFATE**

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | **AB** | GENEVA PHARMS TECH | **200MG** | **N40150 001** | JAN 27, 1996 |
| > DLT > | **AB** | INVAMED | **200MG** | **N40150 001** | JAN 27, 1996 |

HYDROXYUREA

CAPSULE; ORAL
**HYDROXYUREA**

| | | | | |
|---|---|---|---|---|
| **AB** | BARR | **250MG** | **N75143 002** | SEP 21, 2000 |
| **AB** | DURAMED | **250MG** | **N75020 002** | JUN 26, 2000 |
| **AB** + | | **250MG** | **N75020 002** | JUN 26, 2000 |

TABLET; ORAL
HYDROXYUREA

| | | | | |
|---|---|---|---|---|
| + | BARR | 1GM | N75734 001 | AUG 29, 2000 |

INAMRINONE LACTATE

INJECTABLE; INJECTION
**AMRINONE**

| | | | | |
|---|---|---|---|---|
| **AP** | BEDFORD | **EQ 5MG BASE/ML** | **N75513 001** | MAY 09, 2000 |

INAMRINONE LACTATE

INJECTABLE; INJECTION
**AMRINONE LACTATE**

| | | | | |
|---|---|---|---|---|
| **AP** | BAXTER PHARM PROD | **EQ 5MG BASE/ML** | **N75542 001** | MAY 10, 2000 |

INDOMETHACIN

CAPSULE; ORAL
**INDOMETHACIN**

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | **AB** | WATSON LABS | **25MG** | **N70529 001** | OCT 18, 1985 |
| > DLT > | **AB** | | **50MG** | **N70530 001** | OCT 18, 1985 |
| > ADD > | @ | | 25MG | N70529 001 | OCT 18, 1985 |
| > ADD > | @ | | 50MG | N70530 001 | OCT 18, 1985 |

INSULIN ASPART RECOMBINANT

INJECTABLE; INJECTION
NOVOLOG

| | | | | |
|---|---|---|---|---|
| + | NOVO NORDISK | 100 UNITS/ML | N20986 001 | JUN 07, 2000 |

INSULIN GLARGINE

INJECTABLE; INJECTION
LANTUS

| | | | | |
|---|---|---|---|---|
| + | AVENTIS PHARMS | 100 UNITS/ML | N21081 001 | APR 20, 2000 |

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50

| | | | | |
|---|---|---|---|---|
| + | LILLY | 50 UNITS/ML;50 UNITS/ML | N21018 001 | DEC 22, 1999 |

HUMALOG MIX 75/25

| | | | | |
|---|---|---|---|---|
| + | LILLY | 25 UNITS/ML;75 UNITS/ML | N21017 001 | DEC 22, 1999 |

INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50
+ LILLY 100 UNITS/ML N21018 001 DEC 22, 1999

HUMALOG MIX 75/25
+ LILLY 100 UNITS/ML N21017 001 DEC 22, 1999

INULIN

INJECTABLE; INJECTION
INULIN AND SODIUM CHLORIDE
+ CYPROS 100MG/ML N02282 001
+ QUESTCOR PHARM 100MG/ML N02282 001

IOPAMIDOL

INJECTABLE; INJECTION
**IOPAMIDOL-200**
AP COOK IMAGING 41% N74881 001 JUL 28, 2000

**IOPAMIDOL-250**
AP COOK IMAGING 51% N74881 002 JUL 28, 2000

**IOPAMIDOL-300**
AP COOK IMAGING 61% N74881 003 JUL 28, 2000

**IOPAMIDOL-370**
AP COOK IMAGING 76% N74881 004 JUL 28, 2000

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION
GLOFIL-125
CYPROS 250-300 uCi/ML N17279 001
QUESTCOR PHARM 250-300 uCi/ML N17279 001

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
**IPRATROPIUM BROMIDE**
AN STERIPAK 0.02% N75313 001 FEB 07, 2000

ISOCARBOXAZID

TABLET; ORAL
MARPLAN
+ OXFORD PHARM 10MG N11961 001

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
**BRONKOSOL**
AN + SANOFI SYNTHELABO 1% N12339 008
@ 1% N12339 008

**ISOETHARINE HCL**
> DLT > AN + ASTRA PHARMS 0.125% N89615 001 JUN 13, 1991
> DLT > AN + 0.167% N89616 001 JUN 13, 1991
> DLT > + 0.062% N89614 001 JUN 13, 1991
> DLT > AN + ASTRAZENECA 0.2% N89617 001 JUN 13, 1991
> DLT > AN + 0.25% N89618 001 JUN 13, 1991
> ADD > @ 0.062% N89614 001 JUN 13, 1991
> ADD > @ 0.125% N89615 001 JUN 13, 1991
> ADD > @ 0.167% N89616 001 JUN 13, 1991
> ADD > @ 0.2% N89617 001 JUN 13, 1991
> ADD > @ 0.25% N89618 001 JUN 13, 1991
> DLT > AN + INTL MEDICATION 0.1% N86651 003
> DLT > AN + 0.167% N86651 005
> DLT > AN 0.2% N86651 006
> DLT > AN + 0.25% N86651 007
> DLT > AN 1% N86651 008
> DLT > + 0.077% N86651 001
> DLT > + 0.08% N86651 002
> DLT > + 0.143% N86651 004
> ADD > @ 0.077% N86651 001
> ADD > 0.08% N86651 002
> ADD > @ 0.1% N86651 003
> ADD > 0.143% N86651 004
> ADD > @ 0.167% N86651 005
> ADD > @ 0.2% N86651 006
> ADD > @ 0.25% N86651 007

## ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | | @ | INTL MEDICATION | 1% | N86651 008 |
| > DLT > | AN | | ROXANE | 0.1% | N87396 001 |
| > DLT > | AN | | | 0.125% | N87025 001 |
| > DLT > | AN | | | 0.167% | N88226 001 |
| > DLT > | | | | | SEP 16, 1983 |
| > DLT > | AN | | | 0.2% | N87324 001 |
| > DLT > | AN | | | 0.25% | N88275 001 |
| > DLT > | | | | | JUN 03, 1983 |
| | AN | | | 1% | N86899 001 |
| | AN | + | | 1% | N86899 001 |
| > ADD > | | @ | | 0.1% | N87396 001 |
| > ADD > | | @ | | 0.125% | N87025 001 |
| > ADD > | | + | | 0.167% | N88226 001 |
| > ADD > | | | | | SEP 16, 1983 |
| > ADD > | | + | | 0.2% | N87324 001 |
| > ADD > | | @ | | 0.25% | N88275 001 |
| > ADD > | | | | | JUN 03, 1983 |

## ISOETHARINE MESYLATE

AEROSOL, METERED; INHALATION
BRONKOMETER

| | | | | |
|---|---|---|---|---|
| | + | SANOFI SYNTHELABO | 0.34MG/INH | N12339 007 |
| | @ | | 0.34MG/INH | N12339 007 |

## ISOFLURANE

LIQUID; INHALATION
ISOFLURANE

| | | | |
|---|---|---|---|
| AN | RHODIA | 99.9% | N74502 001 |
| | | | JUN 27, 1995 |
| AN | RHONE POULENC | 99.9% | N74502 001 |
| | | | JUN 27, 1995 |

## ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION
ISUPREL

| | | | |
|---|---|---|---|
| + | SANOFI SYNTHELABO | 0.103MG/INH | N11178 001 |
| @ | | 0.103MG/INH | N11178 001 |

SOLUTION; INHALATION
ISUPREL

| | | | |
|---|---|---|---|
| + | SANOFI SYNTHELABO | 0.5% | N06327 002 |

## ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION
ISUPREL

| | | | |
|---|---|---|---|
| + | SANOFI SYNTHELABO | 1% | N06327 003 |
| @ | | 0.5% | N06327 002 |
| @ | | 1% | N06327 003 |

## ISOSORBIDE DINITRATE

TABLET, EXTENDED RELEASE; ORAL
ISORDIL

| | | | | |
|---|---|---|---|---|
| AB | + | WYETH AYERST | 40MG | N12882 001 |
| | | | | JUL 29, 1988 |
| | @ | | 40MG | N12882 001 |
| | | | | JUL 29, 1988 |

ISOSORBIDE DINITRATE

| | | | | |
|---|---|---|---|---|
| AB | | INWOOD LABS | 40MG | N40009 001 |
| | | | | DEC 30, 1998 |
| | + | | 40MG | N40009 001 |
| | | | | DEC 30, 1998 |

## ISOSORBIDE MONONITRATE

TABLET; ORAL
ISOSORBIDE MONONITRATE

| | | | | |
|---|---|---|---|---|
| > ADD > | AB | | WEST WARD | 20MG | N75361 001 |
| > ADD > | | | | | OCT 05, 2000 |

TABLET, EXTENDED RELEASE; ORAL
IMDUR

| | | | | |
|---|---|---|---|---|
| AB | + | SCHERING | 120MG | N20225 003 |
| | | | | MAR 30, 1995 |
| | + | | 120MG | N20225 003 |
| | | | | MAR 30, 1995 |

ISOSORBIDE MONONITRATE

| | | | |
|---|---|---|---|
| AB | DEXCEL LTD | 60MG | N75522 001 |
| | | | APR 17, 2000 |
| AB | KREMERS URBAN | 30MG | N75155 002 |
| | | | JAN 13, 2000 |
| AB | | 120MG | N75155 003 |
| | | | AUG 04, 2000 |
| AB | KV PHARM | 30MG | N75395 001 |
| | | | MAR 16, 2000 |
| AB | | 60MG | N75395 002 |
| | | | MAR 16, 2000 |

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | **ISOSORBIDE MONONITRATE** | | | |
| AB | KV PHARM | 120MG | N75395 003 | MAR 16, 2000 |
| AB | ZENITH GOLDLINE | 60MG | N75448 001 | JUN 19, 2000 |

IVERMECTIN

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | STROMECTOL | | | | |
| | MERCK | 3MG | N50742 002 | > DLT > | OCT 08, 1998 |
| | | | | > DLT > | |
| | | | | > ADD > | |
| | | | | > ADD > | |

KANAMYCIN SULFATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **KANAMYCIN SULFATE** | | |
| AP | PHARMAFAIR | EQ 75MG BASE/2ML | N62668 001 MAY 07, 1987 |
| AP | | EQ 500MG BASE/2ML | N62672 001 MAY 07, 1987 |
| AP | | EQ 1GM BASE/3ML | N62669 001 MAY 07, 1987 |
| @ | | EQ 75MG BASE/2ML | N62668 001 MAY 07, 1987 |
| @ | | EQ 500MG BASE/2ML | N62672 001 MAY 07, 1987 |
| @ | | EQ 1GM BASE/3ML | N62669 001 MAY 07, 1987 |

KETOCONAZOLE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **KETOCONAZOLE** | | | |
| AB | TEVA | 2% | N75581 001 | APR 25, 2000 |
| | **NIZORAL** | | | |
| AB | + MCNEIL CONS | 2% | N19084 001 | DEC 31, 1985 |
| | + | 2% | N19084 001 | DEC 31, 1985 |

KETOCONAZOLE

SHAMPOO; TOPICAL

| | | | | |
|---|---|---|---|---|
| | NIZORAL | | | |
| | + JANSSEN | 2% | N19927 001 | AUG 31, 1990 |
| | + MCNEIL CONS | 2% | N19927 001 | AUG 31, 1990 |

KETOROLAC TROMETHAMINE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | **KETOROLAC TROMETHAMINE** | | | | |
| AB | ROXANE | 10MG | N74790 001 | > DLT > | JUN 26, 1997 |
| @ | | 10MG | N74790 001 | > DLT > | JUN 26, 1997 |

LACTULOSE

SOLUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | **DUPHALAC** | | | |
| AA | SOLVAY | 10GM/15ML | N72372 001 | MAR 22, 1989 |
| @ | | 10GM/15ML | N72372 001 | MAR 22, 1989 |

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **LEUCOVORIN CALCIUM PRESERVATIVE FREE** | | | |
| AP | + ABBOTT | EQ 10MG BASE/ML | N40147 001 | JUN 25, 1997 |
| | + | EQ 10MG BASE/ML | N40147 001 | JUN 25, 1997 |
| AP | BEDFORD | EQ 10MG BASE/ML | N40347 001 | APR 25, 2000 |
| AP | | EQ 350MG BASE/VIAL | N40335 001 | APR 20, 2000 |
| | **WELLCOVORIN** | | | |
| AP | GLAXO WELLCOME | EQ 100MG BASE/VIAL | N89834 001 | JAN 23, 1989 |
| @ | | EQ 100MG BASE/VIAL | N89834 001 | JAN 23, 1989 |

LEUCOVORIN CALCIUM

TABLET; ORAL
**LEUCOVORIN CALCIUM**

| | | | | |
|---|---|---|---|---|
| **AB** | + IMMUNEX | **EQ 15MG BASE** | **N71104 001** | MAR 04, 1987 |
| **AB** | | **EQ 15MG BASE** | **N71104 001** | MAR 04, 1987 |
| **AB** | ROXANE | **EQ 25MG BASE** | **N72736 001** | FEB 22, 1993 |
| **AB** | + | **EQ 25MG BASE** | **N72736 001** | FEB 22, 1993 |

LEUPROLIDE ACETATE

IMPLANT; IMPLANTATION
VIADUR

| | | | | |
|---|---|---|---|---|
| | + ALZA | EQ 65MG BASE | N21088 001 | MAR 03, 2000 |

INJECTABLE; INJECTION
**LEUPROLIDE ACETATE**

| | | | | |
|---|---|---|---|---|
| > ADD > **AP** | GENSIA SICOR PHARMS | **1MG/0.2ML** | **N75471 001** | OCT 25, 2000 |

> ADD >

LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
BETAXON

| | | | | |
|---|---|---|---|---|
| | + ALCON | EQ 0.5% BASE | N21114 001 | FEB 23, 2000 |

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
**LEVOBUNOLOL HCL**

| | | | | |
|---|---|---|---|---|
| **AT** | NOVEX | **0.25%** | **N75473 001** | AUG 03, 2000 |
| **AT** | | **0.5%** | **N75475 001** | AUG 03, 2000 |

LEVOBUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHIROCAINE

| | | | | |
|---|---|---|---|---|
| | PURDUE PHARMA | **EQ 2.5MG BASE/ML** | **N20997 001** | AUG 05, 1999 |
| | | **EQ 5MG BASE/ML** | **N20997 002** | AUG 05, 1999 |
| | + | **EQ 7.5MG BASE/ML** | **N20997 003** | AUG 05, 1999 |
| | PURDUE PHARMA LP | EQ 2.5MG BASE/ML | N20997 001 | AUG 05, 1999 |
| | | EQ 5MG BASE/ML | N20997 002 | AUG 05, 1999 |
| | + | EQ 7.5MG BASE/ML | N20997 003 | AUG 05, 1999 |

LEVOFLOXACIN

SOLUTION/DROPS; OPHTHALMIC
QUIXIN

| | | | | |
|---|---|---|---|---|
| | + SANTEN | 0.5% | N21199 001 | AUG 18, 2000 |

TABLET; ORAL
LEVAQUIN

| | | | | |
|---|---|---|---|---|
| | + JOHNSON RW | 500MG | N20634 002 | DEC 20, 1996 |
| | | 500MG | N20634 002 | DEC 20, 1996 |
| | + | 750MG | N20634 003 | SEP 08, 2000 |

LEVORPHANOL TARTRATE

TABLET; ORAL
**LEVO-DROMORAN**

| | | | | |
|---|---|---|---|---|
| **AB** | + ICN | **2MG** | **N08720 001** | DEC 19, 1991 |
| | + | 2MG | N08720 001 | DEC 19, 1991 |

**LEVORPHANOL TARTRATE**

| | | | | |
|---|---|---|---|---|
| **AB** | ROXANE | **2MG** | **N74278 001** | MAR 31, 2000 |

LEVOTHYROXINE SODIUM

TABLET; ORAL
UNITHROID
STEVENS J

| | | | |
|---|---|---|---|
| | 0.025MG | N21210 001 | AUG 21, 2000 |
| | 0.05MG | N21210 002 | AUG 21, 2000 |
| | 0.075MG | N21210 003 | AUG 21, 2000 |
| | 0.088MG | N21210 004 | AUG 21, 2000 |
| | 0.1MG | N21210 005 | AUG 21, 2000 |
| | 0.112MG | N21210 006 | AUG 21, 2000 |
| | 0.125MG | N21210 007 | AUG 21, 2000 |
| | 0.15MG | N21210 008 | AUG 21, 2000 |
| | 0.175MG | N21210 009 | AUG 21, 2000 |
| | 0.2MG | N21210 010 | AUG 21, 2000 |
| + | 0.3MG | N21210 011 | AUG 21, 2000 |

LINEZOLID

GRANULE, FOR RECONSTITUTION; ORAL
ZYVOX

| | | | |
|---|---|---|---|
| + | PHARMACIA AND UPJOHN 100MG/5ML | N21132 001 | APR 18, 2000 |

INJECTABLE; INJECTION
ZYVOX

| | | | |
|---|---|---|---|
| + | PHARMACIA AND UPJOHN 200MG/100ML | N21131 001 | APR 18, 2000 |

TABLET; ORAL
ZYVOX

| | | | | |
|---|---|---|---|---|
| | PHARMACIA AND UPJOHN 400MG | N21130 001 | > DLT < > DLT < | APR 18, 2000 |
| + | 600MG | N21130 002 | > ADD < | APR 18, 2000 |

LOPINAVIR; RITONAVIR

CAPSULE; ORAL
KALETRA

| | | | |
|---|---|---|---|
| + | ABBOTT | 133.3MG;33.3MG | N21226 001 SEP 15, 2000 |

SOLUTION; ORAL
KALETRA

| | | | |
|---|---|---|---|
| + | ABBOTT | 80MG/ML;20MG/ML | N21251 001 SEP 15, 2000 |

LORAZEPAM

INJECTABLE; INJECTION
**LORAZEPAM**

| | | | |
|---|---|---|---|
| **AP** | MOVA | **2MG/ML** | **N74793 001** MAR 16, 2000 |
| **AP** | | **4MG/ML** | **N74793 002** MAR 16, 2000 |

MAGNESIUM SULFATE

INJECTABLE; INJECTION
**MAGNESIUM SULFATE**

| | | | |
|---|---|---|---|
| **AP** | ABBOTT | **500MG/ML** | **N75151 001** APR 25, 2000 |
| **AP** | + AM PHARM PARTNERS | **500MG/ML** | **N19316 001** SEP 08, 1986 |
| | + | 500MG/ML | N19316 001 SEP 08, 1986 |

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL
AMEN

| | | | |
|---|---|---|---|
| BP | AMARIN PHARMS | 10MG | N83242 001 |
| BP | CARNRICK | 10MG | N83242 001 |
| | CURRETAB | | |
| BP | SOLVAY | 10MG | N85686 001 |
| | @ | 10MG | N85686 001 |

MEGESTROL ACETATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **MEGESTROL ACETATE** | | | |
| **AB** | **PHARMACHEMIE** | **40MG** | **N74745 001** | |
| | | | **FEB 27, 1998** | |
| **AB** | TEVA | **40MG** | **N74745 001** | |
| | | | FEB 27, 1998 | |

MELOXICAM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | MOBIC | | | |
| + | BOEHRINGER INGELHEIM | 7.5MG | N20938 001 | |
| | | | APR 13, 2000 | |

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | MENOTROPINS | | | |
| @ | FERRING | 75 IU/VIAL;75 IU/VIAL | N73598 001 | |
| | | | JAN 30, 1997 | |
| @ | | 150 IU/VIAL;150 IU/VIAL | N73599 001 | |
| | | | JAN 30, 1997 | |
| | **REPRONEX** | | | |
| **AB** | **FERRING** | **75 IU/VIAL;75 IU/VIAL** | **N73598 001** | |
| | | | **JAN 30, 1997** | |
| **AB** | | **150 IU/VIAL;150 IU/VIAL** | **N73599 001** | |
| | | | **JAN 30, 1997** | |

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **MEPERIDINE HCL** | | | |
| **AA** | **MALLINCKRODT** | **50MG** | **N40352 001** | |
| | | | **JUN 13, 2000** | |
| **AA** | | **100MG** | **N40352 002** | |
| | | | **JUN 13, 2000** | |

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | WYAMINE SULFATE | | | |
| + | WYETH AYERST | EQ 30MG BASE/ML | N08248 001 | > DLT > |
| @ | | EQ 30MG BASE/ML | N08248 001 | > DLT > |

MEPROBAMATE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | **MEPROBAMATE** | | |
| **AA** | **LANNETT** | **200MG** | **N14882 002** |
| **AA** | | **400MG** | **N14882 001** |
| @ | | 200MG | N14882 002 |
| @ | | 400MG | N14882 001 |

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | PENTASA | | |
| + | **ROBERTS LABS** | **250MG** | **N20049 001** |
| | | | **MAY 10, 1993** |
| + | SHIRE LABS | 250MG | N20049 001 |
| | | | MAY 10, 1993 |

SUPPOSITORY; RECTAL

| | | | |
|---|---|---|---|
| | **ROWASA** | | |
| + | **SOLVAY** | **500MG** | **N19919 001** |
| | | | **DEC 18, 1990** |
| @ | | 500MG | N19919 001 |
| | | | DEC 18, 1990 |

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20

| | | | |
|---|---|---|---|
| | NORINYL | | |
| @ | SEARLE | 0.1MG;2MG | N13625 004 |
| @ | WATSON LABS | 0.1MG;2MG | N13625 004 |

TABLET; ORAL-21

| | | | |
|---|---|---|---|
| | **NORINYL 1+50 21-DAY** | | |
| **AB** | **SEARLE** | **0.05MG;1MG** | **N13625 002** |
| **AB** | WATSON LABS | **0.05MG;1MG** | **N13625 002** |

METAPROTERENOL SULFATE

SOLUTION; INHALATION

| | | | |
|---|---|---|---|
| | **ALUPENT** | | |
| **AN** | + BOEHRINGER INGELHEIM | **5%** | **N17659 001** |
| | + | 5% | N17659 001 |
| | **METAPROTERENOL SULFATE** | | |
| **AN** | ASTRA PHARMS | **0.4%** | **N71275 001** |
| | | | **JUL 27, 1988** |

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE

| | | | | |
|---|---|---|---|---|
| > DLT > | AN | ASTRA PHARMS | 0.6% | N71018 001<br>JUL 27, 1988 |
| > DLT | | | | |
| > ADD > | | @ ASTRAZENECA | 0.4% | N71275 001<br>JUL 27, 1988 |
| > ADD > | | | | |
| > ADD > | | @ | 0.6% | N71018 001<br>JUL 27, 1988 |
| > ADD > | | | | |
| | | PROMETA | | |
| | AN | MURO | 5% | N73340 001<br>MAR 30, 1992 |
| | | @ | 5% | N73340 001<br>MAR 30, 1992 |

SYRUP; ORAL
METAPROTERENOL SULFATE

| | | | | |
|---|---|---|---|---|
| | AA | NOVEX | 10MG/5ML | N75235 001<br>JAN 27, 2000 |

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
GLUCOPHAGE XR

| | | | | |
|---|---|---|---|---|
| > ADD > | | + BRISTOL MYERS SQUIBB | 500MG | N21202 001<br>OCT 13, 2000 |

METHANTHELINE BROMIDE

TABLET; ORAL
BANTHINE

| | | | | |
|---|---|---|---|---|
| | | + ROBERTS LABS | 50MG | N07390 001 |
| | | + SHIRE LABS | 50MG | N07390 001 |

METHICILLIN SODIUM

INJECTABLE; INJECTION
STAPHCILLIN

| | | | | |
|---|---|---|---|---|
| > DLT > | | + APOTHECON | EQ 900MG BASE/VIAL | N61449 001 |
| > DLT > | | + | EQ 3.6GM BASE/VIAL | N61449 002 |
| > DLT > | | + | EQ 5.4GM BASE/VIAL | N61449 003 |
| > ADD > | | @ | EQ 900MG BASE/VIAL | N61449 001 |
| > ADD > | | @ | EQ 3.6GM BASE/VIAL | N61449 002 |
| > ADD > | | @ | EQ 5.4GM BASE/VIAL | N61449 003 |

METHIMAZOLE

TABLET; ORAL
METHIMAZOLE

| | | | | |
|---|---|---|---|---|
| | AB | APPLIED ANAL | 5MG | N40320 001<br>MAR 31, 2000 |
| | AB | | 10MG | N40320 002<br>MAR 31, 2000 |
| | AB | GENPHARM | 5MG | N40350 001<br>MAR 29, 2000 |
| | AB | | 10MG | N40350 002<br>MAR 29, 2000 |
| | AB | JONES PHARMA | 5MG | N40320 001<br>MAR 31, 2000 |
| | AB | | 10MG | N40320 002<br>MAR 31, 2000 |

TAPAZOLE

| | | | | |
|---|---|---|---|---|
| | AB | LILLY | 5MG | N07517 002 |
| | AB | + | 10MG | N07517 004 |
| | | | 5MG | N07517 002 |
| | | + | 10MG | N07517 004 |

METHOXYFLURANE

LIQUID; INHALATION
PENTHRANE

| | | | | |
|---|---|---|---|---|
| | | + ABBOTT | 99.9% | N13056 001 |
| | | @ | 99.9% | N13056 001 |

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
CONCERTA

| | | | | |
|---|---|---|---|---|
| | | + ALZA | 18MG | N21121 001<br>AUG 01, 2000 |
| | | + | 36MG | N21121 002<br>AUG 01, 2000 |

METADATE ER

| | | | | |
|---|---|---|---|---|
| | AB | + MEDEVA | 10MG | N40306 001<br>OCT 20, 1999 |
| | | + | 10MG | N40306 001<br>OCT 20, 1999 |

METHYLIN ER

| | | | | |
|---|---|---|---|---|
| | AB | MALLINCKRODT | 10MG | N75629 001<br>MAY 09, 2000 |
| | AB | | 20MG | N75629 002<br>MAY 09, 2000 |

METHYLTESTOSTERONE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | ORETON METHYL | | |
| BP | | SCHERING | 10MG | N03158 001 |
| BP | | | 25MG | N03158 002 |
| | @ | | 10MG | N03158 001 |
| | @ | | 25MG | N03158 002 |

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | | METOCLOPRAMIDE HCL | | |
| > DLT > | AB | | WATSON LABS | EQ 10MG BASE | N70645 001 MAY 11, 1987 |
| > DLT > | | | | | N70645 001 |
| > ADD > | | @ | | EQ 10MG BASE | MAY 11, 1987 |
| > ADD > | | | | | |

METOPROLOL TARTRATE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | | LOPRESSOR | | |
| > DLT > | AB | + | NOVARTIS | 50MG | N17963 001 |
| > ADD > | AB | | | 50MG | N17963 001 |

MICONAZOLE NITRATE

INSERT, CREAM; VAGINAL, TOPICAL

| | | | | |
|---|---|---|---|---|
| | | MONISTAT DUAL- PAK | | |
| | + | ADVANCED CARE PRODS | 1.2GM,2% | N20968 001 JUN 30, 1999 |
| | + | PERSONAL PRODS | 1.2GM,2% | N20968 001 JUN 30, 1999 |

TAMPON; VAGINAL

| | | | | |
|---|---|---|---|---|
| | | MONISTAT 5 | | |
| | @ | ADVANCED CARE PRODS | 100MG | N18592 001 OCT 27, 1989 |
| | @ | PERSONAL PRODS | 100MG | N18592 001 OCT 27, 1989 |

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | | MIDAZOLAM HCL | | |
| | AP | | ABBOTT | EQ 1MG BASE/ML | N75293 001 JUN 20, 2000 |
| | AP | | | EQ 1MG BASE/ML | N75409 002 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75293 002 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75409 001 JUN 20, 2000 |
| | AP | | AESGEN | EQ 1MG BASE/ML | N75154 002 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75154 001 JUN 20, 2000 |
| > ADD > | AP | | APOTEX | EQ 1MG BASE/ML | N75637 001 OCT 31, 2000 |
| > ADD > | AP | | | EQ 5MG BASE/ML | N75637 002 OCT 31, 2000 |
| > ADD > | AP | | APOTHECON | EQ 5MG BASE/ML | N75641 001 OCT 19, 2000 |
| > ADD > | AP | | ASTRAZENECA PHARMS | EQ 5MG BASE/ML | N75263 001 JUN 26, 2000 |
| > ADD > | AP | | BAXTER PHARM PROD | EQ 1MG BASE/ML | N75324 001 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75324 002 JUN 20, 2000 |
| | AP | | BEDFORD | EQ 1MG BASE/ML | N75247 002 JUN 23, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75247 001 JUN 23, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75249 001 JUN 23, 2000 |
| | AP | | BEN VENUE | EQ 1MG BASE/ML | N75421 002 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75421 001 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75455 001 JUN 20, 2000 |
| | AP | | ESI LEDERLE | EQ 1MG BASE/ML | N75243 001 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75243 002 JUN 20, 2000 |
| | AP | | FAULDING | EQ 1MG BASE/ML | N75396 001 JUN 20, 2000 |
| | AP | | | EQ 5MG BASE/ML | N75396 002 JUN 20, 2000 |

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

**MIDAZOLAM HCL**

| | | | | |
|---|---|---|---|---|
| AP | | FAULDING | EQ 5MG BASE/ML | N75484 001<br>JUN 20, 2000 |
| AP | | TAYLOR | EQ 5MG BASE/ML | N75481 001<br>JUN 30, 2000 |
| AP | | TAYLOR PHARMA | EQ 1MG BASE/ML | N75494 001<br>JUN 30, 2000 |
| AP | | | EQ 5MG BASE/ML | N75494 002<br>JUN 30, 2000 |

**VERSED**

| | | | | |
|---|---|---|---|---|
| AP | + | HLR | EQ 1MG BASE/ML | N18654 002<br>MAY 26, 1987 |
| AP | + | | EQ 5MG BASE/ML | N18654 001<br>DEC 20, 1985 |
| AP | + | ROCHE | EQ 1MG BASE/ML | N18654 002<br>MAY 26, 1987 |
| AP | + | | EQ 5MG BASE/ML | N18654 001<br>DEC 20, 1985 |

MIFEPRISTONE

TABLET; ORAL

MIFEPREX

| | | | | |
|---|---|---|---|---|
| | + | POPULATION COUNCIL | 200MG | N20687 001<br>SEP 28, 2000 |

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

**MINOCIN**

| | | | | |
|---|---|---|---|---|
| AB | + | LEDERLE | EQ 100MG BASE | N50649 002<br>MAY 31, 1990 |
| AB | | | EQ 100MG BASE | N50649 002<br>MAY 31, 1990 |

**MINOCYCLINE HCL**

| | | | | |
|---|---|---|---|---|
| AB | + | DANBURY PHARMA | EQ 75MG BASE | N63065 002<br>JUN 10, 1999 |
| AB | | | EQ 75MG BASE | N63065 002<br>JUN 10, 1999 |
| AB | | | EQ 100MG BASE | N63065 001<br>DEC 30, 1991 |
| AB | + | | EQ 100MG BASE | N63065 001<br>DEC 30, 1991 |

MONTELUKAST SODIUM

TABLET, CHEWABLE; ORAL

SINGULAIR

| | | | | |
|---|---|---|---|---|
| | | MERCK | EQ 4MG BASE | N20830 002<br>MAR 03, 2000 |

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

**MORPHINE SULFATE**

| | | | | |
|---|---|---|---|---|
| AB | | ENDO PHARMS | 100MG | N75295 004<br>SEP 15, 2000 |
| AB | | | 200MG | N75295 005<br>SEP 15, 2000 |
| AB | | ESI LEDERLE | 15MG | N75407 001<br>JAN 28, 2000 |

NABUMETONE

TABLET; ORAL

**NABUMETONE**

| | | | | |
|---|---|---|---|---|
| AB | | COPLEY PHARM | 750MG | N75179 001<br>JUN 06, 2000 |
| AB | | TEVA | 500MG | N75189 001<br>MAY 26, 2000 |

**RELAFEN**

| | | | | |
|---|---|---|---|---|
| AB | | SMITHKLINE BEECHAM | 500MG | N19583 001<br>DEC 24, 1991 |
| AB | + | | 750MG | N19583 002<br>DEC 24, 1991 |
| | | | 500MG | N19583 001<br>DEC 24, 1991 |
| | + | | 750MG | N19583 002<br>DEC 24, 1991 |

NADOLOL

TABLET; ORAL

**CORGARD**

| | | | | |
|---|---|---|---|---|
| AB | | APOTHECON | 40MG | N18063 001 |
| AB | + | | 40MG | N18063 001 |

NAFCILLIN SODIUM

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | NALLPEN | | | |
| > DLT > | AP | SMITHKLINE BEECHAM | EQ 1GM BASE/VIAL | N62755 001 | DEC 19, 1986 |
| > DLT > | | | | | |
| > DLT > | AP | | EQ 2GM BASE/VIAL | N62755 002 | DEC 19, 1986 |
| > DLT > | | | | | |
| > ADD > | | @ | EQ 1GM BASE/VIAL | N62755 001 | DEC 19, 1986 |
| > ADD > | | | | | |
| > ADD > | | @ | EQ 2GM BASE/VIAL | N62755 002 | DEC 19, 1986 |
| > ADD > | | | | | |

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | UNIPEN | | | |
| | + | WYETH AYERST | EQ 500MG BASE | N50462 001 | |
| | | @ | EQ 500MG BASE | N50462 001 | |

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | REVEX | | | |
| | + | BAXTER PHARM PROD | EQ 0.1MG BASE/ML | N20459 001 | APR 17, 1995 |
| | + | | EQ 1MG BASE/ML | N20459 002 | APR 17, 1995 |
| | + | OHMEDA | EQ 0.1MG BASE/ML | N20459 001 | APR 17, 1995 |
| | + | | EQ 1MG BASE/ML | N20459 002 | APR 17, 1995 |

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | NALOXONE HCL | | | |
| > DLT > | AP | ASTRAZENECA | 0.02MG/ML | N72081 001 | APR 11, 1989 |
| > DLT > | | | | | |
| > DLT > | AP | | 0.4MG/ML | N72086 001 | APR 11, 1989 |
| > DLT > | | | | | |
| > DLT > | AP | | 1MG/ML | N72091 001 | APR 11, 1989 |
| > DLT > | | | | | |
| > ADD > | | @ | 0.02MG/ML | N72081 001 | APR 11, 1989 |
| > ADD > | | | | | |
| > ADD > | | @ | 0.4MG/ML | N72086 001 | APR 11, 1989 |
| > ADD > | | | | | |
| > ADD > | | @ | 1MG/ML | N72091 001 | APR 11, 1989 |
| > ADD > | | | | | |

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | PENTAZOCINE AND NALOXONE HYDROCHLORIDES | | | |
| AB | | RANBAXY | EQ 0.5MG BASE; EQ 50MG BASE | N75523 001 | MAR 17, 2000 |

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | NALTREXONE HCL | | | |
| AB | | EON | 50MG | N75434 001 | MAR 08, 2000 |

NAPROXEN

TABLET, DELAYED RELEASE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | NAPROXEN | | | |
| AB | | GENEVA PHARMS TECH | 375MG | N75061 001 | FEB 18, 1998 |
| AB | | | 500MG | N75061 002 | FEB 18, 1998 |
| AB | | INVAMED | 375MG | N75061 001 | FEB 18, 1998 |
| AB | | | 500MG | N75061 002 | FEB 18, 1998 |

NIACIN

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | NIACIN | | | |
| AA | | GLOBAL PHARM | 500MG | N83115 001 | |
| | | @ IMPAX LABS | 500MG | N83115 001 | |
| | | NIACOR | | | |
| AA | | UPSHER SMITH | 500MG | N40378 001 | MAY 03, 2000 |

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | ADALAT CC | | | |
| AB | + | BAYER | 30MG | N20198 001 | APR 21, 1993 |

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **ADALAT CC** | | |
| BC | + | BAYER | 30MG | N20198 001<br>APR 21, 1993 |
| | | **NIFEDIPINE** | | |
| AB | | BIOVAIL | 60MG | N75289 001<br>SEP 27, 2000 |
| AB | | ELAN PHARM | 30MG | N75128 001<br>MAR 10, 2000 |
| | | **PROCARDIA XL** | | |
| AB | + | PFIZER | 60MG | N19684 002<br>SEP 06, 1989 |
| BC | + | | 60MG | N19684 002<br>SEP 06, 1989 |

NITROFURAZONE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **FURACIN** | | |
| | + | ROBERTS LABS | 0.2% | N83789 001 |
| | + | SHIRE LABS | 0.2% | N83789 001 |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **FURACIN** | | |
| AT | + | ROBERTS LABS | 0.2% | N05795 001 |
| AT | + | SHIRE LABS | 0.2% | N05795 001 |

NITROGLYCERIN

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **NITRO IV** | | |
| AP | + | POHL BOSKAMP | 5MG/ML | N18672 002<br>AUG 30, 1983 |
| | @ | | 5MG/ML | N18672 002<br>AUG 30, 1983 |

TABLET; SUBLINGUAL

| | | | | |
|---|---|---|---|---|
| | | NITROSTAT | | |
| | | PARKE DAVIS | 0.3MG | N21134 001<br>MAY 01, 2000 |
| | | | 0.4MG | N21134 002<br>MAY 01, 2000 |
| | + | | 0.6MG | N21134 003<br>MAY 01, 2000 |

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **NORTRIPTYLINE HCL** | | |
| AB | | TARO | EQ 10MG BASE | N75520 004<br>MAY 08, 2000 |
| AB | | | EQ 25MG BASE | N75520 003<br>MAY 08, 2000 |
| AB | | | EQ 50MG BASE | N75520 001<br>MAY 08, 2000 |
| AB | | | EQ 75MG BASE | N75520 002<br>MAY 08, 2000 |

SOLUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | **NORTRIPTYLINE HCL** | | |
| AA | | PHARM ASSOC | EQ 10MG BASE/5ML | N75606 001<br>AUG 28, 2000 |

NYSTATIN

TABLET; VAGINAL

| | | | | |
|---|---|---|---|---|
| | | **NYSTATIN** | | |
| AT | | ODYSSEY PHARMS | 100,000 UNITS | N62615 001<br>OCT 17, 1985 |
| AT | | SIDMAK LABS NJ | 100,000 UNITS | N62615 001<br>OCT 17, 1985 |

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | SANDOSTATIN | | |
| | | NOVARTIS | EQ 0.2MG BASE/ML | N19667 004<br>JUN 12, 1991 |
| | | | EQ 1MG BASE/ML | N19667 005<br>JUN 12, 1991 |
| | + | | EQ 0.2MG BASE/ML | N19667 004<br>JUN 12, 1991 |
| | + | | EQ 1MG BASE/ML | N19667 005<br>JUN 12, 1991 |
| | | SANDOSTATIN LAR | | |
| | | NOVARTIS | EQ 10MG BASE/VIAL | N21008 001<br>NOV 25, 1998 |
| | | | EQ 20MG BASE/VIAL | N21008 002<br>NOV 25, 1998 |
| | + | | EQ 10MG BASE/VIAL | N21008 001<br>NOV 25, 1998 |

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN LAR

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | NOVARTIS | EQ 20MG BASE/VIAL | N21008 002 NOV 25, 1998 | | | | |

OLANZAPINE

TABLET; ORAL
ZYPREXA

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | LILLY | 2.5MG | N20592 001 SEP 30, 1996 | | | | |
| + | | 10MG | N20592 004 SEP 30, 1996 | | | | |
| @ | | 15MG | N20592 005 SEP 09, 1997 | | | | |
| + | | 2.5MG | N20592 001 SEP 30, 1996 | > DLT > > DLT > | | | |
| | | 10MG | N20592 004 SEP 30, 1996 | > DLT > > DLT > | | | |
| + | | 15MG | N20592 005 SEP 09, 1997 | > DLT > > DLT > | | | |

TABLET, ORALLY DISINTEGRATING; ORAL
ZYPREXA ZYDIS

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | LILLY | 5MG | N21086 001 APR 06, 2000 | > ADD > > ADD > | | | |
| | | 10MG | N21086 002 APR 06, 2000 | > ADD > > ADD > | | | |
| | | 15MG | N21086 003 APR 06, 2000 | > ADD > > ADD > | | | |
| + | | 20MG | N21086 004 APR 06, 2000 | > ADD > > ADD > | | | |

ORLISTAT

CAPSULE; ORAL
XENICAL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| + | HLR | 120MG | N20766 001 APR 23, 1999 | > ADD > > ADD > | | | |
| + | ROCHE | 120MG | N20766 001 APR 23, 1999 | > DLT > > DLT > > ADD > > ADD > | | | |

ORPHENADRINE CITRATE

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

| | | | | |
|---|---|---|---|---|
| **AB** | EON | **100MG** | **N40327 001** | FEB 15, 2000 |
| **AB** | GENEVA PHARMS TECH | **100MG** | **N40284 001** | JUN 19, 1998 |
| **AB** | IMPAX PHARM | **100MG** | **N40368 001** | JUN 23, 2000 |
| **AB** | INVAMED | **100MG** | **N40284 001** | JUN 19, 1998 |

OXACILLIN SODIUM

INJECTABLE; INJECTION
**BACTOCILL**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AP** | + | SMITHKLINE BEECHAM | **EQ 500MG BASE/VIAL** | **N61334 009** | MAR 26, 1982 |
| **AP** | + | | **EQ 1GM BASE/VIAL** | **N61334 006** | MAR 26, 1982 |
| **AP** | + | | **EQ 2GM BASE/VIAL** | **N61334 007** | MAR 26, 1982 |
| **AP** | + | | **EQ 4GM BASE/VIAL** | **N61334 008** | MAR 26, 1982 |
| **AP** | + | | **EQ 10GM BASE/VIAL** | **N61334 010** | |
| | @ | | EQ 500MG BASE/VIAL | N61334 009 | MAR 26, 1982 |
| | @ | | EQ 1GM BASE/VIAL | N61334 006 | MAR 26, 1982 |
| | @ | | EQ 2GM BASE/VIAL | N61334 007 | MAR 26, 1982 |
| | @ | | EQ 4GM BASE/VIAL | N61334 008 | MAR 26, 1982 |
| | @ | | EQ 10GM BASE/VIAL | N61334 010 | |

**OXACILLIN SODIUM**

| | | | | | |
|---|---|---|---|---|---|
| **AP** | | APOTHECON | **EQ 500MG BASE/VIAL** | **N61490 002** | |
| **AP** | + | | **EQ 500MG BASE/VIAL** | **N61490 002** | |
| **AP** | | | **EQ 10GM BASE/VIAL** | **N61490 006** | MAY 09, 1991 |
| **AP** | + | | **EQ 10GM BASE/VIAL** | **N61490 006** | MAY 09, 1991 |
| **AP** | | MARSAM | **EQ 4GM BASE/VIAL** | **N62856 005** | OCT 26, 1988 |
| | | | EQ 4GM BASE/VIAL | N62856 005 | OCT 26, 1988 |

OXCARBAZEPINE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | TRILEPTAL | | | |
| | NOVARTIS | 150MG | N21014 001 | JAN 14, 2000 |
| | | 300MG | N21014 002 | JAN 14, 2000 |
| + | | 600MG | N21014 003 | JAN 14, 2000 |

OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | DITROPAN XL | | | |
| AB | + ALZA | 5MG | N20897 001 | DEC 16, 1998 |
| | + | 5MG | N20897 001 | DEC 16, 1998 |

OXYCODONE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ROXICODONE | | | |
| | ROXANE | 15MG | N21011 001 | AUG 31, 2000 |
| + | | 30MG | N21011 002 | AUG 31, 2000 |

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | OXYCONTIN | | | |
| BX | + PURDUE PHARMA | 10MG | N20553 001 | DEC 12, 1995 |
| | + PURDUE PHARMA LP | 10MG | N20553 001 | DEC 12, 1995 |
| | + | 160MG | N20553 005 | MAR 15, 2000 |
| | ROXICODONE | | | |
| BX | ROXANE | 10MG | N20932 001 | OCT 26, 1998 |
| | + | 30MG | N20932 002 | OCT 26, 1998 |
| | @ | 10MG | N20932 001 | OCT 26, 1998 |
| | @ | 30MG | N20932 002 | OCT 26, 1998 |

PACLITAXEL

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | PACLITAXEL | | | |
| AP | BAKER NORTON | 6MG/ML | N75184 001 | SEP 15, 2000 |
| | TAXOL | | | |
| AP | + BRISTOL MYERS SQUIBB | 6MG/ML | N20262 001 | DEC 29, 1992 |
| | + | 6MG/ML | N20262 001 | DEC 29, 1992 |

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | PROTONIX | | | |
| | + WYETH AYERST | EQ 40MG BASE | N20987 001 | FEB 02, 2000 |

PEMOLINE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PEMOLINE | | | |
| AB | AMIDE PHARM | 18.75MG | N75595 001 | FEB 28, 2000 |
| AB | | 37.5MG | N75595 002 | FEB 28, 2000 |
| AB | | 75MG | N75595 003 | FEB 28, 2000 |
| AB | COPLEY PHARM | 18.75MG | N75030 003 | FEB 22, 2000 |
| AB | GENEVA PHARMS TECH | 18.75MG | N75286 001 | DEC 27, 1999 |
| AB | | 37.5MG | N75286 002 | JUN 30, 1999 |
| AB | | 75MG | N75286 003 | JUN 30, 1999 |
| AB | INVAMED | 18.75MG | N75286 001 | DEC 27, 1999 |
| AB | | 37.5MG | N75286 002 | JUN 30, 1999 |
| AB | | 75MG | N75286 003 | JUN 30, 1999 |
| AB | VINTAGE PHARMS | 18.75MG | N75328 001 | APR 19, 2000 |
| AB | | 37.5MG | N75328 002 | APR 19, 2000 |

PEMOLINE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **PEMOLINE** | | |
| AB | | VINTAGE PHARMS | 75MG | N75328 003<br>APR 19, 2000 |
| AB | | WATSON LABS | 37.5MG | N75287 002<br>SEP 18, 2000 |
| AB | | | 75MG | N75287 003<br>SEP 18, 2000 |

TABLET, CHEWABLE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **CYLERT** | | |
| AB | + | ABBOTT | 37.5MG | N17703 001 |
| | + | | 37.5MG | N17703 001 |
| | | **PEMOLINE** | | |
| AB | | AMIDE PHARM | 37.5MG | N75678 001<br>JUL 26, 2000 |
| AB | | COPLEY PHARM | 37.5MG | N75555 001<br>FEB 18, 2000 |

PENICILLIN G BENZATHINE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | | BICILLIN L-A | | |
| >ADD< | BC | + | KING PHARMS | 600,000 UNITS/ML | N50141 001 |
| >ADD< | | + | | 300,000 UNITS/ML | N50141 003 |
| >DLT< | BC | + | WYETH AYERST | 600,000 UNITS/ML | N50141 001 |
| >DLT< | | + | | 300,000 UNITS/ML | N50141 003 |

PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | | BICILLIN C-R | | |
| >ADD< | | + | KING PHARMS | 150,000 UNITS/ML; | |
| >ADD< | | | | 150,000 UNITS/ML | N50138 002 |
| >ADD< | | + | | 300,000 UNITS/ML; | |
| >ADD< | | | | 300,000 UNITS/ML | N50138 001 |
| >DLT< | | + | WYETH AYERST | 150,000 UNITS/ML; | |
| >DLT< | | | | 150,000 UNITS/ML | N50138 002 |
| >DLT< | | + | | 300,000 UNITS/ML; | |
| >DLT< | | | | 300,000 UNITS/ML | N50138 001 |
| | | | BICILLIN C-R 900/300 | | |
| >ADD< | | + | KING PHARMS | 900,000 UNITS/2ML; | |
| >ADD< | | | | 300,000 UNITS/2ML | N50138 003 |
| >DLT< | | + | WYETH AYERST | 900,000 UNITS/2ML; | |
| >DLT< | | | | 300,000 UNITS/2ML | N50138 003 |

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **WYCILLIN** | | |
| AP | KING PHARMS | 300,000 UNITS/ML | N60101 002 |
| AP | | 600,000 UNITS/ML | N60101 001 |
| AP | WYETH AYERST | 300,000 UNITS/ML | N60101 002 |
| AP | | 600,000 UNITS/ML | N60101 001 |

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **PENTACARINAT** | | |
| AP | ARMOUR PHARM | 300MG/VIAL | N73447 001<br>APR 28, 1994 |
| | Ⓡ | 300MG/VIAL | N73447 001<br>APR 28, 1994 |

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | **PENTOXIFYLLINE** | | |
| AB | IMPAX LABS | 400MG | N75093 001<br>AUG 10, 1999 |
| AB | IMPAX PHARM | 400MG | N75093 001<br>AUG 10, 1999 |

PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE

PASTE; TOPICAL

SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS

| | | | |
|---|---|---|---|
| + | US ARMY | 50%;50% | N21084 001<br>FEB 17, 2000 |

PERGOLIDE MESYLATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | PERMAX | | |
| >DLT< | | LILLY | EQ 0.05MG BASE | N19385 001<br>DEC 30, 1988 |
| >DLT< | + | | EQ 1MG BASE | N19385 003<br>DEC 30, 1988 |
| >DLT< | + | | EQ 0.05MG BASE | N19385 001<br>DEC 30, 1988 |
| >ADD< | | | | |
| >ADD< | | | | |

PERGOLIDE MESYLATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PERMAX | | | |
| > ADD > | LILLY | EQ 1MG BASE | N19385 003 | DEC 30, 1988 |
| > ADD > | | | | |

PERINDOPRIL ERBUMINE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ACEON | | | |
| @ | SOLVAY | 2MG | N20184 001 | DEC 30, 1993 |
| @ | | 4MG | N20184 002 | DEC 30, 1993 |
| @ | | 8MG | N20184 003 | DEC 30, 1993 |
| | SOLVAY PHARMA | 2MG | N20184 001 | DEC 30, 1993 |
| | | 4MG | N20184 002 | DEC 30, 1993 |
| + | | 8MG | N20184 003 | DEC 30, 1993 |

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | BONTRIL PDM | | | |
| AA | AMARIN PHARMS | 35MG | N85272 001 | |
| AA | CARNRICK | 35MG | N85272 001 | |
| | CAM-METRAZINE | | | |
| AA | CAMALL | 35MG | N83922 001 | |
| AA + | | 35MG | N83922 001 | |
| | PLEGINE | | | |
| AA + | WYETH AYERST | 35MG | N12248 001 | |
| @ | | 35MG | N12248 001 | |

PHYTONADIONE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | KONAKION | | | |
| BP | ROCHE | 1MG/0.5ML | N11745 001 | |
| BP | | 10MG/ML | N11745 003 | |
| @ | | 1MG/0.5ML | N11745 001 | |
| @ | | 10MG/ML | N11745 003 | |

PIROXICAM

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | PIROXICAM | | | |
| AB | ROXANE | 10MG | N73651 001 | FEB 26, 1993 |
| AB | | 20MG | N73651 002 | FEB 26, 1993 |
| @ | | 10MG | N73651 001 | FEB 26, 1993 |
| @ | | 20MG | N73651 002 | FEB 26, 1993 |

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | K-DUR 10 | | | |
| AB + | KEY PHARMS | 10MEQ | N19439 002 | JUN 13, 1986 |
| BC + | | 10MEQ | N19439 002 | JUN 13, 1986 |
| | KLOR-CON M10 | | | |
| AB | UPSHER SMITH | 10MEQ | N74726 002 | AUG 09, 2000 |

PREDNISOLONE

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | PREDNISOLONE | | | |
| AA | COPLEY PHARM | 15MG/5ML | N40322 001 | JAN 19, 2000 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PREDNISOLONE | | | |
| BX | GLOBAL PHARM | 5MG | N80780 001 | |
| @ | IMPAX LABS | 5MG | N80780 001 | |
| BX | PHOENIX LABS NY | 5MG | N80322 001 | |
| @ | | 5MG | N80322 001 | |
| > DLT > BX | ROXANE | 5MG | N80327 002 | |
| > ADD > @ | | 5MG | N80327 002 | |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | PREDNISOLONE SODIUM PHOSPHATE | | | |
| AT | ALCON UNIVERSAL | EQ 0.11% PHOSPHATE | N81043 001 | OCT 24, 1991 |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

**PREDNISOLONE SODIUM PHOSPHATE**

| | | | | |
|---|---|---|---|---|
| **AT** | ALCON UNIVERSAL | **EQ 0.9% PHOSPHATE** | **N81044 001** | |
| | | | OCT 24, 1991 | |
| **AT** | STERIS | **EQ 0.11% PHOSPHATE** | **N81043 001** | |
| | | | OCT 24, 1991 | |
| **AT** | | **EQ 0.9% PHOSPHATE** | **N81044 001** | |
| | | | OCT 24, 1991 | |

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

**SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE**

| | | | | |
|---|---|---|---|---|
| **AT** | ALCON UNIVERSAL | **EQ 0.23% PHOSPHATE;10%** | **N73630 001** | |
| | | | MAY 27, 1993 | |
| **AT** | STERIS | **EQ 0.23% PHOSPHATE;10%** | **N73630 001** | |
| | | | MAY 27, 1993 | |

PREDNISONE

SYRUP; ORAL

LIQUID PRED

| | | | | |
|---|---|---|---|---|
| + | MURO | 5MG/5ML | N87611 002 | |
| | | | SEP 07, 1982 | |
| @ | | 5MG/5ML | N87611 002 | |
| | | | SEP 07, 1982 | |

TABLET; ORAL

**PREDNICEN-M**

| | | | | |
|---|---|---|---|---|
| **AB** | CENT PHARMS | **5MG** | **N84655 001** | |
| @ | SCHWARZ PHARMA | 5MG | N84655 001 | |

**PREDNISONE**

| | | | | |
|---|---|---|---|---|
| > DLT > **AB** | GLOBAL PHARM | **5MG** | **N80782 001** | |
| > ADD > @ | IMPAX LABS | 5MG | N80782 001 | |
| BX | PHOENIX LABS NY | 5MG | N80321 001 | |
| BX | | 20MG | N83807 001 | |
| @ | | 5MG | N80321 001 | |
| @ | | 20MG | N83807 001 | |

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

**PROCAN SR**

| | | | | |
|---|---|---|---|---|
| > DLT > > DLT > **AB** + | PARKEDALE | **500MG** | **N86065 001** | |

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

**PROCAN SR**

| | | | | |
|---|---|---|---|---|
| > DLT > > DLT > **AB** + | PARKEDALE | **750MG** | **N87510 001** | |
| > DLT > | | | APR 01, 1982 | |
| > DLT > **AB** + | | **1GM** | **N88489 001** | |
| > DLT > | | | JAN 16, 1985 | |
| > ADD > @ | | 500MG | N86065 001 | |
| > ADD > @ | | 750MG | N87510 001 | |
| > ADD > | | | APR 01, 1982 | |
| > ADD > @ | | 1GM | N88489 001 | |
| > ADD > | | | JAN 16, 1985 | |

PROCHLORPERAZINE

SUPPOSITORY; RECTAL

**COMPRO**

| | | | | |
|---|---|---|---|---|
| **AB** | PADDOCK | **25MG** | **N40246 001** | |
| | | | JUN 28, 2000 | |

PROGESTERONE

CAPSULE; ORAL

PROMETRIUM

| | | | | |
|---|---|---|---|---|
| | SCHERING PLOUGH | 100MG | N19781 001 | |
| | | | MAY 14, 1998 | |
| | | 200MG | N19781 002 | |
| | | | OCT 15, 1999 | |
| + | | 300MG | N19781 003 | |
| | | | OCT 15, 1999 | |
| | UNIMED PHARMS | 100MG | N19781 001 | |
| | | | MAY 14, 1998 | |
| + | | 200MG | N19781 002 | |
| | | | OCT 15, 1999 | |
| @ | | 300MG | N19781 003 | |
| | | | OCT 15, 1999 | |

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

**PROMETHAZINE HCL**

| | | | | |
|---|---|---|---|---|
| **AP** | ABBOTT | **25MG/ML** | **N40372 001** | |
| | | | JUN 08, 2000 | |
| **AP** | | **50MG/ML** | **N40372 002** | |
| | | | JUN 08, 2000 | |

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | | **PROPAFENONE HCL** | | | |
| > ADD > | **AB** | WATSON LABS | **150MG** | **N75203 001** | |
| > ADD > | | | | OCT 24, 2000 | |
| > ADD > | **AB** | | **225MG** | **N75203 002** | |
| > ADD > | | | | OCT 24, 2000 | |
| | | **RYTHMOL** | | | |
| > ADD > | **AB** | KNOLL PHARM | **150MG** | **N19151 001** | |
| > ADD > | | | | NOV 27, 1989 | |
| > ADD > | **AB** | | **225MG** | **N19151 003** | |
| > ADD > | | | | NOV 20, 1992 | |
| > DLT > | | | 150MG | N19151 001 | |
| > DLT > | | | | NOV 27, 1989 | |
| > DLT > | | | 225MG | N19151 003 | |
| > DLT > | | | | NOV 20, 1992 | |

PROPANTHELINE BROMIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | PRO-BANTHINE | | |
| BP | + | ROBERTS LABS | 7.5MG | N08732 003 |
| BP | + | | 15MG | N08732 002 |
| BP | + | SHIRE LABS | 7.5MG | N08732 003 |
| BP | + | | 15MG | N08732 002 |

PROPARACAINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | | **PROPARACAINE HCL** | | |
| **AT** | | TAYLOR PHARMA | **0.5%** | **N40277 001** |
| | | | | MAR 16, 2000 |

PROPOFOL

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **PROPOFOL** | | |
| **AB** | | GENSIA SICOR PHARMS | **10MG/ML** | **N75392 001** |
| | | | | SEP 19, 2000 |

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **INDERAL** | | |
| **AP** | + | WYETH AYERST | **1MG/ML** | **N16419 001** |
| | | **PROPRANOLOL HCL** | | |
| **AP** | | BEDFORD | **1MG/ML** | **N75792 001** |
| | | | | AUG 29, 2000 |

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | VENTAIRE | | |
| | @ | AVENTIS PHARMS | 2MG | N83459 001 |
| | + | HOECHST MARION RSSL | 2MG | N83459 001 |

QUINIDINE POLYGALACTURONATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | CARDIOQUIN | | |
| | + | PURDUE FREDERICK | 275MG | N11642 002 |
| | @ | | 275MG | N11642 002 |

QUINIDINE SULFATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **QUINIDINE SULFATE** | | |
| **AB** | | PHARMAVITE | **200MG** | **N84627 001** |
| | @ | | 200MG | N84627 001 |

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | | **RANITIDINE HCL** | | |
| > ADD > | **AB** | | GENPHARM | **EQ 150MG BASE** | **N75564 001** |
| > ADD > | | | | | OCT 27, 2000 |
| > ADD > | **AB** | | | **EQ 300MG BASE** | **N75564 002** |
| > ADD > | | | | | OCT 27, 2000 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **RANITIDINE** | | |
| **AB** | | RANBAXY | **EQ 150MG BASE** | **N75439 001** |
| | | | | APR 19, 2000 |
| **AB** | | | **EQ 300MG BASE** | **N75439 002** |
| | | | | APR 19, 2000 |

RESERPINE

TABLET; ORAL
RESERPINE

| | | | |
|---|---|---|---|
| BP | GLOBAL PHARM | 0.1MG | N09627 001 |
| BP | | 0.25MG | N09627 002 |
| | @ IMPAX LABS | 0.1MG | N09627 001 |
| | @ | 0.25MG | N09627 002 |

RISEDRONATE SODIUM

TABLET; ORAL
ACTONEL

| | | | |
|---|---|---|---|
| | PROCTER AND GAMBLE | 5MG | N20835 002<br>APR 14, 2000 |

RIVASTIGMINE TARTRATE

CAPSULE; ORAL
EXELON

| | | | |
|---|---|---|---|
| | NOVARTIS | EQ 1.5MG BASE | N20823 003<br>APR 21, 2000 |
| | | EQ 3MG BASE | N20823 004<br>APR 21, 2000 |
| | | EQ 4.5MG BASE | N20823 005<br>APR 21, 2000 |
| + | | EQ 6MG BASE | N20823 006<br>APR 21, 2000 |

SOLUTION; ORAL
EXELON

| | | | |
|---|---|---|---|
| + | NOVARTIS | EQ 2MG BASE/ML | N21025 001<br>APR 21, 2000 |

ROFECOXIB

TABLET; ORAL
VIOXX

| | | | | |
|---|---|---|---|---|
| + | MERCK | 25MG | N21042 002<br>MAY 20, 1999 | > DLT > |
| | | 25MG | N21042 002<br>MAY 20, 1999 | > ADD ><br>> DLT > |
| + | | 50MG | N21042 003<br>FEB 25, 2000 | > DLT ><br>> ADD ><br>> ADD > |

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE

| | | | |
|---|---|---|---|
| AT | ZENITH GOLDLINE | 2.5% | N85777 001 |
| | @ | 2.5% | N85777 001 |

SEVELAMER HYDROCHLORIDE

TABLET; ORAL
RENAGEL

| | | | |
|---|---|---|---|
| | GELTEX | 400MG | N21179 001<br>JUL 12, 2000 |
| + | | 800MG | N21179 002<br>JUL 12, 2000 |

SIROLIMUS

TABLET; ORAL
RAPAMUNE

| | | | |
|---|---|---|---|
| + | WYETH AYERST | 1MG | N21110 001<br>AUG 25, 2000 |

SODIUM FLUORIDE, F-18

INJECTABLE; INTRAVENOUS
FLUORINE F-18

| | | | |
|---|---|---|---|
| | @ NYCOMED AMERSHAM | 2mCi/ML | N17042 001 |

SODIUM IODIDE, I-131

CAPSULE; ORAL
IODOTOPE

| | | | |
|---|---|---|---|
| | BRACCO | 1-130mCi | N10929 001 |
| | | 1-150mCi | N10929 003 |
| + | | 1-130mCi | N10929 001 |
| + | | 1-150mCi | N10929 003 |
| | SODIUM IODIDE I 131 | | |
| | CIS | 100 uCi | N17316 002 |
| + | | 100 uCi | N17316 002 |
| | MALLINCKRODT | 15-100 uCi | N16517 002 |
| | | 0.8-100mCi | N16517 001 |
| + | | 15-100 uCi | N16517 002 |
| + | | 0.8-100mCi | N16517 001 |

SODIUM IODIDE, I-131

SOLUTION; ORAL
IODOTOPE
> DLT > BRACCO 7-106mCi/BOT N10929 002
> ADD > + 7-106mCi/BOT N10929 002
SODIUM IODIDE I 131
> DLT > CIS 50mCi/ML N17315 001
> ADD > + 50mCi/ML N17315 001
> DLT > MALLINCKRODT 3.5-150mCi/VIAL N16515 001
> ADD > + 3.5-150mCi/VIAL N16515 001

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

TABLET; ORAL
VISICOL
+ INKINE 0.398GM;1.102GM N21097 001 SEP 21, 2000

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION
NORDITROPIN
NOVO NORDISK 5MG/1.5ML N21148 001 JUN 20, 2000
10MG/1.5ML N21148 002 JUN 20, 2000
+ 15MG/1.5ML N21148 003 JUN 20, 2000

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE
AB BERLEX LABS 80MG N19865 001 OCT 30, 1992
AB 120MG N19865 005 APR 20, 1994
AB + 160MG N19865 002 OCT 30, 1992
AB 240MG N19865 003 OCT 30, 1992
80MG N19865 001 OCT 30, 1992

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE
BERLEX LABS 120MG N19865 005 APR 20, 1994
+ 160MG N19865 002 OCT 30, 1992
240MG N19865 003 OCT 30, 1992
BETAPACE AF
BERLEX LABS 80MG N21151 001 FEB 22, 2000
120MG N21151 002 FEB 22, 2000
+ 160MG N21151 003 FEB 22, 2000
SOTALOL HCL
AB EON 80MG N75366 001 MAY 01, 2000
AB 120MG N75366 002 MAY 01, 2000
AB 160MG N75366 003 MAY 01, 2000
AB 240MG N75366 004 MAY 01, 2000
AB GENPHARM 80MG N75237 001 MAY 01, 2000
AB 120MG N75237 002 MAY 01, 2000
AB 160MG N75237 003 MAY 01, 2000
AB 240MG N75237 004 MAY 01, 2000
AB TEVA 80MG N75429 001 MAY 01, 2000
AB 120MG N75429 002 MAY 01, 2000
AB 160MG N75429 003 MAY 01, 2000
AB 240MG N75429 004 MAY 01, 2000
AB WATSON LABS 80MG N75238 001 JUL 13, 2000
AB 120MG N75238 002 JUL 13, 2000
AB 160MG N75238 003 JUL 13, 2000

SOTALOL HYDROCHLORIDE

TABLET; ORAL
SOTALOL HCL

| | | | | |
|---|---|---|---|---|
| AB | WATSON LABS | 240MG | N75238 004 | JUL 13, 2000 |

STRONTIUM CHLORIDE, SR-89

INJECTABLE; INJECTION
METASTRON

| | | | | |
|---|---|---|---|---|
| | NYCOMED AMERSHAM | 1mCi/ML | N20134 001 | JUN 18, 1993 |
| + | | 1mCi/ML | N20134 001 | JUN 18, 1993 |

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
OCUSULF-10

| | | | | |
|---|---|---|---|---|
| AT | MIZA PHARMS USA | 10% | N80660 001 | |
| AT | OPTOPICS | 10% | N80660 001 | |

OCUSULF-30

| | | | | |
|---|---|---|---|---|
| | @ MIZA PHARMS USA | 30% | N80660 002 | |
| | @ OPTOPICS | 30% | N80660 002 | |

SULFACETAMIDE SODIUM

| | | | | |
|---|---|---|---|---|
| AT | ALCON UNIVERSAL | 10% | N89560 001 | OCT 18, 1988 |
| AT | STERIS | 10% | N89560 001 | OCT 18, 1988 |

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | AB | GLOBAL PHARM | 500MG | N80109 001 | |
| > ADD > | | @ IMPAX LABS | 500MG | N80109 001 | |

TACRINE HYDROCHLORIDE

CAPSULE; ORAL
COGNEX

| | | | | |
|---|---|---|---|---|
| | FIRST HORIZON | EQ 10MG BASE | N20070 001 | SEP 09, 1993 |

TACRINE HYDROCHLORIDE

CAPSULE; ORAL
COGNEX

| | | | | |
|---|---|---|---|---|
| | FIRST HORIZON | EQ 20MG BASE | N20070 002 | SEP 09, 1993 |
| | | EQ 30MG BASE | N20070 003 | SEP 09, 1993 |
| + | | EQ 40MG BASE | N20070 004 | SEP 09, 1993 |
| | PARKE DAVIS PHARMS | EQ 10MG BASE | N20070 001 | SEP 09, 1993 |
| | | EQ 20MG BASE | N20070 002 | SEP 09, 1993 |
| | | EQ 30MG BASE | N20070 003 | SEP 09, 1993 |
| + | | EQ 40MG BASE | N20070 004 | SEP 09, 1993 |

TAMOXIFEN CITRATE

TABLET; ORAL
TAMOXIFEN CITRATE

| | | | |
|---|---|---|---|
| @ MYLAN | EQ 10MG BASE | N74732 001 | JUN 26, 2000 |
| @ PHARMACHEMIE | EQ 10MG BASE | N74539 001 | MAY 31, 2000 |

TAZAROTENE

CREAM; TOPICAL
TAZORAC

| | | | |
|---|---|---|---|
| ALLERGAN | 0.05% | N21184 001 | SEP 29, 2000 |
| + | 0.1% | N21184 002 | SEP 29, 2000 |

TELMISARTAN

TABLET; ORAL
MICARDIS

| | | | |
|---|---|---|---|
| + BOEHRINGER INGELHEIM | 20MG | N20850 003 | APR 04, 2000 |

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
**TERAZOSIN HCL**

| | | | | |
|---|---|---|---|---|
| AB | INVAMED | EQ 1MG BASE | N75667 001 | JUL 28, 2000 |
| AB | | EQ 2MG BASE | N75667 002 | JUL 28, 2000 |
| AB | | EQ 5MG BASE | N75667 003 | JUL 28, 2000 |
| AB | | EQ 10MG BASE | N75667 004 | JUL 28, 2000 |
| AB | MYLAN | EQ 1MG BASE | N75140 002 | FEB 11, 2000 |
| AB | | EQ 2MG BASE | N75140 003 | FEB 11, 2000 |
| AB | | EQ 5MG BASE | N75140 001 | FEB 11, 2000 |
| AB | | EQ 10MG BASE | N75140 004 | FEB 11, 2000 |

TABLET; ORAL
**TERAZOSIN HCL**

| | | | | |
|---|---|---|---|---|
| AB | INVAMED | EQ 1MG BASE | N74657 001 | APR 28, 2000 |
| AB | | EQ 2MG BASE | N74657 002 | APR 28, 2000 |
| AB | | EQ 5MG BASE | N74657 003 | APR 28, 2000 |
| AB | | EQ 10MG BASE | N74657 004 | APR 28, 2000 |
| AB | NOVOPHARM | EQ 1MG BASE | N74446 001 | MAY 18, 2000 |
| AB | | EQ 2MG BASE | N74446 002 | MAY 18, 2000 |
| AB | | EQ 5MG BASE | N74446 003 | MAY 18, 2000 |
| AB | | EQ 10MG BASE | N74446 004 | MAY 18, 2000 |
| AB | ZENITH GOLDLINE | EQ 1MG BASE | N74530 001 | APR 21, 2000 |
| AB | | EQ 2MG BASE | N74530 002 | APR 21, 2000 |
| AB | | EQ 5MG BASE | N74530 003 | APR 21, 2000 |
| AB | | EQ 10MG BASE | N74530 004 | APR 21, 2000 |

TERBUTALINE SULFATE

AEROSOL, METERED; INHALATION
**BRETHAIRE**

| | | | | |
|---|---|---|---|---|
| | NOVARTIS | 0.2MG/INH | N18762 001 | AUG 17, 1984 |
| @ | | 0.2MG/INH | N18762 001 | AUG 17, 1984 |

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
**ANDRODERM**

| | | | | |
|---|---|---|---|---|
| BX + | THERATECH | 5MG/24HR | N20489 002 | MAY 02, 1997 |
| + | | 2.5MG/24HR | N20489 001 | SEP 29, 1995 |
| BX + | WATSON LABS | 5MG/24HR | N20489 002 | MAY 02, 1997 |
| + | | 2.5MG/24HR | N20489 001 | SEP 29, 1995 |

GEL; TOPICAL
**ANDROGEL**

| | | | | |
|---|---|---|---|---|
| + | UNIMED PHARMS | 1% | N21015 001 | FEB 28, 2000 |

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
**SLO-PHYLLIN**

| | | | | |
|---|---|---|---|---|
| @ | AVENTIS | 60MG | N85206 001 | MAY 24, 1982 |
| @ | | 125MG | N85203 001 | MAY 24, 1982 |
| @ | | 250MG | N85205 001 | MAY 24, 1982 |
| BC | RHONE POULENC RORER | 125MG | N85203 001 | MAY 24, 1982 |
| BC | | 250MG | N85205 001 | MAY 24, 1982 |
| | | 60MG | N85206 001 | MAY 24, 1982 |

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **BETALIN S** | | |
| AP | + | LILLY | **100MG/ML** | **N80853 001** |
| | @ | | 100MG/ML | N80853 001 |
| | | **THIAMINE HCL** | | |
| AP | | AM PHARM PARTNERS | **100MG/ML** | **N80556 001** |
| AP | + | | **100MG/ML** | **N80556 001** |

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **TICLOPIDINE HCL** | | |
| AB | | DANBURY PHARMA | **250MG** | **N75309 001** APR 26, 2000 |

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | | **TIMOLOL MALEATE** | | |
| AT | | NOVEX | **EQ 0.25% BASE** | **N75411 001** SEP 08, 2000 |
| AT | | | **EQ 0.5% BASE** | **N75412 001** SEP 08, 2000 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **TIMOLOL MALEATE** | | |
| > DLT > AB | | NOVOPHARM | **5MG** | **N72648 001** JUN 16, 1993 |
| > DLT > AB | | | **10MG** | **N72649 001** JUN 16, 1993 |
| > DLT > AB | | | **20MG** | **N72650 001** JUN 16, 1993 |
| > ADD > | @ | | 5MG | N72648 001 JUN 16, 1993 |
| > ADD > | @ | | 10MG | N72649 001 JUN 16, 1993 |
| > ADD > | @ | | 20MG | N72650 001 JUN 16, 1993 |

TINZAPARIN SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | INNOHEP | | |
| | + | DUPONT PHARMA | 20,000 IU/ML | N20484 001 JUL 14, 2000 |

TIZANIDINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | ZANAFLEX | | |
| | | ELAN PHARMA | EQ 2MG BASE | N20397 002 FEB 04, 2000 |

TOLBUTAMIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **TOLBUTAMIDE** | | |
| AB | | CHELSEA LABS | **500MG** | **N86109 001** |
| AB | + | | 500MG | N86109 001 |
| AB | + | EON | **500MG** | **N12678 001** |
| | @ | | 500MG | N12678 001 |

TRETINOIN

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | RENOVA | | |
| | + | JOHNSON AND JOHNSON | 0.02% | N21108 001 AUG 31, 2000 |

GEL; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **RETIN-A** | | |
| AB | + | JOHNSON AND JOHNSON | **0.025%** | **N17579 002** |
| BT | + | | 0.025% | N17579 002 |
| | | **TRETINOIN** | | |
| AB | | SPEAR PHARMS | **0.025%** | **N75529 001** FEB 22, 2000 |

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **FLUTEX** | | |
| AT | | ZENITH GOLDLINE | **0.025%** | **N85539 001** |
| AT | | | **0.1%** | **N85539 002** |
| AT | | | **0.5%** | **N85539 003** |
| | @ | | 0.025% | N85539 001 |
| | @ | | 0.1% | N85539 002 |
| | @ | | 0.5% | N85539 003 |
| | | **TRIATEX** | | |
| AT | | ZENITH GOLDLINE | **0.025%** | **N87430 001** NOV 01, 1988 |
| AT | | | **0.1%** | **N87429 001** NOV 01, 1988 |

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **TRIATEX** | | |
| AT | | ZENITH GOLDLINE | 0.5% | N87428 001<br>NOV 01, 1988 |
| | @ | | 0.025% | N87430 001<br>NOV 01, 1988 |
| | @ | | 0.1% | N87429 001<br>NOV 01, 1988 |
| | @ | | 0.5% | N87428 001<br>NOV 01, 1988 |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | **ARISTOCORT A** | | |
| AT | + | FUJISAWA HLTHCARE | 0.5% | N80745 003 |
| AT | | | 0.5% | N80745 003 |
| | | **FLUTEX** | | |
| AT | + | ZENITH GOLDLINE | 0.025% | N87375 001<br>NOV 01, 1988 |
| AT | + | | 0.1% | N87377 001<br>NOV 01, 1988 |
| AT | + | | 0.5% | N87376 001<br>NOV 01, 1988 |
| | @ | | 0.025% | N87375 001<br>NOV 01, 1988 |
| | @ | | 0.1% | N87377 001<br>NOV 01, 1988 |
| | @ | | 0.5% | N87376 001<br>NOV 01, 1988 |
| | | **KENALOG** | | |
| AT | + | APOTHECON | 0.025% | N11600 003 |
| AT | | | 0.025% | N11600 003 |
| AT | + | | 0.1% | N11600 001 |
| AT | | | 0.1% | N11600 001 |
| | | **TRIAMCINOLONE ACETONIDE** | | |
| AT | + | ALTANA | 0.025% | N85691 001 |
| AT | | | 0.025% | N85691 001 |
| AT | + | | 0.1% | N85691 003 |
| AT | | | 0.1% | N85691 003 |
| AT | + | | 0.5% | N85691 002 |
| AT | | | 0.5% | N85691 002 |
| AT | | CLAY PARK | 0.025% | N87356 001 |
| AT | + | | 0.025% | N87356 001 |
| AT | | | 0.1% | N87357 001 |
| AT | + | | 0.1% | N87357 001 |
| AT | | | 0.5% | N87385 001 |
| AT | + | | 0.5% | N87385 001 |

TRIAMCINOLONE ACETONIDE

SPRAY, METERED; NASAL

| | | | | |
|---|---|---|---|---|
| | | **TRI-NASAL** | | |
| | + | MURO | 0.05MG/SPRAY | N20120 001<br>FEB 04, 2000 |

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **TRIFLUOPERAZINE HCL** | | |
| AB | | ZENITH GOLDLINE | EQ 1MG BASE | N87612 001<br>NOV 19, 1982 |
| AB | | | EQ 2MG BASE | N87613 001<br>NOV 19, 1982 |
| AB | | | EQ 5MG BASE | N87328 001<br>NOV 19, 1982 |
| AB | | | EQ 10MG BASE | N87614 001<br>NOV 19, 1982 |
| | @ | | EQ 1MG BASE | N87612 001<br>NOV 19, 1982 |
| | @ | | EQ 2MG BASE | N87613 001<br>NOV 19, 1982 |
| | @ | | EQ 5MG BASE | N87328 001<br>NOV 19, 1982 |
| | @ | | EQ 10MG BASE | N87614 001<br>NOV 19, 1982 |

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **TRIHEXYPHENIDYL HCL** | | |
| AA | | WEST WARD | 2MG | N40337 002<br>FEB 16, 2000 |
| AA | | | 5MG | N40337 001<br>FEB 16, 2000 |

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | PRIMSOL | | |
| | | ASCENT PEDS | EQ 25MG BASE/5ML | N74374 001<br>JUN 23, 1995 |
| | + | | EQ 25MG BASE/5ML | N74374 001<br>JUN 23, 1995 |

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
PRIMSOL
+ ASCENT PEDS — EQ 50MG BASE/5ML — N74973 001 JAN 24, 2000

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
NEUTREXIN
+ MEDIMMUNE ONCOLOGY — EQ 25MG BASE/VIAL — N20326 001 DEC 17, 1993
+ US BIOSCIENCE — EQ 25MG BASE/VIAL — N20326 001 DEC 17, 1993

TRIPTORELIN PAMOATE

INJECTABLE; INJECTION
TRELSTAR DEPOT
+ DEBIO RECHERCHE — EQ 3.75MG BASE/VIAL — N20715 001 JUN 15, 2000

TROGLITAZONE

TABLET; ORAL
**PRELAY**
**AB** SANKYO — **200MG** — **N20719 001 JAN 29, 1997**
**AB** — **300MG** — **N20719 003 AUG 04, 1997**
**AB** — **400MG** — **N20719 002 JAN 29, 1997**
@ — 200MG — N20719 001 JAN 29, 1997
@ — 300MG — N20719 003 AUG 04, 1997
@ — 400MG — N20719 002 JAN 29, 1997
**REZULIN**
**AB** PARKE DAVIS PHARMS — **200MG** — **N20720 001 JAN 29, 1997**
**AB** — **300MG** — **N20720 003 AUG 04, 1997**
**AB** — **400MG** — **N20720 002 JAN 29, 1997**

TROGLITAZONE

TABLET; ORAL
**REZULIN**
@ PARKE DAVIS PHARMS — 200MG — N20720 001 JAN 29, 1997
@ — 300MG — N20720 003 AUG 04, 1997
@ — 400MG — N20720 002 JAN 29, 1997

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
**TROPICACYL**
**AT** AKORN — **0.5%** — **N40314 001 SEP 29, 2000**
**AT** — **1%** — **N40315 001 SEP 29, 2000**
**TROPICAMIDE**
**AT** ALCON UNIVERSAL — **1%** — **N89172 001 DEC 28, 1990**
**AT** MIZA PHARMS USA — **0.5%** — **N87636 001 JUL 30, 1982**
**AT** — **1%** — **N87637 001 AUG 09, 1982**
**AT** OPTOPICS — **0.5%** — **N87636 001 JUL 30, 1982**
**AT** — **1%** — **N87637 001 AUG 09, 1982**
**AT** STERIS — **1%** — **N89172 001 DEC 28, 1990**

UNOPROSTONE ISOPROPYL

SOLUTION/DROPS; OPHTHALMIC
RESCULA
+ CIBA — 0.15% — N21214 001 AUG 03, 2000

URSODIOL

CAPSULE; ORAL
**ACTIGALL**
**AB** + NOVARTIS — **300MG** — **N19594 002 DEC 31, 1987**

URSODIOL

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | ACTIGALL | | | | |
| | + NOVARTIS | 300MG | | N19594 002 | |
| | | | | DEC 31, 1987 | |
| | URSODIOL | | | | |
| AB | AMIDE PHARM | 300MG | | N75517 001 | |
| | | | | MAR 14, 2000 | |
| AB | COPLEY PHARM | 300MG | | N75592 001 | |
| | | | | MAY 25, 2000 | |

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | URSO | | | | |
| | + AXCAN | 250MG | | N20675 001 | |
| | | | | DEC 10, 1997 | |
| | + AXCAN SCANDIPHARM | 250MG | | N20675 001 | |
| | | | | DEC 10, 1997 | |

VECURONIUM BROMIDE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | VECURONIUM BROMIDE | | | | |
| AP | BEDFORD | 10MG/VIAL | | N75549 001 | |
| | | | | JUN 13, 2000 | |
| AP | | 20MG/VIAL | | N75549 002 | |
| | | | | JUN 13, 2000 | |

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | COVERA-HS | | | | |
| BC | SEARLE | 180MG | | N20552 001 | |
| | | | | FEB 26, 1996 | |
| BC | + | 180MG | | N20552 001 | |
| | | | | FEB 26, 1996 | |
| BC | | 240MG | | N20552 002 | |
| | | | | FEB 26, 1996 | |
| BC | + | 240MG | | N20552 002 | |
| | | | | FEB 26, 1996 | |

VERTEPORFIN

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | VISUDYNE | | | | |
| | + QLT | 15MG/VIAL | | N21119 001 | |
| | | | | APR 12, 2000 | |

VITAMIN A

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | | > DLT > | AQUASOL A | |
| AA | + ASTRAZENECA | 50,000 USP UNITS | > DLT > | | N83080 001 |
| | + | 25,000 USP UNITS | > DLT > | | N83080 002 |
| | @ | 25,000 USP UNITS | > ADD > | | N83080 002 |
| | @ | 50,000 USP UNITS | > ADD > | | N83080 001 |
| | VITAMIN A | | | | |
| AA | GLOBAL PHARM | 50,000 USP UNITS | | | N80952 001 |
| | @ IMPAX LABS | 50,000 USP UNITS | | | N80952 001 |
| AA | WEST WARD | 50,000 USP UNITS | > DLT > | | N80985 001 |
| | + | 50,000 USP UNITS | > ADD > | | N80985 001 |

VITAMIN A PALMITATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | VITAMIN A | | | |
| AA | GLOBAL PHARM | EQ 50,000 UNITS BASE | | N80953 001 |
| AA | | EQ 50,000 UNITS BASE | | N80955 001 |
| | @ IMPAX LABS | EQ 50,000 UNITS BASE | | N80953 001 |
| | @ | EQ 50,000 UNITS BASE | | N80955 001 |

WARFARIN SODIUM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | WARFARIN SODIUM | | | |
| AB | INVAMED | 3MG | | N40196 008 |
| | | | | JUL 26, 2000 |
| AB | | 6MG | | N40196 009 |
| | | | | JUL 26, 2000 |

ZAFIRLUKAST

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ACCOLATE | | | |
| | ASTRAZENECA UK | 10MG | | N20547 003 |
| | | | | SEP 17, 1999 |

ZOLMITRIPTAN

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ZOMIG | | | |
| | ASTRAZENECA PHARMS | 2.5MG | | N20768 001 |
| | | | | NOV 25, 1997 |

ZOLMITRIPTAN

| | | |
|---|---|---|
| TABLET; ORAL | | |
| ZOMIG | | |
| + ASTRAZENECA PHARMS | 5MG | N20768 002<br>NOV 25, 1997 |
| ZENECA | 2.5MG | N20768 001<br>NOV 25, 1997 |
| + | 5MG | N20768 002<br>NOV 25, 1997 |

ZONISAMIDE

| | | |
|---|---|---|
| CAPSULE; ORAL | | |
| ZONEGRAN | | |
| + DAINIPPON | 100MG | N20789 001<br>MAR 27, 2000 |

# OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'2000 - OCT'2000

## ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN

| | | | | |
|---|---|---|---|---|
| >DLT> | ROXANE | 120MG | N71010 001 | |
| >DLT> | | | MAY 12, 1987 | |
| >DLT> | | 650MG | N71011 001 | |
| >DLT> | | | MAY 12, 1987 | |
| >ADD> | @ | 120MG | N71010 001 | |
| >ADD> | | | MAY 12, 1987 | |
| >ADD> | @ | 650MG | N71011 001 | |
| >ADD> | | | MAY 12, 1987 | |

TABLET, EXTENDED RELEASE; ORAL
ACETAMINOPHEN

| | | | | |
|---|---|---|---|---|
| | PERRIGO | 650MG | N75077 001 | |
| | | | FEB 25, 2000 | |

## ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
FOAMICON

| | | | | |
|---|---|---|---|---|
| >ADD> | GENEVA PHARMS TECH | 80MG;20MG | N72687 001 | |
| >ADD> | | | JUN 28, 1989 | |
| >DLT> | INVAMED | 80MG;20MG | N72687 001 | |
| >DLT> | | | JUN 28, 1989 | |

## ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
8-HOUR BAYER

| | | | |
|---|---|---|---|
| + | BAYER | 650MG | N16030 001 |
| | @ | 650MG | N16030 001 |

MEASURIN

| | | | |
|---|---|---|---|
| + | BAYER | 650MG | N16030 002 |
| | @ | 650MG | N16030 002 |

## >DLT> AVOBENZONE; PADIMATE O

>DLT> LOTION; TOPICAL
PHOTOPLEX

| | | | |
|---|---|---|---|
| >DLT> | @ ALLERGAN HERBERT | 3%;7% | N19459 001 |
| >DLT> | | | SEP 30, 1988 |

## BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL
DIMETANE

| | | | |
|---|---|---|---|
| | @ WHITEHALL ROBINS | 12MG | N10799 011 |
| | | | JUN 10, 1983 |

DIMETAPP

| | | | |
|---|---|---|---|
| + | WHITEHALL ROBINS | 12MG | N10799 011 |
| | | | JUN 10, 1983 |

## >ADD> CALCIUM CARBONATE, PRECIPITATED; FAMOTIDINE; MAGNESIUM HYDROXIDE

>ADD> TABLET, CHEWABLE; ORAL
>ADD> PEPCID COMPLETE

| | | | | |
|---|---|---|---|---|
| >ADD> | + MERCK | 800MG;10MG;165MG | N20958 001 | |
| >ADD> | | | OCT 16, 2000 | |

## CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
E-Z SCRUB

| | | | |
|---|---|---|---|
| | BECTON DICKINSON | 4% | N73416 001 |
| | | | MAR 14, 2000 |

## CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SOLUTION; TOPICAL
CHLORAPREP

| | | | |
|---|---|---|---|
| + | MEDI FLEX HOSP | 2%;70% | N20832 001 |
| | | | JUL 14, 2000 |

SPONGE; TOPICAL
CHLORAPREP

| | | | |
|---|---|---|---|
| + | MEDI FLEX HOSP | 2%;70% | N20832 001 |
| | | | JUL 14, 2000 |

## CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CONTAC

| | | | |
|---|---|---|---|
| | @ SMITHKLINE | 8MG;75MG | N18099 001 |
| + | | 8MG;75MG | N18099 001 |

CIMETIDINE

| | | | |
|---|---|---|---|
| TABLET; ORAL | | | |
| CIMETIDINE | | | |
| LEINER | 200MG | N74961 001 JUN 19, 1998 | |
| NOVOPHARM | 200MG | N74961 001 JUN 19, 1998 | |

CLOTRIMAZOLE

| | | | |
|---|---|---|---|
| CREAM; VAGINAL | | | > DLT > |
| TRIVAGIZOLE 3 | | | > DLT > |
| + TARO | 2% | N21143 001 APR 12, 2000 | > ADD > |
| | | | > ADD > |
| | | | > DLT > |
| | | | > DLT > |

DOCOSANOL

| | | | |
|---|---|---|---|
| CREAM; TOPICAL | | | > ADD > |
| ABREVA | | | > ADD > |
| + AVANIR | 10% | N20941 001 JUL 25, 2000 | |
| + SMITHKLINE BEECHAM | 10% | N20941 001 JUL 25, 2000 | |

IBUPROFEN

| | | |
|---|---|---|
| CAPSULE; ORAL | | |
| IBUPROFEN | | |
| PHARM FORM | 200MG | N74782 001 JUL 06, 1998 |
| + | 200MG | N74782 001 JUL 06, 1998 |
| TABLET; ORAL | | |
| IBUPROFEN | | |
| LEINER | 200MG | N74931 001 JUL 20, 1998 |
| NOVOPHARM | 200MG | N74931 001 JUL 20, 1998 |

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

| | | |
|---|---|---|
| SUSPENSION; ORAL | | |
| CHILDREN'S MOTRIN COLD | | |
| + MCNEIL CONS | 100MG/5ML;15MG/5ML | N21128 001 AUG 01, 2000 |

LOPERAMIDE HYDROCHLORIDE

| | | |
|---|---|---|
| SOLUTION; ORAL | | |
| LOPERAMIDE HCL | | |
| ALPHARMA | 1MG/5ML | N73187 001 SEP 15, 1992 |
| @ | 1MG/5ML | N73187 001 SEP 15, 1992 |
| WATSON LABS | 1MG/5ML | N73062 001 MAY 28, 1993 |
| @ | 1MG/5ML | N73062 001 MAY 28, 1993 |
| TABLET; ORAL | | |
| LOPERAMIDE HCL | | |
| LEINER | 2MG | N73254 001 JUL 30, 1993 |
| NOVOPHARM NC | 2MG | N73254 001 JUL 30, 1993 |
| PERRIGO | 2MG | N75232 001 JAN 06, 2000 |

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

| | | |
|---|---|---|
| SOLUTION/DROPS; OPHTHALMIC | | |
| VISINE-A | | |
| AKORN | 0.025%;0.3% | N20485 001 JAN 31, 1996 |
| PFIZER | 0.025%;0.3% | N20485 001 JAN 31, 1996 |

NAPROXEN SODIUM

| | | |
|---|---|---|
| TABLET; ORAL | | |
| NAPROXEN SODIUM | | |
| LEINER | EQ 200MG BASE | N74635 001 JAN 13, 1997 |
| NOVOPHARM NC | EQ 200MG BASE | N74635 001 JAN 13, 1997 |

NONOXYNOL-9

AEROSOL; VAGINAL
DELFEN
@ ORTHO 12.5% N14349 002
@ PERSONAL PRODS 12.5% N14349 002

PERMETHRIN

LOTION; TOPICAL
PERMETHRIN
ALPHARMA 1% N75014 001 MAR 28, 2000

PIPERONYL BUTOXIDE; PYRETHRINS

AEROSOL; TOPICAL
RID MOUSSE
+ PFIZER 4%;EQ 0.33% BASE N21043 001 MAR 07, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE
CHELSEA LABS EQ 75MG BASE N75212 001 JAN 14, 2000
CHEMINOR DRUGS EQ 75MG BASE N75294 001 MAR 28, 2000
GENPHARM EQ 75MG BASE N75497 001 JAN 14, 2000
LEINER EQ 75MG BASE N75094 001 JUN 21, 1999
RANBAXY EQ 75MG BASE N75132 001 JAN 14, 2000
EQ 75MG BASE N75254 001 JAN 14, 2000
TORPHARM EQ 75MG BASE N75167 001 MAY 04, 2000
ZENITH GOLDLINE EQ 75MG BASE N75296 001 JAN 14, 2000

RANITIDINE HCL
NOVOPHARM EQ 75MG BASE N75094 001 JUN 21, 1999

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT; ORAL
ZANTAC 75
+ GLAXO WELLCOME EQ 75MG BASE N20745 001 FEB 26, 1998
@ WARNER LAMBERT EQ 75MG BASE N20745 001 FEB 26, 1998

TERBINAFINE HYDROCHLORIDE

SOLUTION; TOPICAL
LAMISIL AT
+ NOVARTIS 1% N21124 001 MAR 17, 2000

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

## CUMULATIVE SUPPLEMENT NUMBER 10 OCTOBER '00

NO OCTOBER 2000 APPROVALS

**This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.**

# Orphan Products Designations and Approvals List
## January through October 2000

| Name:<br>Generic Name<br>TN=Trade Name | Indication Designated: | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| 1-(11-dodecylamino-10-hydroxyundecyl)-3,7-dimethylxanthine hydrogen methanesulfonate<br>TN= | Treatment of hormone refractory prostate carcinoma. | Cell Therapeutics, Inc.<br>201 Elliott Avenue West<br>Suite 400<br>Seattle WA 98119<br>DD= 1/18/00 MA= |
| 3-(3,5-Dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-one<br>TN= | Treatment of von Hippel-Lindau disease. | Sugen, Inc.<br>230 East Grand Ave.<br>South San Francisco CA 94080<br>DD= 3/23/00 MA= |
| Abetimus<br>TN= | Treatment of lupus nephritis. | La Jolla Pharmaceutical Co.<br>6455 Nancy Ridge Dr.<br>San Diego CA 92121<br>DD= 7/28/00 MA= |
| Angiotensin 1-7<br>TN= | Treatment of neutropenia associated with autologous bone marrow transplantation. | Maret Pharmaceuticals<br>4041 MacArthur Blvd.<br>Suite 375<br>Newport Beach CA 92660<br>DD= 2/16/00 MA= |
| Anti-thymocyte Globulin (Rabbitt)<br>TN=Thymoglobulin | Treatment of myelodysplastic syndrome (MDS) | SangStat Medical Corporation<br>6300 Dumbarton Circle<br>Freemont CA 94555<br>DD= 9/6/00 MA= |

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|---|---|---|
| arsenic trioxide<br>TN=Atrivex | Treatment of myelodysplastic syndrome. | Cell Therapeutics, Inc.<br>201 Elliott Avenue West<br>Suite 400<br>Seattle WA 98119<br>DD= 7/17/00 MA= |
| Arsenic trioxide<br>TN=Atrivex | Treatment of multiple myeloma. | Cell Therapeutics, Inc.<br>201 Elliott Ave. West, Suite<br>Seattle WA 98119<br>DD= 4/28/00 MA= |
| Bis(4-fluorophenyl)phenyla cetamide<br>TN= | Treatment of sickle cell disease. | ICAgen Inc.<br>Ion Channel Advances<br>PO Box 14487<br>Durham NC 27709<br>DD= 3/2/00 MA= |
| Bosentan<br>TN= | Treatment of pulmonary arterial hypertension. | Actelion Life Sciences Ltd.<br>1840 Gateway Dr.<br>2nd Floor<br>San Mateo CA 94404<br>DD=10/6/00 MA= |
| Brimonidine<br>TN=Alphagan | Treatment of anterior ischemic optic neuropathy. | Allergan, Inc.<br>2525 Dupont Dr.<br>P.O. Box 19534<br>Irvine CA 92623-9534<br>DD= 2/7/00 MA= |

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|---|---|---|
| Calfactant<br>TN=Infasurf | Acute respiratory distress syndrome (ARDS) | ONY, Inc.<br>Baird Research Park<br>1576 Sweet Home Road<br>Amherst NY 14228<br>DD= 9/5/00 MA= |
| Carmustine<br>TN= | Treatment of intracranial malignancies. | Direct Therapeutics, Inc.<br>1001 Bayhill Dr., Suite 100<br>San Bruno CA 94066<br>DD= 7/3/00 MA= |
| Centruroides immune F(ab)2<br>TN=Alacramyn | Treatment of scorpion envenomations requiring medical attention. | Silanes Laboratories S.A. d<br>Amores #1034 Col Del Valle<br>C.P. 03100 Mexico D.F.<br>DD= 6/12/00 MA= |
| Cetuximab<br>TN= | Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor. | ImClone Systems Incorporate<br>Branchburg Corporate Center<br>22 Chubb Way<br>Somerville NJ 08876<br>DD= 7/3/00 MA= |
| Chimeric (human-murine) G250 IgG monoclonal antibody<br>TN= | Treatment of renal cell carcinoma. | Wilex Biotechnology GmbH<br>Grillparzerstrasse 10B<br>81675 Munich<br>Germany DE<br>DD= 7/24/00 MA= |

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## January through October 2000

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|---|---|---|
| Chimeric, humanized monoclonal antibody to staphylococcus<br>TN= | Prophylaxis of Staphylococcus epidermidis sepsis in low birth weight (1500 grams or less) infants. | Biosynexus, Inc.<br>9610 Medical Center Drive<br>Suite 100<br>Rockville MD 20850<br>DD= 8/3/00 MA= |
| Cisplatin/epinephrine<br>TN=IntraDose | Treatment of metastatic malignant melanoma. | Matrix Pharmaceutical, Inc.<br>34700 Campus Drive<br>Fremont CA 94555-3612<br>DD= 9/7/00 MA= |
| Cisplatin/epinephrine<br>TN= IntraDose | Treatment of squamous cell carcinoma of the head and neck. | Matrix Pharmaceutical, Inc.<br>34700 Campus Drive<br>Fremont CA 94555-3612<br>DD= 4/3/00 MA= |
| Deoxyribose, phosphorothioate<br>TN= | Treatment of advanced malignant melanoma (Stages II,III, IV). | Genta, Inc.<br>99 Hayden Ave., Suite 200<br>Lexington MA 02421-7966<br>DD= 7/31/00 MA= |
| DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2<br>TN=Leuvectin | Treatment of renal cell carcinoma. | Vical Incorporated<br>9373 Towne Center Dr.<br>Suite 100<br>San Diego CA 92121-3088<br>DD= 4/28/00 MA= |

# Orphan Products Designations and Approvals List
## January through October 2000

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|---|---|---|
| DNP-Modified autologous tumor vaccine<br>TN=O-Vax | Adjuvant therapy for the treatment of ovarian cancer | AVAX Technologies, Inc.<br>4520 Main Street<br>Suite 930<br>Kansas City MO 64111<br>DD= 9/21/00 MA= |
| Ethyl eicosapentaenoate<br>TN= | Treatment of Huntington's disease. | Laxdale Ltd.<br>Kings Park House, Laurelhil<br>Polmaise Road, Stirling FK7<br>United Kingdom UK<br>DD= 4/6/00 MA= |
| Flucinolone<br>TN= | Treatment uveitis involving the posterior segment of the eye. | Bausch & Lomb<br>8500 Hidden River Parkway<br>Tampa FL 33637<br>DD= 7/31/00 MA= |
| Fluorouracil<br>TN= | Treatment of glioblastoma multiforme. | Ethypharm SA<br>194 Bureaux de la Colline<br>92213 Saint-Cloud Cedex<br>France FR<br>DD= 6/29/00 MA= |
| Gene plasmid hVEGF165 driven by human cytomegalovirus, and [2,3-bis(oleoyl)propyl]trimethyl ammonium and dioleoyl phosphatidyl<br>TN= | Prevention of complications due to neointimal hyperplasia disease in certain vascular anastomoses. | Eurogene Ltd.<br>6 Warren Mews<br>London W1P 5DJ UK<br>DD= 10/24/00 MA= |

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## January through October 2000

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|---|---|---|
| h5G1.1-mAb<br>TN= | Treatment of dermatomyositis | Alexion Pharmaceuticals, Inc.<br>25 Science Park<br>Suite 360<br>New Haven CT 06511<br>DD= 9/21/00 MA= |
| Halofuginone<br>TN=Stenorol | Treatment of systemic sclerosis. | Collgard Biopharmaceuticals<br>Textile House, 2 Koifman St.<br>Tel-Aviv 68012<br>Israel IL<br>DD= 2/7/00 MA= |
| Histamine<br>TN=Maxamine | For use as an adjunct to cytokine therapy in the treatment of malignant melanoma. | Maxim Pharmaceuticals, Inc.<br>8899 University Center Lane<br>Suite 400<br>San Diego CA 92122<br>DD= 2/1/00 MA= |
| Hydroxycobalamin<br>TN=CYANOKIT | Treatment of acute cyanide poisoning | Orphan Medical, Inc.<br>13911 Ridgedale Drive<br>Suite 250<br>Minnetonka MN 55305<br>DD= 9/22/00 MA= |
| Hypericin<br>TN= | Treatment of glioblastoma multiforme. | Nexell Therapeutics<br>2751 Centerville Rd., Suite<br>Wilmington DE 19808<br>DD= 8/3/00 MA= |

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## January through October 2000

| Name:<br>Generic Name<br>TN=Trade Name | Indication Designated: | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| Hypericin<br>TN= | Treatment of cutaneous T-cell lymphoma. | Nexell Therapeutics, Inc.<br>2751 Centerville Rd., Suite<br>Wilmington DE 19808<br>DD= 2/7/00 MA= |
| IL-4 Pseudomonas Toxin Fusion Protein<br>(IL-4(38-37)-PE38KDEL)<br>TN= | Treatment of astrocytic glioma. | Neurocrine Biosciences, Inc.<br>10555 Science Center Dr.<br>San Diego CA 92121<br>DD= 4/6/00 MA= |
| Iodine I 131 bis(indium-diethylenetriaminepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab')2 bispecific monoclonal antibody<br>TN= Pentacea | Treatment of small-cell lung cancer. | IBC Pharmaceuticals, L.L.C.<br>300 American Rd.<br>Morris Plains NJ 07950<br>DD= 2/22/00 MA= |
| Lanreotide, Somatostatin<br>TN=Ipstyl | Treatment for acromegly | IPSEN, Inc.<br>27 Maple Street<br>Milford MA 01757<br>DD= 9/11/00 MA= |
| Levodopa and carbidopa<br>TN=Duodopa | Treatment of late stage Parkinson's disease. | Nouvel Pharma, Inc.<br>11322 Acuff La.<br>Lenexa KS 66215<br>DD= 1/18/00 MA= |
| Liposomal nystatin<br>TN=Nyotran | Treatment of invasive fungal infections. | Aronex Pharmaceuticals, Inc.<br>8707 Technology Forest Place<br>The Woodlands TX 77381-1191<br>DD= 6/13/00 MA= |

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## January through October 2000

| Name:<br>Generic Name<br>TN=Trade Name | Indication Designated: | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| Meropenem<br>TN=Merrem IV | Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms. | Zeneca Pharmaceuticals<br>1800 Concord Pike<br>PO Box 15437<br>Wilmington DE 19850-5437<br>DD= 4/27/00 MA= |
| Natural human lymphoblastoid interferon-alpha<br>TN= | Treatment of Behcet's disease. | Amarillo Biosciences, Inc.<br>800 West Ninth Avenue<br>Amarillo TX 79101-3206<br>DD= 1/18/00 MA= |
| Natural human lymphoblastoid interferon-alpha<br>TN= | Treatment of papillomavirus warts in the oral cavity of HIV positive patients. | Amarillo Biosciences. Inc.<br>800 West 9th Avenue<br>Amarillo TX 79101<br>DD= 8/10/00 MA= |
| Omega-3 (n-3) polyunsaturated fatty acids<br>TN=Omacor | Treatment of IgA nephropathy. | Pronova Biocare, AS<br>PO Box 420<br>1327 Lysaker<br>Norway<br>DD= 5/4/00 MA= |
| Phenylbutyrate<br>TN= | Treatment of acute promyelocytic leukemia. | Elan Corporation<br>1300 Gould Dr.<br>Gainesville GA 30504<br>DD= 1/19/00 MA= |
| Recombinant glycine2-human glucagon-like peptide-2<br>TN= | Treatment of short bowel syndrome. | NPS Allelix Corp.<br>6850 Goreway Dr.<br>Mississauga, Ontario<br>L4V 1V7 Canada CA<br>DD= 6/29/00 MA= |

# Orphan Products Designations and Approvals List
## January through October 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|---|---|---|
| Recombinant human antithrombin III TN= | Treatment of antithrombin III dependent heparin resistance requiring anticoagulation. | AT III LLC c/o Genzyme Corporation 15 Pleasant St. Connector, Framingham MA 01701 DD= 4/6/00 MA= |
| Recombinant human highly phosphorylated acid alpha-glucosidase TN=TBD | For enzyme replacement therapy in patients with all subtypes of glycogen storage disease type II (GSDII, Pompe Disease) | Novazyme Pharmaceuticals, 800 Research Parkway Suite 200 Oklahoma City OK 73104 DD= 9/20/00 MA= |
| Recombinant human insulin-like growth factor-I TN=PV802 | Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines. | GroPep Pty Ltd. Gate 11, Victoria Dr. Adelaide SA 5000 Australia AU DD= 2/16/00 MA= |
| Recombinant urate oxidase TN= | Treatment of malignancy-associated or chemotherapy-induced hyperuricemia. | Sanofi-Synthelabo Research 9 Great Valley Parkway Malvern PA 19355 DD= 10/11/0 MA= |
| Recombinant urate oxidase TN= | Prophylaxis of chemotherapy-induced hyperuricemia. | Sanofi-Synthelabo Research 9 Great Valley Parkway Malvern PA 19355 DD= 10/11/0 MA= |
| Remacemide TN=Ecovia | Treatment of Huntington's disease. | AstraZeneca LP 725 Chesterbrook Blvd. Wayne PA 19087-5677 DD= 3/6/00 MA= |

# Orphan Products Designations and Approvals List
## January through October 2000

| Name:<br>Generic Name<br>TN=Trade Name | Indication Designated: | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| rSP-C lung surfactant<br>TN=Venticute | Treatment of adult respiratory distress syndrome. | Byk Gulden Pharmaceuticals<br>Byk-Gulden StraBe 2<br>78467 Konstanz<br>Germany DE<br>DD= 4/3/00 MA= |
| Soluble complement receptor type 1<br>TN= | Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass. | Avant Immunotherapeutics,<br>119 Fourth Ave.<br>Needham MA 02494-2725<br>DD= 3/6/00 MA= |
| Synthetic human secretin<br>TN= | For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion. | ChiRhoClin, Inc.<br>15500 Gallaudet Ave.<br>Silver Spring MD 20905-4176<br>DD= 3/7/00 MA= |
| Synthetic porcine secretin<br>TN= | For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion. | ChiRhoClin, Inc.<br>15500 Gallaudet Ave.<br>Silver Spring MD 20905-4176<br>DD= 3/7/00 MA= |
| Technetium Tc 99m pterotetramide<br>TN= | For the identification of ovarian carcinomas. | Endocyte, Inc.<br>1205 Kent Ave.<br>Lafayette IN 47906<br>DD= 2/16/00 MA= |
| Technetium Tc99m rh-Annexin V<br>TN=Apomate | Diagnosis or assessment of rejection status in heart, heart-lung, single lung, or bilateral lung transplants. | Theseus Imaging Corporation<br>124 Mount Auburn Street<br>Suite 200 North<br>Cambridge MA 02138<br>DD= 11/3/00 MA= |

# Orphan Products Designations and Approvals List
## January through October 2000

| Name:<br>Generic Name<br>TN=Trade Name | Indication Designated: | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| Tetraiodothyroacetic acid<br>TN= | Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland. | Danforth, Jr., MD, Elliot<br>University of Vermont<br>84 Beartown Rd.<br>Underhill VT 05489<br>DD= 5/1/00 MA= |
| Thymalfasin<br>TN=Zadaxin | Treatment of hepatocellular carcinoma. | SciClone Pharmaceuticals,<br>901 Mariner's Blvd., Suite<br>San Mateo CA 94404<br>DD= 3/6/00 MA= |
| Trimetrexate<br>TN=Neutrexin | Treatment of metastatic osteogenic sarcoma. | Medimmune Oncology, Inc.<br>One Tower Bridge<br>100 Front St., Suite 400<br>West Conshohocken PA 19428<br>DD= 8/10/00 MA= |
| Vapreotide<br>TN=Octastatin | Treatment of gastrointestinal and pancreatic fistulas. | Debiopharm S.A.<br>17 rue des Terreaux<br>CH-1000 Lausanne 9<br>Switzerland CH<br>DD= 1/10/00 MA= |
| Vapreotide<br>TN=Octastatin | Prevention of early postoperative complications following pancreatic resection. | Debiopharm S.A.<br>17 rue des Terreaux<br>CH-1000 Lausanne 9<br>Switzerland CH<br>DD= 3/6/00 MA= |

# Orphan Products Designations and Approvals List
## January through October 2000

| Name:<br>Generic Name<br>TN=Trade Name | Indication Designated: | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| Vapreotide<br>TN=Octastatin | Treatment of esophageal variceal hemorrhage patients with portal hypertension. | Debiopharm S.A.<br>17 rue des Terreaux<br>CH-1000 Lausanne 9<br>Switzerland CH<br>DD= 1/10/00 MA= |
| vigabatrin<br>TN=Sabril | Treatment of infantile spasms. | Aventis Pharmaceuticals Inc.<br>P.O. Box 9627<br>Kansas City MO 64137<br>DD= 6/12/00 MA= |
| Zoledronate<br>TN=Zometa, Zabel | Treatment of tumor induced hypercalcemia. | Novartis Pharmaceuticals<br>59 Route 10<br>East Hanover NJ 07936-1080<br>DD= 8/18/00 MA= |

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

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**NO OCTOBER 2000 ADDITIONS**



PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| | | | | | PC | NOV 12, 2000 |
| 075077 001 | ACETAMINOPHEN;ACETAMINOPHEN | 4717720 | MAY 31, 2010 | | | |
| 020338 001 | ADAPALENE;DIFFERIN | 4717720 | MAY 31, 2010 | | | |
| 020380 001 | ADAPALENE;DIFFERIN | 4717720 | MAY 31, 2010 | | NCE | MAY 31, 2001 |
| 020748 001 | ADAPALENE;DIFFERIN | RE34440 | MAY 31, 2010 | U-275 | NDF | MAY 26, 2003 |
| | | 6080756 | JUL 05, 2016 | | | |
| 020760 001 | ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE | 6080756 | JUL 05, 2016 | | | |
| 020760 002 | ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE | 6008207 | JUN 06, 2015 | U-303 | M-3 | NOV 24, 2002 |
| 020560 001 | ALENDRONATE SODIUM;FOSAMAX | 6090410 | DEC 02, 2012 | | I-309 | SEP 29, 2003 |
| | | 6008207 | JUN 06, 2015 | U-303 | M-3 | NOV 24, 2002 |
| 020560 002 | ALENDRONATE SODIUM;FOSAMAX | 6090410 | DEC 02, 2012 | | | |
| | | 6008207 | JUN 06, 2015 | U-303 | M-3 | NOV 24, 2002 |
| 020560 003 | ALENDRONATE SODIUM;FOSAMAX | 6090410 | DEC 02, 2012 | | | |
| | | 6015801 | JUL 17, 2018 | U-353 | NS | OCT 20, 2000 |
| 020560 004 | ALENDRONATE SODIUM;FOSAMAX | 4621077 | AUG 06, 2007 | U-114 | D-61 | OCT 20, 2003 |
| | | 5358941 | DEC 02, 2012 | | D-62 | OCT 20, 2003 |
| | | 5681590 | DEC 02, 2012 | | | |
| | | 5804570 | FEB 17, 2015 | | | |
| | | 5849726 | JUN 06, 2015 | | | |
| | | 5944329 | JUL 17, 2018 | | | |
| | | 6008207 | JUN 06, 2015 | | | |
| | | 6015801 | JUL 17, 2018 | U-353 | NS | OCT 20, 2003 |
| 020560 005 | ALENDRONATE SODIUM;FOSAMAX | 4621077 | AUG 06, 2007 | U-114 | D-61 | OCT 20, 2003 |
| | | 5358941 | DEC 02, 2012 | | D-62 | OCT 20, 2003 |
| | | 5681590 | DEC 02, 2012 | | | |
| | | 5804570 | FEB 17, 2015 | | | |
| | | 5849726 | JUN 06, 2015 | | | |
| | | 5994329 | JUL 17, 2018 | | | |
| | | 6008207 | JUN 06, 2015 | | | |
| | | | | | NCE | FEB 09, 2005 |
| 021107 001 | ALOSETRON HYDROCHLORIDE;LOTRONEX | 4508726 | SEP 16, 2002 | U-46 | | |
| 018276 001 | ALPRAZOLAM;XANAX | 4508726 | SEP 16, 2002 | U-46 | | |
| 018276 002 | ALPRAZOLAM;XANAX | 4508726 | SEP 16, 2002 | U-46 | | |
| 018276 003 | ALPRAZOLAM;XANAX | 4508726 | SEP 16, 2002 | U-46 | | |
| 018276 004 | ALPRAZOLAM;XANAX | | | | I-283 | JUN 24, 2002 |
| 020221 001 | AMIFOSTINE;ETHYOL | | | | I-283 | JUN 24, 2002 |
| 020221 002 | AMIFOSTINE;ETHYOL | | | | | |
| 021007 001 | AMPRENAVIR;AGENERASE | 5723490 | MAR 03, 2013 | U-257 | | |
| | | 5646180 | JUL 08, 2014 | U-257 | | |
| | | 5585397 | DEC 17, 2013 | | | |
| 021007 002 | AMPRENAVIR;AGENERASE | 5723490 | MAR 03, 2015 | U-257 | | |
| | | 5646180 | JUL 08, 2014 | U-257 | | |
| | | 5585397 | DEC 17, 2013 | | | |
| 021039 001 | AMPRENAVIR;AGENERASE | 5723490 | MAR 03, 2015 | U-257 | | |
| | | 5646180 | JUL 08, 2014 | U-257 | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 020541 001 | ANASTROZOLE;ARIMIDEX | RE36617 | DEC 27, 2009 | | | |
| | 020883 001 | ARGATROBAN;ACOVA | | | | NCE | JUN 30, 2005 |
| | 021248 001 | ARSENIC TRIOXIDE;TRISENOX | | | | ODE | SEP 25, 2007 |
| | 020971 001 | ARTICAINE HYDROCHLORIDE;SEPTOCAINE | | | | NCE | SEP 25, 2005 |
| >ADD> | 020702 004 | ATORVASTATIN CALCIUM;LIPITOR | | | | NC | APR 03, 2003 |
| | | | 5969166 | JUL 08, 2016 | | NCE | DEC 17, 2001 |
| >ADD> | | | 4681893 | SEP 24, 2009 | U-161 | I-281 | DEC 02, 2002 |
| >ADD> | | | 5273995 | DEC 28, 2010 | U-162 | I-218 | JUL 10, 2001 |
| | 021127 001 | AZELASTINE HYDROCHLORIDE;OPTIVAR | 5686104 | NOV 11, 2014 | U-213 | I-219 | JUL 10, 2001 |
| | | | 5164194 | NOV 01, 2010 | | NCE | NOV 01, 2001 |
| | | | 5164194* | MAY 01, 2011 | | NDF | MAY 22, 2003 |
| | | | | | | PED | MAY 01, 2002 |
| | 020610 001 | BALSALAZIDE DISODIUM;COLAZAL | | | | PED | NOV 22, 2003 |
| >ADD> | 020911 002 | BECLOMETHASONE DIPROPIONATE;QVAR 40 | 4412992 | JUL 08, 2001 | | NCE | JUL 18, 2005 |
| >ADD> | | | 5776432 | JUL 07, 2015 | | | |
| >ADD> | | | 5605674 | FEB 25, 2014 | | | |
| >ADD> | | | 5695743 | JUL 06, 2010 | | | |
| >ADD> | | | 5683677 | NOV 04, 2014 | | | |
| >ADD> | 020911 001 | BECLOMETHASONE DIPROPIONATE;QVAR 80 | 5766573 | NOV 28, 2009 | U-356 | | |
| >ADD> | | | 5776432 | JUL 07, 2015 | | | |
| >ADD> | | | 5605674 | FEB 25, 2014 | | | |
| >ADD> | | | 5695743 | JUL 06, 2010 | | | |
| >ADD> | | | 5683677 | NOV 04, 2014 | | | |
| | | | 5766573 | NOV 28, 2009 | U-356 | | |
| | 021055 001 | BEXAROTENE;TARGRETIN | | | | ODE | DEC 29, 2006 |
| | 021056 001 | BEXAROTENE;TARGRETIN | | | | NCE | DEC 29, 2004 |
| | | | | | | NDF | JUN 28, 2003 |
| | 019982 001 | BISOPROLOL FUMARATE;ZEBETA | 4258062 | MAR 24, 2000 | U-63 | | |
| | | | 4258062*PED | SEP 24, 2000 | U-63 | | |
| | 019982 002 | BISOPROLOL FUMARATE;ZEBETA | 4258062 | MAR 24, 2000 | U-63 | | |
| | | | 4258062*PED | SEP 24, 2000 | U-63 | | |
| | 020186 001 | BISOPROLOL FUMARATE;ZIAC | 4258062 | MAR 24, 2000 | U-63 | | |
| | | | 4258062*PED | SEP 24, 2000 | U-63 | | |
| | 020186 002 | BISOPROLOL FUMARATE;ZIAC | 4258062 | MAR 24, 2000 | U-63 | | |
| | | | 4258062*PED | SEP 24, 2000 | U-63 | | |
| | 020186 003 | BISOPROLOL FUMARATE;ZIAC | 4258062 | MAR 24, 2000 | U-63 | | |
| | | | 4358062*PED | SEP 24, 2000 | U-63 | | |
| | 050443 002 | BLEOMYCIN SULFATE;BLENOXANE | | | | ODE | FEB 20, 2003 |
| | 020929 001 | BUDESONIDE;PULMICORT RESPULES | 4787536 | FEB 27, 2006 | | NDF | AUG 08, 2003 |
| | 020929 002 | BUDESONIDE;PULMICORT RESPULES | 4787536 | FEB 27, 2006 | | NDF | AUG 08, 2003 |
| | 020711 002 | BUPROPION HYDROCHLORIDE;ZYBAN | | | | D-54 | SEP 10, 2002 |
| | 020711 003 | BUPROPION HYDROCHLORIDE;ZYBAN | | | | D-54 | SEP 10, 2002 |
| | 018731 001 | BUSPIRONE HYDROCHLORIDE;BUSPAR | 4182763 | MAY 22, 2000 | U-13 | | |
| | | | 5015646 | MAY 14, 2008 | | | |
| | | | 4182763*PED | NOV 22, 2000 | U-13 | | |
| | | | 5015646*PED | NOV 14, 2008 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 018731 002 | BUSPIRONE HYDROCHLORIDE;BUSPAR | 4182763 | MAY 22, 2000 | U-13 | | |
| | | | 5015646 | MAY 14, 2008 | | | |
| | | | 4182763*PED | NOV 22, 2000 | U-13 | | |
| | | | 5015646*PED | NOV 14, 2008 | | | |
| | 018731 003 | BUSPIRONE HYDROCHLORIDE;BUSPAR | 5015646 | MAY 14, 2008 | | | |
| | | | 4182763 | MAY 22, 2000 | U-13 | | |
| | | | 4182763*PED | NOV 22, 2000 | U-13 | | |
| | | | 5015646*PED | NOV 14, 2008 | | | |
| | 018731 004 | BUSPIRONE HYDROCHLORIDE;BUSPAR | 4182763 | MAY 22, 2000 | U-13 | | |
| | | | 5015646 | MAY 14, 2008 | | | |
| | | | 4182763*PED | NOV 22, 2000 | | | |
| | | | 5015646*PED | NOV 14, 2008 | U-13 | | |
| | 020793 001 | CAFFEINE CITRATE;CAFCIT | | | | ODE | SEP 21, 2006 |
| | 020313 002 | CALCITONIN, SALMON;MIACALCIN | 5759565 | MAR 31, 2015 | | | |
| | 018874 001 | CALCITRIOL;CALCIJEX | 6051567 | AUG 02, 2019 | | | |
| | 018874 002 | CALCITRIOL;CALCIJEX | 6051567 | AUG 02, 2019 | | | |
| >ADD> | 020958 001 | CALCIUM CARBONATE, PRECIPITATED;PEPCID COMPLETE | 5229137 | MAY 16, 2012 | U-349 | NC | OCT 15, 2003 |
| >ADD> | | | 4283408 | OCT 15, 2000 | | PED | APR 15, 2004 |
| >ADD> | | | 5817340 | DEC 01, 2012 | | | |
| >ADD> | | | 5989588 | SEP 30, 2015 | U-349 | | |
| >ADD> | | | 5989588*PED | MAR 30, 2018 | U-349 | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | | | 5229137*PED | NOV 16, 2012 | | | |
| >ADD> | | | 5817340*PED | JUN 01, 2013 | | | |
| | 021093 001 | CANDESARTAN CILEXETIL;ATACAND HCT | 5705517 | APR 18, 2011 | U-3 | NCE | JUN 04, 2003 |
| | | | 5721263 | FEB 24, 2015 | U-3 | NC | SEP 05, 2003 |
| | | | 5958961 | JUN 06, 2014 | U-3 | | |
| | | | 5196444 | APR 18, 2011 | U-3 | | |
| | | | 5534534 | JUL 09, 2013 | | | |
| | | | 5703110 | APR 18, 2011 | U-3 | | |
| | 021093 002 | CANDESARTAN CILEXETIL;ATACAND HCT | 5705517 | APR 18, 2011 | U-3 | NCE | JUN 04, 2003 |
| | | | 5721263 | FEB 24, 2015 | U-3 | NC | SEP 05, 2003 |
| | | | 5958961 | JUN 06, 2014 | U-3 | | |
| | | | 5196444 | APR 18, 2011 | U-3 | | |
| | | | 5534534 | JUL 09, 2013 | | | |
| | | | 5703110 | APR 18, 2011 | U-3 | | |
| | 020896 001 | CAPECITABINE;XELODA | 4966891 | JAN 13, 2011 | U-272 | | |
| | 020896 002 | CAPECITABINE;XELODA | 4966891 | JAN 13, 2011 | U-272 | | |
| | 020297 001 | CARVEDILOL;COREG | 5902821 | FEB 07, 2016 | U-313 | | |
| | 020297 002 | CARVEDILOL;COREG | 5902821 | FEB 07, 2016 | U-313 | | |
| | 020297 003 | CARVEDILOL;COREG | 5902821 | FEB 07, 2016 | U-313 | | |
| | 020297 004 | CARVEDILOL;COREG | 5902821 | FEB 07, 2016 | U-313 | | |
| | 020740 001 | CERIVASTATIN SODIUM;BAYCOL | | | | D-59 | JUL 21, 2003 |
| | | | | | | I-303 | JUL 21, 2003 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 020740 002 | CERIVASTATIN SODIUM;BAYCOL | | | | D-59 | JUL 21, 2003 |
| | | | | | | I-303 | JUL 21, 2003 |
| | 020740 003 | CERIVASTATIN SODIUM;BAYCOL | | | | D-59 | JUL 21, 2003 |
| | | | | | | I-303 | JUL 21, 2003 |
| | 020740 004 | CERIVASTATIN SODIUM;BAYCOL | | | | D-59 | JUL 21, 2003 |
| | | | | | | I-303 | JUL 21, 2003 |
| | 020740 005 | CERIVASTATIN SODIUM;BAYCOL | | | | D-59 | JUL 21, 2003 |
| | | | | | | I-303 | JUL 21, 2003 |
| | 020740 006 | CERIVASTATIN SODIUM;BAYCOL | 5006530 | JAN 17, 2009 | | D-59 | JUL 21, 2003 |
| | | | 5177080 | JAN 26, 2011 | | I-303 | JUL 21, 2003 |
| | | | | | | NS | JUL 21, 2003 |
| | 021197 001 | CETRORELIX;CETROTIDE | 4800191 | JUL 17, 2007 | | NCE | AUG 11, 2005 |
| | | | 5198533 | JUL 17, 2007 | | | |
| | 021197 002 | CETRORELIX;CETROTIDE | 4800191 | JUL 17, 2007 | | NCE | AUG 11, 2005 |
| | | | 5198533 | JUL 17, 2007 | | | |
| | 020989 002 | CEVIMELINE HYDROCHLORIDE;EVOXAC | 4855290 | AUG 08, 2006 | | NCE | JAN 11, 2005 |
| | | | 5340821 | AUG 23, 2011 | U-309 | | |
| | | | 5580880 | JUN 06, 2015 | U-310 | | |
| | 020832 001 | CHLORHEXIDINE GLUCONATE;CHLORAPREP | | | | NC | JUL 14, 2003 |
| >ADD> | 020780 001 | CIPROFLOXACIN;CIPRO | 6136347 | JAN 06, 2013 | | | |
| >ADD> | 020780 002 | CIPROFLOXACIN;CIPRO | 6136347 | JAN 06, 2013 | | | |
| | 020822 001 | CITALOPRAM HYDROBROMIDE;CELEXA | | | | NCE | JUL 17, 2003 |
| | 021046 001 | CITALOPRAM HYDROBROMIDE;CELEX | | | | NCE | JUL 17, 2003 |
| | 021142 001 | CLOBETASOL PROPIONATE;OLUX FO | | | | NDF | MAY 26, 2003 |
| | 021143 001 | CLOTRIMAZOLE;TRIVAGIZOLE 3 | | | | NP | NOV 24, 2001 |
| | 021141 001 | COLESEVELAM HYDROCHLORIDE;WELCHOL | 5624963 | APR 29, 2014 | U-323 | NCE | MAY 26, 2005 |
| | | | 5679717 | APR 29, 2014 | U-323 | | |
| | | | 5693675 | DEC 02, 2014 | | | |
| | | | 5607669 | JUN 10, 2014 | U-323 | | |
| | | | 5917007 | APR 29, 2014 | U-323 | | |
| | | | 5919832 | JUN 10, 2014 | | | |
| | 021176 001 | COLESEVELAM HYDROCHLORIDE;WELCHOL | 5919832 | JUN 10, 2014 | | NCE | MAY 26, 2005 |
| | | | 5917007 | APR 29, 2014 | U-323 | | |
| | | | 5607669 | JUN 10, 2014 | U-323 | | |
| | | | 5693675 | DEC 02, 2014 | | | |
| | | | 5679717 | APR 29, 2014 | U-323 | | |
| | | | 5624963 | APR 29, 2014 | U-323 | | |
| | 020287 001 | DALTEPARIN SODIUM;FRAGMIN | | | | D-60 | AUG 03, 2003 |
| | 020287 003 | DALTEPARIN SODIUM;FRAGMIN | | | | D-60 | AUG 03, 2003 |
| | 020287 004 | DALTEPARIN SODIUM;FRAGMIN | | | | D-60 | AUG 03, 2003 |
| | 020713 001 | DESOGESTREL;MIRCETTE | RE35724 | OCT 20, 2008 | | | |
| | 020212 001 | DEXRAZOXANE HYDROCHLORIDE;ZINECARD | 5242901 | SEP 07, 2010 | U-339 | | |
| | | | 4963551 | DEC 21, 2007 | | | |
| | | | 4275063 | JUN 23, 2003 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 020212 002 | DEXRAZOXANE HYDROCHLORIDE;ZINECARD | 5242901 | SEP 07, 2010 | U-339 | | |
| | | 4963551 | DEC 21, 2007 | | | |
| | | 4275063 | JUN 23, 2003 | | | |
| 020154 002 | DIDANOSINE;VIDEX | | | | D-58 | OCT 28, 2002 |
| 020154 003 | DIDANOSINE;VIDEX | | | | D-58 | OCT 28, 2002 |
| 020154 004 | DIDANOSINE;VIDEX | 5616566 | AUG 29, 2006 | U-180 | D-58 | OCT 28, 2002 |
| 020154 005 | DIDANOSINE;VIDEX | | | | D-58 | OCT 28, 2002 |
| 020154 006 | DIDANOSINE;VIDEX | | | | NS | OCT 28, 2002 |
| | | | | | D-58 | OCT 28, 2002 |
| 020939 001 | DILTIAZEM HYDROCHLORIDE;DILTIAZEM HCL | 5288505 | JUN 26, 2011 | | | |
| | | 5529791 | JUN 25, 2013 | | | |
| 020939 002 | DILTIAZEM HYDROCHLORIDE;DILTIAZEM HCL | 5288505 | JUN 26, 2011 | | | |
| | | 5529791 | JUN 25, 2013 | | | |
| 020939 003 | DILTIAZEM HYDROCHLORIDE;DILTIAZEM HCL | 5288505 | JUN 26, 2011 | | | |
| | | 5529791 | JUN 25, 2013 | | | |
| 020939 004 | DILTIAZEM HYDROCHLORIDE;DILTIAZEM HCL | 5288505 | JUN 26, 2011 | | | |
| | | 5529791 | JUN 25, 2013 | | | |
| 021168 001 | DIVALPROEX SODIUM;DEPAKOTE ER | 4988731 | JAN 29, 2008 | | NP | AUG 04, 2003 |
| | | 4913906 | APR 03, 2007 | | | |
| 020941 001 | DOCOSANOL;ABREVA | | | | NCE | JUL 25, 2005 |
| 020931 001 | DOFETILIDE;TIKOSYN | 6124363 | OCT 09, 2018 | | | |
| 020931 002 | DOFETILIDE;TIKOSYN | 6124363 | OCT 09, 2018 | | | |
| 020931 003 | DOFETILIDE;TIKOSYN | 6124363 | OCT 09, 2018 | | | |
| 020623 001 | DOLASETRON MESYLATE MONOHYDRATE;ANZEMET | 4906775 | MAR 06, 2007 | | | |
| 020623 002 | DOLASETRON MESYLATE MONOHYDRATE;ANZEMET | 4906775 | MAR 06, 2007 | | | |
| 020624 001 | DOLASETRON MESYLATE MONOHYDRATE;ANZEMET | 4906775 | MAR 06, 2007 | | | |
| 020869 001 | DORZOLAMIDE HYDROCHLORIDE;COSOPT | 4797413 | APR 28, 2008 | U-103 | | |
| | | 4619939 | OCT 28, 2003 | U-104 | | |
| 021027 001 | DOXERCALCIFEROL;HECTOROL | 5602116 | APR 03, 2115 | U-321 | NDF | APR 06, 2003 |
| | | 5707980 | FEB 11, 2117 | U-321 | NCE | JUN 09, 2004 |
| 021145 001 | EFLORNITHINE HYDROCHLORIDE;VANIQA | 4413141 | NOV 01, 2000 | | NP | JUL 27, 2003 |
| | | 4720489 | JAN 19, 2005 | U-334 | | |
| | | 5648394 | JUL 15, 2014 | U-334 | | |
| 019221 001 | ENALAPRIL MALEATE;VASERETIC | 4472380 | SEP 18, 2001 | | | |
| | | 4374829 | FEB 22, 2000 | | | |
| | | 4374829*PED | AUG 22, 2000 | | | |
| | | 4472380*PED | MAR 18, 2002 | | | |
| 019221 003 | ENALAPRIL MALEATE;VASERETIC | 4472380 | SEP 18, 2001 | | | |
| | | 4374829 | FEB 22, 2000 | | | |
| | | 4374829*PED | AUG 22, 2000 | | | |
| | | 4472380*PED | MAR 18, 2002 | | | |
| 018998 001 | ENALAPRIL MALEATE;VASOTEC | 4374829 | FEB 22, 2000 | | | |
| | | 4374829*PED | AUG 22, 2000 | | | |
| 018998 002 | ENALAPRIL MALEATE;VASOTEC | 4374829 | FEB 22, 2000 | | | |
| | | 4374829*PED | AUG 22, 2000 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 018998 003 | ENALAPRIL MALEATE;VASOTEC | 4374829 | FEB 22, 2000 | | | |
| | | | 4374829*PED | AUG 22, 2000 | | | |
| | 018998 005 | ENALAPRIL MALEATE;VASOTEC | 4374829 | FEB 22, 2000 | | | |
| | | | 4374829*PED | AUG 22, 2000 | | | |
| | 019309 001 | ENALAPRILAT;VASOTEC | 4374829 | FEB 22, 2000 | | | |
| | | | 4374829*PED | AUG 22, 2000 | | | |
| | 020444 001 | EPOPROSTENOL SODIUM;FLOLAN | | | | ODE | APR 14, 2007 |
| | | | | | | I-296 | APR 14, 2003 |
| | 020444 002 | EPOPROSTENOL SODIUM;FLOLAN | | | | ODE | APR 14, 2007 |
| | | | | | | I-296 | APR 14, 2003 |
| | 020874 001 | ESTRADIOL CYPIONATE;LUNELLE | | | | NP | OCT 05, 2003 |
| | 020907 001 | ESTRADIOL;ACTIVELLE | | | | I-295 | APR 11, 2003 |
| | 020655 001 | ESTRADIOL;ALORA | 5122383 | MAY 17, 2011 | | | |
| | | | 5227169 | MAY 17, 2011 | | | |
| | | | 5212199 | MAY 17, 2011 | | | |
| | | | 5164190 | DEC 11, 2010 | | | |
| | 020655 002 | ESTRADIOL;ALORA | 5122383 | MAY 17, 2011 | | | |
| | | | 5227169 | MAY 17, 2011 | | | |
| | | | 5212199 | MAY 17, 2011 | | | |
| | | | 5164190 | DEC 11, 2010 | | | |
| | 020655 003 | ESTRADIOL;ALORA | 5122383 | MAY 17, 2011 | | | |
| | | | 5227169 | MAY 17, 2011 | | | |
| | | | 5212199 | MAY 17, 2011 | | | |
| | | | 5164190 | DEC 11, 2010 | | | |
| | 021040 001 | ESTRADIOL;ORTHO-PREFEST | 5108995 | APR 28, 2009 | U-311 | | |
| | | | 5382573 | JAN 17, 2012 | | | |
| | 020323 001 | ESTRADIOL;VIVELLE | | | | I-254 | AUG 16, 2003 |
| | 020323 002 | ESTRADIOL;VIVELLE | | | | I-254 | AUG 16, 2003 |
| | 020323 003 | ESTRADIOL;VIVELLE | | | | I-254 | AUG 16, 2003 |
| | 020323 004 | ESTRADIOL;VIVELLE | | | | I-254 | AUG 16, 2003 |
| | 020323 005 | ESTRADIOL;VIVELLE | 4994278 | MAR 04, 2008 | | NS | AUG 16, 2003 |
| | | | 5300291 | APR 05, 2011 | | I-254 | AUG 16, 2003 |
| | | | 4814168 | MAR 04, 2008 | | | |
| | | | 4994267 | MAR 04, 2008 | | | |
| | 075696 001 | ETODOLAC;ETODOLAC | | | | | |
| | 020584 001 | ETODOLAC;LODINE XL | 4966768*PED | APR 30, 2008 | | PC | FEB 04, 2001 |
| | | | 4966768 | OCT 30, 2007 | | | |
| | 020584 002 | ETODOLAC;LODINE XL | 4966768*PED | APR 30, 2008 | | | |
| | | | 4966768 | OCT 30, 2007 | | | |
| | 020584 003 | ETODOLAC;LODINE XL | 4966768*PED | APR 30, 2008 | | | |
| | | | 4966768 | OCT 30, 2007 | | | |
| >ADD> >ADD> | 019462 001 | FAMOTIDINE;PEPCID | 4283408 | OCT 15, 2000 | | | |
| | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> >ADD> | 019462 002 | FAMOTIDINE;PEPCID | 4283408 | OCT 15, 2000 | | | |
| | | | 4283408*PED | APR 15, 2001 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 019510 001 | FAMOTIDINE;PEPCID | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | 019527 001 | FAMOTIDINE;PEPCID | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | 020325 001 | FAMOTIDINE;PEPCID AC | 4283408 | OCT 15, 2000 | | D-47 | NOV 09, 2001 |
| >ADD> | | | 5667794 | MAY 02, 2015 | U-205 | PED | MAY 09, 2002 |
| >ADD> | | | 5854267 | DEC 29, 2015 | U-267 | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | | | 5667794*PED | NOV 02, 2015 | U-205 | | |
| >ADD> | | | 5854267*PED | JUN 29, 2016 | U-267 | | |
| >ADD> | 020801 001 | FAMOTIDINE;PEPCID AC | 5667794 | MAY 02, 2015 | | | |
| >ADD> | | | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 5854267 | DEC 29, 2015 | U-267 | | |
| >ADD> | | | 5075114 | DEC 24, 2008 | | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | | | 5075114*PED | JUN 24, 2009 | | | |
| >ADD> | | | 5667794*PED | NOV 02, 2015 | | | |
| >ADD> | | | 5854267*PED | JUN 29, 2016 | | | |
| >ADD> | 020902 001 | FAMOTIDINE;PEPCID AC | 5854267 | JUN 02, 2015 | | | |
| >ADD> | | | 5854267*PED | DEC 02, 2015 | | | |
| >ADD> | | | 5677794 | MAY 02, 2015 | | | |
| >ADD> | | | 5677794*PED | NOV 02, 2015 | | | |
| >ADD> | | | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | 019510 004 | FAMOTIDINE;PEPCID PRESERVATIVE | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | 020249 001 | FAMOTIDINE;PEPCID PRESERVATIVE | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 4238408*PED | APR 15, 2001 | | | |
| >ADD> | 020752 001 | FAMOTIDINE;PEPCID RPD | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| >ADD> | 020752 002 | FAMOTIDINE;PEPCID RPD | 4283408 | OCT 15, 2000 | | | |
| >ADD> | | | 4283408*PED | APR 15, 2001 | | | |
| | 019304 002 | FENOFIBRATE;TRICOR (MICRONIZED) | | | | I-298 | APR 24, 2003 |
| | 019304 003 | FENOFIBRATE;TRICOR (MICRONIZED) | | | | I-298 | APR 24, 2003 |
| | 019304 004 | FENOFIBRATE;TRICOR (MICRONIZED) | | | | I-298 | APR 24, 2003 |
| | 020625 001 | FEXOFENADINE HYDROCHLORIDE;ALLEGRA | 6037353 | MAR 14, 2017 | U-138 | | |
| | | | 6113942 | FEB 28, 2015 | | | |
| | 020872 001 | FEXOFENADINE HYDROCHLORIDE;ALLEGRA | 5578610 | NOV 26, 2013 | U-139 | NDF | FEB 25, 2003 |
| | | | 5932247 | FEB 28, 2015 | | NCE | JUL 25, 2001 |
| | | | 5855912 | FEB 28, 2015 | | | |
| | | | 4254129 | FEB 17, 2001 | U-139 | | |
| | | | 6037353 | MAR 14, 2017 | U-138 | | |
| | | | 6113942 | FEB 28, 2015 | | | |
| | 020872 002 | FEXOFENADINE HYDROCHLORIDE;ALLEGRA | 5578610 | NOV 26, 2013 | U-139 | NDF | FEB 25, 2003 |
| | | | 5932247 | FEB 28, 2015 | | NCE | JUL 25, 2001 |
| | | | 5855912 | FEB 28, 2015 | | | |
| | | | 4254129 | FEB 17, 2001 | U-139 | | |
| | | | 6037353 | MAR 14, 2017 | U-138 | | |
| | | | 6113942 | FEB 28, 2015 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 020872 004 | FEXOFENADINE HYDROCHLORIDE;ALLEGRA | 5578610 | NOV 26, 2013 | U-139 | NDF | FEB 25, 2003 |
| | | | 5932247 | FEB 28, 2015 | | NCE | JUL 25, 2001 |
| | | | 5855912 | FEB 28, 2015 | | | |
| | | | 4254129 | FEB 17, 2001 | U-139 | | |
| | 020786 001 | FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D | 6037353 | MAR 14, 2017 | U-138 | | |
| | | | 6113942 | FEB 28, 2015 | | | |
| | | | 6037353 | MAR 14, 2017 | U-138 | | |
| | 019949 004 | FLUCONAZOLE;DIFLUCAN | 6039974 | JUL 31, 2018 | | | |
| | | | 6113942 | FEB 28, 2015 | | | |
| >ADD> | 018936 001 | FLUOXETINE HYDROCHLORIDE;PROZAC | 4416682 | JUN 02, 2001 | | | |
| >ADD> | | | 4404216 | JAN 29, 2004 | | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-154 | | |
| >ADD> | | | 4314081 | FEB 02, 2001 | | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-84 | | |
| >ADD> | | | 4314081*PED | AUG 02, 2001 | | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-154 | | |
| >ADD> | 018936 003 | FLUOXETINE HYDROCHLORIDE;PROZAC | 4626549*PED | JUN 02, 2004 | U-84 | | |
| >ADD> | | | 4314081 | FEB 02, 2001 | | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-154 | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-84 | | |
| >ADD> | | | 4314081*PED | AUG 02, 2001 | | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-154 | | |
| >ADD> | 018936 004 | FLUOXETINE HYDROCHLORIDE;PROZAC | 4626549*PED | JUN 02, 2004 | U-84 | | |
| >ADD> | | | 4314081 | FEB 02, 2001 | | | |
| >ADD> | | | 4314081*PED | AUG 02, 2001 | | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-154 | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-84 | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-154 | | |
| >ADD> | 018936 006 | FLUOXETINE HYDROCHLORIDE;PROZAC | 4626549*PED | JUN 02, 2004 | U-84 | | |
| >ADD> | | | 4314081 | FEB 02, 2001 | | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-154 | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-84 | | |
| >ADD> | | | 4314081*PED | AUG 02, 2001 | | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-154 | | |
| >ADD> | 020101 001 | FLUOXETINE HYDROCHLORIDE;PROZAC | 4626549*PED | JUN 02, 2004 | U-84 | | |
| >ADD> | | | 4314081 | FEB 02, 2001 | | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-84 | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-154 | | |
| >ADD> | | | 4314081*PED | AUG 02, 2001 | | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-84 | | |
| >ADD> | 020974 001 | FLUOXETINE HYDROCHLORIDE;PROZAC | 4626549*PED | JUN 02, 2004 | U-154 | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-84 | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-154 | | |
| >ADD> | | | 4314081 | FEB 02, 2001 | | | |
| >ADD> | | | 4314081*PED | AUG 02, 2001 | | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-84 | | |
| | | | 4626549*PED | JUN 02, 2004 | U-154 | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 020974 002 | FLUOXETINE HYDROCHLORIDE;PROZAC | 4626549 | DEC 02, 2003 | U-84 | | |
| >ADD> | | | 4626549 | DEC 02, 2003 | U-154 | | |
| >ADD> | | | 4314081 | FEB 02, 2001 | | | |
| >ADD> | | | 4314081*PED | AUG 02, 2001 | | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-84 | | |
| >ADD> | | | 4626549*PED | JUN 02, 2004 | U-154 | | |
| >ADD> | 018936 007 | FLUOXETINE HYDROCHLORIDE;SARAFEM | 4971998*PED | MAY 20, 2008 | U-338 | NP | JUL 06, 2003 |
| >ADD> | | | 5114976*PED | NOV 19, 2009 | U-341 | PED | JUN 06, 2004 |
| >ADD> | | | 5744501*PED | NOV 19, 2009 | U-342 | | |
| >ADD> | | | 4971998 | NOV 20, 2007 | U-338 | | |
| | | | 5114976 | MAY 19, 2009 | U-341 | | |
| | | | 5744501 | MAY 19, 2009 | U-342 | | |
| >ADD> | 018936 008 | FLUOXETINE HYDROCHLORIDE;SARAFEM | 4971998*PED | MAY 20, 2008 | U-338 | NP | JUL 06, 2003 |
| >ADD> | | | 5114976*PED | NOV 19, 2009 | U-341 | PED | JAN 06, 2004 |
| >ADD> | | | 5744501*PED | NOV 19, 2009 | U-342 | | |
| | | | 4971998 | NOV 20, 2007 | U-338 | | |
| | | | 5114976 | MAY 19, 2009 | U-341 | | |
| | | | 5744501 | MAY 19, 2009 | U-342 | | |
| | 021077 001 | FLUTICASONE PROPIONATE;ADVAIR DISKUS 100/50 | | | | NC | AUG 24, 2003 |
| | 021077 002 | FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50 | | | | NC | AUG 24, 2003 |
| | 021077 003 | FLUTICASONE PROPIONATE;ADVAIR DISKUS 500/50 | | | | NC | AUG 24, 2003 |
| | 020378 001 | FOLLITROPIN ALFA/BETA;GONAL-F | | | | ODE | MAY 24, 2007 |
| | | | | | | I-306 | MAY 24, 2003 |
| | 020378 002 | FOLLITROPIN ALFA/BETA;GONAL-F | | | | ODE | MAY 24, 2007 |
| | | | | | | I-306 | MAY 24, 2003 |
| | 020378 003 | FOLLITROPIN ALFA/BETA;GONAL-F | 4589402 | JUL 26, 2004 | U-242 | I-306 | MAY 24, 2003 |
| | | | 5767251 | JUN 16, 2015 | | ODE | MAY 24, 2007 |
| | 020235 001 | GABAPENTIN;NEURONTIN | 4087544 | JAN 16, 2000 | U-86 | PED | MAR 29, 2002 |
| | | | 5084479 | JAN 02, 2010 | U-125 | D-43 | SEP 29, 2001 |
| >ADD> | | | 4894476*PED | NOV 02, 2008 | | I-311 | OCT 12, 2003 |
| | | | 4087544*PED | JUL 16, 2000 | U-86 | | |
| | | | 5084479*PED | JUL 02, 2010 | U-125 | | |
| | | | 4894476 | MAY 02, 2008 | | | |
| | | | 6054482 | APR 25, 2017 | | | |
| | | | 6054482*PED | OCT 25, 2017 | | | |
| | 020235 002 | GABAPENTIN;NEURONTIN | 4894476 | MAY 02, 2008 | | PED | MAR 29, 2002 |
| | | | 5084479 | JAN 02, 2010 | U-125 | D-43 | SEP 29, 2001 |
| >ADD> | | | 4087544 | JAN 16, 2000 | U-86 | I-311 | OCT 12, 2003 |
| | | | 5084479*PED | JUL 02, 2010 | U-125 | | |
| | | | 4894476*PED | NOV 02, 2008 | | | |
| | | | 4087544*PED | JUL 16, 2000 | U-86 | | |
| | | | 6054482 | APR 25, 2017 | | | |
| | | | 6054482*PED | OCT 25, 2017 | | | |
| | 020235 003 | GABAPENTIN;NEURONTIN | 4087544 | JAN 16, 2000 | U-86 | PED | MAR 29, 2002 |
| | | | 5084479 | JAN 02, 2010 | U-125 | D-43 | SEP 29, 2001 |
| >ADD> | | | 4894476 | MAY 02, 2008 | | I-311 | OCT 12, 2003 |
| | | | 4087544*PED | JUL 16, 2000 | U-86 | | |
| | | | 5084479*PED | JUL 02, 2010 | | | |
| | | | 4894476*PED | NOV 02, 2008 | | | |
| | | | 6054482 | APR 25, 2017 | | | |
| | | | 6054482*PED | OCT 25, 2017 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 020882 001 | GABAPENTIN;NEURONTIN | 4087544 | JAN 16, 2000 | U-106 | I-311 | OCT 12, 2003 |
| | | | 4894476 | MAY 02, 2008 | | | |
| | | | 5084479 | JAN 02, 2010 | U-258 | | |
| | | | 5084479*PED | JUL 02, 2010 | U-258 | | |
| | | | 4087544*PED | JUL 16, 2000 | U-106 | | |
| | | | 4894476*PED | NOV 02, 2008 | | | |
| | | | 6054482 | APR 25, 2017 | | | |
| | | | 6054482*PED | OCT 25, 2017 | | | |
| >ADD> | 020882 002 | GABAPENTIN;NEURONTIN | 4087544 | JAN 16, 2000 | U-106 | I-311 | OCT 12, 2003 |
| | | | 4894476 | MAY 02, 2008 | | | |
| | | | 5084479 | JAN 02, 2010 | U-258 | | |
| | | | 4087544*PED | JUL 16, 2000 | U-106 | | |
| | | | 4894476*PED | NOV 02, 2008 | | | |
| | | | 5084479*PED | JUL 02, 2010 | U-258 | | |
| | | | 6054482 | APR 25, 2017 | | | |
| | | | 6054482*PED | OCT 25, 2017 | | | |
| >ADD> | 021129 001 | GABAPENTIN;NEURONTIN | | | | I-311 | OCT 12, 2003 |
| | 021037 001 | GADOPENTETATE DIMEGLUMINE;MAGNEVIST | 5362475 | NOV 08, 2011 | | | |
| | | | 5560903 | OCT 01, 2013 | | | |
| | | | 4647447 | MAR 03, 2004 | | | |
| | | | 4957939 | MAR 03, 2004 | | | |
| | | | 4963344 | MAR 03, 2004 | | | |
| | 020460 002 | GANCICLOVIR;CYTOVENE | 4507305 | MAY 21, 2001 | U-64 | | |
| | | | 4423050 | MAY 21, 2001 | U-64 | | |
| | | | 4355032 | JUN 23, 2003 | U-64 | | |
| | | | 4642346 | JUN 24, 2005 | | | |
| | 021174 001 | GEMTUZUMAB OZOGAMICIN;MYLOTARG | 5606040 | FEB 25, 2014 | | ODE | MAY 17, 2007 |
| | | | 5693762 | DEC 02, 2014 | | NCE | MAY 17, 2005 |
| | | | 5739116 | APR 14, 2015 | | | |
| | | | 5767285 | JUN 16, 2015 | | | |
| | | | 5773001 | JUN 30, 2015 | U-320 | | |
| | | | 4970198 | NOV 30, 2007 | | | |
| | | | 5079233 | JAN 07, 2009 | | | |
| | | | 5585089 | DEC 17, 2013 | | | |
| | | | 5981589 | MAY 24, 2014 | | | |
| | 020622 001 | GLATIRAMER ACETATE;COPAXONE | 6054430 | MAY 24, 2014 | | | |
| | 021178 001 | GLYBURIDE;GLUCOVANCE | | | | NC | JUL 31, 2003 |
| | 021178 002 | GLYBURIDE;GLUCOVANCE | | | | NC | JUL 31, 2003 |
| | 021178 003 | GLYBURIDE;GLUCOVANCE | | | | NC | JUL 31, 2003 |
| | 021149 002 | GONADOTROPIN CHORIONIC RECOMBINANT HUMAN;OVIDREL | 5767251 | JUN 16, 2015 | | NP | SEP 20, 2003 |
| | 020125 001 | HYDROCHLOROTHIAZIDE;ACCURETIC | | | | NC | DEC 28, 2002 |
| | 020125 002 | HYDROCHLOROTHIAZIDE;ACCURETIC | | | | NC | DEC 28, 2002 |
| | 020125 003 | HYDROCHLOROTHIAZIDE;ACCURETIC | | | | NC | DEC 28, 2002 |
| | 020387 002 | HYDROCHLOROTHIAZIDE;HYZAAR | 5138069 | AUG 11, 2009 | | | |
| | | | 5153197 | OCT 06, 2009 | U-3 | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 019778 001 | HYDROCHLOROTHIAZIDE;PRINZIDE | 4374829 | DEC 29, 2001 | | | |
| | 019778 002 | HYDROCHLOROTHIAZIDE;PRINZIDE | 4374829 | DEC 29, 2001 | | | |
| | 019778 003 | HYDROCHLOROTHIAZIDE;PRINZIDE | 4374829 | DEC 29, 2001 | U-3 | | |
| | 019771 001 | IBUPROFEN;ADVIL COLD AND SINUS | 4552899 | APR 09, 2004 | | | |
| | | | 4552899*PED | OCT 09, 2004 | | | |
| >ADD> | 021128 001 | IBUPROFEN;CHILDREN'S MOTRIN CO | | | | NP | AUG 01, 2003 |
| | 019763 003 | IFOSFAMIDE;IFEX/MESNEX KIT | 4220660 | MAR 06, 2001 | U-21 | | |
| | | | 5696172 | OCT 06, 2013 | | | |
| | 019763 004 | IFOSFAMIDE;IFEX/MESNEX KIT | 4220660 | MAR 06, 2001 | U-21 | | |
| | | | 5696172 | OCT 06, 2013 | | | |
| | 020986 001 | INSULIN ASPART RECOMBINANT;NOVOLOG | | | | NCE | JUN 07, 2005 |
| | 021081 001 | INSULIN GLARGINE;LANTUS | | | | PED | OCT 20, 2005 |
| | | | | | | NCE | APR 20, 2005 |
| | 020563 001 | INSULIN LISPRO;HUMALOG | | | | D-56 | APR 04, 2003 |
| | 021018 001 | INSULIN LISPRO;HUMALOG MIX 50/50 | | | | NC | DEC 22, 2002 |
| | 020563 002 | INSULIN LISPRO;HUMALOG PEN | 5474978 | JUN 16, 2014 | | D-56 | APR 04, 2003 |
| | | | 5514646 | MAY 07, 2013 | U-111 | NCE | JUN 14, 2001 |
| | 020571 001 | IRINOTECAN HYDROCHLORIDE;CAMPTOSAR | | | | I-299 | APR 20, 2003 |
| >ADD> | 021135 001 | IRON SUCROSE;VENOFER | | | | NP | NOV 07, 2003 |
| | 020966 001 | ITRACONAZOLE;SPORANOX | 4727064 | FEB 23, 2005 | | | |
| | 019084 001 | KETOCONAZOLE;NIZORAL | 4942162 | FEB 11, 2003 | | | |
| | 020857 001 | LAMIVUDINE;COMBIVIR | 4828838*PED | MAR 17, 2006 | | NCE | NOV 17, 2000 |
| | | | 4833130*PED | MAR 17, 2006 | | PED | MAY 17, 2001 |
| | | | 4837208 | SEP 17, 2005 | | | |
| | | | 5047407*PED | AUG 08, 2009 | | | |
| | | | 4724232*PED | MAR 17, 2006 | | | |
| | | | 4818538*PED | MAR 17, 2006 | | | |
| | | | 5859021*PED | NOV 15, 2012 | U-248 | | |
| | | | 5905082*PED | NOV 18, 2016 | U-248 | | |
| | | | 6113920 | OCT 23, 2017 | U-257 | | |
| | | | 6113920*PED | APR 23, 2018 | U-257 | | |
| | | | 4724232 | SEP 17, 2005 | | | |
| | | | 4818538 | SEP 17, 2005 | | | |
| | | | 4828838 | SEP 17, 2005 | | | |
| | | | 4833130 | SEP 17, 2005 | | | |
| | | | 5047407 | FEB 08, 2009 | | | |
| | | | 5859021 | MAY 15, 2012 | U-248 | | |
| | | | 5905082 | MAY 18, 2016 | U-248 | | |
| | | | 4837208*PED | MAR 17, 2006 | | | |
| | 020564 001 | LAMIVUDINE;EPIVIR | 5047407 | NOV 17, 2009 | | NCE | NOV 17, 2000 |
| | | | 5905082 | MAY 18, 2016 | | PED | MAY 17, 2001 |
| | | | 5905082*PED | NOV 18, 2016 | | | |
| | | | 5047407*PED | MAY 17, 2010 | | | |
| | 020596 001 | LAMIVUDINE;EPIVIR | 5047407 | NOV 17, 2009 | | NCE | NOV 17, 2000 |
| | | | 6004968 | MAR 20, 2018 | | PED | MAY 17, 2001 |
| | | | 6004968*PED | SEP 20, 2018 | | | |
| | | | 5047407*PED | MAY 17, 2010 | | | |

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | USE CODE | EXCL CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 021003 001 | LAMIVUDINE;EPIVIR-HBV | 5047407 | FEB 08, 2009 | | | |
| | | | 5532246 | JUL 02, 2013 | U-250 | I-257 | DEC 08, 2001 |
| | | | 5905082 | MAY 18, 2016 | | PED | JUN 08, 2002 |
| | 021004 001 | LAMIVUDINE;EPIVIR-HBV | 5047407*PED | AUG 08, 2009 | | | |
| | | | 5532246*PED | JAN 02, 2014 | U-250 | | |
| | | | 5905082*PED | NOV 18, 2016 | | | |
| >ADD> | 021088 001 | LEUPROLIDE ACETATE;VIADUR | 5047407 | FEB 08, 2009 | | | |
| | | | 5532246 | JUL 02, 2013 | U-250 | NCE | NOV 17, 2000 |
| | | | 6004968 | MAR 20, 2018 | | I-257 | DEC 08, 2001 |
| | | | 5047407*PED | AUG 08, 2009 | | PED | MAY 17, 2001 |
| | | | 5532246*PED | JAN 02, 2014 | | PED | JUN 08, 2002 |
| | | | 6004968*PED | SEP 20, 2018 | U-250 | | |
| | 020837 001 | LEVALBUTEROL HYDROCHLORIDE;XOPENEX | 6132420 | JAN 30, 2017 | | | |
| | | | 5728396 | JAN 30, 2017 | | NP | MAR 03, 2003 |
| | | | 5932547 | JUN 13, 2017 | U-316 | | |
| | 020837 002 | LEVALBUTEROL HYDROCHLORIDE;XOPENEX | 5985305 | JAN 30, 2017 | | | |
| | | | 6113938 | JUL 24, 2018 | | | |
| | | | 6124261 | JUN 13, 2017 | | | |
| | 021114 001 | LEVOBETAXOLOL HYDROCHLORIDE;BETAXON | 5362755 | NOV 08, 2011 | U-332 | | |
| | 020634 001 | LEVOFLOXACIN;LEVAQUIN | 5547994 | AUG 20, 2013 | U-332 | | |
| | 020634 002 | LEVOFLOXACIN;LEVAQUIN | 5760090 | JAN 05, 2010 | U-332 | | |
| | 020635 001 | LEVOFLOXACIN;LEVAQUIN | 5844002 | JAN 05, 2010 | U-332 | | |
| | 020635 002 | LEVOFLOXACIN;LEVAQUIN IN DEXTROSE | 5362755 | NOV 08, 2011 | U-332 | | |
| | 020635 003 | LEVOFLOXACIN;LEVAQUIN IN DEXTROSE | 5547994 | AUG 20, 2013 | U-332 | | |
| | 021199 001 | LEVOFLOXACIN;QUIXIN | 5760090 | JAN 05, 2010 | U-332 | | |
| | | | 5844002 | JAN 05, 2010 | U-332 | | |
| | | | | | | NP | FEB 23, 2003 |
| | | | | | | I-305 | FEB 02, 2003 |
| | | | | | | I-305 | FEB 02, 2003 |
| | | | | | | I-305 | FEB 02, 2003 |
| | | | | | | I-305 | FEB 02, 2003 |
| | | | | | | I-305 | FEB 02, 2003 |
| | | | | | | NDF | AUG 18, 2003 |
| | 020612 001 | LIDOCAINE;LIDODERM | 4382892 | SEP 02, 2003 | | | |
| | 021130 001 | LINEZOLID;ZYVOX | 5503407 | OCT 01, 2008 | | | |
| | 021130 002 | LINEZOLID;ZYVOX | 4551456 | NOV 14, 2003 | | | |
| | 021131 001 | LINEZOLID;ZYVOX | 5053407 | OCT 01, 2008 | | | |
| | 021132 001 | LINEZOLID;ZYVOX | | | | | |
| | 019558 001 | LISINOPRIL;PRINIVIL | 5688792 | NOV 18, 2014 | | NP | MAR 19, 2002 |
| | 019558 002 | LISINOPRIL;PRINIVIL | 5688792 | NOV 18, 2014 | U-319 | NCE | APR 18, 2005 |
| | 019558 003 | LISINOPRIL;PRINIVIL | 5688792 | NOV 18, 2014 | U-319 | NCE | APR 18, 2005 |
| | | | 5688792 | NOV 18, 2014 | U-319 | NCE | APR 18, 2005 |
| | | | 4374829 | DEC 29, 2001 | U-319 | NCE | APR 18, 2005 |
| | | | 4374829 | DEC 29, 2001 | | | |
| | | | 4374829 | DEC 29, 2001 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 019558 004 | LISINOPRIL;PRINIVIL | 4374829 | DEC 29, 2001 | | | |
| | 019558 006 | LISINOPRIL;PRINIVIL | 4374829 | DEC 29, 2001 | | | |
| | 019777 001 | LISINOPRIL;ZESTRIL | | | | I-288 | FEB 07, 2003 |
| | 019777 002 | LISINOPRIL;ZESTRIL | | | | I-288 | FEB 07, 2003 |
| | 019777 003 | LISINOPRIL;ZESTRIL | | | | I-288 | FEB 07, 2003 |
| | 019777 004 | LISINOPRIL;ZESTRIL | | | | I-288 | FEB 07, 2003 |
| | 019777 005 | LISINOPRIL;ZESTRIL | | | | I-288 | FEB 07, 2003 |
| | 019777 006 | LISINOPRIL;ZESTRIL | | | | I-288 | FEB 07, 2003 |
| >ADD> | 021226 001 | LOPINAVIR;KALETRA | 5914332 | DEC 13, 2015 | U-351 | NC | SEP 15, 2003 |
| | | | 5635523 | JUN 30, 2014 | U-352 | | |
| | | | 5541206 | JUL 30, 2013 | U-348 | | |
| | | | 5674882 | OCT 07, 2014 | U-344 | | |
| | | | 5886036 | DEC 29, 2012 | U-345 | | |
| | | | 6037157 | JUN 26, 2016 | U-346 | | |
| | | | 5846987 | DEC 29, 2012 | U-350 | | |
| | | | 5648497 | JUL 15, 2014 | | | |
| >ADD> | 021251 001 | LOPINAVIR;KALETRA | 5541206 | JUL 30, 2013 | U-348 | NC | SEP 15, 2003 |
| | | | 5914332 | DEC 13, 2005 | U-351 | | |
| | | | 5635523 | JUN 03, 2014 | U-352 | | |
| | | | 5846987 | DEC 29, 2012 | U-350 | | |
| | | | 5648497 | JUL 15, 2014 | | | |
| | | | 5674882 | OCT 07, 2014 | U-344 | | |
| | | | 5886036 | DEC 29, 2012 | U-345 | | |
| | | | 6037157 | JUN 26, 2016 | U-346 | | |
| | 019658 001 | LORATADINE;CLARITIN | 4282233 | JUN 19, 2002 | U-77 | | |
| | | | 4659716 | APR 21, 2004 | U-142 | | |
| | | | 4863931 | SEP 15, 2008 | | | |
| | | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | | 4863931*PED | MAR 15, 2009 | | | |
| | 020641 001 | LORATADINE;CLARITIN | 4659716 | APR 21, 2004 | U-142 | | |
| | | | 4282233 | JUN 19, 2002 | U-77 | | |
| | | | 4863931 | SEP 15, 2008 | | | |
| | | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | | 4863931*PED | MAR 15, 2009 | | | |
| | | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | 020704 001 | LORATADINE;CLARITIN REDITABS | 6132758 | JUN 01, 2018 | | | |
| | | | 4659716 | APR 21, 2004 | U-142 | | |
| | | | 4282233 | JUN 19, 2002 | U-77 | | |
| | | | 4371516 | FEB 01, 2000 | | | |
| | | | 4863931 | SEP 15, 2008 | | | |
| | | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | | 4371516*PED | AUG 01, 2000 | | | |
| | | | 4863931*PED | MAR 15, 2009 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 019670 001 | LORATADINE;CLARITIN-D | | | | | |
| | | 4282233 | JUN 19, 2002 | U-77 | | |
| | | 4659716 | APR 21, 2004 | U-142 | | |
| | | 4863931 | SEP 15, 2008 | | | |
| | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | 4863931*PED | MAR 15, 2009 | | | |
| 020470 001 | LORATADINE;CLARITIN-D 24 HOUR | 4659716 | APR 21, 2004 | U-142 | | |
| | | 4282233 | JUN 19, 2002 | U-77 | | |
| | | 5314697*PED | APR 23, 2013 | | | |
| | | 4863931 | SEP 15, 2008 | | | |
| | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | 4863931*PED | MAR 15, 2009 | | | |
| 020803 001 | LOTEPREDNOL ETABONATE;ALREX | 5314697 | APR 23, 2013 | | | |
| 020583 001 | LOTEPREDNOL ETABONATE;LOTEMAX | 4966335 | MAR 09, 2012 | | | |
| 020938 001 | MELOXICAM;MOBIC | 4966335 | MAR 09, 2012 | | | |
| 020049 001 | MESALAMINE;PENTASA | | | | NCE | APR 13, 2005 |
| 019884 001 | MESNA;MESNEX | 4980173 | JAN 29, 2002 | U-78 | | |
| 020357 001 | METFORMIN HYDROCHLORIDE;GLUCOPHAGE | 5696172 | OCT 06, 2013 | | | |
| | | | | | PED | SEP 03, 2000 |
| | | | | | NCE | MAR 03, 2000 |
| | | | | | I-307 | OCT 22, 2001 |
| | | | | | PED | APR 22, 2002 |
| 020357 002 | METFORMIN HYDROCHLORIDE;GLUCOPHAGE | | | | PED | SEP 03, 2000 |
| | | | | | NCE | MAR 03, 2000 |
| | | | | | I-307 | OCT 22, 2001 |
| | | | | | PED | APR 22, 2002 |
| 020357 003 | METFORMIN HYDROCHLORIDE;GLUCOPHAGE | | | | NCE | MAR 03, 2000 |
| | | | | | I-307 | OCT 22, 2001 |
| | | | | | PED | SEP 03, 2000 |
| | | | | | PED | APR 22, 2002 |
| 020357 004 | METFORMIN HYDROCHLORIDE;GLUCOPHAGE | | | | NCE | MAR 03, 2000 |
| | | | | | I-307 | OCT 22, 2001 |
| | | | | | PED | SEP 03, 2000 |
| | | | | | PED | APR 22, 2002 |
| 020357 005 | METFORMIN HYDROCHLORIDE;GLUCOPHAGE | | | | NCE | MAR 03, 2000 |
| | | | | | I-307 | OCT 22, 2001 |
| | | | | | PED | APR 22, 2002 |
| 021202 001 | METFORMIN HYDROCHLORIDE;GLUCOPHAGE XR | | | | NDF | OCT 13, 2003 |
| 021121 001 | METHYLPHENIDATE HYDROCHLORIDE;CONCERTA | | | | NP | AUG 01, 2003 |
| 021121 002 | METHYLPHENIDATE HYDROCHLORIDE;CONCERTA | | | | NP | AUG 01, 2003 |
| 019815 001 | MIDODRINE HYDROCHLORIDE;PROAMATINE | | | | ODE | SEP 06, 2003 |
| 019815 002 | MIDODRINE HYDROCHLORIDE;PROAMATINE | | | | ODE | SEP 06, 2003 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 020687 001 | MIFEPRISTONE;MIFEPREX | 4386085 | JAN 08, 2002 | | NCE | SEP 28, 2005 |
| | | | 4447424 | JAN 08, 2002 | | | |
| | | | 4626531 | OCT 12, 2004 | | | |
| >ADD> | 021120 001 | MITOXANTRONE HYDROCHLORIDE;NOVANTRONE | | | | ODE | OCT 13, 2007 |
| | 020762 001 | MOMETASONE FUROATE MONOHYDRATE;NASONEX | 6127353 | OCT 03, 2017 | | | |
| | 020830 002 | MONTELUKAST SODIUM;SINGULAIR | 5565473 | NOV 30, 2010 | U-228 | I-300 | MAR 03, 2003 |
| | | | | | | NS | MAR 03, 2003 |
| | | | | | | NCE | FEB 20, 2003 |
| | 019516 001 | MORPHINE SULFATE;MS CONTIN | 4366310 | DEC 10, 2000 | | | |
| | 019516 002 | MORPHINE SULFATE;MS CONTIN | 4366310 | DEC 10, 2000 | | | |
| | 019516 003 | MORPHINE SULFATE;MS CONTIN | 4366310 | DEC 10, 2000 | | | |
| | 019516 004 | MORPHINE SULFATE;MS CONTIN | 4366310 | DEC 10, 2000 | | | |
| | 019516 005 | MORPHINE SULFATE;MS CONTIN | 4366310 | DEC 10, 2000 | | | |
| | 020152 001 | NEFAZODONE HYDROCHLORIDE;SERZONE | 5256664 | APR 28, 2012 | | | |
| | 020152 002 | NEFAZODONE HYDROCHLORIDE;SERZONE | 5256664 | APR 28, 2012 | | | |
| | 020152 003 | NEFAZODONE HYDROCHLORIDE;SERZONE | 5256664 | APR 28, 2012 | | | |
| | 020152 004 | NEFAZODONE HYDROCHLORIDE;SERZONE | 5256664 | APR 28, 2012 | | | |
| | 020152 005 | NEFAZODONE HYDROCHLORIDE;SERZONE | 5256664 | APR 28, 2012 | | | |
| | 020152 006 | NEFAZODONE HYDROCHLORIDE;SERZONE | 5256664 | APR 28, 2012 | | | |
| >ADD> | 020381 001 | NIACIN;NIASPAN | 6129930 | SEP 20, 2013 | U-354 | | |
| | | | 6080428 | MAY 27, 2017 | U-331 | | |
| >ADD> | 020381 002 | NIACIN;NIASPAN | 6129930 | SEP 20, 2013 | U-354 | | |
| | | | 6080428 | MAY 27, 2017 | U-331 | | |
| >ADD> | 020381 003 | NIACIN;NIASPAN | 6129930 | SEP 20, 2013 | U-354 | | |
| | | | 6080428 | MAY 27, 2017 | U-331 | | |
| >ADD> | 020381 004 | NIACIN;NIASPAN | 6129930 | SEP 20, 2013 | U-354 | | |
| | | | 6080428 | MAY 27, 2017 | U-331 | | |
| | 020381 005 | NIACIN;NIASPAN TITRATION ST | 6080428 | MAY 27, 2017 | U-331 | | |
| >ADD> | 020076 001 | NICOTINE;HABITROL | 5834011 | MAY 01, 2007 | U-355 | | |
| >ADD> | 020076 002 | NICOTINE;HABITROL | 5834011 | MAY 01, 2007 | U-355 | | |
| >ADD> | 020076 003 | NICOTINE;HABITROL | 5834011 | MAY 01, 2007 | U-355 | | |
| >ADD> | 020076 004 | NICOTINE;HABITROL | 5834011 | MAY 01, 2007 | U-355 | | |
| >ADD> | 020076 005 | NICOTINE;HABITROL | 5834011 | MAY 01, 2007 | U-355 | | |
| >ADD> | 020076 006 | NICOTINE;HABITROL | 5834011 | MAY 01, 2007 | U-355 | | |
| | 020536 001 | NICOTINE;NICOTROL | 5501236 | JUN 08, 2010 | | | |
| | | | 6098632 | JUN 08, 2010 | | | |
| | 020714 001 | NICOTINE;NICOTROL | 6098632 | JUN 08, 2010 | | | |
| | 021134 001 | NITROGLYCERIN;NITROSTAT | | | | NDF | MAY 01, 2003 |
| | 021134 002 | NITROGLYCERIN;NITROSTAT | | | | NDF | MAY 01, 2003 |
| | 021134 003 | NITROGLYCERIN;NITROSTAT | | | | NDF | MAY 01, 2003 |
| | 019921 001 | OFLOXACIN;OCUFLOX | 4382892 | SEP 02, 2003 | | | |
| | | | 4551456 | NOV 14, 2003 | U-80 | | |
| | 020592 001 | OLANZAPINE;ZYPREXA | | | | I-297 | MAR 17, 2003 |
| | 020592 002 | OLANZAPINE;ZYPREXA | | | | I-297 | MAR 17, 2003 |

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 020592 003 | OLANZAPINE;ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 020592 004 | OLANZAPINE;ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 020592 005 | OLANZAPINE;ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 020592 006 | OLANZAPINE;ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 021086 001 | OLANZAPINE;ZYPREXA ZYDIS | | | | NCE | SEP 30, 2001 |
| | | 5457895 | SEP 30, 2013 | | | |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| 021086 002 | OLANZAPINE;ZYPREXA ZYDIS | | | | NCE | SEP 30, 2001 |
| | | 5457895 | SEP 30, 2013 | | | |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| 021086 003 | OLANZAPINE;ZYPREXA ZYDIS | | | | NCE | SEP 30, 2001 |
| | | 5457895 | SEP 30, 2013 | | | |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| 021086 004 | OLANZAPINE;ZYPREXA ZYDIS | | | | NCE | SEP 30, 2001 |
| | | 5457895 | SEP 30, 2013 | | | |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| 020688 001 | OLOPATADINE HYDROCHLORIDE;PATANOL | | | | I-301 | MAR 20, 2003 |
| 019715 001 | OLSALAZINE SODIUM;DIPENTUM | 4559330 | JUL 31, 2004 | U-58 | | |
| 020103 001 | ONDANSETRON HYDROCHLORIDE;ZOFRAN | 5344658 | SEP 06, 2011 | | | |
| 020103 002 | ONDANSETRON HYDROCHLORIDE;ZOFRAN | 5344658 | SEP 06, 2011 | | | |
| 020103 003 | ONDANSETRON HYDROCHLORIDE;ZOFRAN | 5344658 | SEP 06, 2011 | | | |
| | | 5578628 | JUN 24, 2006 | U-44 | I-269 | AUG 27, 2002 |
| | | 4753789 | JUN 24, 2006 | U-44 | | |
| 020605 001 | ONDANSETRON HYDROCHLORIDE;ZOFRAN | 4695578 | JAN 25, 2005 | | | |
| 020781 001 | ONDANSETRON;ZOFRAN ODT | 4695578 | JAN 25, 2005 | U-183 | | |
| | | 5955488 | NOV 14, 2015 | | | |
| | | 6063802 | NOV 14, 2015 | | | |
| | | 5578628 | JUN 24, 2006 | U-330 | | |
| | | 4695578 | JAN 25, 2005 | U-330 | | |
| | | 4753789 | JUN 24, 2006 | U-329 | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 020781 002 | ONDANSETRON;ZOFRAN ODT | 5955488 | NOV 14, 2015 | | | |
| | | | 6063802 | NOV 14, 2015 | | | |
| | | | 5578628 | JUN 24, 2006 | U-330 | | |
| | | | 4695578 | JAN 25, 2005 | U-330 | | |
| | | | 4753789 | JUN 24, 2006 | U-330 | | |
| | 020766 001 | ORLISTAT;XENICAL | 6004996 | JAN 06, 2018 | | | |
| | 021014 001 | OXCARBAZEPINE;TRILEPTAL | | | | NCE | JAN 14, 2005 |
| | 021014 002 | OXCARBAZEPINE;TRILEPTAL | | | | NCE | JAN 14, 2005 |
| | 021014 003 | OXCARBAZEPINE;TRILEPTAL | | | | NCE | JAN 14, 2005 |
| >ADD> | 075184 001 | PACLITAXEL;PACLITAXEL | | | | PC | APR 21, 2001 |
| | 020262 001 | PACLITAXEL;TAXOL | 6096331 | FEB 22, 2013 | | D-57 | JUN 20, 2003 |
| | 020987 001 | PANTOPRAZOLE SODIUM;PROTONIX | 4758579 | JUL 19, 2005 | | NCE | FEB 02, 2005 |
| >ADD> | 020819 001 | PARICALCITOL;ZEMPLAR | 6136799 | APR 08, 2018 | | | |
| | | | 5246925 | SEP 21, 2010 | U-314 | | |
| | | | 5587497 | DEC 24, 2013 | | | |
| >ADD> | 020031 001 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | | | 6113944 | DEC 14, 2014 | | | |
| | | | 6121291 | MAR 17, 2017 | U-286 | | |
| >ADD> | 020031 002 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | | | 6113944 | DEC 14, 2014 | | | |
| | | | 6121291 | MAR 17, 2017 | U-286 | | |
| >ADD> | 020031 003 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | | | 6113944 | DEC 14, 2014 | | | |
| | | | 6121291 | MAR 17, 2017 | U-286 | | |
| >ADD> | 020031 004 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 15, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | | | 6113944 | DEC 14, 2014 | | | |
| >ADD> | 020031 005 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 15, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | | | 6113944 | DEC 14, 2014 | | | |
| | | | 6121291 | MAR 17, 2017 | U-286 | | |
| >ADD> | 020710 001 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | | | 6121291 | MAR 17, 2017 | U-286 | | |
| >ADD> | 020885 001 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | | | 6121291 | MAR 17, 2017 | U-286 | | |

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 020885 002 | PAROXETINE HYDROCHLORIDE;PAXIL | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| >ADD> | 020885 003 | PAROXETINE HYDROCHLORIDE;PAXIL | 6121291 | MAR 17, 2017 | U-286 | | |
| | | | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| >ADD> | 020885 004 | PAROXETINE HYDROCHLORIDE;PAXIL | 6121291 | MAR 17, 2017 | U-286 | | |
| | | | 6133289 | MAY 19, 2015 | U-358 | | |
| | | | 6062927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| >ADD> | 020936 001 | PAROXETINE HYDROCHLORIDE;PAXIL CR | 6121291 | MAR 17, 2017 | U-286 | | |
| | | | 6133289 | MAY 19, 2015 | U-286 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| >ADD> | 020936 002 | PAROXETINE HYDROCHLORIDE;PAXIL CR | 6121291 | MAR 17, 2017 | U-286 | | |
| | | | 6133289 | MAY 19, 2015 | U-286 | | |
| | | | 6063927 | APR 23, 2019 | | | |
| | | | 6080759 | MAY 19, 2015 | | | |
| | 021084 001 | PERFLUOROPOLYMETHYLISOPROPYL ETHER;SKIN EXPOSURE REDUCT | 6121291 | MAR 17, 2017 | U-286 | | |
| | 020698 001 | POLYETHYLENE GLYCOL 3350;MIRALAX | 5607979 | MAY 30, 2015 | | | |
| | 019898 002 | PRAVASTATIN SODIUM;PRAVACHOL | 6048901 | APR 20, 2019 | U-343 | NCE | FEB 17, 2005 |
| | | | 5622985 | APR 22, 2014 | U-335 | I-281 | JUN 09, 2003 |
| | | | | | | I-304 | JAN 18, 2003 |
| | | | | | | I-287 | FEB 10, 2003 |
| | | | | | | I-286 | JAN 18, 2003 |
| | | | | | | D-51 | JAN 18, 2003 |
| | 019898 003 | PRAVASTATIN SODIUM;PRAVACHOL | 5622985 | APR 22, 2014 | U-335 | I-281 | JUN 09, 2003 |
| | | | | | | I-304 | JAN 18, 2003 |
| | | | | | | I-287 | FEB 10, 2003 |
| | | | | | | I-286 | JAN 18, 2003 |
| | | | | | | D-51 | JAN 18, 2003 |
| | 019898 004 | PRAVASTATIN SODIUM;PRAVACHOL | 5622985 | APR 22, 2014 | U-335 | I-281 | JUN 09, 2003 |
| | | | | | | I-304 | JAN 18, 2003 |
| | | | | | | I-287 | FEB 10, 2003 |
| | | | | | | I-286 | JAN 18, 2003 |
| | | | | | | D-51 | JAN 18, 2003 |
| | 019157 001 | PREDNISOLONE SODIUM PHOSPHATE;PEDIAPRED | | | | | |
| | 019901 001 | RAMIPRIL;ALTACE | 4448774 | DEC 22, 2002 | | | |
| | | | 4587258 | JAN 27, 2005 | | | |
| | 019901 002 | RAMIPRIL;ALTACE | 5061722 | OCT 19, 2008 | U-3 | I-310 | OCT 04, 2003 |
| | | | 4587258 | JAN 27, 2005 | | | |
| | 019901 003 | RAMIPRIL;ALTACE | 5061722 | OCT 19, 2008 | U-3 | I-310 | OCT 04, 2003 |
| | | | 4587258 | JAN 27, 2005 | | | |
| | | | 5061722 | OCT 19, 2008 | U-3 | I-310 | OCT 04, 2003 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 019901 004 | RAMIPRIL;ALTACE | 5061722 | OCT 19, 2008 | U-3 | I-310 | OCT 04, 2003 |
| | | 4587258 | JAN 27, 2005 | | | |
| 020630 001 | REMIFENTANIL HYDROCHLORIDE;ULTIVA | 5019583*PED | AUG 15, 2009 | | NPP | OCT 15, 2002 |
| | | 5466700 | AUG 30, 2013 | U-156 | PED | APR 15, 2003 |
| | | 5019583 | FEB 15, 2009 | | PED | JAN 12, 2002 |
| 020630 002 | REMIFENTANIL HYDROCHLORIDE;ULTIVA | 5466700*PED | MAR 01, 2014 | U-156 | NCE | JUL 12, 2001 |
| | | 5019583 | FEB 15, 2009 | | NPP | OCT 15, 2002 |
| | | 5466700 | AUG 30, 2013 | U-156 | PED | APR 15, 2003 |
| | | 5019583*PED | AUG 15, 2009 | | PED | JAN 12, 2002 |
| 020630 003 | REMIFENTANIL HYDROCHLORIDE;ULTIVA | 5466700*PED | MAR 01, 2014 | | NCE | JUL 12, 2001 |
| | | 5019583 | FEB 15, 2009 | | NPP | OCT 15, 2002 |
| | | 5466700 | AUG 30, 2013 | U-156 | PED | APR 15, 2003 |
| | | 5019583*PED | AUG 15, 2009 | | PED | JAN 12, 2002 |
| | | 5466700*PED | MAR 01, 2014 | U-156 | NCE | JUL 12, 2001 |
| 020903 001 | RIBAVIRIN;REBETOL | 6051252 | DEC 22, 2017 | | | |
| 020835 001 | RISEDRONATE SODIUM;ACTONEL | | | | I-292 | APR 14, 2003 |
| | | | | | I-291 | APR 14, 2003 |
| | | | | | I-290 | APR 14, 2003 |
| 020835 002 | RISEDRONATE SODIUM;ACTONEL | | | | I-293 | APR 14, 2003 |
| | | 5583122 | DEC 10, 2013 | U-222 | I-292 | APR 14, 2003 |
| | | | | | NCE | MAR 27, 2003 |
| | | | | | I-291 | APR 14, 2003 |
| | | | | | I-293 | APR 14, 2003 |
| 020588 001 | RISPERIDONE;RISPERDAL | | | | I-290 | APR 14, 2003 |
| | | 5453425 | JUL 11, 2014 | | | |
| 020659 001 | RITONAVIR;NORVIR | 5616587 | JUL 11, 2014 | | | |
| | | 6037157 | JUN 26, 2016 | | | |
| 020945 001 | RITONAVIR;NORVIR | 5674882 | OCT 07, 2014 | | | |
| | | 5886036 | DEC 29, 2012 | | | |
| | | 5648497 | JUL 15, 2014 | | NCE | MAR 01, 2001 |
| 020823 003 | RIVASTIGMINE TARTRATE;EXELON | 5846987 | DEC 29, 2012 | U-347 | | |
| | | 5541206 | JUL 30, 2013 | U-348 | | |
| 020823 004 | RIVASTIGMINE TARTRATE;EXELON | 5635523 | JUN 03, 2014 | U-347 | | |
| | | 4948807 | AUG 14, 2007 | U-322 | NCE | APR 21, 2005 |
| 020823 005 | RIVASTIGMINE TARTRATE;EXELON | 5602176 | FEB 11, 2014 | U-322 | | |
| | | 4948807 | AUG 14, 2007 | U-322 | NCE | APR 21, 2005 |
| 020823 006 | RIVASTIGMINE TARTRATE;EXELON | 5602176 | FEB 11, 2014 | U-322 | | |
| | | 4948807 | AUG 14, 2007 | U-322 | NCE | APR 21, 2005 |
| 021025 001 | RIVASTIGMINE TARTRATE;EXELON | 5602176 | FEB 11, 2014 | U-322 | | |
| | | 4948807 | AUG 14, 2007 | U-322 | NCE | APR 21, 2005 |
| 020864 001 | RIZATRIPTAN BENZOATE;MAXALT | 5602176 | FEB 11, 2014 | U-322 | | |
| | | 5602162 | FEB 11, 2014 | | | |

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | EXCL USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 020864 002 | RIZATRIPTAN BENZOATE;MAXALT | 5602162 | FEB 11, 2014 | | | |
| 021042 001 | ROFECOXIB;VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021042 002 | ROFECOXIB;VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021042 003 | ROFECOXIB;VIOXX | | | | NCE | MAY 20, 2004 |
| 021052 001 | ROFECOXIB;VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021052 002 | ROFECOXIB;VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021071 002 | ROSIGLITAZONE MALEATE;AVANDIA | 5002953 | AUG 30, 2008 | U-329 | I-289 | APR 03, 2003 |
| | | 5741803 | APR 21, 2015 | U-329 | | |
| 021071 003 | ROSIGLITAZONE MALEATE;AVANDIA | 5002953 | AUG 30, 2008 | U-329 | I-289 | APR 03, 2003 |
| | | 5741803 | APR 21, 2015 | U-329 | | |
| 021071 004 | ROSIGLITAZONE MALEATE;AVANDIA | 5002953 | AUG 30, 2008 | U-329 | I-289 | APR 03, 2003 |
| | | 5741803 | APR 21, 2015 | U-329 | | |
| 020990 001 | SERTRALINE HYDROCHLORIDE;ZOLOFT | 4536518 | DEC 30, 2005 | U-286 | | |
| | | 4940731 | AUG 30, 2009 | U-312 | | |
| 021179 001 | SEVELAMER HYDROCHLORIDE;RENAGEL | 5496545 | AUG 11, 2013 | U-246 | NCE | OCT 30, 2003 |
| | | 5667775 | SEP 16, 2014 | U-246 | | |
| 021179 002 | SEVELAMER HYDROCHLORIDE;RENAGEL | 5496545 | AUG 11, 2013 | U-246 | NCE | OCT 30, 2003 |
| | | 5667775 | SEP 16, 2014 | U-246 | | |
| 020478 001 | SEVOFLURANE;ULTANE | 5990176 | JAN 27, 2017 | | NCE | JUN 07, 2000 |
| | | 6074668 | JAN 09, 2018 | | PED | DEC 07, 2000 |
| >ADD> 021097 001 | SODIUM PHOSPHATE, DIBASIC, ANHYDROUS;VISICOL | 5990176*PED | JUL 27, 2017 | | | |
| 020280 006 | SOMATROPIN RECOMBINANT;GENOTROPIN | 6074668*PED | JUL 09, 2018 | | | |
| 020280 007 | SOMATROPIN RECOMBINANT;GENOTROPIN | 5616346 | APR 01, 2017 | U-359 | NP | SEP 21, 2003 |
| | | 4968299 | JUN 28, 2008 | | I-302 | JUN 20, 2003 |
| 020280 001 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | | | | ODE | JUN 20, 2007 |
| | | 4968299 | JUN 28, 2008 | | I-302 | JUN 20, 2003 |
| 020280 002 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | | | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| 020280 003 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| 020280 004 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| 020280 005 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| 020280 008 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2000 |
| 020280 009 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| 020280 010 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| 020280 011 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | | | | ODE | JUN 20, 2007 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 020280 012 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 013 | SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 019721 001 | SOMATROPIN RECOMBINANT;NORDITROPIN | 5633352 | MAY 27, 2014 | | | |
| 019721 002 | SOMATROPIN RECOMBINANT;NORDITROPIN | 5633352 | MAY 27, 2014 | | | |
| 019676 001 | SOMATROPIN RECOMBINANT;NUTROPIN | | | | D-55 | APR 13, 2003 |
| | | | | | M-2 | DEC 01, 2002 |
| 019676 002 | SOMATROPIN RECOMBINANT;NUTROPIN | | | | D-55 | APR 13, 2003 |
| | | | | | M-2 | DEC 01, 2002 |
| 020522 001 | SOMATROPIN RECOMBINANT;NUTROPIN AQ | | | | D-55 | APR 13, 2003 |
| | | | | | M-2 | DEC 01, 2002 |
| 021075 001 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 6051259 | DEC 02, 2012 | U-340 | | |
| 021075 002 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 6051259 | DEC 02, 2012 | U-340 | | |
| 021075 003 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 6051259 | DEC 02, 2012 | U-340 | | |
| 021151 001 | SOTALOL HYDROCHLORIDE;BETAPACE AF | | | | NP | FEB 22, 2003 |
| 021151 002 | SOTALOL HYDROCHLORIDE;BETAPACE AF | | | | NP | FEB 22, 2003 |
| 021151 003 | SOTALOL HYDROCHLORIDE;BETAPACE AF | | | | NP | FEB 22, 2003 |
| 007073 002 | SULFASALAZINE;AZULFIDINE EN-TABS | | | | I-308 | AUG 18, 2003 |
| 020256 001 | TECHNETIUM TC-99M BICISATE KIT;NEUROLITE | 5431900 | JUL 11, 2012 | U-336 | | |
| 019785 001 | TECHNETIUM TC-99M SESTAMIBI KIT;CARDIOLITE | 4894445 | JAN 16, 2007 | U-337 | | |
| | | 5324824 | JAN 16, 2007 | | | |
| | | 4885100 | SEP 11, 2007 | | | |
| | | 4988827 | JAN 29, 2008 | | | |
| 019785 003 | TECHNETIUM TC-99M SESTAMIBI KIT;MIRALUMA | 4452774 | SEP 09, 2004 | | | |
| | | 4894445 | JAN 16, 2007 | U-337 | | |
| | | 5324824 | JAN 16, 2007 | | | |
| | | 4885100 | SEP 11, 2007 | | | |
| | | 4988827 | JAN 29, 2008 | | | |
| 021124 001 | TERBINAFINE HYDROCHLORIDE;LAMISIL AT | 4680291 | JUL 14, 2004 | U-73 | | |
| | | 4755534 | DEC 30, 2006 | U-73 | | |
| | | 5681849 | OCT 28, 2014 | | | |
| 021015 001 | TESTOSTERONE;ANDROGEL | | | | NDF | FEB 28, 2003 |
| 020484 001 | TINZAPARIN SODIUM;INNOHEP | | | | NCE | JUL 14, 2005 |
| 020771 001 | TOLTERODINE TARTRATE;DETROL | 5559269 | MAY 05, 2015 | U-318 | | |
| 020771 002 | TOLTERODINE TARTRATE;DETROL | 5559269 | MAY 05, 2015 | U-318 | | |
| 020281 001 | TRAMADOL HYDROCHLORIDE;ULTRAM | | | | PED | SEP 03, 2000 |
| | | | | | PED | FEB 21, 2002 |
| | | | | | NCE | MAR 03, 2000 |
| 020281 002 | TRAMADOL HYDROCHLORIDE;ULTRAM | | | | D-44 | AUG 21, 2001 |
| | | | | | PED | FEB 21, 2002 |
| | | | | | PED | SEP 03, 2000 |
| | | | | | NCE | MAR 03, 2000 |
| | | | | | D-44 | AUG 21, 2001 |

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 074973 001 | TRIMETHOPRIM HYDROCHLORIDE;PRIMSOL | | | | | |
| 020326 001 | TRIMETREXATE GLUCURONATE;NEUTREXIN | 5763449 | AUG 07, 2016 | | | |
| 020326 002 | TRIMETREXATE GLUCURONATE;NEUTREXIN | 5962461 | AUG 07, 2016 | | | |
| 020715 001 | TRIPTORELIN PAMOATE;TRELSTAR DEPOT | 6017922 | MAY 18, 2018 | | | |
| | | 6017922 | MAY 18, 2018 | | | |
| | | 5134122 | JUL 20, 2010 | | | |
| 020719 001 | TROGLITAZONE;PRELAY | 5225205 | JUL 20, 2010 | | NCE | JUN 15, 2005 |
| 020719 002 | TROGLITAZONE;PRELAY | 5192741 | MAR 09, 2010 | | | |
| 020719 003 | TROGLITAZONE;PRELAY | 6046202 | SEP 15, 2013 | U-317 | | |
| 020720 001 | TROGLITAZONE;REZULIN | 6046202 | SEP 15, 2013 | U-317 | | |
| 020720 002 | TROGLITAZONE;REZULIN | 6046202 | SEP 15, 2013 | U-317 | | |
| 020720 003 | TROGLITAZONE;REZULIN | 6046202 | SEP 15, 2013 | U-317 | | |
| 020759 001 | TROVAFLOXACIN MESYLATE;TROVAN | 6046202 | SEP 15, 2013 | U-317 | | |
| 020759 002 | TROVAFLOXACIN MESYLATE;TROVAN | 6046202 | SEP 15, 2013 | U-317 | | |
| 021214 001 | UNOPROSTONE ISOPROPYL;RESCULA | 5164402 | DEC 18, 2011 | U-282 | | |
| | | 5164402 | DEC 18, 2011 | U-282 | | |
| | | 5001153 | SEP 19, 2008 | | | |
| | | 5151444 | MAR 19, 2008 | | NCE | AUG 03, 2005 |
| | | 5166178 | NOV 24, 2009 | U-333 | | |
| | | 5212200 | MAY 18, 2010 | U-333 | | |
| 020552 001 | VERAPAMIL HYDROCHLORIDE;COVERA-HS | 5208256 | MAY 21, 2011 | U-333 | | |
| | | 5221763 | JUN 22, 2010 | | | |
| | | 5232705 | AUG 31, 2010 | | | |
| | | 5200196 | JAN 22, 2008 | | | |
| | | 5141752 | JUN 27, 2006 | | | |
| | | 5082668 | JAN 21, 2009 | | | |
| | | 5030456 | NOV 07, 2008 | | | |
| 020552 002 | VERAPAMIL HYDROCHLORIDE;COVERA-HS | 4946687 | OCT 02, 2007 | | | |
| | | 5785994 | OCT 22, 2009 | U-315 | | |
| | | 5232705 | AUG 31, 2010 | | | |
| | | 5200196 | JAN 22, 2008 | | | |
| | | 5141752 | JUN 27, 2006 | | | |
| | | 5082668 | JAN 21, 2009 | | | |
| | | 5030456 | NOV 07, 2008 | | | |
| | | 4946687 | OCT 02, 2007 | | | |
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| >ADD> | | 5707608 | AUG 02, 2015 | | | |
| >ADD> | | 6074666 | FEB 05, 2012 | | NCE | APR 12, 2005 |
| >ADD> | | 4920143 | APR 24, 2007 | | | |
| >ADD> | | 5095030 | APR 24, 2007 | | | |
| >ADD> | | 5214036 | MAY 25, 2010 | | | |
| >ADD> | | 5770619 | JAN 06, 2015 | U-357 | | |
| 021119 001 | VERTEPORFIN;VISUDYNE | 5798349 | AUG 25, 2015 | U-357 | | |
| | | 5756541 | MAR 11, 2016 | U-357 | | |
| | | 5583152 | SEP 26, 2010 | | | |
| 020547 001 | ZAFIRLUKAST;ACCOLATE | | | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 020547 003 | ZAFIRLUKAST;ACCOLATE | | | | | |
| | | 4859692 | SEP 26, 2010 | | NCE | SEP 26, 2001 |
| | | 5294636 | DEC 11, 2011 | | I-268 | SEP 17, 2002 |
| | | 5319097 | DEC 11, 2011 | | NS | SEP 17, 2002 |
| | | 5482963 | JAN 09, 2013 | | | |
| | | 5583152 | SEP 26, 2010 | | | |
| | | 5612367 | MAR 18, 2014 | U-189 | | |
| 021036 001 | ZANAMIVIR;RELENZA | | | | I-294 | APR 26, 2003 |
| 020789 001 | ZONISAMIDE;ZONEGRAN | | | | NCE | MAR 27, 2005 |

# PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 20TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

## ABBREVIATIONS

| | |
|---|---|
| **NPP** | **NEW PATIENT POPULATION** |

## REFERENCES

*NEW DOSING SCHEDULE*

| | |
|---|---|
| **D-51** | **OPTIONAL STARTING DOSE OF 40MG/DAY** |
| **D-52** | **ALTERNATE DOSING REGIMEN OF 1250MG TWICE DAILY** |
| **D-53** | **USE IN PEDIATRIC PATIENTS FROM 1 MONTH TO 16 YEARS OF AGE** |
| **D-54** | **USE OF ZYBAN FOR MAINTENANCE THERAPY. TREATMENT UP TO 6 MONTHS WAS SHOWN EFFICACIOUS** |
| **D-55** | **ADDITION OF A HIGHER DOSE OF NUTROPIN FOR PUBERTAL PATIENTS (PUBERTAL DOSE LESS THAN OR EQUAL TO 0.7MG/KG/WEEK)** |
| **D-56** | **ADDITION OF POSTPRANDIAL DOSING** |
| **D-57** | **3-HOUR INFUSION OF TAXOL GIVEN EVERY THREE WEEKS AT A DOSE OF 175MG/M2 FOLLOWED BY CISPLATIN AT A DOSE OF 75MG/M2 FOR THE FIRST-LINE TREATMENT OF ADVANCED OVARIAN CANCER** |
| **D-58** | **CHANGE IN DOSING INTERVAL TO ONCE-DAILY ADMINISTRATION** |
| **D-59** | **REDUCTION OF ELEVATED LDL-C IN A NEW, HIGHER STRENGTH TABLET, 0.8MG, AND FOR EXTENSION OF THE DOSAGE RANGE TO 0.8MG DAILY** |
| **D-60** | **ADDITION OF A POST-OPERATIVE DOSING REGIMEN** |
| **D-61** | **ONCE WEEKLY DOSING FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS** |
| **D-62** | **ONCE WEEKLY DOSING FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS** |

*NEW INDICATION*

| | |
|---|---|
| **I-283** | **TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS** |
| **I-286** | **TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III** |
| **I-287** | **USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH** |
| **I-288** | **CHANGES SEVERAL SECTIONS OF THE PACKAGE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINOPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE** |
| **I-289** | **USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL** |
| **I-290** | **TREATMENT OF CORTICOSTEOID-INDUCED OSTEOPOROSIS** |
| **I-291** | **PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS** |

# PATENT AND EXCLUSIVITY TERMS

*NEW INDICATION*

| | |
|---|---|
| I-292 | TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS |
| I-293 | TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS |
| I-294 | TREATMENT OF UNCOMPLICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS |
| I-295 | PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS |
| I-296 | LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY |
| I-297 | SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER |
| I-298 | TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA |
| I-299 | USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUROURACIL AND LEUCOVARIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM |
| I-300 | PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE |
| I-301 | TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS |
| I-302 | TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME |
| I-303 | INCREASING HDL-CHOLESTEROL IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIAS |
| I-304 | TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IV |
| I-305 | TREATMENT OF LEVOFLOXACIN SUSCEPTIBLE STRAINS OF PENICILLIN-RESISTANT STREPTOCOCCUS PNEUMONIAE IN PATIENTS WITH COMMUNITY ACQUIRED PNEUMONIA |
| I-306 | INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE |
| I-307 | NEW COMBINATION USE OF METFORMIN AND INSULIN IN TYPE 2 DIABETES |
| I-308 | TREATMENT OF PEDIATRIC PATIENTS WITH POLYARTICULAR COURSE JUVENILE RHEUMOTOID ARTHRITIS WHO RESPONDED INADEQUATELY TO SALICYLATES OR OTHER NSAIDS |
| I-309 | INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS |
| I-310 | REDUCTION IN RISK OF MYOCARDIAL INFARCTION, STROKE, AND DEATH FROM CARDIOVASCULAR CAUSES |
| I-311 | ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL SEIZURES IN PEDIATRIC PATIENTS AGE 3 TO 12 YEARS |

*MISCELLANEOUS EXCLUSIVITY CODES*

| | |
|---|---|
| M-2 | APPROVAL FOR ADDTION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE |
| M-3 | ADDITION OF EFFICACY AND SAFETY INFORMATION IN WHICH FOSAMAX WAS USED CONCOMITANTLY WITH ESTROGEN ALONE OR WITH ESTROGEN PLUS PROGESTIN |

# PATENT AND EXCLUSIVITY TERMS

*PATENT USE CODE*

| | |
|---|---|
| U-266 | RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS; MANAGEMENT OF ACUTE PAIN IN ADULTS; TREATMENT OF PRIMARY DYSMENORRHEA |
| U-309 | TREATING SJOEGREN SYNDROME |
| U-310 | TREATMENT OF XEROSTOMIA |
| U-311 | HORMONE REPLACEMENT |
| U-312 | PANIC DISORDER OBSESSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER |
| U-313 | TREATMENT OF CONGESTIVE HEART FAILURE |
| U-314 | METHOD FOR TREATING HYPERPARATHYROIDISM WHICH COMPRISES SUPPRESSING PARATHYROID ACTIVITY |
| U-315 | METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT |
| U-316 | METHOD OF TREATING A SUBJECT SUFFERING FROM PROSTATE CANCER |
| U-317 | METHOD OF USING TROGLITAZONE TO TREAT PATIENTS HAVING INSULIN RESISTANCE |
| U-318 | TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER WITH SYMPTOMS OF URINARY FREQUENCY, URGENCY, OR URGE INCONTINENCE |
| U-319 | TREATMENT OF MICROBIAL INFECTIONS |
| U-320 | INHIBITING OR ELIMINATING ACUTE MYELOID LEUKEMIA |
| U-321 | REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS |
| U-322 | TREATMENT OF ALZHEIMER'S DEMENTIA |
| U-323 | USE AS A BILE ACID SEQUESTRANT |
| U-324 | METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE |
| U-325 | METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE |
| U-326 | METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER |
| U-327 | METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE |
| U-328 | METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH |
| U-329 | USE OF AVANDIA AS MONOTHERAPY, IN COMBINATION WITH METFORMIN, AND IN COMBINATION WITH SULFONYLUREAS TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS |
| U-330 | TREATMENT OF NAUSEA AND VOMITING |
| U-331 | METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT |
| U-332 | TREATMENT OR PREVENTION OF BRONCHOSPASM |
| U-333 | METHOD OF TREATING OCULAR HYPERTENSION |
| U-334 | TREATMENT OF EXCESSIVE FEMALE FACIAL HAIR |
| U-335 | USE OF PRAVASTATIN SODIUM FOR SECONDARY PREVENTION OF CORONARY EVENTS IN MEN AND WOMEN WHO HAVE HAD A MYOCARDIAL INFARCTION AND HAVE NORMAL CHOLESTEROL LEVELS |
| U-336 | DIAGNOSTIC RADIOIMAGING |
| U-337 | USE OF CARDIOLITE/MIRALUMA KIT FOR THE PREPARATION OF TC99M SESTAMIBI |
| U-338 | METHODS FOR TREATING DISTURBANCES OF MOOD, DISTURBANCES OF APPETITE, DEPRESSED MOOD, OR CARBOHYDRATE CRAVING ALL ASSOCIATED WITH PREMENSTRUAL SYNDROME |
| U-339 | PREVENTION OF CARDIO-TOXICITY CAUSED BY THE ADMINISTRATION OF DOXORUBICIN |
| U-340 | THE LONG TERM TREATMENT OF GROWTH FAILURE DUE TO LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION IN CHILDREN |
| U-341 | METHOD FOR ENHANCING THE TREATMENT OF ... LATE LUTEAL PHASE DYSPHORIC DISORDER |
| U-342 | METHOD FOR TREATMENT OF LATE LUTEAL PHASE DYSPHORIC DISORDER |

# PATENT AND EXCLUSIVITY TERMS

*PATENT USE CODE*

| | |
|---|---|
| U-343 | REDUCTION OF INTESTINAL GAS, CRAMPING AND ANORECTAL IRRITATION |
| U-344 | METHOD FOR INHIBITING HIV INFECTION BY ADMINISTERING RITONAVIR IN COMBINATION WITH ANOTHER HIV PROTEASE INHIBITOR |
| U-345 | RITONAVIR AND ANOTHER HIV PROTEASE INHIBITOR FOR CONCOMITANT ADMINISTRATION FOR THE TREATMENT OF AN HIV INFECTION |
| U-346 | METHOD FOR INHIBITING CYTOCHROME P450 MONOOXYGENASE WITH RITONAVIR AND A METHOD FOR IMPROVING THE PHARMCOKINETICS OF A DRUG THAT IS METABOLIZED BY CYTOCHROME P450 MONOOXYGENASE BY ADMIN THE DRUG AND RITONAVIR |
| U-347 | METHOD OF USE IN COMBINATION WITH REVERSE TRANSCRIPTASE INHIBITORS |
| U-348 | METHOD OF USE FOR INHIBITING HIV INFECTION |
| U-349 | METHOD OF USE WHICH IS SUBJECT OF THE APPLICATION |
| U-350 | PREPARATION OF A PHARMACEUTICAL COMPOSITION FOR CONCOMITANT ADMIN WITH A REVERSE TRANSCRIPTASE INHIBITOR |
| U-351 | INHIBITING PROTEASE WITH LOPINAVIR AND INHIBITING AN HIV INFECTION WITH LOPINAVIR |
| U-352 | INHIBITING HIV INFECTION BY ADMINISTERING RITONAVIR IN COMBINATION WITH A REVERSE TRANSCRIPTASE INHIBITOR |
| U-353 | PREVENTION AND TREATMENT OF OSTEOPOROSIS |
| U-354 | METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID WITHOUT CAUSING TREATMENT- LIMITING ELEVATIONS IN URIC ACID OR GLUCOSE LEVELS OR CAUSING LIVER DAMAGE, BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT |
| U-355 | METHOD OF ASSISTING PERSON TO QUIT SMOKING...TRANSDERMALLY ADMIN NICOTINE VIA.. PATCH ADHERED TO SKIN AT DOSING RATE APPROX SAME AS ABSORBED FROM SMOKING |
| U-356 | DELIVERING A MEDICINAL AEROSOL FORMULATION USING CFC-FREE PROPELLANT 134A. |
| U-357 | USE OF THE DRUG PRODUCT IN PHOTODYNAMIC THERAPEUTIC PROTOCOLS FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION AND RELATED CONDITIONS INVOLVING UNWANTED NEOVASCULATURE IN THE EYE |
| U-358 | DEPRESSION, OBSESSIVE COMPULSIVE DISORDER, PANIC DISORDER AND SOCIAL ANXIETY DISORDER |
| U-359 | METHOD OF USE OF VISICOL |

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