

**Approved Drug Product List - Orange Book**  
**Reference Listed Drugs by ANDA Reference Standard List**

February 2022

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This list refers to drug products approved under an Abbreviated New Drug Application (ANDA) that FDA has selected as reference standards and the associated reference listed drugs (RLDs). The purpose of this list is to assist applicants submitting an ANDA to seek approval of a generic drug in identifying an RLD when an ANDA RS has been selected. If the applicant has a question about which listed drug it should refer to as the RLD, the applicant may consult with FDA (refer to section 1.4 Reference Listed Drug and Reference Standard of the Orange Book Preface for more information).

This list is updated monthly. Information in this list is sorted by Active Ingredient(s), Dosage Form, Route, Trade Name, Applicant Name and Strength. Additional information included are marketing status (RX, OTC, DISCN), Application Number, Product Number, and approval date of the Reference Standard.

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### ACETAMINOPHEN

SOLUTION; INTRAVENOUS

ACETAMINOPHEN

|    |            |                     |         |     |              |              |
|----|------------|---------------------|---------|-----|--------------|--------------|
| RX | SANDOZ INC | 1GM/100ML (10MG/ML) | A204052 | 001 | Mar 22, 2016 | RLD: N022450 |
|----|------------|---------------------|---------|-----|--------------|--------------|

### ACYCLOVIR

CREAM; TOPICAL

ACYCLOVIR

|    |                |    |         |     |              |              |
|----|----------------|----|---------|-----|--------------|--------------|
| RX | PADAGIS ISRAEL | 5% | A208702 | 001 | Feb 04, 2019 | RLD: N021478 |
|----|----------------|----|---------|-----|--------------|--------------|

### ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

|    |         |                        |         |     |              |              |
|----|---------|------------------------|---------|-----|--------------|--------------|
| RX | NEPHRON | EQ 0.083% BASE; 0.017% | A076749 | 001 | Dec 31, 2007 | RLD: N020950 |
|----|---------|------------------------|---------|-----|--------------|--------------|

### ALMOTRIPTAN MALATE

TABLET; ORAL

ALMOTRIPTAN MALATE

|    |                   |                |         |     |              |              |
|----|-------------------|----------------|---------|-----|--------------|--------------|
| RX | AJANTA PHARMA LTD | EQ 12.5MG BASE | A205523 | 002 | Mar 03, 2016 | RLD: N021001 |
|----|-------------------|----------------|---------|-----|--------------|--------------|

### AMINOCAPROIC ACID

TABLET; ORAL

AMINOCAPROIC ACID

|    |       |     |         |     |              |              |
|----|-------|-----|---------|-----|--------------|--------------|
| RX | SUNNY | 1GM | A209060 | 002 | Nov 27, 2018 | RLD: N015197 |
|----|-------|-----|---------|-----|--------------|--------------|

### AMIODARONE HYDROCHLORIDE

TABLET; ORAL

AMIODARONE HYDROCHLORIDE

|    |                   |       |         |     |              |              |
|----|-------------------|-------|---------|-----|--------------|--------------|
| RX | UPSHER SMITH LABS | 200MG | A075315 | 001 | Dec 23, 1998 | RLD: N018972 |
|----|-------------------|-------|---------|-----|--------------|--------------|

### AMLODIPINE BESYLATE; TELMISARTAN

TABLET; ORAL

TELMISARTAN AND AMLODIPINE

|    |       |                    |         |     |              |              |
|----|-------|--------------------|---------|-----|--------------|--------------|
| RX | MYLAN | EQ 10MG BASE; 80MG | A202516 | 004 | Aug 26, 2014 | RLD: N022401 |
|----|-------|--------------------|---------|-----|--------------|--------------|

### AMOXICILLIN

TABLET, CHEWABLE; ORAL

AMOXICILLIN

|    |      |       |         |     |              |              |
|----|------|-------|---------|-----|--------------|--------------|
| RX | TEVA | 250MG | A064013 | 001 | Dec 22, 1992 | RLD: N050542 |
|----|------|-------|---------|-----|--------------|--------------|

### AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE

CAPSULE, TABLET, CAPSULE, DELAYED REL PELLETS; ORAL

LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN (COPACKAGED)

|    |        |                    |         |     |              |              |
|----|--------|--------------------|---------|-----|--------------|--------------|
| RX | RISING | 500MG; 500MG; 30MG | A206006 | 001 | Oct 07, 2016 | RLD: N050757 |
|----|--------|--------------------|---------|-----|--------------|--------------|

### AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

|    |        |                      |         |     |              |              |
|----|--------|----------------------|---------|-----|--------------|--------------|
| RX | SANDOZ | 250MG; EQ 125MG BASE | A065189 | 001 | Aug 23, 2005 | RLD: N050564 |
|----|--------|----------------------|---------|-----|--------------|--------------|

|    |            |                      |         |     |              |              |
|----|------------|----------------------|---------|-----|--------------|--------------|
| RX | SANDOZ INC | 500MG; EQ 125MG BASE | A065117 | 001 | Nov 27, 2002 | RLD: N050564 |
|----|------------|----------------------|---------|-----|--------------|--------------|

### ARIPIPRAZOLE

SOLUTION; ORAL

ARIPIPRAZOLE

|    |               |        |         |     |              |              |
|----|---------------|--------|---------|-----|--------------|--------------|
| RX | AMNEAL PHARMS | 1MG/ML | A203906 | 001 | Aug 14, 2015 | RLD: N021713 |
|----|---------------|--------|---------|-----|--------------|--------------|

### BIMATOPROST

SOLUTION/DROPS; OPHTHALMIC

BIMATOPROST

|    |                    |       |         |     |              |              |
|----|--------------------|-------|---------|-----|--------------|--------------|
| RX | ALEMBIC PHARMS LTD | 0.03% | A210263 | 001 | Apr 12, 2019 | RLD: N021275 |
|----|--------------------|-------|---------|-----|--------------|--------------|

### BISMUTH SUBSALICYLATE; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE

TABLET, CHEWABLE, TABLET, CAPSULE; ORAL

BISMUTH SUBSALICYLATE, METRONIDAZOLE AND TETRACYCLINE HYDROCHLORIDE

|    |                  |                                                     |         |     |              |              |
|----|------------------|-----------------------------------------------------|---------|-----|--------------|--------------|
| RX | AILEX PHARMS LLC | 262.4MG, N/A, N/A; N/A, 250MG, N/A; N/A, N/A, 500MG | A202584 | 001 | Nov 30, 2018 | RLD: N050719 |
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### BRETYLIUM TOSYLATE

INJECTABLE; INJECTION  
BRETYLIUM TOSYLATE  
RX BRECKENRIDGE 50MG/ML A204386 001 Dec 21, 2018 RLD: N019030

### BROMOCRIPTINE MESYLATE

CAPSULE; ORAL  
BROMOCRIPTINE MESYLATE  
RX MYLAN EQ 5MG BASE A077226 001 Apr 04, 2005 RLD: N017962  
TABLET; ORAL  
BROMOCRIPTINE MESYLATE  
RX PADAGIS US EQ 2.5MG BASE A077646 001 Oct 01, 2008 RLD: N017962

### BUPROPION HYDROCHLORIDE

TABLET; ORAL  
BUPROPION HYDROCHLORIDE  
RX APOTEX INC 100MG A076143 002 Jan 17, 2006 RLD: N018644

### CABERGOLINE

TABLET; ORAL  
CABERGOLINE  
RX INGENUS PHARMS LLC 0.5MG A204735 001 Aug 01, 2018 RLD: N020664

### CALCITONIN SALMON

SPRAY, METERED; NASAL  
CALCITONIN-SALMON  
RX APOTEX INC 200 IU/SPRAY A076396 001 Nov 17, 2008 RLD: N020313

### CARBOPLATIN

INJECTABLE; INTRAVENOUS  
CARBOPLATIN  
RX ACCORD HLTHCARE 1GM/100ML (10MG/ML) A206775 005 Apr 06, 2020 RLD: N020452

### CEFAZOLIN SODIUM

INJECTABLE; INJECTION  
CEFAZOLIN SODIUM  
RX QILU EQ 10GM BASE/VIAL A209217 001 Oct 17, 2018 RLD: N050461

### CEFIXIME

CAPSULE; ORAL  
CEFIXIME  
RX ALKEM LABS LTD 400MG A210574 001 Oct 09, 2018 RLD: N203195

### CEFOTAXIME SODIUM

INJECTABLE; INJECTION  
CEFOTAXIME  
RX HIKMA EQ 500MG BASE/VIAL A065072 001 Nov 20, 2002 RLD: N050547  
RX EQ 1GM BASE/VIAL A065072 002 Nov 20, 2002 RLD: N050547  
RX EQ 2GM BASE/VIAL A065072 003 Nov 20, 2002 RLD: N050547  
RX EQ 10GM BASE/VIAL A065071 001 Nov 20, 2002 RLD: N050547

### CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL  
CETIRIZINE HYDROCHLORIDE  
RX PADAGIS US 5MG/5ML A078398 001 Jun 17, 2008 RLD: N020346

### CHLOROQUINE PHOSPHATE

TABLET; ORAL  
CHLOROQUINE PHOSPHATE  
RX NATCO PHARMA LTD 500MG A090612 001 Jan 21, 2011 RLD: N006002

### CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL  
CHLORPROMAZINE HYDROCHLORIDE  
RX GENUS 30MG/ML A214542 001 Jun 02, 2021 RLD: N009149  
RX 100MG/ML A214542 002 Jun 02, 2021 RLD: N009149

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### CHLORZOXAZONE

TABLET; ORAL  
CHLORZOXAZONE  
RX MIKART 250MG A207483 001 Jun 24, 2016 RLD: N011300

### CIPROFLOXACIN

INJECTABLE; INJECTION  
CIPROFLOXACIN  
RX BAXTER HLTHCARE 200MG/20ML (10MG/ML) A078062 001 Apr 29, 2008 RLD: N019847  
CORP  
RX 400MG/40ML (10MG/ML) A078062 002 Apr 29, 2008 RLD: N019847  
CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER  
RX HOSPIRA 200MG/100ML A077753 001 Mar 18, 2008 RLD: N019857  
RX 400MG/200ML A077753 002 Mar 18, 2008 RLD: N019857

### CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION  
CLINDAMYCIN PHOSPHATE IN 5% DEXTROSE IN PLASTIC CONTAINER  
RX SANDOZ INC EQ 6MG BASE/ML A201692 001 May 31, 2012 RLD: N050639  
RX EQ 12MG BASE/ML A201692 002 May 31, 2012 RLD: N050639  
RX EQ 18MG BASE/ML A201692 003 May 31, 2012 RLD: N050639

### CLOBETASOL PROPIONATE

OINTMENT; TOPICAL  
CLOBETASOL PROPIONATE  
RX FOUGERA PHARMS 0.05% A074407 001 Feb 23, 1996 RLD: N019323

### CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL  
CYCLOBENZAPRINE HYDROCHLORIDE  
RX RUBICON 10MG A208170 003 May 31, 2017 RLD: N017821

### CYTARABINE

INJECTABLE; INJECTION  
CYTARABINE  
RX FRESENIUS KABI USA 100MG/ML A076512 001 Jan 15, 2004 RLD: N016793  
RX HOSPIRA 20MG/ML A071868 001 Jun 04, 1990 RLD: N016793  
RX WEST-WARD PHARMS 2GM/VIAL A074245 002 Aug 31, 1994 RLD: N016793  
INT

### DACARBAZINE

INJECTABLE; INJECTION  
DACARBAZINE  
RX FRESENIUS KABI USA 100MG/VIAL A075371 001 Aug 27, 1999 RLD: N017575  
RX 200MG/VIAL A075371 002 Aug 27, 1999 RLD: N017575

### DARIFENACIN HYDROBROMIDE

TABLET, EXTENDED RELEASE; ORAL  
DARIFENACIN  
RX MACLEODS PHARMS EQ 15MG BASE A207302 002 Jul 28, 2017 RLD: N021513  
LTD

### DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL  
DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)  
RX SUN PHARM 0.01MG/SPRAY A078271 001 Dec 23, 2013 RLD: N017922

### DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28  
DESOGESTREL AND ETHINYL ESTRADIOL  
RX DURAMED PHARMS 0.15MG; 0.03MG A075256 002 Aug 12, 1999 RLD: N020301  
BARR

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### DESONIDE

|              |             |       |         |     |              |              |
|--------------|-------------|-------|---------|-----|--------------|--------------|
| GEL; TOPICAL |             |       |         |     |              |              |
| DESONIDE     |             |       |         |     |              |              |
| RX           | CINTEX SVCS | 0.05% | A202470 | 001 | May 11, 2020 | RLD: N021844 |

### DEXAMETHASONE SODIUM PHOSPHATE

|                                                  |                    |                      |         |     |              |              |
|--------------------------------------------------|--------------------|----------------------|---------|-----|--------------|--------------|
| INJECTABLE; INJECTION                            |                    |                      |         |     |              |              |
| DEXAMETHASONE SODIUM PHOSPHATE PRESERVATIVE FREE |                    |                      |         |     |              |              |
| RX                                               | FRESENIUS KABI USA | EQ 10MG PHOSPHATE/ML | A040491 | 001 | Apr 11, 2003 | RLD: N014694 |

### DICLOFENAC POTASSIUM

|                      |           |      |         |     |              |              |
|----------------------|-----------|------|---------|-----|--------------|--------------|
| TABLET; ORAL         |           |      |         |     |              |              |
| DICLOFENAC POTASSIUM |           |      |         |     |              |              |
| RX                   | RK PHARMA | 50MG | A075463 | 001 | Jul 26, 1999 | RLD: N020142 |

### DICLOFENAC SODIUM

|                                |            |       |         |     |              |              |
|--------------------------------|------------|-------|---------|-----|--------------|--------------|
| GEL; TOPICAL                   |            |       |         |     |              |              |
| DICLOFENAC SODIUM              |            |       |         |     |              |              |
| RX                             | TARO       | 3%    | A206298 | 001 | Apr 28, 2016 | RLD: N021005 |
| TABLET, EXTENDED RELEASE; ORAL |            |       |         |     |              |              |
| DICLOFENAC SODIUM              |            |       |         |     |              |              |
| RX                             | DEXCEL LTD | 100MG | A076201 | 001 | Nov 06, 2002 | RLD: N020254 |

### DICYCLOMINE HYDROCHLORIDE

|                           |          |          |         |     |              |              |
|---------------------------|----------|----------|---------|-----|--------------|--------------|
| SYRUP; ORAL               |          |          |         |     |              |              |
| DICYCLOMINE HYDROCHLORIDE |          |          |         |     |              |              |
| RX                        | GENERICS | 10MG/5ML | A040169 | 001 | Mar 24, 2005 | RLD: N007961 |

### DOXORUBICIN HYDROCHLORIDE

|                                       |           |                    |         |     |              |              |
|---------------------------------------|-----------|--------------------|---------|-----|--------------|--------------|
| INJECTABLE, LIPOSOMAL; INJECTION      |           |                    |         |     |              |              |
| DOXORUBICIN HYDROCHLORIDE (LIPOSOMAL) |           |                    |         |     |              |              |
| RX                                    | SUN PHARM | 20MG/10ML (2MG/ML) | A203263 | 001 | Feb 04, 2013 | RLD: N050718 |
| RX                                    |           | 50MG/25ML (2MG/ML) | A203263 | 002 | Feb 04, 2013 | RLD: N050718 |

### DYCLONINE HYDROCHLORIDE

|                   |             |      |         |     |              |              |
|-------------------|-------------|------|---------|-----|--------------|--------------|
| SOLUTION; TOPICAL |             |      |         |     |              |              |
| DYCLOPRO          |             |      |         |     |              |              |
| RX                | NOVOCOL INC | 0.5% | A200480 | 001 | Nov 20, 2018 | RLD: N009925 |
| RX                |             | 1%   | A200480 | 002 | Nov 20, 2018 | RLD: N009925 |

### EPTIFIBATIDE

|                       |                |            |         |     |              |              |
|-----------------------|----------------|------------|---------|-----|--------------|--------------|
| INJECTABLE; INJECTION |                |            |         |     |              |              |
| EPTIFIBATIDE          |                |            |         |     |              |              |
| RX                    | MYLAN LABS LTD | 2MG/ML     | A203258 | 001 | Jul 20, 2018 | RLD: N020718 |
| RX                    |                | 75MG/100ML | A203258 | 002 | Jul 20, 2018 | RLD: N020718 |

### ESOMEPRAZOLE SODIUM

|                         |              |                   |         |     |              |              |
|-------------------------|--------------|-------------------|---------|-----|--------------|--------------|
| INJECTABLE; INTRAVENOUS |              |                   |         |     |              |              |
| ESOMEPRAZOLE SODIUM     |              |                   |         |     |              |              |
| RX                      | EUGIA PHARMA | EQ 40MG BASE/VIAL | A204657 | 002 | Aug 10, 2016 | RLD: N021689 |

### ETHINYL ESTRADIOL; NORETHINDRONE

|                 |      |                |         |     |              |              |
|-----------------|------|----------------|---------|-----|--------------|--------------|
| TABLET; ORAL-28 |      |                |         |     |              |              |
| BALZIVA-28      |      |                |         |     |              |              |
| RX              | BARR | 0.035MG; 0.4MG | A076238 | 001 | Apr 22, 2004 | RLD: N017716 |

### ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

|                 |             |                                        |         |     |              |              |
|-----------------|-------------|----------------------------------------|---------|-----|--------------|--------------|
| TABLET; ORAL-28 |             |                                        |         |     |              |              |
| CHABELINA FE    |             |                                        |         |     |              |              |
| RX              | NOVAST LABS | 0.02MG, 0.03MG, 0.035MG; 1MG, 1MG, 1MG | A202962 | 001 | Apr 15, 2020 | RLD: N020130 |

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### ETHINYL ESTRADIOL; NORGESTIMATE

TABLET;ORAL-28

NORGESTIMATE AND ETHINYL ESTRADIOL

|    |                 |                                                   |         |     |              |              |
|----|-----------------|---------------------------------------------------|---------|-----|--------------|--------------|
| RX | GLENMARK PHARMS | 0.025MG,0.025MG,0.025MG;0.18MG,<br>0.215MG,0.25MG | A204057 | 001 | Feb 23, 2016 | RLD: N021241 |
|----|-----------------|---------------------------------------------------|---------|-----|--------------|--------------|

### FAMCICLOVIR

TABLET;ORAL

FAMCICLOVIR

|    |             |       |         |     |              |              |
|----|-------------|-------|---------|-----|--------------|--------------|
| RX | TEVA PHARMS | 500MG | A077487 | 003 | Aug 24, 2007 | RLD: N020363 |
|----|-------------|-------|---------|-----|--------------|--------------|

### FAMOTIDINE

TABLET;ORAL

FAMOTIDINE

|    |                      |      |         |     |              |              |
|----|----------------------|------|---------|-----|--------------|--------------|
| RX | AUROBINDO PHARMA LTD | 40MG | A206530 | 002 | Dec 22, 2015 | RLD: N019462 |
|----|----------------------|------|---------|-----|--------------|--------------|

### FLUCONAZOLE

INJECTABLE;INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

|    |           |                      |         |     |              |              |
|----|-----------|----------------------|---------|-----|--------------|--------------|
| RX | INFORLIFE | 200MG/100ML (2MG/ML) | A079104 | 001 | Jul 30, 2009 | RLD: N019950 |
| RX |           | 400MG/200ML (2MG/ML) | A079104 | 002 | Jul 30, 2009 | RLD: N019950 |

### FLUDEOXYGLUCOSE F-18

INJECTABLE;INTRAVENOUS

FLUDEOXYGLUCOSE F18

|    |                     |              |         |     |              |              |
|----|---------------------|--------------|---------|-----|--------------|--------------|
| RX | QUEEN HAMAMATSU PET | 10-100mCi/ML | A203771 | 001 | Aug 31, 2015 | RLD: N021768 |
|----|---------------------|--------------|---------|-----|--------------|--------------|

### FLUNISOLIDE

SPRAY, METERED;NASAL

FLUNISOLIDE

|    |                 |               |         |     |              |              |
|----|-----------------|---------------|---------|-----|--------------|--------------|
| RX | BAUSCH AND LOMB | 0.025MG/SPRAY | A074805 | 001 | Feb 20, 2002 | RLD: N018148 |
|----|-----------------|---------------|---------|-----|--------------|--------------|

### FLUOXETINE HYDROCHLORIDE

TABLET;ORAL

FLUOXETINE HYDROCHLORIDE

|    |                    |              |         |     |              |              |
|----|--------------------|--------------|---------|-----|--------------|--------------|
| RX | DR REDDYS LABS LTD | EQ 20MG BASE | A076006 | 002 | Apr 23, 2018 | RLD: N020974 |
| RX | TORRENT            | EQ 20MG BASE | A206937 | 002 | Oct 21, 2016 | RLD: N021860 |

### FLUTICASONE PROPIONATE

SPRAY, METERED;NASAL

FLUTICASONE PROPIONATE

|     |       |              |         |     |              |              |
|-----|-------|--------------|---------|-----|--------------|--------------|
| RX  | HIKMA | 0.05MG/SPRAY | A076504 | 001 | Feb 22, 2006 | RLD: N020121 |
| OTC |       | 0.05MG/SPRAY | A207957 | 001 | May 26, 2016 | RLD: N205434 |

### GALANTAMINE HYDROBROMIDE

SOLUTION;ORAL

GALANTAMINE HYDROBROMIDE

|    |       |        |         |     |              |              |
|----|-------|--------|---------|-----|--------------|--------------|
| RX | HIKMA | 4MG/ML | A078185 | 001 | Jan 30, 2009 | RLD: N021224 |
|----|-------|--------|---------|-----|--------------|--------------|

### GANCICLOVIR SODIUM

INJECTABLE;INJECTION

GANCICLOVIR SODIUM

|    |                   |                    |         |     |              |              |
|----|-------------------|--------------------|---------|-----|--------------|--------------|
| RX | PHARMASCIENCE INC | EQ 500MG BASE/VIAL | A207645 | 001 | Dec 08, 2017 | RLD: N019661 |
|----|-------------------|--------------------|---------|-----|--------------|--------------|

### GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET;ORAL

GLYBURIDE AND METFORMIN HYDROCHLORIDE

|    |                  |             |         |     |              |              |
|----|------------------|-------------|---------|-----|--------------|--------------|
| RX | AUROBINDO PHARMA | 2.5MG;500MG | A077870 | 002 | Nov 14, 2007 | RLD: N021178 |
|----|------------------|-------------|---------|-----|--------------|--------------|

### GLYCOPYRROLATE

INJECTABLE;INJECTION

GLYCOPYRROLATE

|    |                    |          |         |     |              |              |
|----|--------------------|----------|---------|-----|--------------|--------------|
| RX | HIKMA FARMACEUTICA | 0.2MG/ML | A090963 | 001 | Sep 21, 2011 | RLD: N017558 |
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### HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET;ORAL  
MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE  
RX TEVA 25MG;15MG A076980 002 Mar 07, 2007 RLD: N020729

### HYDROCODONE BITARTRATE

CAPSULE, EXTENDED RELEASE;ORAL  
HYDROCODONE BITARTRATE  
RX ALVOGEN 10MG A206986 001 Jan 21, 2020 RLD: N202880

### HYDROCODONE BITARTRATE; IBUPROFEN

TABLET;ORAL  
HYDROCODONE BITARTRATE AND IBUPROFEN  
RX AMNEAL PHARMS NY 7.5MG;200MG A076642 001 Oct 12, 2004 RLD: N020716

### HYDROMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
HYDROMORPHONE HYDROCHLORIDE  
RX OSMOTICA PHARM US 32MG A205629 004 Jul 07, 2016 RLD: N021217

### HYDROXYCHLOROQUINE SULFATE

TABLET;ORAL  
HYDROXYCHLOROQUINE SULFATE  
RX ACCORD HLTHCARE 400MG A213342 004 Aug 18, 2021 RLD: N009768

### HYDROXYPROGESTERONE CAPROATE

SOLUTION;INTRAMUSCULAR  
HYDROXYPROGESTERONE CAPROATE  
RX ASPEN GLOBAL INC 1250MG/5ML (250MG/ML) A200271 001 Aug 24, 2015 RLD: N016911

### IBANDRONATE SODIUM

TABLET;ORAL  
IBANDRONATE SODIUM  
RX DR REDDYS LABS LTD EQ 150MG BASE A078997 001 Apr 30, 2012 RLD: N021455

### IMIPRAMINE PAMOATE

CAPSULE;ORAL  
IMIPRAMINE PAMOATE  
RX HIKMA EQ 75MG HYDROCHLORIDE A091099 001 Apr 16, 2010 RLD: N017090

### INDOMETHACIN SODIUM

INJECTABLE;INJECTION  
INDOMETHACIN SODIUM  
RX NAVINTA LLC EQ 1MG BASE/VIAL A206561 001 Jul 19, 2017 RLD: N018878

### IPRATROPIUM BROMIDE

SPRAY, METERED;NASAL  
IPRATROPIUM BROMIDE  
RX HIKMA 0.021MG/SPRAY A076664 001 Nov 05, 2003 RLD: N020393  
RX 0.042MG/SPRAY A076598 001 Nov 05, 2003 RLD: N020394

### ISOSULFAN BLUE

INJECTABLE;INJECTION  
ISOSULFAN BLUE  
RX MYLAN 1% A090874 001 Jul 20, 2010 RLD: N018310  
INSTITUTIONAL

### ISRADIPINE

CAPSULE;ORAL  
ISRADIPINE  
RX WATSON LABS TEVA 5MG A077317 002 Jan 05, 2006 RLD: N019546

### KETOTIFEN FUMARATE

SOLUTION/DROPS;OPHTHALMIC  
ZADITOR  
OTC ALCON PHARMS LTD EQ 0.025% BASE A077200 001 Sep 02, 2008 RLD: N021066

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### LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION

LABETALOL HYDROCHLORIDE

|    |         |        |         |     |              |              |
|----|---------|--------|---------|-----|--------------|--------------|
| RX | HOSPIRA | 5MG/ML | A075239 | 001 | Nov 29, 1999 | RLD: N018686 |
|----|---------|--------|---------|-----|--------------|--------------|

TABLET; ORAL

LABETALOL HYDROCHLORIDE

|    |        |       |         |     |              |              |
|----|--------|-------|---------|-----|--------------|--------------|
| RX | SANDOZ | 200MG | A075113 | 002 | Aug 04, 1998 | RLD: N018687 |
|----|--------|-------|---------|-----|--------------|--------------|

### LACTULOSE

SOLUTION; ORAL

LACTULOSE

|    |       |           |         |     |              |              |
|----|-------|-----------|---------|-----|--------------|--------------|
| RX | AKORN | 10GM/15ML | A074076 | 001 | Jul 03, 1995 | RLD: N017884 |
|----|-------|-----------|---------|-----|--------------|--------------|

### LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

|    |                   |     |         |     |              |              |
|----|-------------------|-----|---------|-----|--------------|--------------|
| RX | GLENMARK GENERICS | 5MG | A090385 | 001 | Feb 24, 2011 | RLD: N022064 |
|----|-------------------|-----|---------|-----|--------------|--------------|

### LEVOFLOXACIN

INJECTABLE; INJECTION

LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

|    |           |                           |         |     |              |              |
|----|-----------|---------------------------|---------|-----|--------------|--------------|
| RX | INFORLIFE | EQ 250MG/50ML (EQ 5MG/ML) | A090343 | 001 | Jul 07, 2011 | RLD: N020635 |
|----|-----------|---------------------------|---------|-----|--------------|--------------|

|    |  |                            |         |     |              |              |
|----|--|----------------------------|---------|-----|--------------|--------------|
| RX |  | EQ 500MG/100ML (EQ 5MG/ML) | A090343 | 002 | Jul 07, 2011 | RLD: N020635 |
|----|--|----------------------------|---------|-----|--------------|--------------|

|    |  |                            |         |     |              |              |
|----|--|----------------------------|---------|-----|--------------|--------------|
| RX |  | EQ 750MG/150ML (EQ 5MG/ML) | A090343 | 003 | Jul 07, 2011 | RLD: N020635 |
|----|--|----------------------------|---------|-----|--------------|--------------|

SOLUTION; ORAL

LEVOFLOXACIN

|    |       |            |         |     |              |              |
|----|-------|------------|---------|-----|--------------|--------------|
| RX | AKORN | 250MG/10ML | A091678 | 001 | Jun 20, 2011 | RLD: N021721 |
|----|-------|------------|---------|-----|--------------|--------------|

### LEVOLEUCOVORIN CALCIUM

SOLUTION; INTRAVENOUS

LEVOLEUCOVORIN CALCIUM

|    |                  |                                        |         |     |              |              |
|----|------------------|----------------------------------------|---------|-----|--------------|--------------|
| RX | GLAND PHARMA LTD | EQ 175MG BASE/17.5ML (EQ 10MG BASE/ML) | A210892 | 001 | Sep 14, 2018 | RLD: N020140 |
|----|------------------|----------------------------------------|---------|-----|--------------|--------------|

|    |  |                                      |         |     |              |              |
|----|--|--------------------------------------|---------|-----|--------------|--------------|
| RX |  | EQ 250MG BASE/25ML (EQ 10MG BASE/ML) | A210892 | 002 | Sep 14, 2018 | RLD: N020140 |
|----|--|--------------------------------------|---------|-----|--------------|--------------|

### LEVONORGESTREL

TABLET; ORAL

LEVONORGESTREL

|    |              |        |         |     |              |              |
|----|--------------|--------|---------|-----|--------------|--------------|
| RX | L PERRIGO CO | 0.75MG | A090740 | 001 | Dec 30, 2010 | RLD: N021045 |
|----|--------------|--------|---------|-----|--------------|--------------|

|     |  |        |         |     |              |              |
|-----|--|--------|---------|-----|--------------|--------------|
| OTC |  | 0.75MG | A090740 | 001 | Dec 30, 2010 | RLD: N021045 |
|-----|--|--------|---------|-----|--------------|--------------|

### LEVORPHANOL TARTRATE

TABLET; ORAL

LEVORPHANOL TARTRATE

|    |                 |     |         |     |              |              |
|----|-----------------|-----|---------|-----|--------------|--------------|
| RX | SENTYNL THERAPS | 3MG | A074278 | 003 | Jun 18, 2018 | RLD: N008720 |
|----|-----------------|-----|---------|-----|--------------|--------------|

INC

### LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL

LIDOCAINE HYDROCHLORIDE

|    |       |    |         |     |              |              |
|----|-------|----|---------|-----|--------------|--------------|
| RX | HIKMA | 4% | A088803 | 001 | Apr 03, 1985 | RLD: N010417 |
|----|-------|----|---------|-----|--------------|--------------|

### LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

LOPERAMIDE HYDROCHLORIDE

|    |       |     |         |     |              |              |
|----|-------|-----|---------|-----|--------------|--------------|
| RX | MYLAN | 2MG | A072741 | 001 | Sep 18, 1991 | RLD: N017694 |
|----|-------|-----|---------|-----|--------------|--------------|

### LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET, CHEWABLE; ORAL

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

|     |         |            |         |     |              |              |
|-----|---------|------------|---------|-----|--------------|--------------|
| OTC | PERRIGO | 2MG; 125MG | A076029 | 001 | Aug 30, 2002 | RLD: N020606 |
|-----|---------|------------|---------|-----|--------------|--------------|



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### MAFENIDE ACETATE

FOR SOLUTION; TOPICAL  
MAFENIDE ACETATE

|    |          |    |         |     |              |              |
|----|----------|----|---------|-----|--------------|--------------|
| RX | PAR FORM | 5% | A201511 | 001 | Feb 12, 2013 | RLD: N019832 |
|----|----------|----|---------|-----|--------------|--------------|

### MEFLOQUINE HYDROCHLORIDE

TABLET; ORAL  
MEFLOQUINE HYDROCHLORIDE

|    |      |       |         |     |              |              |
|----|------|-------|---------|-----|--------------|--------------|
| RX | BARR | 250MG | A076392 | 001 | Dec 29, 2003 | RLD: N019591 |
|----|------|-------|---------|-----|--------------|--------------|

### MELOXICAM

CAPSULE; ORAL  
MELOXICAM

|    |           |      |         |     |              |              |
|----|-----------|------|---------|-----|--------------|--------------|
| RX | LUPIN LTD | 10MG | A209487 | 002 | Jun 01, 2020 | RLD: N207233 |
|----|-----------|------|---------|-----|--------------|--------------|

### MELPHALAN

TABLET; ORAL  
MELPHALAN

|    |         |     |         |     |              |              |
|----|---------|-----|---------|-----|--------------|--------------|
| RX | ALVOGEN | 2MG | A207809 | 001 | Mar 22, 2017 | RLD: N014691 |
|----|---------|-----|---------|-----|--------------|--------------|

### METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
METFORMIN HYDROCHLORIDE

|    |                |       |         |     |              |              |
|----|----------------|-------|---------|-----|--------------|--------------|
| RX | ALKEM LABS LTD | 750MG | A206145 | 002 | Oct 22, 2018 | RLD: N021202 |
|----|----------------|-------|---------|-----|--------------|--------------|

### METHADONE HYDROCHLORIDE

TABLET; ORAL  
METHADONE HYDROCHLORIDE

|    |            |      |         |     |              |              |
|----|------------|------|---------|-----|--------------|--------------|
| RX | SPECGX LLC | 5MG  | A040517 | 001 | Apr 27, 2004 | RLD: N006134 |
| RX |            | 10MG | A040517 | 002 | Apr 27, 2004 | RLD: N006134 |

### METHENAMINE HIPPURATE

TABLET; ORAL  
METHENAMINE HIPPURATE

|    |                      |     |         |     |              |              |
|----|----------------------|-----|---------|-----|--------------|--------------|
| RX | AUROBINDO PHARMA LTD | 1GM | A205661 | 001 | Jul 05, 2016 | RLD: N017681 |
|----|----------------------|-----|---------|-----|--------------|--------------|

### METHOCARBAMOL

TABLET; ORAL  
METHOCARBAMOL

|    |                  |       |         |     |              |              |
|----|------------------|-------|---------|-----|--------------|--------------|
| RX | AUSTARPHARMA LLC | 1GM   | A200958 | 003 | Dec 06, 2021 | RLD: N011011 |
| RX | GRANULES         | 500MG | A209312 | 001 | May 07, 2018 | RLD: N011011 |
| RX |                  | 750MG | A209312 | 002 | May 07, 2018 | RLD: N011011 |

### METHOTREXATE SODIUM

INJECTABLE; INJECTION  
METHOTREXATE SODIUM PRESERVATIVE FREE

|    |                 |                                      |         |     |              |              |
|----|-----------------|--------------------------------------|---------|-----|--------------|--------------|
| RX | ACCORD HLTHCARE | EQ 250MG BASE/10ML (EQ 25MG BASE/ML) | A040768 | 001 | Apr 30, 2007 | RLD: A088760 |
|----|-----------------|--------------------------------------|---------|-----|--------------|--------------|

TABLET; ORAL  
METHOTREXATE SODIUM

|    |       |               |         |     |              |              |
|----|-------|---------------|---------|-----|--------------|--------------|
| RX | HIKMA | EQ 2.5MG BASE | A040054 | 001 | Aug 01, 1994 | RLD: N008085 |
|----|-------|---------------|---------|-----|--------------|--------------|

### METHYLERGONOVINE MALEATE

TABLET; ORAL  
METHYLERGONOVINE MALEATE

|    |                |       |         |     |              |              |
|----|----------------|-------|---------|-----|--------------|--------------|
| RX | NOVEL LABS INC | 0.2MG | A091577 | 001 | May 02, 2011 | RLD: N006035 |
|----|----------------|-------|---------|-----|--------------|--------------|

### METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
METHYLPHENIDATE HYDROCHLORIDE

|    |              |      |         |     |              |              |
|----|--------------|------|---------|-----|--------------|--------------|
| RX | MAYNE PHARMA | 60MG | A078458 | 004 | Jun 23, 2016 | RLD: N021284 |
|----|--------------|------|---------|-----|--------------|--------------|

TABLET, CHEWABLE; ORAL  
METHYLPHENIDATE HYDROCHLORIDE

|    |                   |      |         |     |              |              |
|----|-------------------|------|---------|-----|--------------|--------------|
| RX | ASCENT PHARMS INC | 10MG | A210354 | 003 | Dec 29, 2017 | RLD: N021475 |
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| TABLET, EXTENDED RELEASE;ORAL<br>METHYLPHENIDATE HYDROCHLORIDE                                  |                  |                                  |         |     |                           |
| RX                                                                                              | OSMOTICA         | 72MG                             | A205327 | 005 | Jul 28, 2017 RLD: N021121 |
| <u>METOPROLOL TARTRATE</u>                                                                      |                  |                                  |         |     |                           |
| TABLET;ORAL<br>METOPROLOL TARTRATE                                                              |                  |                                  |         |     |                           |
| RX                                                                                              | MYLAN            | 100MG                            | A076704 | 003 | Jan 16, 2004 RLD: N017963 |
| <u>MOEXIPRIL HYDROCHLORIDE</u>                                                                  |                  |                                  |         |     |                           |
| TABLET;ORAL<br>MOEXIPRIL HYDROCHLORIDE                                                          |                  |                                  |         |     |                           |
| RX                                                                                              | TEVA             | 15MG                             | A076204 | 002 | May 08, 2003 RLD: N020312 |
| <u>MOMETASONE FUROATE</u>                                                                       |                  |                                  |         |     |                           |
| SPRAY, METERED;NASAL<br>MOMETASONE FUROATE                                                      |                  |                                  |         |     |                           |
| RX                                                                                              | APOTEX INC       | 0.05MG/SPRAY                     | A091161 | 001 | Mar 22, 2016 RLD: N020762 |
| <u>MOXIFLOXACIN HYDROCHLORIDE</u>                                                               |                  |                                  |         |     |                           |
| SOLUTION;INTRAVENOUS<br>MOXIFLOXACIN HYDROCHLORIDE IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER |                  |                                  |         |     |                           |
| RX                                                                                              | MYLAN LABS LTD   | 400MG/250ML (1.6MG/ML)           | A205833 | 001 | May 05, 2017 RLD: N021277 |
| <u>NAFTIFINE HYDROCHLORIDE</u>                                                                  |                  |                                  |         |     |                           |
| CREAM;TOPICAL<br>NAFTIFINE HYDROCHLORIDE                                                        |                  |                                  |         |     |                           |
| RX                                                                                              | TARO PHARMS      | 1%                               | A205975 | 001 | Sep 08, 2016 RLD: N019599 |
| <u>NALMEFENE HYDROCHLORIDE</u>                                                                  |                  |                                  |         |     |                           |
| SOLUTION;INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS<br>NALMEFENE HYDROCHLORIDE                    |                  |                                  |         |     |                           |
| RX                                                                                              | PURDUE PHARMA LP | EQ 2MG BASE/2ML (EQ 1MG BASE/ML) | A212955 | 001 | Feb 08, 2022 RLD: N020459 |
| <u>NALTREXONE HYDROCHLORIDE</u>                                                                 |                  |                                  |         |     |                           |
| TABLET;ORAL<br>NALTREXONE HYDROCHLORIDE                                                         |                  |                                  |         |     |                           |
| RX                                                                                              | SPECGX LLC       | 50MG                             | A076264 | 002 | Mar 22, 2002 RLD: N018932 |
| <u>NATEGLINIDE</u>                                                                              |                  |                                  |         |     |                           |
| TABLET;ORAL<br>NATEGLINIDE                                                                      |                  |                                  |         |     |                           |
| RX                                                                                              | ZYDUS PHARMS     | 120MG                            | A205248 | 002 | Jul 06, 2016 RLD: N021204 |
| <u>NICARDIPINE HYDROCHLORIDE</u>                                                                |                  |                                  |         |     |                           |
| CAPSULE;ORAL<br>NICARDIPINE HYDROCHLORIDE                                                       |                  |                                  |         |     |                           |
| RX                                                                                              | EPIC PHARMA      | 30MG                             | A074928 | 002 | Mar 19, 1998 RLD: N019488 |
| <u>NIFEDIPINE</u>                                                                               |                  |                                  |         |     |                           |
| TABLET, EXTENDED RELEASE;ORAL<br>NIFEDIPINE                                                     |                  |                                  |         |     |                           |
| RX                                                                                              | NOVAST LABS      | 60MG                             | A202987 | 002 | Aug 25, 2016 RLD: N020198 |
| RX                                                                                              |                  | 90MG                             | A202987 | 003 | Aug 25, 2016 RLD: N020198 |
| <u>NIZATIDINE</u>                                                                               |                  |                                  |         |     |                           |
| SOLUTION;ORAL<br>NIZATIDINE                                                                     |                  |                                  |         |     |                           |
| RX                                                                                              | AMNEAL PHARMS    | 15MG/ML                          | A090576 | 001 | Nov 18, 2009 RLD: N021494 |
| <u>OFLOXACIN</u>                                                                                |                  |                                  |         |     |                           |
| SOLUTION/DROPS;OTIC<br>OFLOXACIN                                                                |                  |                                  |         |     |                           |
| RX                                                                                              | BAUSCH AND LOMB  | 0.3%                             | A076128 | 001 | Mar 17, 2008 RLD: N020799 |

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### OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS;ORAL  
OMEPRAZOLE

|    |        |      |         |     |              |              |
|----|--------|------|---------|-----|--------------|--------------|
| RX | SANDOZ | 20MG | A075757 | 002 | Jan 28, 2003 | RLD: N019810 |
| RX |        | 40MG | A076515 | 001 | Jan 21, 2009 | RLD: N019810 |

### OXALIPLATIN

INJECTABLE;INTRAVENOUS  
OXALIPLATIN

|    |                   |                     |         |     |              |              |
|----|-------------------|---------------------|---------|-----|--------------|--------------|
| RX | QILU PHARM HAINAN | 200MG/40ML (5MG/ML) | A204368 | 003 | Jun 07, 2016 | RLD: N021759 |
|----|-------------------|---------------------|---------|-----|--------------|--------------|

### OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
OXYBUTYNIN CHLORIDE

|    |                 |      |         |     |              |              |
|----|-----------------|------|---------|-----|--------------|--------------|
| RX | ACCORD HLTHCARE | 15MG | A207138 | 003 | Feb 29, 2016 | RLD: N020897 |
|----|-----------------|------|---------|-----|--------------|--------------|

### PALONOSETRON HYDROCHLORIDE

INJECTABLE;INTRAVENOUS  
PALONOSETRON HYDROCHLORIDE

|    |                    |                                        |         |     |              |              |
|----|--------------------|----------------------------------------|---------|-----|--------------|--------------|
| RX | DR REDDYS LABS LTD | EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML) | A201533 | 002 | Apr 21, 2016 | RLD: N021372 |
|----|--------------------|----------------------------------------|---------|-----|--------------|--------------|

### PANCURONIUM BROMIDE

INJECTABLE;INJECTION  
PANCURONIUM BROMIDE

|    |           |        |         |     |              |              |
|----|-----------|--------|---------|-----|--------------|--------------|
| RX | DR REDDYS | 1MG/ML | A072759 | 001 | Jul 31, 1990 | RLD: N017015 |
| RX |           | 2MG/ML | A072760 | 001 | Jul 31, 1990 | RLD: N017015 |

### PARICALCITOL

CAPSULE;ORAL  
PARICALCITOL

|    |                 |      |         |     |              |              |
|----|-----------------|------|---------|-----|--------------|--------------|
| RX | TEVA PHARMS USA | 4MCG | A090829 | 003 | Sep 27, 2013 | RLD: N021606 |
|----|-----------------|------|---------|-----|--------------|--------------|

### PENTOXIFYLLINE

TABLET, EXTENDED RELEASE;ORAL  
PENTOXIFYLLINE

|    |        |       |         |     |              |              |
|----|--------|-------|---------|-----|--------------|--------------|
| RX | APOTEX | 400MG | A075191 | 001 | Jun 09, 1999 | RLD: N018631 |
|----|--------|-------|---------|-----|--------------|--------------|

### PHENOXYBENZAMINE HYDROCHLORIDE

CAPSULE;ORAL  
PHENOXYBENZAMINE HYDROCHLORIDE

|    |               |      |         |     |              |              |
|----|---------------|------|---------|-----|--------------|--------------|
| RX | PAR PHARM INC | 10MG | A204522 | 001 | Jan 24, 2017 | RLD: N008708 |
|----|---------------|------|---------|-----|--------------|--------------|

### PHENTERMINE HYDROCHLORIDE

TABLET;ORAL  
LOMAIRA

|    |             |     |         |     |              |              |
|----|-------------|-----|---------|-----|--------------|--------------|
| RX | AVANTHI INC | 8MG | A203495 | 001 | Sep 12, 2016 | RLD: N012737 |
|----|-------------|-----|---------|-----|--------------|--------------|

### PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE;INJECTION  
PIPERACILLIN AND TAZOBACTAM

|    |                  |                                      |         |     |              |              |
|----|------------------|--------------------------------------|---------|-----|--------------|--------------|
| RX | WOCKHARDT BIO AG | EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL  | A206996 | 001 | Mar 22, 2017 | RLD: N050684 |
| RX |                  | EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL  | A206996 | 002 | Mar 22, 2017 | RLD: N050684 |
| RX |                  | EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL  | A206996 | 003 | Mar 22, 2017 | RLD: N050684 |
| RX |                  | EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL | A207146 | 001 | Mar 17, 2017 | RLD: N050684 |

### POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE;ORAL  
KLOR-CON M20

|    |                   |       |         |     |              |              |
|----|-------------------|-------|---------|-----|--------------|--------------|
| RX | UPSHER SMITH LABS | 20MEQ | A074726 | 001 | Nov 20, 1998 | RLD: N019439 |
|----|-------------------|-------|---------|-----|--------------|--------------|

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PRILOCAINE HYDROCHLORIDE

|                          |               |    |         |                               |
|--------------------------|---------------|----|---------|-------------------------------|
| INJECTABLE; INJECTION    |               |    |         |                               |
| PRILOCAINE HYDROCHLORIDE |               |    |         |                               |
| RX                       | SEPTODONT INC | 4% | A079235 | 001 Sep 29, 2010 RLD: N021382 |

SELEGILINE HYDROCHLORIDE

|                          |        |     |         |                               |
|--------------------------|--------|-----|---------|-------------------------------|
| CAPSULE; ORAL            |        |     |         |                               |
| SELEGILINE HYDROCHLORIDE |        |     |         |                               |
| RX                       | APOTEX | 5MG | A075321 | 001 Dec 04, 1998 RLD: N020647 |

SODIUM BICARBONATE

|                       |              |           |         |                               |
|-----------------------|--------------|-----------|---------|-------------------------------|
| INJECTABLE; INJECTION |              |           |         |                               |
| SODIUM BICARBONATE    |              |           |         |                               |
| RX                    | EXELA PHARMA | 0.5MEQ/ML | A211091 | 001 Jun 20, 2019 RLD: N019443 |
| RX                    |              | 0.9MEQ/ML | A211091 | 002 Jun 20, 2019 RLD: N019443 |
| RX                    |              | 1MEQ/ML   | A211091 | 003 Jun 20, 2019 RLD: N019443 |

SODIUM POLYSTYRENE SULFONATE

|                      |          |           |         |                               |
|----------------------|----------|-----------|---------|-------------------------------|
| POWDER; ORAL, RECTAL |          |           |         |                               |
| KALEXATE             |          |           |         |                               |
| RX                   | KVK TECH | 454GM/BOT | A040905 | 001 Mar 30, 2009 RLD: N011287 |

STERILE WATER FOR INJECTION

|                             |             |              |         |                               |
|-----------------------------|-------------|--------------|---------|-------------------------------|
| LIQUID; N/A                 |             |              |         |                               |
| STERILE WATER FOR INJECTION |             |              |         |                               |
| RX                          | MEDEFIL INC | 100% (2.5ML) | A211188 | 002 Dec 02, 2019 RLD: N018801 |
| RX                          |             | 100% (3ML)   | A211188 | 003 Dec 02, 2019 RLD: N018801 |
| RX                          |             | 100% (5ML)   | A211188 | 004 Dec 02, 2019 RLD: N018801 |

SUCCINYLCHOLINE CHLORIDE

|                          |              |         |         |                               |
|--------------------------|--------------|---------|---------|-------------------------------|
| INJECTABLE; INJECTION    |              |         |         |                               |
| SUCCINYLCHOLINE CHLORIDE |              |         |         |                               |
| RX                       | ZYDUS PHARMS | 20MG/ML | A209467 | 001 May 04, 2018 RLD: N008845 |

SULFADIAZINE

|              |        |       |         |                               |
|--------------|--------|-------|---------|-------------------------------|
| TABLET; ORAL |        |       |         |                               |
| SULFADIAZINE |        |       |         |                               |
| RX           | SANDOZ | 500MG | A040091 | 001 Jul 29, 1994 RLD: N004122 |

SULFAMETHOXAZOLE; TRIMETHOPRIM

|                                   |                |                  |         |                               |
|-----------------------------------|----------------|------------------|---------|-------------------------------|
| INJECTABLE; INJECTION             |                |                  |         |                               |
| SULFAMETHOXAZOLE AND TRIMETHOPRIM |                |                  |         |                               |
| RX                                | MYLAN LABS LTD | 80MG/ML; 16MG/ML | A206607 | 001 Aug 30, 2017 RLD: N018374 |

TERBUTALINE SULFATE

|                     |                |     |         |                               |
|---------------------|----------------|-----|---------|-------------------------------|
| TABLET; ORAL        |                |     |         |                               |
| TERBUTALINE SULFATE |                |     |         |                               |
| RX                  | LANNETT CO INC | 5MG | A077152 | 002 Mar 25, 2005 RLD: N017849 |

TERCONAZOLE

|                |      |      |         |                               |
|----------------|------|------|---------|-------------------------------|
| CREAM; VAGINAL |      |      |         |                               |
| TERCONAZOLE    |      |      |         |                               |
| RX             | TARO | 0.8% | A075953 | 001 Apr 06, 2004 RLD: N019964 |

TESTOSTERONE

|                                |                     |                             |         |                               |
|--------------------------------|---------------------|-----------------------------|---------|-------------------------------|
| GEL, METERED; TRANSDERMAL      |                     |                             |         |                               |
| TESTOSTERONE                   |                     |                             |         |                               |
| RX                             | ACTAVIS LABS UT INC | 12.5MG/1.25GM ACTUATION     | A076737 | 003 Mar 09, 2015 RLD: N021015 |
| GEL; TRANSDERMAL               |                     |                             |         |                               |
| TESTOSTERONE                   |                     |                             |         |                               |
| RX                             | PADAGIS ISRAEL      | 1.62% (40.5MG/2.5GM PACKET) | A205781 | 002 Jul 12, 2017 RLD: N022309 |
| SOLUTION, METERED; TRANSDERMAL |                     |                             |         |                               |
| TESTOSTERONE                   |                     |                             |         |                               |
| RX                             | PADAGIS ISRAEL      | 30MG/1.5ML ACTUATION        | A204255 | 001 Feb 28, 2017 RLD: N022504 |

**Approved Drug Product List - Orange Book**  
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THIOTHIXENE

|              |                 |     |         |     |                           |
|--------------|-----------------|-----|---------|-----|---------------------------|
| CAPSULE;ORAL |                 |     |         |     |                           |
| THIOTHIXENE  |                 |     |         |     |                           |
| RX           | NOVITIUM PHARMA | 5MG | A211642 | 003 | Apr 05, 2019 RLD: N016584 |

TIMOLOL MALEATE

|                                        |                    |               |         |     |                           |
|----------------------------------------|--------------------|---------------|---------|-----|---------------------------|
| SOLUTION, GEL FORMING/DROPS;OPHTHALMIC |                    |               |         |     |                           |
| TIMOLOL MALEATE                        |                    |               |         |     |                           |
| RX                                     | ALEMBIC PHARMS LTD | EQ 0.25% BASE | A212942 | 001 | Oct 22, 2020 RLD: N020330 |
| RX                                     |                    | EQ 0.5% BASE  | A212942 | 002 | Oct 22, 2020 RLD: N020330 |
| SOLUTION/DROPS;OPHTHALMIC              |                    |               |         |     |                           |
| TIMOLOL MALEATE                        |                    |               |         |     |                           |
| RX                                     | SANDOZ INC         | EQ 0.25% BASE | A074261 | 001 | Apr 28, 1995 RLD: N018086 |
| RX                                     |                    | EQ 0.5% BASE  | A074262 | 001 | Apr 28, 1995 RLD: N018086 |
| TABLET;ORAL                            |                    |               |         |     |                           |
| TIMOLOL MALEATE                        |                    |               |         |     |                           |
| RX                                     | MYLAN              | 20MG          | A072668 | 001 | Jun 08, 1990 RLD: N018017 |

TRAVOPROST

|                           |                |        |         |     |                           |
|---------------------------|----------------|--------|---------|-----|---------------------------|
| SOLUTION/DROPS;OPHTHALMIC |                |        |         |     |                           |
| TRAVOPROST                |                |        |         |     |                           |
| RX                        | STRIDES PHARMA | 0.004% | A091340 | 001 | Mar 01, 2013 RLD: N021257 |

TRIMIPRAMINE MALEATE

|                      |                |              |         |     |                           |
|----------------------|----------------|--------------|---------|-----|---------------------------|
| CAPSULE;ORAL         |                |              |         |     |                           |
| TRIMIPRAMINE MALEATE |                |              |         |     |                           |
| RX                   | CROSSMEDIKA SA | EQ 50MG BASE | A208127 | 002 | Apr 15, 2016 RLD: N016792 |

URSODIOL

|              |            |       |         |     |                           |
|--------------|------------|-------|---------|-----|---------------------------|
| CAPSULE;ORAL |            |       |         |     |                           |
| URSODIOL     |            |       |         |     |                           |
| RX           | LGM PHARMA | 400MG | A205789 | 002 | May 08, 2020 RLD: N019594 |

VARDENAFIL HYDROCHLORIDE

|                          |              |              |         |     |                           |
|--------------------------|--------------|--------------|---------|-----|---------------------------|
| TABLET;ORAL              |              |              |         |     |                           |
| VARDENAFIL HYDROCHLORIDE |              |              |         |     |                           |
| RX                       | ZYDUS PHARMS | EQ 20MG BASE | A208960 | 004 | Oct 31, 2018 RLD: N021400 |

VARENICLINE TARTRATE

|                      |               |             |         |     |                           |
|----------------------|---------------|-------------|---------|-----|---------------------------|
| TABLET;ORAL          |               |             |         |     |                           |
| VARENICLINE TARTRATE |               |             |         |     |                           |
| RX                   | PAR PHARM INC | EQ 1MG BASE | A201785 | 002 | Aug 11, 2021 RLD: N021928 |

VERAPAMIL HYDROCHLORIDE

|                               |                   |          |         |     |                           |
|-------------------------------|-------------------|----------|---------|-----|---------------------------|
| INJECTABLE;INJECTION          |                   |          |         |     |                           |
| VERAPAMIL HYDROCHLORIDE       |                   |          |         |     |                           |
| RX                            | EUGIA PHARMA      | 2.5MG/ML | A212965 | 001 | Jul 06, 2020 RLD: N018485 |
| TABLET, EXTENDED RELEASE;ORAL |                   |          |         |     |                           |
| VERAPAMIL HYDROCHLORIDE       |                   |          |         |     |                           |
| RX                            | GLENMARK GENERICS | 180MG    | A090700 | 002 | Aug 03, 2011 RLD: N019152 |
| TABLET;ORAL                   |                   |          |         |     |                           |
| VERAPAMIL HYDROCHLORIDE       |                   |          |         |     |                           |
| RX                            | HERITAGE PHARMS   | 120MG    | A071881 | 001 | Apr 05, 1988 RLD: N018593 |

VINBLASTINE SULFATE

|                      |       |           |         |     |                           |
|----------------------|-------|-----------|---------|-----|---------------------------|
| INJECTABLE;INJECTION |       |           |         |     |                           |
| VINBLASTINE SULFATE  |       |           |         |     |                           |
| RX                   | HIKMA | 10MG/VIAL | A089395 | 001 | Apr 09, 1987 RLD: N012665 |