

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

March 2026

Page 1 of 34

DESCRIPTION

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.

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

March 2026

Page 2 of 34

ABACAVIR SULFATE

TABLET;ORAL
 ABACAVIR SULFATE
 RX HETERO LABS LTD EQ 300MG BASE A091560 001 Sep 13, 2013 RLD: N020977
 III

ABACAVIR SULFATE; LAMIVUDINE

TABLET;ORAL
 ABACAVIR SULFATE AND LAMIVUDINE
 RX CIPLA EQ 600MG BASE;300MG A091144 001 Mar 28, 2017 RLD: N021652

ACAMPROSATE CALCIUM

TABLET, DELAYED RELEASE;ORAL
 ACAMPROSATE CALCIUM
 RX GLENMARK PHARMS 333MG A202229 001 Jul 16, 2013 RLD: N021431
 LTD

ACETAMINOPHEN

SOLUTION;INTRAVENOUS
 ACETAMINOPHEN
 RX BAXTER HLTHCARE 650MG/65ML (10MG/ML) A214331 002 May 21, 2025 RLD: N022450
 CORP
 RX SANDOZ 1GM/100ML (10MG/ML) A204052 001 Mar 22, 2016 RLD: N022450

ACETAMINOPHEN; BUTALBITAL

TABLET;ORAL
 BUTAPAP
 RX MIKART 325MG;50MG A089987 001 Oct 26, 1992 RLD: A087550

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE;ORAL
 BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
 RX DR REDDYS LABS SA 325MG;50MG;40MG A089007 001 Mar 17, 1986 RLD: A088825
 TABLET;ORAL
 BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
 RX STRIDES PHARMA 325MG;50MG;40MG A040511 001 Aug 27, 2003 RLD: A088616
 INTL

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET;ORAL
 ACETAMINOPHEN AND CODEINE PHOSPHATE
 RX SPECGX LLC 300MG;15MG A040419 001 May 31, 2001 RLD: A085055
 RX 300MG;30MG A040419 002 May 31, 2001 RLD: A085055
 RX 300MG;60MG A040419 003 May 31, 2001 RLD: A085055

ACETAZOLAMIDE

CAPSULE, EXTENDED RELEASE;ORAL
 ACETAZOLAMIDE
 RX CADILA 500MG A205301 001 Jan 16, 2019 RLD: N012945

ACETIC ACID, GLACIAL

SOLUTION/DROPS;OTIC
 ACETIC ACID
 RX SCIEGEN PHARMS 2% A040607 001 Feb 24, 2005 RLD: N012179

ACYCLOVIR

CREAM;TOPICAL
 ACYCLOVIR
 RX PADAGIS ISRAEL 5% A208702 001 Feb 04, 2019 RLD: N021478
 SUSPENSION;ORAL
 ACYCLOVIR
 RX NOVITIUM PHARMA 200MG/5ML A212252 001 Jul 10, 2020 RLD: N019909

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

March 2026

Page 3 of 34

ALBENDAZOLE

TABLET;ORAL
 ALBENDAZOLE
 RX DR REDDYS 200MG A211034 001 Jan 26, 2021 RLD: N020666

ALBUTEROL SULFATE

SOLUTION;INHALATION
 ALBUTEROL SULFATE
 RX RITEDOSE CORP EQ 0.021% BASE A214531 001 Dec 28, 2021 RLD: N020949

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

ALLOPURINOL

TABLET;ORAL
 ALLOPURINOL
 RX UNICHEM 300MG A211820 002 Mar 12, 2019 RLD: N016084

ALMOTRIPTAN MALATE

TABLET;ORAL
 ALMOTRIPTAN MALATE
 RX AJANTA PHARMA LTD EQ 12.5MG BASE A205523 002 Mar 03, 2016 RLD: N021001

ALVIMOPAN

CAPSULE;ORAL
 ALVIMOPAN
 RX WATSON LABS TEVA 12MG A208295 001 Dec 19, 2019 RLD: N021775

AMINOCAPROIC ACID

SOLUTION;ORAL
 AMINOCAPROIC ACID
 RX TP ANDA HOLDINGS 0.25GM/ML A212494 001 Aug 11, 2020 RLD: N015230

TABLET;ORAL
 AMINOCAPROIC ACID
 RX SUNNY 1GM A209060 002 Nov 27, 2018 RLD: N015197

AMLODIPINE BESYLATE; TELMISARTAN

TABLET;ORAL
 TELMISARTAN AND AMLODIPINE
 RX MYLAN EQ 10MG BASE;80MG A202516 004 Aug 26, 2014 RLD: N022401

AMMONIA N-13

INJECTABLE;INTRAVENOUS
 AMMONIA N 13
 RX WA UNIV SCH MED 37.5mCi-800mCi/10ML (3.75-80mCi/ML) A204506 002 Feb 13, 2026 RLD: N022119

AMMONIUM LACTATE

CREAM;TOPICAL
 AMMONIUM LACTATE
 RX SUN PHARMA CANADA EQ 12% BASE A075883 001 Apr 10, 2003 RLD: N020508

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

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

March 2026

Page 4 of 34

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL
 AMOXICILLIN AND CLAVULANATE POTASSIUM
 RX SANDOZ 250MG; EQ 125MG BASE A065189 001 Aug 23, 2005 RLD: N050564

AMPHETAMINE SULFATE

TABLET; ORAL
 EVEKEO
 RX AZURITY 10MG A200166 002 Aug 09, 2012 RLD: A083901

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
 AMPICILLIN TRIHYDRATE
 RX SANDOZ EQ 500MG BASE A064082 002 Aug 29, 1995 RLD: N050056

ARFORMOTEROL TARTRATE

SOLUTION; INHALATION
 ARFORMOTEROL TARTRATE
 RX MANKIND PHARMA EQ 0.015MG BASE/2ML A216128 001 Nov 15, 2022 RLD: N021912

ARGATROBAN

INJECTABLE; INJECTION
 ARGATROBAN
 RX HOSPIRA 250MG/2.5ML (100MG/ML) A204120 001 Sep 21, 2016 RLD: N020833

ARIPIPIRAZOLE

SOLUTION; ORAL
 ARIPIPIRAZOLE
 RX AMNEAL PHARMS 1MG/ML A203906 001 Aug 14, 2015 RLD: N021713

ARSENIC TRIOXIDE

INJECTABLE; INJECTION
 ARSENIC TRIOXIDE
 RX FRESENIUS KABI USA 1MG/ML A208231 001 Aug 31, 2018 RLD: N021248

ASPIRIN; DIPYRIDAMOLE

CAPSULE, EXTENDED RELEASE; ORAL
 ASPIRIN AND DIPYRIDAMOLE
 RX GLENMARK SPECLT 25MG; 200MG A210318 001 May 24, 2019 RLD: N020884

ATOMOXETINE HYDROCHLORIDE

CAPSULE; ORAL
 ATOMOXETINE HYDROCHLORIDE
 RX HETERO LABS LTD V EQ 60MG BASE A202682 005 Mar 11, 2021 RLD: N021411

ATORVASTATIN CALCIUM; EZETIMIBE

TABLET; ORAL
 LYPQOZET
 RX PHARMOBEDIANT EQ 80MG BASE; 10MG A206084 004 Apr 26, 2017 RLD: N200153

ATROPINE SULFATE

SOLUTION/DROPS; OPHTHALMIC
 ATROPINE SULFATE
 RX AMNEAL 1% A214752 001 Jul 14, 2022 RLD: N206289
 SOLUTION; INTRAVENOUS
 ATROPINE SULFATE
 RX AM REGENT 0.4MG/ML (0.4MG/ML) A216120 001 May 26, 2022 RLD: N214652
 RX 1MG/ML (1MG/ML) A216120 002 May 26, 2022 RLD: N214652

AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL
 AZELASTINE HYDROCHLORIDE AND FLUTICASONE PROPIONATE
 RX APOTEX 0.137MG/SPRAY; 0.05MG/SPRAY A207712 001 Apr 28, 2017 RLD: N202236

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

March 2026

Page 5 of 34

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION
 BECLOMETHASONE DIPROPIONATE
 RX AMNEAL IRELAND LTD 0.04MG/INH A213811 001 Dec 16, 2025 RLD: N020911
 RX 0.08MG/INH A213811 002 Dec 16, 2025 RLD: N020911

BENZONATATE

CAPSULE; ORAL
 BENZONATATE
 RX PURACAP PHARM LLC 100MG A206948 001 Dec 19, 2018 RLD: N011210
 RX 200MG A206948 002 Dec 19, 2018 RLD: N011210

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
 CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE
 RX GLENMARK SPECLT 5%; EQ 1% BASE A209252 001 Mar 14, 2019 RLD: N050756

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL
 BETAMETHASONE DIPROPIONATE
 RX SUN PHARMA CANADA EQ 0.05% BASE A076543 001 Dec 09, 2003 RLD: N019555

BETAMETHASONE VALERATE

AEROSOL, FOAM; TOPICAL
 BETAMETHASONE VALERATE
 RX TARO 0.12% A208204 001 May 24, 2017 RLD: N020934

BETHANECHOL CHLORIDE

TABLET; ORAL
 BETHANECHOL CHLORIDE
 RX AMNEAL PHARM 10MG A040855 002 Nov 21, 2007 RLD: A088440
 RX 25MG A040855 003 Nov 21, 2007 RLD: A088441

BIMATOPROST

SOLUTION/DROPS; OPHTHALMIC
 BIMATOPROST
 RX ALEMBIC 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

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
 BROMFENAC SODIUM
 RX ALEMBIC EQ 0.09% ACID A210560 001 Jun 21, 2019 RLD: N021664

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

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL
 BROMPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE
 RX PADAGIS US 2MG/5ML; 10MG/5ML; 30MG/5ML A205292 001 Jul 15, 2014 RLD: A088811

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

March 2026

Page 6 of 34

BUDESONIDE

AEROSOL, FOAM;RECTAL
 BUDESONIDE
 RX PADAGIS ISRAEL 2MG/ACTUATION A215328 001 Apr 12, 2023 RLD: N205613

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE;INJECTION
 BUPRENORPHINE HYDROCHLORIDE
 RX PH HEALTH EQ 0.3MG BASE/ML A206586 001 Jul 28, 2015 RLD: N018401

BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE

TABLET;SUBLINGUAL
 BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE
 RX HIKMA EQ 8MG BASE;EQ 2MG BASE A203326 002 Jun 27, 2014 RLD: N020733

BUPROPION HYDROCHLORIDE

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

BUSPIRONE HYDROCHLORIDE

CAPSULE;ORAL
 BUCAPSOL
 RX EPIC PHARMA LLC 15MG A218628 003 Mar 13, 2025 RLD: N021190
 TABLET;ORAL
 BUSPIRONE HYDROCHLORIDE
 RX UNICHEM 15MG A210907 003 Nov 14, 2019 RLD: N018731

CABERGOLINE

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

CAFFEINE; ERGOTAMINE TARTRATE

TABLET;ORAL
 ERGOTAMINE TARTRATE AND CAFFEINE
 RX MIKART 100MG;1MG A040590 001 Sep 16, 2005 RLD: A084294

CALCIPOTRIENE

OINTMENT;TOPICAL
 CALCIPOTRIENE
 RX GLENMARK PHARMS 0.005% A090633 001 Mar 24, 2010 RLD: N020273

CALCITONIN SALMON

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

CALCIUM ACETATE

CAPSULE;ORAL
 CALCIUM ACETATE
 RX INVAGEN PHARMS 667MG A203135 001 Feb 07, 2013 RLD: N021160

CALCIUM GLUCONATE

SOLUTION;INTRAVENOUS
 CALCIUM GLUCONATE IN SODIUM CHLORIDE
 RX AMNEAL 1GM/50ML (20MG/ML) A217174 001 Sep 05, 2023 RLD: N208418
 RX 2GM/100ML (20MG/ML) A217174 002 Sep 05, 2023 RLD: N208418

CAPECITABINE

TABLET;ORAL
 CAPECITABINE
 RX DR REDDYS 500MG A204345 002 Dec 04, 2020 RLD: N020896

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

March 2026

Page 7 of 34

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE;ORAL
 CARBIDOPA AND LEVODOPA
 RX SCIEGEN PHARMS 50MG;200MG A214091 002 Oct 05, 2021 RLD: N019856

CARBOPLATIN

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

CARVEDILOL PHOSPHATE

CAPSULE, EXTENDED RELEASE;ORAL
 CARVEDILOL PHOSPHATE
 RX SUN PHARM 40MG A090132 003 Oct 25, 2017 RLD: N022012
 INDUSTRIES

CASPOFUNGIN ACETATE

POWDER;INTRAVENOUS
 CASPOFUNGIN ACETATE
 RX HENGRUI PHARMA 50MG/VIAL A200833 001 Jun 28, 2018 RLD: N021227
 RX 70MG/VIAL A200833 002 Jun 28, 2018 RLD: N021227

CEFAZOLIN SODIUM

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

CEFEPIME HYDROCHLORIDE

INJECTABLE;INJECTION
 CEFEPIME HYDROCHLORIDE
 RX QILU ANTIBIOTICS EQ 500MG BASE/VIAL A203704 001 Feb 01, 2016 RLD: N050679
 RX EQ 1GM BASE/VIAL A203704 002 Feb 01, 2016 RLD: N050679
 RX EQ 2GM BASE/VIAL A203704 003 Feb 01, 2016 RLD: N050679
 POWDER;INTRAVENOUS
 CEFEPIME HYDROCHLORIDE IN PLASTIC CONTAINER
 RX SAMSON MEDCL EQ 100GM BASE A209408 001 Aug 21, 2018 RLD: N050679

CEFIXIME

TABLET;ORAL
 CEFIXIME
 RX FDC LTD 400MG A206358 001 Dec 17, 2024 RLD: N050621

CEFOTETAN DISODIUM

INJECTABLE;INJECTION
 CEFOTETAN
 RX FRESENIUS KABI USA EQ 1GM BASE/VIAL A065374 001 Aug 09, 2007 RLD: N050588
 RX EQ 2GM BASE/VIAL A065374 002 Aug 09, 2007 RLD: N050588

CEFUROXIME SODIUM

INJECTABLE;INJECTION
 CEFUROXIME SODIUM
 RX HIKMA EQ 1.5GM BASE/VIAL A065048 002 Jan 09, 2004 RLD: N050558
 INJECTABLE;INTRAMUSCULAR, INTRAVENOUS
 CEFUROXIME SODIUM
 RX HIKMA EQ 750MG BASE/VIAL A065048 001 Jan 09, 2004 RLD: N050558

CETIRIZINE HYDROCHLORIDE

SOLUTION;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

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

March 2026

Page 8 of 34

CHLOROTHIAZIDE SODIUM

INJECTABLE; INJECTION
 CHLOROTHIAZIDE SODIUM
 RX SAGENT PHARMS INC EQ 500MG BASE/VIAL A202462 001 May 29, 2015 RLD: N011145

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

CHLORTHALIDONE

TABLET; ORAL
 CHLORTHALIDONE
 RX ALKEM LABS LTD 50MG A213412 002 Feb 11, 2020 RLD: N012283

CHLORZOXAZONE

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

CHOLINE FENOFIBRATE

CAPSULE, DELAYED RELEASE; ORAL
 FENOFIBRIC ACID
 RX AUROBINDO PHARMA EQ 135MG FENOFIBRIC ACID A212598 002 Jul 25, 2019 RLD: N022224
 LTD

CICLOPIROX

SHAMPOO; TOPICAL
 CICLOPIROX
 RX PADAGIS US 1% A078594 001 Feb 16, 2010 RLD: N021159

CIDOFOVIR

SOLUTION; INTRAVENOUS
 CIDOFOVIR
 RX MYLAN EQ 375MG BASE/5ML (EQ 75MG A201276 001 Jun 27, 2012 RLD: N020638
 INSTITUTIONAL BASE/ML)

CINACALCET HYDROCHLORIDE

TABLET; ORAL
 CINACALCET HYDROCHLORIDE
 RX STRIDES PHARMA EQ 90MG BASE A209226 003 Apr 30, 2018 RLD: N021688

CIPROFLOXACIN

INJECTABLE; INJECTION
 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

CISATRACURIUM BESYLATE

INJECTABLE; INJECTION
 CISATRACURIUM BESYLATE
 RX MEITHEAL EQ 2MG BASE/ML A211668 001 Apr 25, 2019 RLD: N020551
 RX EQ 2MG BASE/ML A211669 001 Apr 25, 2019 RLD: N020551
 RX EQ 10MG BASE/ML A211668 002 Apr 25, 2019 RLD: N020551

CITRIC ACID; MAGNESIUM OXIDE; SODIUM PICOSULFATE

FOR SOLUTION; ORAL
 SODIUM PICOSULFATE, MAGNESIUM OXIDE AND ANHYDROUS CITRIC ACID
 RX HETERO LABS LTD V 12GM/PACKET; 3.5GM/PACKET; 10MG/P A212789 001 Jul 18, 2022 RLD: N202535
 ACKET

CLINDAMYCIN PHOSPHATE

AEROSOL, FOAM; TOPICAL
 CLINDAMYCIN PHOSPHATE
 RX PADAGIS ISRAEL 1% A090785 001 Mar 31, 2010 RLD: N050801

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

March 2026

Page 9 of 34

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
<u>CLOBETASOL PROPIONATE</u>					
AEROSOL, FOAM; TOPICAL					
CLOBETASOL PROPIONATE					
RX	PADAGIS ISRAEL	0.05%	A201402	001	Aug 14, 2012 RLD: N022013
RX	TARO	0.05%	A208779	001	Oct 04, 2018 RLD: N021142
CREAM; TOPICAL					
CLOBETASOL PROPIONATE					
RX	ENCUBE	0.05%	A212982	001	Aug 28, 2020 RLD: N019322
OINTMENT; TOPICAL					
CLOBETASOL PROPIONATE					
RX	ENCUBE	0.05%	A211295	001	Nov 15, 2019 RLD: N019323
<u>CLOFARABINE</u>					
SOLUTION; INTRAVENOUS					
CLOFARABINE					
RX	MEITHEAL	20MG/20ML (1MG/ML)	A213461	001	Oct 23, 2020 RLD: N021673
<u>CLONIDINE HYDROCHLORIDE</u>					
TABLET, EXTENDED RELEASE; ORAL					
CLONIDINE HYDROCHLORIDE					
RX	AJANTA PHARMA LTD	0.1MG	A209686	001	Nov 20, 2017 RLD: N022331
TABLET; ORAL					
CLONIDINE HYDROCHLORIDE					
RX	TP ANDA HOLDINGS	0.05MG	A070923	004	Apr 06, 2026 RLD: N017407
<u>COLCHICINE</u>					
TABLET; ORAL					
COLCHICINE					
RX	PH HEALTH	0.6MG	A203976	001	Aug 12, 2021 RLD: N022352
<u>CUPRIC SULFATE</u>					
INJECTABLE; INJECTION					
CUPRIC SULFATE					
RX	AM REGENT	EQ 0.4MG COPPER/ML	A216324	001	Dec 16, 2022 RLD: N019350
<u>CYANOCOBALAMIN</u>					
SPRAY, METERED; NASAL					
CYANOCOBALAMIN					
RX	PADAGIS ISRAEL	0.5MG/SPRAY	A212458	001	Sep 09, 2020 RLD: N021642
<u>CYCLOBENZAPRINE HYDROCHLORIDE</u>					
TABLET; ORAL					
CYCLOBENZAPRINE HYDROCHLORIDE					
RX	RUBICON RESEARCH	10MG	A208170	003	May 31, 2017 RLD: N017821
<u>CYPROHEPTADINE HYDROCHLORIDE</u>					
TABLET; ORAL					
CYPROHEPTADINE HYDROCHLORIDE					
RX	ZYDUS PHARMS	4MG	A208938	001	May 19, 2017 RLD: N012649
<u>CYTARABINE</u>					
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					

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

March 2026

Page 10 of 34

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

DACTINOMYCIN

INJECTABLE; INJECTION
 DACTINOMYCIN
 RX EUGIA PHARMA 0.5MG/VIAL A203385 001 Nov 09, 2017 RLD: N050682

DAPAGLIFLOZIN; SAXAGLIPTIN HYDROCHLORIDE

TABLET; ORAL
 DAPAGLIFLOZIN AND SAXAGLIPTIN HYDROCHLORIDE
 RX MSN 10MG;EQ 5MG BASE A211533 001 Apr 06, 2026 RLD: N209091

DAPSONE

TABLET; ORAL
 DAPSONE
 RX NOVITIUM PHARMA 100MG A206505 002 Dec 01, 2016 RLD: A086842

DAPTOMYCIN

POWDER; INTRAVENOUS
 DAPTOMYCIN
 RX QILU PHARM HAINAN 500MG/VIAL A215316 001 Aug 24, 2021 RLD: N021572

DARIFENACIN HYDROBROMIDE

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

DEFERIPRONE

TABLET; ORAL
 DEFERIPRONE
 RX HIKMA 1GM A213239 002 Feb 08, 2022 RLD: N021825

DESLORATADINE

SOLUTION; ORAL
 DESLORATADINE
 RX TARO 0.5MG/ML A202936 001 May 26, 2016 RLD: N021300

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

DESONIDE

CREAM; TOPICAL
 DESONIDE
 RX CADILA 0.05% A210198 001 Nov 20, 2019 RLD: N017010
 GEL; TOPICAL
 DESONIDE
 RX SENORES PHARMS 0.05% A202470 001 May 11, 2020 RLD: N021844

DESOXIMETASONE

OINTMENT; TOPICAL
 DESOXIMETASONE
 RX ZYDUS LIFESCIENCES 0.25% A205206 001 Sep 19, 2017 RLD: N018763

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

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

March 2026

Page 11 of 34

DIAZEPAM

INJECTABLE; INJECTION
 DIAZEPAM
 RX REGCON HOLDINGS 10MG/2ML (5MG/ML) A210363 001 Mar 18, 2019 RLD: N016087

DICLOFENAC SODIUM

GEL; TOPICAL
 DICLOFENAC SODIUM
 RX SUN PHARMA CANADA 3% A206298 001 Apr 28, 2016 RLD: N021005
 SOLUTION; TOPICAL
 DICLOFENAC SODIUM
 RX LUPIN PHARMS 2% A208021 001 Sep 20, 2022 RLD: N204623
 TABLET, EXTENDED RELEASE; ORAL
 DICLOFENAC SODIUM
 RX DEXCEL LTD 100MG A076201 001 Nov 06, 2002 RLD: N020254

DICYCLOMINE HYDROCHLORIDE

INJECTABLE; INJECTION
 DICYCLOMINE HYDROCHLORIDE
 RX FOSUN PHARMA 10MG/ML A210979 001 Jul 02, 2018 RLD: N008370
 SYRUP; ORAL
 DICYCLOMINE HYDROCHLORIDE
 RX PH HEALTH 10MG/5ML A040169 001 Mar 24, 2005 RLD: N007961
 TABLET; ORAL
 DICYCLOMINE HYDROCHLORIDE
 RX RUBICON RESEARCH 40MG A216736 002 Mar 25, 2025 RLD: N007409

DIHYDROERGOTAMINE MESYLATE

INJECTABLE; INJECTION
 DIHYDROERGOTAMINE MESYLATE
 RX HIKMA PHARMS 1MG/ML A206621 001 Sep 15, 2017 RLD: N005929

DIMENHYDRINATE

INJECTABLE; INJECTION
 DIMENHYDRINATE
 RX FRESENIUS KABI USA 50MG/ML A040519 001 Jun 23, 2004 RLD: A080615

DOCETAXEL

INJECTABLE; INJECTION
 DOCETAXEL
 RX AMNEAL 20MG/ML (20MG/ML) A209640 001 Jan 19, 2018 RLD: N020449
 RX 80MG/4ML (20MG/ML) A209640 002 Jan 19, 2018 RLD: N020449
 RX 160MG/8ML (20MG/ML) A209640 003 Jan 19, 2018 RLD: N020449

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
 DORZOLAMIDE HYDROCHLORIDE
 RX MICRO LABS EQ 2% BASE A204778 001 Nov 08, 2019 RLD: N020408

DOXERCALCIFEROL

CAPSULE; ORAL
 DOXERCALCIFEROL
 RX AVET 2.5MCG A205360 003 Sep 15, 2020 RLD: N020862
 INJECTABLE; INJECTION
 DOXERCALCIFEROL
 RX MEITHEAL 4MCG/2ML (2MCG/ML) A211670 001 Feb 07, 2020 RLD: N021027

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

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

March 2026

Page 12 of 34

DOXYCYCLINE HYCLATE

CAPSULE;ORAL		DOXYCYCLINE HYCLATE					
RX	HIKMA INTL PHARMS	EQ 100MG BASE	A062396	001	May 07, 1984	RLD: N050007	
INJECTABLE;INJECTION		DOXYCYCLINE					
RX	ZYDUS PHARMS	EQ 100MG BASE/VIAL	A207757	001	Sep 28, 2017	RLD: N050442	
TABLET, DELAYED RELEASE;ORAL		DOXYCYCLINE HYCLATE					
RX	HERITAGE	EQ 200MG BASE	A200856	004	Nov 13, 2018	RLD: N050795	

DROPERIDOL

INJECTABLE;INJECTION		DROPERIDOL					
RX	AM REGENT	2.5MG/ML	A072123	001	Oct 24, 1988	RLD: N016796	

DULOXETINE HYDROCHLORIDE

CAPSULE, DELAYED REL PELLETS;ORAL		DULOXETINE HYDROCHLORIDE					
RX	AJANTA PHARMA LTD	EQ 60MG BASE	A208706	003	Jan 06, 2017	RLD: N021427	

DUTASTERIDE; TAMSULOSIN HYDROCHLORIDE

CAPSULE;ORAL		DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE					
RX	ZYDUS PHARMS	0.5MG;0.4MG	A207769	001	May 24, 2018	RLD: N022460	

DYCLONINE HYDROCHLORIDE

SOLUTION;TOPICAL		DYCLOPRO					
RX	SEPTODONT	0.5%	A200480	001	Nov 20, 2018	RLD: N009925	
RX		1%	A200480	002	Nov 20, 2018	RLD: N009925	

EDARAVONE

SOLUTION;INTRAVENOUS		EDARAVONE					
RX	GLAND	30MG/100ML (0.3MG/ML)	A216199	001	May 06, 2024	RLD: N209176	
RX	PHARMOBEDIENT	60MG/100ML (0.6MG/ML)	A217565	002	Oct 31, 2024	RLD: N209176	

EDETATE CALCIUM DISODIUM

INJECTABLE;INJECTION		EDETATE CALCIUM DISODIUM					
RX	CASPER PHARMA LLC	200MG/ML	A216435	001	May 03, 2023	RLD: N008922	

EFAVIRENZ

CAPSULE;ORAL		EFAVIRENZ					
RX	AUROBINDO PHARMA	200MG	A078064	003	Dec 15, 2017	RLD: N020972	
TABLET;ORAL		EFAVIRENZ					
RX	HETERO LABS LTD	600MG	A078886	001	Apr 27, 2018	RLD: N021360	
III							

EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL		EFAVIRENZ, EMTRICITABINE, AND TENOFOVIR DISOPROXIL FUMARATE					
RX	AUROBINDO PHARMA	600MG;200MG;300MG	A203041	001	Sep 04, 2018	RLD: N021937	

EFAVIRENZ; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE

TABLET;ORAL		EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE					
RX	LAURUS	400MG;300MG;300MG	A213038	001	May 14, 2020	RLD: N208255	

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

March 2026

Page 13 of 34

EPOPROSTENOL SODIUM

INJECTABLE; INJECTION						
EPOPROSTENOL SODIUM						
RX	MEITHEAL	EQ 0.5MG BASE/VIAL	A078396	001	Apr 23, 2008	RLD: N020444
RX		EQ 1.5MG BASE/VIAL	A078396	002	Apr 23, 2008	RLD: N020444
RX	SUN PHARM	EQ 0.5MG BASE/VIAL	A210473	001	Jan 15, 2021	RLD: N022260

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

ERGOCALCIFEROL

CAPSULE; ORAL						
ERGOCALCIFEROL						
RX	ONESOURCE SPECIALTY	50,000 IU	A090455	001	Aug 03, 2010	RLD: N003444

ERLOTINIB HYDROCHLORIDE

TABLET; ORAL						
ERLOTINIB HYDROCHLORIDE						
RX	ZYDUS PHARMS	EQ 150MG BASE	A213065	003	Apr 16, 2020	RLD: N021743

ESOMEPRAZOLE MAGNESIUM; NAPROXEN

TABLET, DELAYED RELEASE; ORAL						
NAPROXEN AND ESOMEPRAZOLE MAGNESIUM						
RX	DR REDDYS	EQ 20MG BASE; 500MG	A204206	002	Feb 18, 2020	RLD: N022511

ESOMEPRAZOLE SODIUM

INJECTABLE; INTRAVENOUS						
ESOMEPRAZOLE SODIUM						
RX	GLAND	EQ 20MG BASE/VIAL	A203349	001	Apr 01, 2020	RLD: N021689
RX	SLATE RUN PHARMA	EQ 40MG BASE/VIAL	A215732	001	Feb 10, 2022	RLD: N021689

ESTRADIOL

TABLET; ORAL						
ESTRADIOL						
RX	BARR LABS INC	2MG	A040197	003	Oct 22, 1997	RLD: A084500

ESTRADIOL VALERATE

INJECTABLE; INJECTION						
ESTRADIOL VALERATE						
RX	XIROMED	40MG/ML	A216656	003	Apr 28, 2023	RLD: N009402

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						
HAILEY 24 FE						
RX	GLENMARK PHARMS LTD	0.02MG; 1MG	A204847	001	Nov 17, 2017	RLD: N021871
NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE						
RX	GLENMARK PHARMS LTD	0.02MG; 1MG	A210369	001	Dec 26, 2017	RLD: N203667
TABLET; ORAL-28						
CHABELINA FE						
RX	NOVAST LABS	0.02MG, 0.03MG, 0.035MG; 1MG, 1MG, 1MG	A202962	001	Apr 15, 2020	RLD: N020130

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

March 2026

Page 14 of 34

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28
 NORGESTIMATE AND ETHINYL ESTRADIOL
 RX GLENMARK SPECLT 0.025MG, 0.025MG, 0.025MG; 0.18MG, A204057 001 Feb 23, 2016 RLD: N021241
 0.215MG, 0.25MG

EXENATIDE SYNTHETIC

INJECTABLE; SUBCUTANEOUS
 EXENATIDE SYNTHETIC
 RX AMNEAL 300MCG/1.2ML (250MCG/ML) A206697 001 Nov 19, 2024 RLD: N021773
 RX 600MCG/2.4ML (250MCG/ML) A206697 002 Nov 19, 2024 RLD: N021773

FAMCICLOVIR

TABLET; ORAL
 FAMCICLOVIR
 RX TEVA PHARMS 500MG A077487 003 Aug 24, 2007 RLD: N020363

FAMOTIDINE

FOR SUSPENSION; ORAL
 FAMOTIDINE
 RX NOVITIUM PHARMA 40MG/5ML A215043 001 Apr 20, 2021 RLD: N019527
 TABLET; ORAL
 FAMOTIDINE
 RX AUROBINDO PHARMA 40MG A206530 002 Dec 22, 2015 RLD: N019462
 LTD

FAMOTIDINE; IBUPROFEN

TABLET; ORAL
 IBUPROFEN AND FAMOTIDINE
 RX ALKEM LABS LTD 26.6MG; 800MG A211890 001 Aug 03, 2021 RLD: N022519

FELBAMATE

SUSPENSION; ORAL
 FELBAMATE
 RX NOVITIUM PHARMA 600MG/5ML A211333 001 May 31, 2019 RLD: N020189

FENOFIBRATE

CAPSULE; ORAL
 FENOFIBRATE (MICRONIZED)
 RX AJANTA PHARMA LTD 200MG A210705 003 Sep 10, 2018 RLD: N019304
 TABLET; ORAL
 FENOFIBRATE
 RX AUROBINDO PHARMA 145MG A205118 002 May 05, 2016 RLD: N021656
 RX MYLAN PHARMS INC 120MG A204475 002 Jun 23, 2016 RLD: N022118

FENOPROFEN CALCIUM

CAPSULE; ORAL
 FENOPROFEN CALCIUM
 RX RISING EQ 400MG BASE A214475 001 Jul 18, 2022 RLD: N017604

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 CARDINAL HEALTH 20-500mCi/ML A203603 002 Sep 27, 2018 RLD: N021870
 414
 RX QUEEN HAMAMATSU 10-100mCi/ML A203771 001 Aug 31, 2015 RLD: N021768
 PET

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

March 2026

Page 15 of 34

FLUNISOLIDE

SPRAY, METERED;NASAL
 FLUNISOLIDE
 RX BAUSCH 0.025MG/SPRAY A074805 001 Feb 20, 2002 RLD: N018148

FLUOCINONIDE

CREAM;TOPICAL
 FLUOCINONIDE
 RX AMNEAL 0.05% A210554 001 Aug 21, 2018 RLD: N019117

FLUORESCEIN SODIUM

INJECTABLE;INTRAVENOUS
 FLUORESCEIN SODIUM
 RX NEXUS EQ 500MG BASE/2ML (EQ 250MG
 BASE/ML) A215709 002 Sep 25, 2023 RLD: N022186

FLUOROURACIL

INJECTABLE;INJECTION
 FLUOROURACIL
 RX ALEMBIC 2.5GM/50ML (50MG/ML) A217295 001 Mar 03, 2023 RLD: N012209

SOLUTION;TOPICAL
 FLUOROURACIL
 RX TARO 5% A076526 002 Nov 05, 2003 RLD: N016831

FLUOXETINE HYDROCHLORIDE

TABLET;ORAL
 FLUOXETINE HYDROCHLORIDE
 RX AUROBINDO PHARMA EQ 20MG BASE A213286 002 Apr 08, 2020 RLD: N020974
 LTD
 RX EQ 60MG BASE A213265 001 Jun 10, 2020 RLD: N202133
 RX TORRENT EQ 20MG BASE A206937 002 Oct 21, 2016 RLD: N021860

FLUOXETINE HYDROCHLORIDE; OLANZAPINE

CAPSULE;ORAL
 OLANZAPINE AND FLUOXETINE HYDROCHLORIDE
 RX TEVA PHARMS EQ 50MG BASE;EQ 6MG BASE A077528 003 Jun 19, 2012 RLD: N021520

FLURANDRENOLIDE

LOTION;TOPICAL
 FLURANDRENOLIDE
 RX PADAGIS ISRAEL 0.05% A207133 001 Aug 30, 2016 RLD: N013790

OINTMENT;TOPICAL
 FLURANDRENOLIDE
 RX TELIGENT 0.05% A207851 001 Dec 30, 2016 RLD: N012806

FLURBIPROFEN

TABLET;ORAL
 FLURBIPROFEN
 RX NEW HEIGHTSRX 100MG A074431 001 May 31, 1995 RLD: N018766

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

FOLIC ACID

TABLET;ORAL
 FOLIC ACID
 RX AMNEAL PHARM 1MG A040625 001 Jul 21, 2005 RLD: A080680

FOSAMPRENAVIR CALCIUM

TABLET;ORAL
 FOSAMPRENAVIR CALCIUM
 RX MYLAN EQ 700MG BASE A204060 001 Apr 15, 2016 RLD: N021548

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

March 2026

Page 16 of 34

FOSFOMYCIN TROMETHAMINE

FOR SOLUTION;ORAL
 FOSFOMYCIN TROMETHAMINE
 RX XIROMED EQ 3GM BASE/PACKET A212548 001 Oct 06, 2020 RLD: N050717

FROVATRIPTAN SUCCINATE

TABLET;ORAL
 FROVATRIPTAN SUCCINATE
 RX RENATA EQ 2.5MG BASE A213891 001 Apr 06, 2022 RLD: N021006

FUROSEMIDE

SOLUTION;ORAL
 FUROSEMIDE
 RX HIKMA 40MG/5ML A070433 001 Apr 22, 1987 RLD: N016273
 TABLET;ORAL
 FUROSEMIDE
 RX GRAVITI PHARMS 80MG A216629 003 Oct 17, 2022 RLD: N016273

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE;ORAL
 GALANTAMINE HYDROBROMIDE
 RX AUROBINDO PHARMA EQ 8MG BASE A204895 001 Aug 05, 2016 RLD: N021615

GANCICLOVIR SODIUM

INJECTABLE;INJECTION
 GANCICLOVIR SODIUM
 RX PHARMASCIENCE INC EQ 500MG BASE/VIAL A207645 001 Dec 08, 2017 RLD: N019661

GLIMEPIRIDE

TABLET;ORAL
 GLIMEPIRIDE
 RX DR REDDYS LABS LTD 1MG A077091 001 Oct 06, 2005 RLD: N020496

GLIPIZIDE

TABLET, EXTENDED RELEASE;ORAL
 GLIPIZIDE
 RX UNIQUE 10MG A204720 003 Dec 29, 2016 RLD: N020329
 TABLET;ORAL
 GLIPIZIDE
 RX RUBICON RESEARCH 15MG A214874 004 Feb 04, 2026 RLD: N017783

GLUCAGON

INJECTABLE;INJECTION
 GLUCAGON
 RX AMPHASTAR PHARMS 1MG/VIAL A208086 001 Dec 28, 2020 RLD: N020928
 INC

GLYBURIDE

TABLET;ORAL
 GLYBURIDE (MICRONIZED)
 RX TEVA 6MG A074686 004 Apr 20, 1999 RLD: N020051

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
 TABLET;ORAL
 GLYCOPYRROLATE
 RX LGM PHARMA 1.5MG A091522 001 Mar 12, 2012 RLD: N012827

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

March 2026

Page 17 of 34

GRANISETRON HYDROCHLORIDE

TABLET; ORAL
 GRANISETRON HYDROCHLORIDE
 RX ORBION PHARMS EQ 1MG BASE A078678 001 Feb 13, 2008 RLD: N020305

HALCINONIDE

SOLUTION; TOPICAL
 HALCINONIDE
 RX ENCUBE 0.1% A217671 001 May 29, 2024 RLD: N017823

HALOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL
 HALOBETASOL PROPIONATE
 RX PADAGIS ISRAEL 0.05% A215266 001 Aug 11, 2023 RLD: N210566

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
 HALOPERIDOL DECANOATE
 RX MANKIND PHARMA EQ 50MG BASE/ML A216730 001 May 23, 2023 RLD: N018701
 RX EQ 100MG BASE/ML A216730 002 May 23, 2023 RLD: N018701

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL
 HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE
 RX ABHAI LLC 1.5MG/5ML; 5MG/5ML A207487 001 Feb 21, 2017 RLD: N005213
 TABLET; ORAL
 HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE
 RX AVANTHI INC 1.5MG; 5MG A207176 001 Aug 07, 2017 RLD: N005213

HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET; ORAL
 LISINAPRIL AND HYDROCHLOROTHIAZIDE
 RX INVAGEN PHARMS 12.5MG; 20MG A204058 002 May 23, 2017 RLD: N019888
 RX 25MG; 20MG A204058 003 May 23, 2017 RLD: N019888

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL
 METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE
 RX MYLAN 50MG; 100MG A076792 003 Aug 20, 2004 RLD: N018303

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

HYDROCORTISONE

CREAM; TOPICAL
 HYDROCORTISONE
 RX FOUGERA PHARMS INC 2.5% A089414 001 Dec 16, 1986 RLD: A087457

HYDROCORTISONE BUTYRATE

LOTION; TOPICAL
 HYDROCORTISONE BUTYRATE
 RX LUPIN LTD 0.1% A210209 001 Aug 17, 2018 RLD: N022076
 OINTMENT; TOPICAL
 HYDROCORTISONE BUTYRATE
 RX TARO 0.1% A076842 001 Dec 27, 2004 RLD: N018652

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

March 2026

Page 18 of 34

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
 RX APPCO 100MG A210441 002 Sep 19, 2022 RLD: N009768

HYDROXYZINE HYDROCHLORIDE

TABLET;ORAL
 HYDROXYZINE HYDROCHLORIDE
 RX GRAVITI PHARMS 50MG A217652 003 Aug 17, 2023 RLD: N010392

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

IMIQUIMOD

CREAM;TOPICAL
 IMIQUIMOD
 RX GLENMARK PHARMS 5% A201994 001 Mar 06, 2012 RLD: N020723

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

ISOPROTERENOL HYDROCHLORIDE

INJECTABLE;INJECTION
 ISOPROTERENOL HYDROCHLORIDE
 RX NEXUS 0.2MG/ML A206961 001 Aug 02, 2017 RLD: N010515

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE;ORAL
 ISOSORBIDE MONONITRATE
 RX RICONPHARMA LLC 120MG A210918 003 Nov 05, 2018 RLD: N020225

ISOSULFAN BLUE

SOLUTION;SUBCUTANEOUS
 ISOSULFAN BLUE
 RX MYLAN 10MG/ML (10MG/ML) A090874 002 Jan 28, 2026 RLD: N018310
 INSTITUTIONAL
 RX 30MG/3ML (10MG/ML) A090874 003 Jan 28, 2026 RLD: N018310
 RX 50MG/5ML (10MG/ML) A090874 001 Jul 20, 2010 RLD: N018310

ISRADIPINE

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

IVABRADINE HYDROCHLORIDE

TABLET;ORAL
 IVABRADINE HYDROCHLORIDE
 RX INGENUS PHARMS LLC EQ 7.5MG BASE A214051 002 Dec 30, 2021 RLD: N206143

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

March 2026

Page 19 of 34

KETAMINE HYDROCHLORIDE

SOLUTION; INTRAMUSCULAR, INTRAVENOUS
 KETAMINE HYDROCHLORIDE
 RX BAXTER HLTHCARE EQ 100MG BASE/10ML (EQ 10MG A219684 001 Sep 17, 2025 RLD: N016812
 CORP BASE/ML)

KETOCONAZOLE

AEROSOL, FOAM; TOPICAL
 KETOCONAZOLE
 RX XIROMED 2% A213601 001 May 21, 2021 RLD: N021738
 CREAM; TOPICAL
 KETOCONAZOLE
 RX ENCUBE 2% A212443 001 May 20, 2021 RLD: N019084

KETOTIFEN FUMARATE

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

LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION
 LABETALOL HYDROCHLORIDE
 RX HOSPIRA 5MG/ML A075239 001 Nov 29, 1999 RLD: N018686
 TABLET; ORAL
 LABETALOL HYDROCHLORIDE
 RX AIPING PHARM INC 200MG A075113 002 Aug 04, 1998 RLD: N018687

LAMIVUDINE; ZIDOVUDINE

TABLET; ORAL
 LAMIVUDINE AND ZIDOVUDINE
 RX HETERO LABS LTD 150MG; 300MG A079124 001 Sep 17, 2015 RLD: N020857
 III

LEUCOVORIN CALCIUM

SOLUTION; INTRAMUSCULAR, INTRAVENOUS
 LEUCOVORIN CALCIUM
 RX FRESENIUS KABI USA EQ 100MG BASE/10ML (EQ 10MG A207241 001 Mar 14, 2018 RLD: N008107
 BASE/ML)
 RX EQ 500MG BASE/50ML (EQ 10MG A207226 001 Jul 27, 2018 RLD: N008107
 BASE/ML)

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL
 LEVOCETIRIZINE DIHYDROCHLORIDE
 RX GLENMARK PHARMS 5MG A090385 001 Feb 24, 2011 RLD: N022064
 LTD

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 NOVITIUM PHARMA 250MG/10ML A091678 001 Jun 20, 2011 RLD: N021721

LEVOLEUCOVORIN CALCIUM

SOLUTION; INTRAVENOUS
 LEVOLEUCOVORIN CALCIUM
 RX GLAND EQ 250MG BASE/25ML (EQ 10MG A210892 002 Sep 14, 2018 RLD: N020140
 BASE/ML)
 RX MEITHEAL EQ 175MG BASE/17.5ML (EQ 10MG A211002 001 Aug 16, 2019 RLD: N020140
 BASE/ML)

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

March 2026

Page 20 of 34

LEVORPHANOL TARTRATE

TABLET;ORAL
 LEVORPHANOL TARTRATE
 RX SUN PHARM INDS INC 3MG A213906 002 Apr 25, 2023 RLD: N008720

LIDOCAINE HYDROCHLORIDE

SOLUTION;ORAL
 LIDOCAINE HYDROCHLORIDE
 RX RUBICON RESEARCH 2% A216780 001 Mar 28, 2023 RLD: N009470
 SOLUTION;TOPICAL

LIDOCAINE HYDROCHLORIDE
 RX HIKMA 4% A088803 001 Apr 03, 1985 RLD: N010417

LIDOCAINE; PRILOCAINE

CREAM;TOPICAL
 LIDOCAINE AND PRILOCAINE
 RX FOUGERA PHARMS 2.5%;2.5% A076453 001 Aug 18, 2003 RLD: N019941

LINEZOLID

TABLET;ORAL
 LINEZOLID
 RX ALKEM LABS LTD 600MG A205517 001 Dec 21, 2015 RLD: N021130

LITHIUM CITRATE

SYRUP;ORAL
 LITHIUM CITRATE
 RX RUBICON RESEARCH EQ 300MG CARBONATE/5ML A218036 001 Aug 14, 2023 RLD: N018421

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL
 LOPERAMIDE HYDROCHLORIDE
 RX MYLAN 2MG A072741 001 Sep 18, 1991 RLD: N017694

MAGNESIUM SULFATE

INJECTABLE;INJECTION
 MAGNESIUM SULFATE
 RX BAXTER HLTHCARE 3GM/100ML (30MG/ML) A211966 004 Jan 08, 2026 RLD: N020309
 CORP

MEFLOQUINE HYDROCHLORIDE

TABLET;ORAL
 MEFLOQUINE HYDROCHLORIDE
 RX BARR 250MG A076392 001 Dec 29, 2003 RLD: N019591

MEGESTROL ACETATE

SUSPENSION;ORAL
 MEGESTROL ACETATE
 RX TWI PHARMS 125MG/ML A203139 001 Aug 27, 2014 RLD: N021778

MELOXICAM

CAPSULE;ORAL
 MELOXICAM
 RX LUPIN LTD 10MG A209487 002 Jun 01, 2020 RLD: N207233

MEMANTINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL
 MEMANTINE HYDROCHLORIDE
 RX ZYDUS PHARMS 28MG A203293 004 Aug 03, 2017 RLD: N022525

MEPERIDINE HYDROCHLORIDE

INJECTABLE;INJECTION
 MEPERIDINE HYDROCHLORIDE PRESERVATIVE FREE
 RX WEST-WARD PHARMS 10MG/ML A081002 001 Jul 30, 1993 RLD: A088432
 INT

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

March 2026

Page 21 of 34

TABLET; ORAL					
MEPERIDINE HYDROCHLORIDE					
RX	EPIC PHARMA LLC	50MG	A040331	001	May 28, 1999 RLD: N005010
<u>MEPIVACAINE HYDROCHLORIDE</u>					
INJECTABLE; INJECTION					
POLOCAINE					
RX	FRESENIUS KABI USA	1%	A089407	001	Dec 01, 1986 RLD: N012250
RX		2%	A089410	001	Dec 01, 1986 RLD: N012250
POLOCAINE-MPF					
RX	FRESENIUS KABI USA	1%	A089406	001	Dec 01, 1986 RLD: N012250
RX		1.5%	A089408	001	Dec 01, 1986 RLD: N012250
RX		2%	A089409	001	Dec 01, 1986 RLD: N012250
<u>MEPROBAMATE</u>					
TABLET; ORAL					
MEPROBAMATE					
RX	ALEMBIC PHARMS LTD	200MG	A090122	001	Feb 18, 2009 RLD: A083304
RX		400MG	A090122	002	Feb 18, 2009 RLD: A083308
<u>MEROPENEM</u>					
INJECTABLE; INJECTION					
MEROPENEM					
RX	ACS DOBFAR	500MG/VIAL	A091404	001	Oct 26, 2011 RLD: N050706
RX		1GM/VIAL	A091404	002	Oct 26, 2011 RLD: N050706
<u>MESALAMINE</u>					
CAPSULE, DELAYED RELEASE; ORAL					
MESALAMINE					
RX	TEVA PHARMS USA	400MG	A207873	001	May 09, 2019 RLD: N204412
TABLET, DELAYED RELEASE; ORAL					
MESALAMINE					
RX	ZYDUS PHARMS	800MG	A203286	001	Jul 21, 2017 RLD: N021830
<u>METAXALONE</u>					
TABLET; ORAL					
METAXALONE					
RX	AMNEAL PHARMS	800MG	A203399	001	Jun 21, 2013 RLD: N013217
<u>METFORMIN HYDROCHLORIDE</u>					
SOLUTION; ORAL					
METFORMIN HYDROCHLORIDE					
RX	SAPTALIS PHARMS	500MG/5ML	A211309	001	Mar 03, 2020 RLD: N021591
TABLET, EXTENDED RELEASE; ORAL					
METFORMIN HYDROCHLORIDE					
RX	AJANTA PHARMA LTD	1GM	A213962	002	Mar 09, 2021 RLD: N021748
RX	ALKEM LABS LTD	750MG	A206145	002	Oct 22, 2018 RLD: N021202
<u>METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE</u>					
TABLET, EXTENDED RELEASE; ORAL					
SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE					
RX	DR REDDYS LABS SA	1GM; EQ 5MG BASE	A207678	003	Aug 09, 2023 RLD: N200678
<u>METHADONE HYDROCHLORIDE</u>					
TABLET; ORAL					
METHADONE HYDROCHLORIDE					
RX	SPECGX LLC	5MG	A040517	001	Apr 27, 2004 RLD: N006134
RX		10MG	A040517	002	Apr 27, 2004 RLD: N006134
<u>METHENAMINE HIPURATE</u>					
TABLET; ORAL					
METHENAMINE HIPURATE					
RX	AUROBINDO PHARMA LTD	1GM	A205661	001	Jul 05, 2016 RLD: N017681

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

March 2026

Page 22 of 34

METHOCARBAMOL

TABLET; ORAL		METHOCARBAMOL					
RX	BOSTAL	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 HLHCARE	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	

METHYLENE BLUE

SOLUTION; INTRAVENOUS		METHYLENE BLUE					
RX	ZYDUS LIFESCIENCES	5MG/ML (5MG/ML)	A215636	003	Feb 02, 2026	RLD: N204630	
RX		100MG/10ML (10MG/ML)	A215636	004	Mar 31, 2026	RLD: N204630	

METHYLERGONOVINE MALEATE

INJECTABLE; INJECTION		METHYLERGONOVINE MALEATE					
RX	AM REGENT	0.2MG/ML	A090193	001	Nov 24, 2008	RLD: N006035	
TABLET; ORAL		METHYLERGONOVINE MALEATE					
RX	CHARTWELL RX	0.2MG	A091577	001	May 02, 2011	RLD: N006035	

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL		METHYLPHENIDATE HYDROCHLORIDE					
RX	GRANULES	60MG	A211796	005	May 23, 2019	RLD: N021284	
TABLET, CHEWABLE; ORAL		METHYLPHENIDATE HYDROCHLORIDE					
RX	ASCENT PHARMS INC	10MG	A210354	003	Dec 29, 2017	RLD: N021475	
TABLET, EXTENDED RELEASE; ORAL		METHYLPHENIDATE HYDROCHLORIDE					
RX	OSMOTICA PHARM US	72MG	A205327	005	Jul 28, 2017	RLD: N021121	

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION		METHYLPREDNISOLONE ACETATE					
RX	AMNEAL	40MG/ML	A210043	001	May 20, 2019	RLD: N011757	
RX		80MG/ML	A210043	002	May 20, 2019	RLD: N011757	
RX	SAGENT PHARMS INC	40MG/ML	A201835	002	Jun 27, 2018	RLD: N011757	
RX		80MG/ML	A201835	003	Jun 27, 2018	RLD: N011757	

METHYLTESTOSTERONE

CAPSULE; ORAL		METHYLTESTOSTERONE					
RX	IMPAX LABS INC	10MG	A204851	001	Sep 21, 2015	RLD: A083976	

METOPROLOL TARTRATE

TABLET; ORAL		METOPROLOL TARTRATE					
RX	MYLAN	100MG	A076704	003	Jan 16, 2004	RLD: N017963	

METRONIDAZOLE

GEL; TOPICAL		METRONIDAZOLE					
RX	COSETTE	0.75%	A078178	001	Jan 19, 2011	RLD: N019737	

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

March 2026

Page 23 of 34

GEL; VAGINAL					
METRONIDAZOLE					
RX	ENCUBE	0.75%	A215610	001	Jun 16, 2023 RLD: N020208
INJECTABLE; INJECTION					
METRONIDAZOLE IN PLASTIC CONTAINER					
RX	INFORLIFE	500MG/100ML	A206191	001	Feb 25, 2019 RLD: N018900
TABLET; ORAL					
METRONIDAZOLE					
RX	AUROBINDO PHARMA LTD	500MG	A203974	002	May 29, 2015 RLD: N012623
<u>MICAFUNGIN SODIUM</u>					
INJECTABLE; INTRAVENOUS					
MICAFUNGIN SODIUM					
RX	FRESENIUS KABI USA	EQ 50MG BASE/VIAL	A207344	001	May 17, 2019 RLD: N021506
RX		EQ 100MG BASE/VIAL	A207344	002	May 17, 2019 RLD: N021506
<u>MIDAZOLAM</u>					
SOLUTION; INTRAVENOUS					
MIDAZOLAM IN 0.8% SODIUM CHLORIDE					
RX	B BRAUN MEDICAL	50MG/50ML (1MG/ML)	A218454	001	May 01, 2025 RLD: N215868
RX		100MG/100ML (1MG/ML)	A218454	002	May 01, 2025 RLD: N215868
<u>MIGLITOL</u>					
TABLET; ORAL					
MIGLITOL					
RX	ORIENT PHARMA	25MG	A203965	001	Feb 24, 2015 RLD: N020682
<u>MINOCYCLINE HYDROCHLORIDE</u>					
TABLET, EXTENDED RELEASE; ORAL					
MINOCYCLINE HYDROCHLORIDE					
RX	ALKEM LABS LTD	EQ 115MG BASE	A204453	007	Mar 16, 2018 RLD: N050808
RX		EQ 135MG BASE	A204453	005	Sep 28, 2016 RLD: N050808
<u>MITOMYCIN</u>					
INJECTABLE; INJECTION					
MITOMYCIN					
RX	MEITHEAL	20MG/VIAL	A214505	002	Sep 08, 2022 RLD: N050450
<u>MOMETASONE FUROATE</u>					
CREAM; TOPICAL					
MOMETASONE FUROATE					
RX	COSETTE	0.1%	A077447	001	May 22, 2006 RLD: N019625
OINTMENT; TOPICAL					
MOMETASONE FUROATE					
RX	PADAGIS US	0.1%	A076067	001	Mar 18, 2002 RLD: N019543
SPRAY, METERED; NASAL					
MOMETASONE FUROATE					
RX	APOTEX	0.05MG/SPRAY	A091161	001	Mar 22, 2016 RLD: N020762
<u>MORPHINE SULFATE</u>					
CAPSULE, EXTENDED RELEASE; ORAL					
MORPHINE SULFATE					
RX	UPSHER SMITH LABS	100MG	A202104	007	Jun 03, 2013 RLD: N020616
<u>MOXIFLOXACIN HYDROCHLORIDE</u>					
SOLUTION/DROPS; OPHTHALMIC					
MOXIFLOXACIN HYDROCHLORIDE					
RX	LUPIN LTD	EQ 0.5% BASE	A204079	001	May 28, 2015 RLD: N022428
SOLUTION; INTRAVENOUS					
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

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

March 2026

Page 24 of 34

NABUMETONE

TABLET; ORAL
 NABUMETONE
 RX LGM PHARMA 1GM A203166 003 Aug 30, 2019 RLD: N019583

NADOLOL

TABLET; ORAL
 NADOLOL
 RX INVAGEN PHARMS 80MG A203455 003 Dec 18, 2015 RLD: N018063

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL
 NAFTIFINE HYDROCHLORIDE
 RX SUN PHARMA CANADA 1% A205975 001 Sep 08, 2016 RLD: N019599

NALBUPHINE HYDROCHLORIDE

SOLUTION; INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS
 NALBUPHINE HYDROCHLORIDE
 RX HOSPIRA 10MG/ML (10MG/ML) A070914 001 Feb 03, 1989 RLD: N018024
 RX 20MG/ML (20MG/ML) A070916 001 Feb 03, 1989 RLD: N018024
 RX 100MG/10ML (10MG/ML) A070915 001 Feb 03, 1989 RLD: N018024
 RX 200MG/10ML (20MG/ML) A070918 001 Feb 03, 1989 RLD: N018024

NALMEFENE HYDROCHLORIDE

SOLUTION; INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS
 NALMEFENE HYDROCHLORIDE
 RX CHENGDU SHUODE EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) A216007 001 Nov 15, 2023 RLD: N020459
 RX PURDUE PHARMA LP EQ 2MG BASE/2ML (EQ 1MG BASE/ML) A212955 001 Feb 08, 2022 RLD: N020459

NALTREXONE HYDROCHLORIDE

TABLET; ORAL
 NALTREXONE HYDROCHLORIDE
 RX SPECGX LLC 50MG A076264 002 Mar 22, 2002 RLD: N018932

NARATRIPTAN HYDROCHLORIDE

TABLET; ORAL
 NARATRIPTAN
 RX HERITAGE EQ 2.5MG BASE A200502 002 Feb 28, 2011 RLD: N020763

NATEGLINIDE

TABLET; ORAL
 NATEGLINIDE
 RX ZYDUS PHARMS 120MG A205248 002 Jul 06, 2016 RLD: N021204

NELARABINE

INJECTABLE; INTRAVENOUS
 NELARABINE
 RX SHORLA 375MG/75ML (5MG/ML) A214809 002 Jul 16, 2025 RLD: N021877

NEOSTIGMINE METHYLSULFATE

SOLUTION; INTRAVENOUS
 NEOSTIGMINE METHYLSULFATE
 RX HIKMA 5MG/10ML (0.5MG/ML) A207042 001 Dec 28, 2015 RLD: N204078
 RX 10MG/10ML (1MG/ML) A207042 002 Dec 28, 2015 RLD: N204078

NEVIRAPINE

TABLET, EXTENDED RELEASE; ORAL
 NEVIRAPINE
 RX MACLEODS PHARMS 400MG A206879 001 Oct 06, 2017 RLD: N201152
 LTD
 TABLET; ORAL
 NEVIRAPINE
 RX MACLEODS PHARMS 200MG A090688 001 Jan 14, 2019 RLD: N020636
 LTD

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

March 2026

Page 25 of 34

NIACIN

TABLET;ORAL
 NIACOR
 RX AVONDALE PHARMS 500MG A040378 001 May 03, 2000 RLD: A083823

NICARDIPINE HYDROCHLORIDE

CAPSULE;ORAL
 NICARDIPINE HYDROCHLORIDE
 RX EPIC PHARMA LLC 30MG A074928 002 Mar 19, 1998 RLD: N019488

NIFEDIPINE

CAPSULE;ORAL
 NIFEDIPINE
 RX HERITAGE PHARMA 10MG A202644 001 Apr 25, 2013 RLD: N018482
 TABLET, EXTENDED RELEASE;ORAL
 NIFEDIPINE
 RX NOVAST LABS 60MG A202987 002 Aug 25, 2016 RLD: N020198
 RX 90MG A202987 003 Aug 25, 2016 RLD: N020198

NIMODIPINE

SOLUTION;ORAL
 NIMODIPINE
 RX ANNORA PHARMA 3MG/ML A216937 001 Jul 09, 2024 RLD: N203340

NITAZOXANIDE

TABLET;ORAL
 NITAZOXANIDE
 RX RISING 500MG A213820 001 Nov 27, 2020 RLD: N021497

NITROGLYCERIN

OINTMENT;INTRA-ANAL
 NITROGLYCERIN
 RX COSETTE 0.4% A216103 001 Feb 16, 2024 RLD: N021359

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE;ORAL
 NORTRIPTYLINE HYDROCHLORIDE
 RX TEVA EQ 75MG BASE A074132 004 Mar 27, 1995 RLD: N018013
 SOLUTION;ORAL
 NORTRIPTYLINE HYDROCHLORIDE
 RX PHARM ASSOC EQ 10MG BASE/5ML A075606 001 Aug 23, 2000 RLD: N014685

NYSTATIN

SUSPENSION;ORAL
 NYSTATIN
 RX SENORES PHARMS 100,000 UNITS/ML A214346 001 Mar 10, 2022 RLD: N050299

OFLOXACIN

SOLUTION/DROPS;OTIC
 OFLOXACIN
 RX BAUSCH AND LOMB 0.3% A076128 001 Mar 17, 2008 RLD: N020799

OLOPATADINE HYDROCHLORIDE

SPRAY, METERED;NASAL
 OLOPATADINE HYDROCHLORIDE
 RX AMNEAL 0.665MG/SPRAY A210901 001 Jan 28, 2020 RLD: N021861

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

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

March 2026

Page 26 of 34

OMEPRAZOLE; SODIUM BICARBONATE

CAPSULE;ORAL					
OMEPRAZOLE AND SODIUM BICARBONATE					
RX	AJANTA PHARMA LTD	40MG;1.1GM	A204228	002	Jul 15, 2016 RLD: N021849
FOR SUSPENSION;ORAL					
OMEPRAZOLE AND SODIUM BICARBONATE					
RX	AJANTA PHARMA LTD	40MG/PACKET;1.68GM/PACKET	A205545	002	Jul 27, 2016 RLD: N021636

ONDANSETRON

TABLET, ORALLY DISINTEGRATING;ORAL					
ONDANSETRON					
RX	CHARTWELL	16MG	A077406	001	Dec 26, 2006 RLD: N020781
MOLECULES					
RX		24MG	A077406	002	Dec 26, 2006 RLD: N020781

ONDANSETRON HYDROCHLORIDE

SOLUTION;ORAL					
ONDANSETRON HYDROCHLORIDE					
RX	HIKMA	EQ 4MG BASE/5ML	A076960	001	Dec 26, 2006 RLD: N020605

OXACILLIN SODIUM

INJECTABLE;INJECTION					
OXACILLIN SODIUM					
RX	FRESENIUS KABI USA	EQ 1GM BASE/VIAL	A206198	001	Jul 20, 2020 RLD: N050195
RX		EQ 2GM BASE/VIAL	A206198	002	Jul 20, 2020 RLD: N050195

OXALIPLATIN

INJECTABLE;INTRAVENOUS					
OXALIPLATIN					
RX	GLAND	50MG/10ML (5MG/ML)	A207325	001	Feb 10, 2017 RLD: N021759
RX		100MG/20ML (5MG/ML)	A207325	002	Feb 10, 2017 RLD: N021759
RX	QILU PHARM HAINAN	200MG/40ML (5MG/ML)	A204368	003	Jun 07, 2016 RLD: N021759

OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE;ORAL					
OXYBUTYNIN CHLORIDE					
RX	ZYDUS PHARMS	15MG	A202332	003	Jun 26, 2017 RLD: N020897
TABLET;ORAL					
OXYBUTYNIN CHLORIDE					
RX	NOVITIUM PHARMA	5MG	A209823	001	Oct 23, 2017 RLD: N017577
RX	RISING	2.5MG	A209025	002	Feb 07, 2023 RLD: N017577

PALONOSETRON HYDROCHLORIDE

INJECTABLE;INTRAVENOUS					
PALONOSETRON HYDROCHLORIDE					
RX	AVET LIFESCIENCES	EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)	A202951	001	Jun 29, 2021 RLD: N021372
RX	DR REDDYS	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

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

March 2026

Page 27 of 34

PAROXETINE HYDROCHLORIDE

SUSPENSION;ORAL

PAROXETINE HYDROCHLORIDE

RX	NOVITIUM PHARMA	EQ 10MG BASE/5ML	A215003	001	Sep 03, 2021	RLD: N020710
----	-----------------	------------------	---------	-----	--------------	--------------

PEMETREXED DISODIUM

POWDER; INTRAVENOUS

PEMETREXED DISODIUM

RX	FRESENIUS KABI USA	EQ 750MG BASE/VIAL	A090384	003	May 25, 2022	RLD: N021462
RX		EQ 1GM BASE/VIAL	A090384	004	May 25, 2022	RLD: N021462

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE;ORAL

PENTOXIFYLLINE

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

PHENOXYBENZAMINE HYDROCHLORIDE

CAPSULE;ORAL

PHENOXYBENZAMINE HYDROCHLORIDE

RX	PH HEALTH	10MG	A204522	001	Jan 24, 2017	RLD: N008708
----	-----------	------	---------	-----	--------------	--------------

PHENTERMINE HYDROCHLORIDE

CAPSULE;ORAL

PHENTERMINE HYDROCHLORIDE

RX	NUVO PHARM	37.5MG	A205017	001	Sep 25, 2014	RLD: A088023
----	------------	--------	---------	-----	--------------	--------------

TABLET;ORAL

LOMAIRA

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

PHENYLEPHRINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC

PHENYLEPHRINE HYDROCHLORIDE

RX	MANKIND PHARMA	2.5%	A216859	001	Sep 29, 2022	RLD: N207926
RX		10%	A216496	001	Jan 11, 2023	RLD: N207926

SOLUTION; INTRAVENOUS

PHENYLEPHRINE HYDROCHLORIDE

RX	SANDOZ	10MG/ML (10MG/ML)	A208905	001	Jan 31, 2019	RLD: N204300
RX		50MG/5ML (10MG/ML)	A208905	002	Jan 31, 2019	RLD: N204300
RX		100MG/10ML (10MG/ML)	A208905	003	Jan 31, 2019	RLD: N204300

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP;ORAL

PHENYLEPHRINE HYDROCHLORIDE AND PROMETHAZINE HYDROCHLORIDE

RX	GENUS	5MG/5ML; 6.25MG/5ML	A040654	001	Dec 07, 2006	RLD: A088761
----	-------	---------------------	---------	-----	--------------	--------------

PHYTONADIONE

INJECTABLE; INJECTION

PHYTONADIONE

RX	CIPLA	1MG/0.5ML	A214596	001	Apr 22, 2022	RLD: N012223
RX		10MG/ML	A214596	002	Apr 22, 2022	RLD: N012223

TABLET;ORAL

PHYTONADIONE

RX	ZYDUS LIFESCIENCES	5MG	A210189	001	Feb 20, 2019	RLD: N010104
----	--------------------	-----	---------	-----	--------------	--------------

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION

PIPERACILLIN AND TAZOBACTAM

RX	APOTEX	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

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

March 2026

Page 28 of 34

PODOFILOX

GEL; TOPICAL
 PODOFILOX
 RX PADAGIS US 0.5% A211871 001 Nov 22, 2023 RLD: N020529

POSACONAZOLE

SOLUTION; INTRAVENOUS
 POSACONAZOLE
 RX GLAND 300MG/16.7ML (18MG/ML) A217553 001 Dec 26, 2023 RLD: N205596
 TABLET, DELAYED RELEASE; ORAL
 POSACONAZOLE
 RX AET PHARMA 100MG A213454 001 Feb 01, 2021 RLD: N205053

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 Klor-Con M20
 RX UPSHER SMITH LABS 20MEQ A074726 001 Nov 20, 1998 RLD: N019439
 POTASSIUM CHLORIDE
 RX RUBICON RESEARCH 15MEQ A215725 003 Aug 22, 2024 RLD: N018279
 RX TWI PHARMS 20MEQ A209688 002 Jan 12, 2018 RLD: N018279

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 PRAMIPEXOLE DIHYDROCHLORIDE
 RX DR REDDYS 0.375MG A203354 001 Aug 07, 2015 RLD: N022421

PRAZICUANTEL

TABLET; ORAL
 PRAZICUANTEL
 RX PH HEALTH 600MG A208820 001 Nov 27, 2017 RLD: N018714

PREDNISOLONE

SOLUTION; ORAL
 PREDNISOLONE
 RX CHARTWELL RX 15MG/5ML A040323 001 May 13, 1999 RLD: A080326

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
 PREDNISOLONE SODIUM PHOSPHATE
 RX BAUSCH AND LOMB EQ 0.9% PHOSPHATE A040070 001 Jul 29, 1994 RLD: A080751
 SOLUTION; ORAL
 PREDNISOLONE SODIUM PHOSPHATE
 RX PHARM ASSOC EQ 15MG BASE/5ML A076913 001 Apr 25, 2005 RLD: N019157

PREDNISON

TABLET, DELAYED RELEASE; ORAL
 PREDNISON
 RX DR REDDYS 1MG A219477 001 Oct 01, 2025 RLD: N202020

PRILOCAINE HYDROCHLORIDE

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

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
 PROCAINAMIDE HYDROCHLORIDE
 RX GLAND 100MG/ML A218135 001 Jul 22, 2024 RLD: N007335
 RX 500MG/ML A218135 002 Jul 22, 2024 RLD: N007335

PROGESTERONE

INJECTABLE; INJECTION
 PROGESTERONE
 RX EUGIA PHARMA 50MG/ML A210965 001 Dec 06, 2018 RLD: N017362

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

March 2026

Page 29 of 34

PROPAFENONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL
 PROPAFENONE HYDROCHLORIDE
 RX STRIDES PHARMA 425MG A078540 003 Oct 18, 2010 RLD: N021416
 INTL

PROPARACAINE HYDROCHLORIDE

SOLUTION/DROPS;OPHTHALMIC
 PROPARACAINE HYDROCHLORIDE
 RX BAUSCH AND LOMB 0.5% A040074 001 Sep 29, 1995 RLD: N008883

PROTAMINE SULFATE

SOLUTION;INTRAVENOUS
 PROTAMINE SULFATE
 RX FRESENIUS KABI USA 50MG/5ML (10MG/ML) A089454 001 Apr 07, 1987 RLD: N006460
 RX 250MG/25ML (10MG/ML) A089454 002 Apr 07, 1987 RLD: N006460

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
 PSEUDOEPHEDRINE HYDROCHLORIDE
 OTC AUROBINDO PHARMA 240MG A218854 001 Dec 29, 2025 RLD: N020021
 LTD

PYRAZINAMIDE

TABLET;ORAL
 PYRAZINAMIDE
 RX HIKMA 500MG A081319 001 Jun 30, 1992 RLD: A080157

QUINAPRIL HYDROCHLORIDE

TABLET;ORAL
 QUINAPRIL HYDROCHLORIDE
 RX LUPIN EQ 40MG BASE A077690 004 Jun 20, 2006 RLD: N019885

QUININE SULFATE

CAPSULE;ORAL
 QUININE SULFATE
 RX NOVAST LABS 324MG A204372 001 Jul 22, 2015 RLD: N021799

RANOLAZINE

TABLET, EXTENDED RELEASE;ORAL
 RANOLAZINE
 RX CADILA 1GM A210188 002 Aug 19, 2019 RLD: N021526

RILUZOLE

TABLET;ORAL
 RILUZOLE
 RX ALKEM LABS LTD 50MG A204048 001 Mar 30, 2016 RLD: N020599

RITONAVIR

TABLET;ORAL
 RITONAVIR
 RX AUROBINDO PHARMA 100MG A206614 001 Sep 17, 2018 RLD: N022417
 LTD

ROCURONIUM BROMIDE

INJECTABLE;INJECTION
 ROCURONIUM BROMIDE
 RX GLAND 50MG/5ML (10MG/ML) A205656 001 Apr 04, 2018 RLD: N020214
 RX 100MG/10ML (10MG/ML) A205656 002 Apr 04, 2018 RLD: N020214

SAXAGLIPTIN HYDROCHLORIDE

TABLET;ORAL
 SAXAGLIPTIN
 RX MYLAN EQ 5MG BASE A205980 002 Jul 31, 2023 RLD: N022350

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

March 2026

Page 30 of 34

SCOPOLAMINE

SYSTEM; TRANSDERMAL
 SCOPOLAMINE
 RX RICONPHARMA LLC 1MG/72HR A212342 001 Nov 24, 2020 RLD: N017874

SELEGILINE HYDROCHLORIDE

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

SILDENAFIL CITRATE

FOR SUSPENSION; ORAL
 SILDENAFIL CITRATE
 RX AUROBINDO PHARMA LTD EQ 10MG BASE/ML A214773 001 Dec 23, 2022 RLD: N203109

SILODOSIN

CAPSULE; ORAL
 SILODOSIN
 RX LUPIN LTD 4MG A206541 001 Dec 03, 2018 RLD: N022206

SODIUM ACETATE

SOLUTION; INTRAVENOUS
 SODIUM ACETATE
 RX FRESENIUS KABI USA 400MEQ/100ML (4MEQ/ML) A206687 001 Oct 30, 2017 RLD: N018893

SODIUM BENZOATE; SODIUM PHENYLACETATE

SOLUTION; INTRAVENOUS
 SODIUM PHENYLACETATE AND SODIUM BENZOATE
 RX AILEX PHARMS LLC 10%; 10% (5GM/50ML; 5GM/50ML) A207096 001 Feb 24, 2016 RLD: N020645

SODIUM BICARBONATE

SOLUTION; INTRAVENOUS
 SODIUM BICARBONATE
 RX EXELA PHARMA 5MEQ/10ML (0.5MEQ/ML) A211091 001 Jun 20, 2019 RLD: N019443
 RX 10MEQ/10ML (1MEQ/ML) A211091 003 Jun 20, 2019 RLD: N019443
 RX 44.6MEQ/50ML (0.9MEQ/ML) A211091 002 Jun 20, 2019 RLD: N019443
 RX 50MEQ/50ML (1MEQ/ML) A211091 004 Jun 20, 2019 RLD: N019443
 RX HOSPIRA 2.5MEQ/5ML (0.5MEQ/ML) A202981 001 Mar 04, 2016 RLD: N019443

SODIUM CHLORIDE

SOLUTION; INJECTION
 SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 RX TARO 45MG/5ML (9MG/ML) A077407 001 Aug 11, 2006 RLD: N019217
 RX 90MG/10ML (9MG/ML) A077407 002 Aug 11, 2006 RLD: N019217

SODIUM PHENYL BUTYRATE

POWDER; ORAL
 SODIUM PHENYL BUTYRATE
 RX PH HEALTH 3GM/TEASPOONFUL A203918 001 Jun 15, 2016 RLD: N020573
 TABLET; ORAL
 SODIUM PHENYL BUTYRATE
 RX PH HEALTH 500MG A204395 001 Apr 15, 2016 RLD: N020572

SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE

SOLUTION; INTRAVENOUS
 SODIUM PHOSPHATES
 RX FRESENIUS KABI USA 1.34GM/5ML; 1.38GM/5ML (268MG/ML; 276MG/ML) A209997 001 Mar 30, 2022 RLD: N018892
 RX 13.4GM/50ML; 13.8GM/50ML (268MG/ML; 276MG/ML) A209997 003 Mar 30, 2022 RLD: N018892

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

March 2026

Page 31 of 34

SODIUM POLYSTYRENE SULFONATE

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

SOLIFENACIN SUCCINATE

TABLET;ORAL
 SOLIFENACIN SUCCINATE
 RX SCIEGEN PHARMS 10MG A211657 002 May 20, 2019 RLD: N021518

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
 SOLUTION;INTRAMUSCULAR, INTRAVENOUS
 SUCCINYLCHOLINE CHLORIDE
 RX FRESENIUS KABI USA 100MG/5ML (20MG/ML) A217884 001 Feb 11, 2025 RLD: N215143

SULFADIAZINE

TABLET;ORAL
 SULFADIAZINE
 RX EPIC PHARMA LLC 500MG A040091 001 Jul 29, 1994 RLD: N004122

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE;INJECTION
 SULFAMETHOXAZOLE AND TRIMETHOPRIM
 RX PHARMOBEDIENT 80MG/ML;16MG/ML A206607 001 Aug 30, 2017 RLD: N018374

TAMSULOSIN HYDROCHLORIDE

CAPSULE;ORAL
 TAMSULOSIN HYDROCHLORIDE
 RX ZYDUS PHARMS USA 0.4MG A078225 001 Apr 27, 2010 RLD: N020579
 INC

TAVABOROLE

SOLUTION;TOPICAL
 TAVABOROLE
 RX ENCUBE 5% A211297 001 Oct 13, 2020 RLD: N204427

TEMOZOLOMIDE

CAPSULE;ORAL
 TEMOZOLOMIDE
 RX AMNEAL PHARMS 250MG A203691 006 May 08, 2015 RLD: N021029

TERBUTALINE SULFATE

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

TERCONAZOLE

CREAM;VAGINAL
 TERCONAZOLE
 RX SUN PHARMA CANADA 0.8% A075953 001 Apr 06, 2004 RLD: N019964

TESTOSTERONE

GEL, METERED;TRANSDERMAL
 TESTOSTERONE
 RX ACTAVIS LABS UT 10MG/0.5GM ACTUATION A204571 001 Aug 05, 2015 RLD: N021463
 INC
 RX 12.5MG/1.25GM ACTUATION A076737 003 Mar 09, 2015 RLD: N021015

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

March 2026

Page 32 of 34

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	
<u>TESTOSTERONE ENANTHATE</u>							
INJECTABLE; INJECTION							
TESTOSTERONE ENANTHATE							
RX	HIKMA FARMACEUTICA	200MG/ML	A091120	001	Sep 18, 2012	RLD: N009165	
<u>TETRACYCLINE HYDROCHLORIDE</u>							
CAPSULE; ORAL							
TETRACYCLINE HYDROCHLORIDE							
RX	AMNEAL PHARMS NY	500MG	A210674	002	Sep 18, 2018	RLD: N050278	
<u>THEOPHYLLINE</u>							
SOLUTION; ORAL							
THEOPHYLLINE							
RX	CHARTWELL	80MG/15ML	A091156	001	Apr 13, 2011	RLD: A087449	
MOLECULAR							
TABLET, EXTENDED RELEASE; ORAL							
THEOPHYLLINE							
RX	ALEMBIC	450MG	A090430	002	Oct 27, 2010	RLD: A085328	
<u>THIOTHIXENE</u>							
CAPSULE; ORAL							
THIOTHIXENE							
RX	NOVITIUM PHARMA	5MG	A211642	003	Apr 05, 2019	RLD: N016584	
<u>TIMOLOL MALEATE</u>							
SOLUTION, GEL FORMING/DROPS; OPHTHALMIC							
TIMOLOL MALEATE							
RX	ALEMBIC	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	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	RISING	20MG	A207556	003	May 02, 2019	RLD: N018017	
<u>TIZANIDINE HYDROCHLORIDE</u>							
CAPSULE; ORAL							
TIZANIDINE HYDROCHLORIDE							
RX	RUBICON RESEARCH	EQ 8MG BASE	A213798	004	Aug 28, 2025	RLD: N021447	
<u>TOBRAMYCIN</u>							
SOLUTION/DROPS; OPHTHALMIC							
TOBRAMYCIN							
RX	SOMERSET THERAPS LLC	0.3%	A207444	001	Jun 28, 2017	RLD: N050541	
<u>TOLMETIN SODIUM</u>							
CAPSULE; ORAL							
TOLMETIN SODIUM							
RX	RISING	EQ 400MG BASE	A073393	001	May 27, 1993	RLD: N018084	
<u>TOREMIFENE CITRATE</u>							
TABLET; ORAL							
TOREMIFENE CITRATE							
RX	RISING	EQ 60MG BASE	A208813	001	Dec 04, 2018	RLD: N020497	

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

March 2026

Page 33 of 34

TRAMADOL HYDROCHLORIDE

TABLET;ORAL
 TRAMADOL HYDROCHLORIDE
 RX RUBICON RESEARCH 100MG A208708 002 Jun 28, 2019 RLD: N020281

TRAVOPROST

SOLUTION/DROPS;OPHTHALMIC
 TRAVOPROST
 RX CHARTWELL RX 0.004% A091340 001 Mar 01, 2013 RLD: N021257

TRIAMCINOLONE ACETONIDE

OINTMENT;TOPICAL
 TRIAMCINOLONE ACETONIDE
 RX ENCUBE 0.05% A212384 001 Nov 29, 2019 RLD: N011600

SPRAY;TOPICAL
 TRIAMCINOLONE ACETONIDE
 RX PADAGIS ISRAEL 0.147MG/GM A205782 001 Apr 13, 2015 RLD: N012104

TRIENTINE HYDROCHLORIDE

CAPSULE;ORAL
 TRIENTINE HYDROCHLORIDE
 RX RISING 500MG A212238 002 Sep 22, 2023 RLD: N019194

TRIMETHOBENZAMIDE HYDROCHLORIDE

CAPSULE;ORAL
 TRIMETHOBENZAMIDE HYDROCHLORIDE
 RX HERITAGE PHARMA 300MG A205950 001 Nov 21, 2023 RLD: N017531
 AVET

TRIMIPRAMINE MALEATE

CAPSULE;ORAL
 TRIMIPRAMINE MALEATE
 RX BRECKENRIDGE EQ 50MG BASE A208127 002 Apr 15, 2016 RLD: N016792

URSODIOL

CAPSULE;ORAL
 URSODIOL
 RX LGM PHARMA 200MG A205789 001 May 08, 2020 RLD: N019594
 RX 400MG A205789 002 May 08, 2020 RLD: N019594

TABLET;ORAL
 URSODIOL
 RX ZYDUS LIFESCIENCES 500MG A211145 002 Oct 30, 2018 RLD: N020675

VALSARTAN

SOLUTION;ORAL
 VALSARTAN
 RX NOVITIUM PHARMA 4MG/ML A214102 001 Nov 02, 2021 RLD: N209139

VARDENAFIL HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING;ORAL
 VARDENAFIL HYDROCHLORIDE
 RX ALEMBIC 10MG A208324 001 Nov 16, 2018 RLD: N200179

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

VARENICLINE TARTRATE

TABLET;ORAL
 VARENICLINE TARTRATE
 RX PH HEALTH 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

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

March 2026

Page 34 of 34

TABLET, EXTENDED RELEASE;ORAL				
VERAPAMIL HYDROCHLORIDE				
RX	GLENMARK PHARMS LTD	180MG	A090700 002	Aug 03, 2011 RLD: N019152
TABLET;ORAL				
VERAPAMIL HYDROCHLORIDE				
RX	HERITAGE	120MG	A071881 001	Apr 05, 1988 RLD: N018593
<u>VINBLASTINE SULFATE</u>				
INJECTABLE;INJECTION				
VINBLASTINE SULFATE				
RX	HIKMA	10MG/VIAL	A089395 001	Apr 09, 1987 RLD: N012665
<u>VORICONAZOLE</u>				
SOLUTION;INTRAVENOUS				
VORICONAZOLE				
RX	HAINAN POLY PHARM	200MG/20ML (10MG/ML)	A220043 001	Nov 14, 2025 RLD: N021267
<u>ZALEPLON</u>				
CAPSULE;ORAL				
ZALEPLON				
RX	UNICHEM	10MG	A078989 002	Jun 06, 2008 RLD: N020859
<u>ZILEUTON</u>				
TABLET, EXTENDED RELEASE;ORAL				
ZILEUTON				
RX	RISING	600MG	A204929 001	Mar 17, 2017 RLD: N022052
<u>ZOLEDRONIC ACID</u>				
INJECTABLE;INTRAVENOUS				
ZOLEDRONIC				
RX	GLAND	EQ 4MG BASE/100ML	A205749 001	Jun 29, 2018 RLD: N021223
<u>ZOLMITRIPTAN</u>				
TABLET, ORALLY DISINTEGRATING;ORAL				
ZOLMITRIPTAN				
RX	ZYDUS PHARMS USA INC	5MG	A202890 002	May 15, 2013 RLD: N021231
TABLET;ORAL				
ZOLMITRIPTAN				
RX	AJANTA PHARMA LTD	5MG	A204041 002	May 20, 2016 RLD: N020768