



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

34th EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER
SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
OFFICE OF GENERIC DRUGS

2014

EXHIBIT

ACTAVIS, AMNEAL,
AUROBINDO,
BRECKENRIDGE,
VENNOOT, SANDOZ,
SUN

IPR2014-01126-1011, p. 1

PRESCRIPTION DRUG PRODUCT LIST

KETOROLAC TROMETHAMINE

TABLET; ORAL

KETOROLAC TROMETHAMINE

AB	TEVA	10MG	A074754	001	May 16, 1997
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LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION

LABETALOL HYDROCHLORIDE

AP	AKORN INC	5MG/ML	A075431	001	Nov 29, 1999
AP		5MG/ML	A075524	001	Nov 29, 1999
AP	BEDFORD	5MG/ML	A075303	001	May 28, 1999
AP	GLAND PHARMA LTD	5MG/ML	A090699	001	Apr 03, 2012
AP	+ HOSPIRA	5MG/ML	A075239	001	Nov 29, 1999
AP	+	5MG/ML	A075240	001	Nov 29, 1999

LABETALOL HYDROCHLORIDE

AP	SAGENT STRIDES	5MG/ML	A079134	001	Feb 03, 2010
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TABLET; ORAL

LABETALOL HYDROCHLORIDE

AB	IVAX SUB TEVA PHARMS	100MG	A074787	001	Aug 03, 1998
AB		200MG	A074787	002	Aug 03, 1998
AB		300MG	A074787	003	Aug 03, 1998
AB	PAR FORM	100MG	A200908	001	Jul 10, 2012
AB		200MG	A200908	002	Jul 10, 2012
AB		300MG	A200908	003	Jul 10, 2012
AB	SANDOZ	100MG	A075113	001	Aug 04, 1998
AB	+	200MG	A075113	002	Aug 04, 1998
AB		300MG	A075113	003	Aug 04, 1998
AB	WATSON LABS	100MG	A075133	001	Aug 03, 1998
AB		200MG	A075133	002	Aug 03, 1998
AB		300MG	A075133	003	Aug 03, 1998

LACOSAMIDE

SOLUTION; INTRAVENOUS

VIMPAT

+ UCB INC

200MG/20ML (10MG/ML)

N022254 001 Oct 28, 2008

SOLUTION; ORAL

VIMPAT

+ UCB INC

10MG/ML

N022255 001 Apr 20, 2010

TABLET; ORAL

VIMPAT

UCB INC

50MG

N022253 001 Oct 28, 2008

100MG

N022253 002 Oct 28, 2008

150MG

N022253 003 Oct 28, 2008

+

200MG

N022253 004 Oct 28, 2008

LACTULOSE

FOR SOLUTION; ORAL

LACTULOSE

+ CUMBERLAND PHARMS

10GM/PACKET

A074712 001 Dec 10, 1997

+

20GM/PACKET

A074712 002 Dec 10, 1997

SOLUTION; ORAL

CONSTILAC

AA	ALRA	10GM/15ML	A071054	001	Jul 26, 1988
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CONSTULOSE

AA	+ ACTAVIS MID ATLANTIC	10GM/15ML	A070288	001	Aug 15, 1988
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LACTULOSE

AA	ANI PHARMS	10GM/15ML	A078430	001	Nov 28, 2007
AA	FRESENIUS KABI	10GM/15ML	A090503	001	Jan 25, 2012
AA	HI TECH PHARMA	10GM/15ML	A074076	001	Jul 03, 1995
AA	MORTON GROVE	10GM/15ML	A074602	001	Nov 14, 1996
AA	PHARM ASSOC	10GM/15ML	A074623	001	Jul 30, 1996
AA	ROXANE	10GM/15ML	A073591	001	May 29, 1992
AA	VINTAGE PHARMS	10GM/15ML	A075993	001	Jul 26, 2001
AA	VISTAPHARM	10GM/15ML	A074138	001	Sep 30, 1992

SOLUTION; ORAL, RECTAL

CHOLAC

AA	ALRA	10GM/15ML	A071331	001	Jul 26, 1988
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ENULOSE

AA	+ ACTAVIS MID ATLANTIC	10GM/15ML	A071548	001	Aug 15, 1988
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GENERLAC

AA	MORTON GROVE PHARMS	10GM/15ML	A074603	001	Oct 31, 1996
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LACTULOSE

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>IVACAFTOR - KALYDECO</u>						
N 203188	001 7495103	May 20, 2027	DS DP		NCE	Jan 31, 2017
	8324242	Apr 18, 2027		U-1311	ODE	Jan 31, 2019
	8410274	Dec 28, 2026	DP			
<u>IVERMECTIN - SKLICE</u>						
N 202736	001 6103248	May 22, 2018	DP		NP	Feb 07, 2015
<u>IXABEPILONE - IXEMPRA KIT</u>						
N 022065	001 6670384	Jan 23, 2022	DP	U-959	M-61	Oct 18, 2014
	6670384	Jan 23, 2022	DP	U-960	PED	Apr 18, 2015
	7022330	Jan 23, 2022	DP	U-958		
	7125899	May 26, 2018	DS DP	U-957		
	7312237	Aug 21, 2024		U-965		
	RE41393	Feb 08, 2022		U-961		
	RE41911	Sep 28, 2020	DS DP	U-961		
<u>IXABEPILONE - IXEMPRA KIT</u>						
N 022065	002 6670384	Jan 23, 2022	DP	U-959	M-61	Oct 18, 2014
	6670384	Jan 23, 2022	DP	U-960	PED	Apr 18, 2015
	7022330	Jan 23, 2022	DP	U-958		
	7125899	May 26, 2018	DS DP	U-957		
	7312237	Aug 21, 2024		U-965		
	RE41393	Feb 08, 2022		U-961		
	RE41911	Sep 28, 2020	DS DP	U-961		
<u>KETOCONAZOLE - NIZORAL A-D</u>						
N 020310	001 5456851	Apr 07, 2014				
<u>KETOCONAZOLE - EXTINA</u>						
N 021738	001 7553835	Oct 19, 2018	DP	U-245		
	8026238	Oct 19, 2018	DP	U-1213		
<u>KETOCONAZOLE - XOLEGEL</u>						
N 021946	001 7179475	Dec 04, 2018	DP	U-792		
	8232276	Nov 24, 2020	DP			
<u>KETOROLAC TROMETHAMINE - ACULAR LS</u>						
N 021528	001 8008338	May 24, 2027	DS DP	U-1181		
	8207215	May 28, 2024		U-1251		
	8377982	May 28, 2024		U-1363		
	8377982*PED	Nov 28, 2024				
	8541463	May 28, 2024		U-1441		
	8541463*PED	Nov 28, 2024				
<u>KETOROLAC TROMETHAMINE - SPRIX</u>						
N 022382	001 6333044	Dec 25, 2018	DP	U-1057		
<u>KETOROLAC TROMETHAMINE - ACUVAIL</u>						
N 022427	001 7842714	Aug 15, 2029	DS DP			
	8512717	Mar 07, 2028	DP			
<u>LACOSAMIDE - VIMPAT</u>						
N 022253	001 5654301	Aug 05, 2014	DS DP	U-914	NCE	Oct 28, 2013
	RE38551	Mar 17, 2022	DS DP	U-914		
<u>LACOSAMIDE - VIMPAT</u>						
N 022253	002 5654301	Aug 05, 2014	DS DP	U-914	NCE	Oct 28, 2013
	RE38551	Mar 17, 2022	DS DP	U-914		
<u>LACOSAMIDE - VIMPAT</u>						
N 022253	003 5654301	Aug 05, 2014	DS DP	U-914	NCE	Oct 28, 2013
	RE38551	Mar 17, 2022	DS DP	U-914		
<u>LACOSAMIDE - VIMPAT</u>						
N 022253	004 5654301	Aug 05, 2014	DS DP	U-914	NCE	Oct 28, 2013
	RE38551	Mar 17, 2022	DS DP	U-914		
<u>LACOSAMIDE - VIMPAT</u>						
N 022254	001 5654301	Aug 05, 2014	DS DP	U-911	NCE	Oct 28, 2013
	RE38551	Mar 17, 2022	DS DP	U-911		

PATENT USE

- U-897 METHOD OF TREATING TONSILLITIS AND/OR PHARYNGITIS SECONDARY TO STREPTOCOCCUS PYOGENES IN A ONCE-A-DAY AMOXICILLIN PRODUCT
- U-898 USE OF GLUTAMINE TOGETHER WITH GROWTH HORMONE FOR THE TREATMENT OF PATIENTS WITH SHORT BOWEL SYNDROME
- U-899 USE OF THALIDOMIDE IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA
- U-900 INTEGRASE INHIBITION FOR THE TREATMENT OF HIV INFECTION
- U-901 PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING
- U-902 USE IN THE TREATMENT OF THE SIGNS AND SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA (BPH)
- U-903 TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN ADULT PATIENTS
- U-904 TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE
- U-905 TREATMENT OF MODERATE TO SEVERE VAGINAL DRYNESS AND PAIN WITH INTERCOURSE, SYMPTOMS OF VULVAR AND VAGINAL ATROPHY, ASSOCIATED WITH MENOPAUSE
- U-906 PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS FOR THE MAINTENANCE OF REMISSION OF ULCERATIVE COLITIS IN SUBJECTS 18 YEARS OF AGE AND OLDER
- U-907 PROPHYLAXIS OF ORGAN REJECTION IN PATIENTS RECEIVING ALLOGENEIC RENAL TRANSPLANTS
- U-908 TREATMENT OF CYSTIC FIBROSIS PATIENTS WITH PSEUDOMONAS AERUGINOSA
- U-909 TREATMENT OF METASTATIC CARCINOMA OF THE OVARY AFTER FAILURE OF INITIAL OR SUBSEQUENT CHEMOTHERAPY
- U-911 METHOD OF TREATING, AS ADJUNCTIVE THERAPY, PARTIAL-ONSET SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS AND OLDER WHEN ORAL TREATMENT IS TEMPORARILY NOT FEASIBLE
- U-912 SEDATION OF NON-INTUBATED PATIENTS PRIOR TO AND/OR DURING SURGICAL AND OTHER PROCEDURES
- U-913 TREATMENT OF OVERACTIVE BLADDER WITH SYMPTOMS OF URGE URINARY INCONTINENCE, URGENCY, AND FREQUENCY
- U-914 METHOD OF TREATING, AS ADJUNCTIVE THERAPY, PARTIAL-ONSET SEIZURES IN A PATIENT WITH EPILEPSY AGED 17 YEARS AND OLDER
- U-915 TREATMENT OF MUSCULOSKELETAL CONDITIONS
- U-916 TOPICAL TREATMENT OF ACNE VULGARIS IN PATIENTS 12 YEARS OR OLDER
- U-917 TREATMENT OF INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS TO TREAT OR PREVENT INFECTIONS CAUSED BY SUSCEPTIBLE BACTERIA USING DELAYED-RELEASE TABLETS CONSISTING OF DOXYCYCLINE HYCLATE COATED PELLETS IN A TABLET FOR THE TREATMENT OF DERMATITIS
- U-919 STEROID-RESPONSIVE INFLAMMATORY OCULAR CONDITIONS FOR WHICH A CORTICOSTEROID IS INDICATED AND WHERE SUPERFICIAL BACTERIAL OCULAR INFECTION OR A RISK OF BACTERIAL OCULAR INFECTION EXISTS
- U-921 TREATMENT OF ACNE VULGARIS
- U-922 FOR THE TREATMENT OF FUNGAL INFECTIONS
- U-923 METHOD OF TREATING OPHTHALMIC INFLAMMATION AND INFECTION
- U-924 TREATMENT OF MILD TO MODERATE INFECTION CAUSED BY SUSCEPTIBLE STRAINS
- U-925 TREATMENT OF ONLY INFLAMMATORY LESIONS (PAPULES AND PUSTULES) OF ROSACEA
- U-926 MGT SPECIFIC BACTERIAL INFECTIONS. TREATMENT PTS W/ COMMUNITY ACQUIRED PNEUMONIA OR BACTERIAL SINUSITIS DUE TO CONFIRMED, OR SUSPECTED B-LACTAMASE PRODUCING PATHOGENS & S. PNEUMONIAE WITH REDUCED SUSCEPTIBILITY TO PENICILLIN (MIC=2MC/ML)
- U-927 METHOD FOR INCREASING TEAR PRODUCTION
- U-928 TREATMENT OF BACTERIAL INFECTIOUS DISEASE
- U-929 TREATMENT OF OBSESSIVE COMPULSIVE DISORDER TREATABLE WITH AN SSRI
- U-930 TREATMENT OF IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP)
- U-931 RELIEF OF MODERATE TO SEVERE ACUTE PAIN
- U-932 PYLERA CAPSULES, IN COMBINATION WITH OMEPRAZOLE ARE INDICATED FOR THE TREATMENT OF PATIENTS WITH HELICOBACTER PYLORI INFECTION AND DUODENAL ULCER DISEASE TO ERADICATE H. PYLORI
- U-933 FOR THE TREATMENT OF PATIENTS WITH HELICOBACTER PYLORI INFECTION AND DUODENAL ULCER DISEASE TO ERADICATE H. PYLORI. THE ERADICATION OF HELICOBACTER PYLORI HAS BEEN SHOWN TO REDUCE THE RISK OF DUODENAL ULCER RECURRENCE
- U-934 IN COMBINATION WITH GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF) TO MOBILIZE HEMATOPOIETIC STEM CELL TO THE PERIPHERAL BLOOD FOR COLLECTION AND SUBSEQUENT AUTOLOGOUS TRANSPLANTATION WITH NON-HODGKINS LYMPHOMA AND MULTIPLE MYELOMA
- U-935 TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION IN ADULT PATIENTS, AND TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PEDIATRIC PATIENTS 6 YEARS OF