

Volume I

Drug Information for the Health Care Professional

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21ST EDITION

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CUMULATIVE LIST OF ORPHAN PRODUCT DESIGNATIONS AND APPROVALS (continued)

NAME Generic/Chemical TN = Trade Name	INDICATION DESIGNATED	SPONSOR AND ADDRESS DD = Date Designated *** = Marketing Approval
SODIUM PHENYL BUTYRATE	FOR USE AS AN ADJUNCT TO SURGERY, RADIATION THERAPY AND CHEMOTHERAPY FOR THE TREATMENT OF PATIENTS WITH PRIMARY OR RECURRENT MALIGNANT GLIOMA.	ELAN PHARMACEUTICAL RESEARCH CORPORATION GAINESVILLE, GA PHONE: (770) 534-8239 DD 04/24/1998
SODIUM TETRADECYL SULFATE TN= SOTRADECOL	TREATMENT OF BLEEDING ESOPHAGEAL VARICES.	ELKINS-SINN, INC. CHERRY HILL, NJ PHONE: (609) 424-3700 DD 06/10/1986
SOLUBLE COMPLEMENT RECEPTOR TYPE 1	PREVENTION OF POST-CARDIOPULMONARY BYPASS SYNDROME IN CHILDREN UNDERGOING CARDIOPULMONARY BYPASS.	AVANT IMMUNOTHERAPEUTICS, INC. NEEDHAM, MA PHONE: (781) 433-3129 DD 03/06/2000
SOLUBLE RECOMBINANT HUMAN COMPLEMENT RECEPTOR TYPE 1	PREVENTION OR REDUCTION OF ADULT RESPIRATORY DISTRESS SYNDROME.	T CELL SCIENCES, INC. NEEDHAM HEIGHTS, MA PHONE: (617) 621-1400 DD 11/21/1994
SOMATOSTATIN TN= ZECNIL	ADJUNCT TO THE NON-OPERATIVE MANAGEMENT OF SECRETING CUTANEOUS FISTULAS OF THE STOMACH, DUODENUM, SMALL INTESTINE (JEJUNUM AND ILEUM), OR PANCREAS.	FERRING LABORATORIES, INC. SUFFERN, NY PHONE: (888) 793-6367 DD 06/20/1988
SOMATOSTATIN	TREATMENT OF BLEEDING ESOPHAGEAL VARICES.	UCB PHARMACEUTICALS, INC. SMYRNA, GA PHONE: (770) 437-5654 DD 12/22/1994
SOMATREM FOR INJECTION*** TN= PROTROPIN	FOR LONG-TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	GENENTECH, INC. SOUTH SAN FRANCISCO, CA PHONE: (415) 225-1000 DD 12/09/1985
SOMATREM FOR INJECTION TN= PROTROPIN	TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	GENENTECH, INC. SOUTH SAN FRANCISCO, CA PHONE: (415) 225-1000 DD 12/09/1985
SOMATROPIN*** TN= NUTROPIN	FOR USE IN THE LONG-TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	GENENTECH, INC. SOUTH SAN FRANCISCO, CA PHONE: (415) 225-1000 DD 03/06/1987
SOMATROPIN TN= NORDITROPIN	TREATMENT OF GROWTH FAILURE IN CHILDREN DUE TO INADEQUATE GROWTH HORMONE SECRETION.	NOVO NORDISK PHARMACEUTICALS PRINCETON, NJ PHONE: (609) 987-5847 DD 07/10/1987
SOMATROPIN*** TN= HUMATROPE	TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER SYNDROME.	ELI LILLY AND COMPANY INDIANAPOLIS, IN PHONE: (317) 276-2000 DD 05/08/1990
SOMATROPIN*** TN= GENOTROPIN	TREATMENT OF ADULTS WITH GROWTH HORMONE DEFICIENCY.	PHARMACIA & UPJOHN KALAMAZOO, MI PHONE: (616) 833-8239 DD 09/06/1994
SOMATROPIN (RDNA) TN= SAIZEN	FOR THE ENHANCEMENT OF NITROGEN RETENTION IN HOSPITALIZED PATIENTS SUFFERING FROM SEVERE BURNS.	SERONO LABORATORIES, INC. NORWELL, MA PHONE: (781) 982-9000 DD 05/03/1989
SOMATROPIN (R-DNA) TN= SEROSTIM	FOR USE WITH GLUTAMINE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE).	SERONO LABORATORIES, INC. NORWELL, MA PHONE: (781) 982-9000 DD 03/06/1995
SOMATROPIN (R-DNA) FOR INJECTION TN= SEROSTIM	TREATMENT OF CHILDREN WITH AIDS-ASSOCIATED FAILURE-TO-THRIVE INCLUDING AIDS-ASSOCIATED WASTING.	SERONO LABORATORIES, INC. NORWELL, MA PHONE: (781) 982-9000 DD 03/26/1996

CUMULATIVE LIST OF ORPHAN PRODUCT DESIGNATIONS AND APPROVALS (continued)

NAME Generic/Chemical TN = Trade Name	INDICATION DESIGNATED	SPONSOR AND ADDRESS DD = Date Designated *** = Marketing Approval
PHENYLACETATE	FOR USE AS AN ADJUNCT TO SURGERY, RADIATION THERAPY AND CHEMOTHERAPY FOR THE TREATMENT OF PATIENTS WITH PRIMARY OR RECURRENT MALIGNANT GLIOMA.	ELAN PHARMACEUTICAL RESEARCH CORP. GAINESVILLE, GA PHONE: (770) 534-8239 DD 03/06/1998
PHENYLALANINE AMMONIA LYASE TN= PHENYLASE	TREATMENT OF HYPERPHENYLALANINEMIA.	IBEX TECHNOLOGIES, INC. CANADA H4P 1P7, PHONE: (610) 407-4200 DD 03/08/1995
PHENYLBUTYRATE	TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA.	ELAN CORPORATION GAINESVILLE, GA PHONE: (770) 538-6360 DD 01/19/2000
PHOSPHOCYSTEAMINE	TREATMENT OF CYSTINOSIS.	MEDEA RESEARCH LABORATORIES PORT JEFFERSON, NY PHONE: (516) 331-7718 DD 09/12/1988
PHYSOSTIGMINE SALICYLATE TN= ANTILIRIUM	TREATMENT OF FRIEDREICH'S AND OTHER INHERITED ATAXIAS.	FOREST PHARMACEUTICALS, INC. NEW YORK, NY PHONE: (212) 421-7850 DD 01/16/1985
PILOCARPINE*** TN= SALAGEN	TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY FOR HEAD AND NECK CANCER.	MGI PHARMA, INC. BLOOMINGTON, MN PHONE: (612) 346-4722 DD 09/24/1990
PILOCARPINE HCL*** TN= SALAGEN	TREATMENT OF XEROSTOMIA AND KERATOCONJUNCTIVITIS SICCA IN SJOGREN'S SYNDROME PATIENTS.	MGI PHARMA, INC. BLOOMINGTON, MN PHONE: (612) 346-4722 DD 02/28/1992
PIRACETAM TN= NOOTROPIL	TREATMENT OF MYOCLONUS.	UCB PHARMA, INC. SMYRNA, GA PHONE: (770) 437-5645 DD 10/02/1987
POLIFEPROSAN 20 WITH CARMUSTINE*** TN= GLIADEL	TREATMENT OF MALIGNANT GLIOMA.	GUILFORD PHARMACEUTICALS, INC. BALTIMORE, MD PHONE: (410) 631-6306 DD 12/13/1989
POLOXAMER 188 TN= FLOCOR	TREATMENT OF SICKLE CELL CRISIS.	CYTRX CORPORATION NORCROSS, GA PHONE: (609) 799-7580 DD 06/27/1989
POLOXAMER 188 TN= FLORCOR	TREATMENT OF SEVERE BURNS REQUIRING HOSPITALIZATION.	CYTRX CORPORATION NORCROSS, GA PHONE: (609) 799-7580 DD 02/22/1990
POLOXAMER 188	TREATMENT OF VASOSPASM IN SUBARACHNOID HEMORRHAGE PATIENTS FOLLOWING SURGICAL REPAIR OF A RUPTURED CEREBRAL ANEURYSM.	CYTRX CORPORATION NORCROSS, GA PHONE: (770) 368-9500 DD 08/05/1997
POLOXAMER 331 TN= PROTOX	INITIAL THERAPY OF TOXOPLASMOSIS IN PATIENTS WITH AIDS.	CYTRX CORPORATION NORCROSS, GA PHONE: (770) 453-0107 DD 03/21/1991
POLY I: POLY C12U TN= AMPLIGEN	TREATMENT OF AIDS.	HEMISPHERX BIOPHARMA, INC. PHILADELPHIA, PA PHONE: (215) 988-0080 DD 07/19/1988
POLY I: POLY C12U TN= AMPLIGEN	TREATMENT OF RENAL CELL CARCINOMA.	HEMISPHERX BIOPHARMA, INC. PHILADELPHIA, PA PHONE: (215) 988-0080 DD 05/20/1991