



PHYSICIANS' DESK REFERENCE®

Medical Consultant

Ronald Arky, MD, Charles S. Davidson Professor of Medicine and Master, Francis Weld Peabody Society, Harvard Medical School

Vice President of Directory Services: Stephen B. Greenberg

Director of Product Management: David P. Reiss

Senior Product Manager: Mark A. Friedman

Associate Product Manager: Bill Shaughnessy

Director of Sales: Dikran N. Barsamian

National Sales Manager: Anthony Sorce

National Account Manager: Don Bruccoleri

Account Managers:

Marion Gray, RPh

Lawrence C. Keary

Jeffrey F. Pfohl

Christopher N. Schmidt

Stephen M. Silverberg

Suzanne E. Yarrow, RN

National Sales Manager, Trade Group: Bill Gaffney

Director of Direct Marketing: Michael Bennett

Direct Marketing Manager: Lorraine M. Loening

Promotion Manager: Donna R. Lynn

Director, Professional Support Services: Mukesh Mehta, RPh

Senior Drug Information Specialist: Thomas Fleming, RPh

Drug Information Specialist: Maria Deutsch, MS, RPh, CDE

Editor, Special Projects: David W. Sifton

Vice President of Production: David A. Pittler

Director of Print Purchasing: Marjorie A. Duffy

Director of Operations: Carrie Williams

Manager of Production: Kimberly H. Vivas

Senior Production Coordinators: Amy B. Brooks, Dawn McCall

Production Coordinator: Mary Ellen R. Breun

PDR Data Manager: Jeffrey D. Schaefer

Senior Format Editor: Gregory J. Westley

Index Editors: Johanna M. Mazur, Robert N. Woerner

Art Associate: Joan K. Akerlind

Senior Digital Imaging Coordinator: Shawn W. Cahill

Digital Imaging Coordinator: Frank J. McElroy, III

Electronic Publishing Designer: Robert K. Grossman

Fulfillment Managers: Stephanie DeNardi, Kenneth Siebert

TRIAL EXHIBIT

TX 1374

Copyright © 1999 and published by Medical Economics Company, Inc. at Montvale, NJ 07645-1742. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, resold, redistributed, or transmitted in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without the prior written permission of the publisher. PHYSICIANS' DESK REFERENCE®, PDR®, PDR For Nonprescription Drugs®, PDR For Ophthalmology®, Pocket PDR®, and The PDR® Family Guide to Prescription Drugs® are registered trademarks used herein under license. PDR Companion Guide™, PDR® for Herbal Medicines™, PDR® Medical Dictionary™, PDR® Nurse's Handbook™, PDR® Nurse's Dictionary™, The PDR® Family Guide Encyclopedia of Medical Care™, PDR® Electronic Library™, and PDR® Drug Interactions, Side Effects, Indications, Contraindications System™ are trademarks used herein under license.

Officers of Medical Economics Company: *President and Chief Executive Officer:* Curtis B. Allen; *Vice President, New Media:* L. Suzanne BeDell; *Vice President, Corporate Human Resources:* Pamela M. Bilash; *Vice President and Chief Information Officer:* Steven M. Bressler; *Senior Vice President, Finance, and Chief Financial Officer:* Thomas W. Ehardt; *Vice President, Directory Services:* Stephen B. Greenberg; *Vice President, New Business Planning:* Linda G. Hope; *Executive Vice President, Healthcare Publishing and Communications:* Thomas J. Kelly; *Executive Vice President, Magazine Publishing:* Lee A. Maniscalco; *Vice President, Group Publisher:* Terrence W. Meacock; *Vice President, Production:* David A. Pittler; *Vice President, Group Publisher:* Thomas C. Pizor; *Vice President, Magazine Business Management:* Eric Schlett; *Senior Vice President, Operations:* John R. Ware



Printed on recycled paper

ISBN: 1-56363-288-8

DPEM2_0002904

**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.

Verapamil Hydrochloride Tablets (Watson) 3216
 Verapamil Sustained Release Tablets (Warner Chilcott) 3214
VERELAN CAPSULES (Lederle Labs) 320, 1549
VERMOX CHEWABLE TABLETS (Janssen) 317, 1442
VERSED INJECTION (Roche Laboratories) 2720
VERSENATE, CALCIUM DISODIUM
 Calcium Disodium Versenate Injection (JM) 1655
VERTIGOHEEL LIQUID IN ORAL VIALS (Heel) 1288
VERTIGOHEEL ORAL DROPS (Heel) 1288
VERTIGOHEEL TABLETS (Heel) 1288
VESANOID CAPSULES (Roche Laboratories) 335, 2726
VIAGRA TABLETS (Pfizer) 331, 2424
VIBRAMYCIN CALCIUM ORAL SUSPENSION SYRUP (Pfizer) 2427
VIBRAMYCIN HYCLATE CAPSULES (Pfizer) 2427
VIBRAMYCIN HYCLATE INTRAVENOUS (Pfizer) 2429
VIBRAMYCIN MONOHYDRATE FOR ORAL SUSPENSION (Pfizer) 2427
VIBRA-TABS FILM COATED TABLETS (Pfizer) 2427
VICKS 44 COUGH RELIEF (Procter & Gamble) 80
VICKS 44D COUGH & HEAD CONGESTION RELIEF (Procter & Gamble) 80
VICKS 44E COUGH & CHEST CONGESTION RELIEF (Procter & Gamble) 80
PEDIATRIC VICKS 44E COUGH & CHEST CONGESTION RELIEF (Procter & Gamble) 80
VICKS 44M COUGH, COLD & FLU RELIEF (Procter & Gamble) 80
PEDIATRIC VICKS 44M COUGH & COLD RELIEF (Procter & Gamble) 80
ORIGINAL VICKS CHLORASEPTIC COUGH AND THROAT DROPS (Procter & Gamble) 80
VICKS CHLORASEPTIC SORE THROAT LOZENGES (Procter & Gamble) 80
VICKS CHLORASEPTIC SORE THROAT SPRAY (Procter & Gamble) 80
VICKS COUGH DROPS, MENTHOL FLAVOR (Procter & Gamble) 80
ORIGINAL VICKS COUGH DROPS (Procter & Gamble) 80
VICKS DAYQUIL MULTI-SYMPTOM COLD/FLU RELIEF LIQUID & LIQUICAPS (Procter & Gamble) 80
VICKS DAYQUIL SINUS PRESSURE & PAIN RELIEF WITH IBUPROFEN (Procter & Gamble) 80
CHILDREN'S VICKS NYQUIL COLD/COUGH RELIEF (Procter & Gamble) 80
VICKS NYQUIL HOT THERAPY (Procter & Gamble) 80
VICKS NYQUIL LIQUICAPS (Procter & Gamble) 80
VICKS NYQUIL LIQUID (Procter & Gamble) 80
VICKS SINEX 12 HOUR NASAL SPRAY AND ULTRA FINE MIST FOR SINUS RELIEF (Procter & Gamble) 80
VICKS SINEX NASAL SPRAY AND ULTRA FINE MIST FOR SINUS RELIEF (Procter & Gamble) 80
VICKS VAPOR INHALER (Procter & Gamble) 80
VICKS VAPORUB CREAM (Procter & Gamble) 80
VICKS VAPORUB OINTMENT (Procter & Gamble) 80
VICKS VAPOSTEAM (Procter & Gamble) 80

VICODIN TABLETS (Knoll Labs) 318, 1486
VICODIN ES TABLETS (Knoll Labs) 318, 1487
VICODIN HP TABLETS (Knoll Labs) 318, 1484
VICODIN TUSS EXPECTORANT (Knoll Labs) 319, 1488
VICON FORTE CAPSULES (UCB) 341, 3170
VICOPROFEN TABLETS (Knoll Labs) 319, 1489
VIDARABINE
 Vira-A Ophthalmic Ointment, 3% (Monarch) 1950
VI-DAYLIN ADC VITAMINS DROPS (Ross) 2743
VI-DAYLIN ADC VITAMINS + IRON DROPS (Ross) 2743
VI-DAYLIN MULTIVITAMIN CHEWABLE TABLETS (Ross) 2743
VI-DAYLIN MULTIVITAMIN + IRON CHEWABLE TABLETS (Ross) 2743
VI-DAYLIN MULTIVITAMIN DROPS (Ross) 2743
VI-DAYLIN MULTIVITAMIN + IRON DROPS (Ross) 2743
VI-DAYLIN MULTIVITAMIN LIQUID (Ross) 2743
VI-DAYLIN MULTIVITAMIN + IRON LIQUID (Ross) 2743
VI-DAYLIN/F ADC VITAMINS DROPS WITH FLUORIDE (Ross) 2743
VI-DAYLIN/F ADC VITAMINS + IRON DROPS WITH FLUORIDE (Ross) 2743
VI-DAYLIN/F MULTIVITAMIN CHEWABLE TABLETS WITH FLUORIDE (Ross) 2743
VI-DAYLIN/F MULTIVITAMIN + IRON CHEWABLE TABLETS WITH FLUORIDE (Ross) 2743
VI-DAYLIN/F MULTIVITAMIN DROPS WITH FLUORIDE (Ross) 2743
VI-DAYLIN/F MULTIVITAMIN + IRON DROPS WITH FLUORIDE (Ross) 2743
VIDEX POWDER FOR ORAL SOLUTION (Bristol-Myers Squibb Oncology/Immunology) 806
VIDEX PEDIATRIC POWDER FOR ORAL SOLUTION (Bristol-Myers Squibb Oncology/Immunology) 806
VIDEX CHEWABLE TABLETS (Bristol-Myers Squibb Oncology/Immunology) 308, 806
VINBLASTINE SULFATE
 Velban Vials (Lilly) 1639
VINCRISTINE SULFATE
 Oncovin Solution Vials & Hypocrets (Lilly) 1624
VINORELBINE TARTRATE
 Navelbine Injection (Glaxo Wellcome) 313, 1184
VIKASE POWDER (Axcan) 620
VIKASE TABLETS (Axcan) 305, 620
VIRA-A OPHTHALMIC OINTMENT, 3% (Monarch) 1950
VIRACEPT ORAL POWDER (Agouron) 303, 484
VIRACEPT TABLETS (Agouron) 303, 484
VIRAMUNE TABLETS (Roche) 335, 2766
VIRAZOLE (ICN) 1382
VIRILON CAPSULES (Star) 3131
VIRILON IM INJECTION (Star) 3131
VISTARIL CAPSULES (Pfizer) 2430
VISTARIL INTRAMUSCULAR SOLUTION (Pfizer) 2431
VISTARIL ORAL SUSPENSION (Pfizer) 2430
VISTIDE INJECTION (Gilead Sciences) 1079
VITAFOL CAPLETS (Everett) 995

VITAFOL-PN CAPLETS (Everett) 995
VITAMIN A
 Aquasol A Capsules, USP (Astra) 547
 Aquasol A Parenteral (Astra) 548
 Megadose Tablets (Arco) 545
 Vitamist Intra-Oral Spray Dietary Supplements (Mayor) 1666
 Revitalize (Mayor) 1666
 ACES Antioxidant Soft Gels (Carlson) 867
 LazerCreme (Pedinol) 2354
 Vi-Daylin ADC Vitamins Drops (Ross) 2743
 Vi-Daylin ADC Vitamins + Iron Drops (Ross) 2743
 Vi-Daylin/F ADC Vitamins Drops With Fluoride (Ross) 2743
 Vi-Daylin/F ADC Vitamins + Iron Drops With Fluoride (Ross) 2743
VITAMIN B₁
 Mega-B Tablets (Arco) 545
VITAMIN B₂
 Mega-B Tablets (Arco) 545
VITAMIN B₃
 (see under: NIACIN)
VITAMIN B₆
 Beechth Tablets (Beach) 306, 698
 Lurtine PMS Tablets (Fielding) 1011
 Marlyn Formula 50 Capsules (Marlyn) 1666
 Mega-B Tablets (Arco) 545
 Vitamist Intra-Oral Spray Dietary Supplements (Mayor) 1666
 Polacin (Mayor) 1666
 VitaMotion-S (Mayor) 1666
VITAMIN B₁₂
 Benvital Tablets (Westlake) 3242
 Chromagen FA Capsules (Savage) 336, 2811
 Chromagen Forte Capsules (Savage) 336, 2811
 Mega-B Tablets (Arco) 545
 Nascobal Gel (Schwarz) 337, 2913
 Niferex-150 Forte Capsules (Schwarz) 337, 2916
 Trisicon Capsules (UCB) 341, 3170
 Vitamist Intra-Oral Spray Dietary Supplements (Mayor) 1666
 B12 (Mayor) 1666
 Folacin (Mayor) 1666
 GinkgoMist (Mayor) 1666
 VitaZac (Mayor) 1666
 Chromagen Capsules (Savage) 2810
 Cyanocobalamin (Vit. B₁₂) Injection (Elkins-Sinn) 963
 Fetrin Capsules (Lunisco) 1649
 Hemocyte-F Elixir (U.S. Pharmaceutical) 3175
 Nu-Iron Plus Elixir (Merz) 1927
VITAMIN B COMPLEX
 Mega-B Tablets (Arco) 545
VITAMIN B COMPLEX WITH VITAMIN C
 Cefol Filmtab Tablets (Abbott) 415
 Germed Tablets (Fielding) 1011
 Iberet Liquid (Abbott) 455
 Iberet-500 Filmtab Tablets (Abbott) 455
 Iberet-500 Liquid (Abbott) 455
 Iberet-Folic-500 Filmtab Tablets (Abbott) 446
 Megadose Tablets (Arco) 545
 Nephro-Vite + Fe Tablets (R&D) 2578
 Nephro-Vite Rx Tablets (R&D) 2577
 Hemocyte Plus Tablets (U.S. Pharmaceutical) 3175
 Nephro-Vite Tablets (R&D) 2578
VITAMIN C
 Chromagen FA Capsules (Savage) 336, 2811
 Chromagen Forte Capsules (Savage) 336, 2811
 Fero-Folic-500 Filmtab Tablets (Abbott) 446
 Fero-Grad-500 Filmtab Tablets (Abbott) 446
 Irospan Capsules (Fielding) 1011
 Irospan Tablets (Fielding) 1011
 Proflavanol Tablets (USANA) 341, 3185
 Trisicon Capsules (UCB) 341, 3170
 Vitamist Intra-Oral Spray Dietary Supplements (Mayor) 1666
 C + Zinc (Mayor) 1666
 CardioCare (Mayor) 1666
 ACES Antioxidant Soft Gels (Carlson) 867
 Chromagen Capsules (Savage) 2810
 CitraDerm Facial Complex Cream (Pedinol) 2353
 Fetrin Capsules (Lunisco) 1649
 Peridin-C Tablets (Beutlich) 734
 Vi-Daylin ADC Vitamins Drops (Ross) 2743

Vi-Daylin/F ADC Vitamins Drops With Fluoride (Ross) 2743
 Vi-Daylin/F ADC Vitamins + Iron Drops With Fluoride (Ross) 2743
VITAMIN D
 CalMag Plus Tablets (USANA) 341, 3185
 Megadose Tablets (Arco) 545
 Vitamist Intra-Oral Spray Dietary Supplements (Mayor) 1666
 Herbal OsteoCalMag (Mayor) 1666
 Citracal Caplets + D (Mission) 1928
 Vi-Daylin ADC Vitamins Drops (Ross) 2743
 Vi-Daylin ADC Vitamins + Iron Drops (Ross) 2743
 Vi-Daylin/F ADC Vitamins Drops With Fluoride (Ross) 2743
 Vi-Daylin/F ADC Vitamins + Iron Drops With Fluoride (Ross) 2743
VITAMIN E
 Cefol Filmtab Tablets (Abbott) 415
 Megadose Tablets (Arco) 545
 Nutr-E-Sol Liquid (Advanced Nutritional) 483
 Unique E Vitamin E Capsules (Grace) 1286
 Vitamist Intra-Oral Spray Dietary Supplements (Mayor) 1666
 Blue-Green Sea Spray (Mayor) 1666
 CardioCare (Mayor) 1666
 E + Selenium (Mayor) 1666
 Revitalize (Mayor) 1666
 ACES Antioxidant Soft Gels (Carlson) 867
 Co-Q10 (Carlson) 867
 E-Gems Soft Gels (Carlson) 867
 Lactinol-E Creme (Pedinol) 2354
 LazerCreme (Pedinol) 2354
VITAMIN K₁
 AquaMEPHYTON Injection (Merck) 1735
 Mephyton Tablets (Merck) 323, 1832
VITAMINS, MULTIPLE
 Germed Tablets (Fielding) 1011
 Materna Tablets (Lederle Labs) 319, 1522
 Mega Antioxidant Tablets (USANA) 341, 3185
 Nephrocaps (Fleming) 1014
 Nephro-Vite Rx Tablets (R&D) 2577
 Vitamist Intra-Oral Spray Dietary Supplements (Mayor) 1666
 Anti-Oxidant (Mayor) 1666
 Pro-Bio Mist PB and GS (Mayor) 1666
 VitaMinophen (Mayor) 1666
 Calcet Plus Tablets (Mission) 1929
 M.V.I.-12 Multi-Vitamin Infusion (Astra) 575
 M.V.I. Pediatric for Infusion (Astra) 575
 Nephro-Vite Tablets (R&D) 2578
 Vi-Daylin Multivitamin Chewable Tablets (Ross) 2743
 Vi-Daylin Multivitamin Drops (Ross) 2743
 Vi-Daylin Multivitamin Liquid (Ross) 2743
 Vi-Daylin/F Multivitamin Chewable Tablets With Fluoride (Ross) 2743
 Vi-Daylin/F Multivitamin + Iron Chewable Tablets With Fluoride (Ross) 2743
 Vi-Daylin/F Multivitamin Drops With Fluoride (Ross) 2743
 Vi-Daylin/F Multivitamin + Iron Drops With Fluoride (Ross) 2743
VITAMINS, PRENATAL
 Enfamil Natalin Rx Tablets (Mead Johnson Nutritionals) 1692
 Niferex-PN Tablets (Schwarz) 337, 2916
 Niferex-PN Forte Tablets (Schwarz) 337, 2917
 Precare Prenatal Multi-Vitamin/Mineral (UCB) 3163
 Prenate Ultra Tablets (Sanofi) 335, 2802
 Advanced Formula Zenate Tablets (Solway) 340, 3128
 Lactocal-F Tablets (Laser) 1509
 Mission Prenatal Tablets (Mission) 1929
 Mission Prenatal F.A. Tablets (Mission) 1929
 Mission Prenatal H.P. Tablets (Mission) 1929
 Mission Prenatal Rx Tablets (Mission) 1929
VITAMINS WITH FLUORIDE
 Infant Formula Multi-Vit/Fluoride Drops 0.25 mg (Atra) 510
 Infant Formula Multi-Vit/Fluoride Drops 0.50 mg (Atra) 510
 Infant Formula Tri-Vit/Fluoride Drops 0.25 mg (Atra) 510
 Infant Formula Tri-Vit/Fluoride Drops 0.50 mg (Atra) 510
 Vi-Daylin/F ADC Vitamins Drops With Fluoride (Ross) 2743

Described in PDR For Nonprescription Drugs

Underline Denotes Generic Name

Described in PDR For Prescription Drugs



Before isoniazid preventive therapy is initiated, bacteriologically positive or radiographically progressive tuberculosis must be excluded. Appropriate evaluations should be performed in Extra pulmonary tuberculosis is suspected.
Adults over 30 Kg: 300 mg per day in a single dose.
Infants and Children: 10 mg/kg (up to 300 mg daily) in a single dose.

In situations where adherence with daily preventative therapy cannot be assured, 20-30 mg/kg (not to exceed 900 mg) twice weekly under the direct observation of a health care worker at the time of administration⁵.

Continuous administration of isoniazid for a sufficient period of time is an essential part of the regimen because relapse rates are higher if chemotherapy is stopped prematurely. In the treatment of tuberculosis, resistant organisms may multiply and the emergence during the treatment may necessitate a change in the regimen.

For following patient compliance: the Potts-Cozart test³, a simple colorimetric method of checking for isoniazid in the urine, is a useful tool for assuring patient compliance, which is essential for effective tuberculosis control. Additionally, isoniazid test strips are also available to check patient compliance.

Concomitant administration of pyridoxine (B₆) is recommended in the malnourished and in those predisposed to neuropathy (e.g., alcoholics and diabetics).

HOW SUPPLIED

Nydrazid Injection (Isoniazid Injection USP) is available for intramuscular use in 10 mL vials providing 100 mg isoniazid per mL (NDC 0093-0643-50).

Storage

Store at controlled room temperature 15°-30°C (59°-86°F). Protect from light.

Nydrazid Injection may crystallize at low temperatures. If this occurs, warm the vial to room temperature before use to redissolve the crystals.

REFERENCES

- Murphy, R. et al: *Annals of Internal Medicine*; 1990; November 15; volume 113:799-800.
- Burke, R.F., et al: *Res Commun Chem Pathol Pharmacol*, 1990; July; vol. 69; 115-118.
- Fleener, M.F., et al: *Chest (United States) Letter*; 1991; June; 99 (6):1554.
- Baciewicz, A.M. and Baciewicz, Jr. F.A.; *Arch Int Med* 1993, September; volume 153; 1970-1971.
- Jonville, A.P., et al: *European Journal of Clinical Pharmacology (Germany)*, 1991; 40 (2) p198.
- American Thoracic Society/Centers for disease Control: *Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children*. *Amer. J. Respir Crit Care Med*. 1994; 149: p1359-1374.
- Hoglund P., et al: *European Journal of Respir Dis (Denmark)* 1987; February; 70 (2) p110-116.
- Committee on Infectious Diseases American Academy of Pediatrics: 1994, Red Book: Report of the Committee on Infectious Diseases; 23 edition; p487.
- Schraufnagel, DE; *Testing for Isoniazid; Chest (United States)* 1990, August; 98 (2) p314-316.

CAUTION: Federal law prohibits dispensing without prescription.

APOTHECON®
 A Bristol-Myers Squibb Company
 Princeton, NJ 08540 USA

J4-491A

STADOL®

[sta 'dōl]
 (butorphanol tartrate injection, USP)

Full prescribing information for the above product appears under Bristol-Myers Squibb Company.

NOTICE

Before prescribing or administering any product described in **PHYSICIANS' DESK REFERENCE** check the PDR Supplements for revised information.

ARCO Pharmaceuticals, Inc.
 105 ORVILLE DRIVE
 BOHEMIA, NY 11716

Direct Inquiries to:
 Professional Service Department
 (516) 567-9500

ARCO-LASE® OTC
 (broad pH spectrum digestant)

COMPOSITION

Each soft, mint flavored tablet contains Trizyme®, 38 mg., and Lipase, 25 mg.
 *Contains the following standardized enzymes: amylolytic 30 mg.; proteolytic 6 mg.; cellulolytic 2 mg.

ACTION AND USES

Indicated for most gastrointestinal disorders due to poor digestion. Flatulence, gas and bloating, dyspepsia, distention, fullness, heartburn, or in any condition where normal digestion is impaired by digestive insufficiencies. Arcolase provides the highest standardized enzymatic activity, plus the protective action of the widest pH range. Thus it is effective throughout the entire G.I. tract. Requiring no enteric coating, there is assurance of a positive breakdown of its factors. This is advantageous, because quite often patients with digestive disorders cannot digest their food properly, let alone hard, or enteric coated capsules or tablets.

SIDE EFFECTS

None.

ADMINISTRATION AND DOSAGE

One tablet with or immediately following meals. Tablet may be swallowed or chewed.

SUPPLIED

Bottles of 50's. NDC 275-4040.

ARCO-LASE® PLUS

COMPOSITION

Same as Arco-Lase, plus the addition of Hyoscyamine sulfate 0.10 mg., atropine sulfate 0.02 mg. and phenobarbital 1/8 gr. (Warning: may be habit forming.)

ACTION AND USES

Gastrointestinal disturbances, such as cramps, bloating, spasms, diarrhea, nausea, vomiting and peptic ulcer. The enzymes correct the digestive insufficiencies. The antispasmodic and phenobarbital contribute to the symptomatic relief of hypermotility and nervous tension, which usually accompanies functional disturbances of the bowel.

ADMINISTRATION AND DOSAGE

One tablet following meals.

SIDE EFFECTS

May cause rapid pulse, dryness of mouth and blurred vision.

CONTRAINDICATIONS

This product is contraindicated in the presence of glaucoma or prostatic hypertrophy.

SUPPLIED

Bottles of 50's. NDC 275-45-45.

LITERATURE AVAILABLE

Yes.

MEGA-B® OTC
 (super potency vitamin B complex, sugar & starch free)

COMPOSITION

Each Mega-B Tablet contains the following Mega Vitamins:

B ₁ (Thiamine Mononitrate)	100 mg.
B ₂ (Riboflavin)	100 mg.
B ₆ (Pyridoxine Hydrochloride)	100 mg.
B ₁₂ (Cyanocobalamin)	100 mcg.
Choline Bitartrate	100 mg.
Inositol	100 mg.
Niacinamide	100 mg.
Folic Acid	100 mcg.
Pantothenic Acid	100 mg.

d-Biotin 100 mcg.
 Para-Aminobenzoic Acid (PABA) 100 mg.
 In a base of yeast to provide the identified and unidentified B-Complex Factors.

ADVANTAGES

Each Mega-B capsule-shaped tablet provides the highest vitamin B complex available in a single dose. Mega-B was designed for those patients who require truly Mega vitamin potencies with the convenience of minimum dosage.

INDICATIONS

Mega-B is indicated in conditions characterized by depletions or increased demand of the water-soluble B-complex vitamins. It may be useful in the nutritional management of patients during prolonged convalescence associated with major surgery. It is also indicated for stress conditions, as an adjunct to antibiotics and diuretic therapy, pre and post operative cases, liver conditions, gastrointestinal disorders interfering with intake or absorption of water-soluble vitamins, prolonged or wasting diseases, diabetes, burns, fractures, severe infections, and some psychological disorders.

WARNING

NOT INTENDED FOR TREATMENT OF PERNICIOUS ANEMIA, OR OTHER PRIMARY OR SECONDARY ANEMIAS.

DOSAGE

Usual dosage is one Mega-B tablet daily, or varied, depending on clinical needs.

SUPPLIED

Yellow capsule shaped tablets in bottles of 30, 100 and 500.

MEGADOSE™ OTC
 (multiple mega-vitamin formula with minerals, sugar and starch free)

COMPOSITION

Vitamin A	25,000 USP Units
Vitamin D	1,000 USP Units
Vitamin C w/Rose Hips	250 mg.
Vitamin E	100 IU
Folic Acid	400 mcg.
Vitamin B ₁	80 mg.
Vitamin B ₂	80 mg.
Niacinamide	80 mg.
Vitamin B ₆	80 mg.
Vitamin B ₁₂	80 mcg.
Biotin	80 mcg.
Pantothenic Acid	80 mg.
Choline Bitartrate	80 mg.
Inositol	80 mg.
Para-Aminobenzoic Acid	80 mg.
Rutin	30 mg.
Citrus Bioflavonoids	30 mg.
Betaine Hydrochloride	30 mg.
Glutamic Acid	30 mg.
Hesperidin Complex	5 mg.
Iodine (from Kelp)	0.15 mg.
Calcium Gluconate*	50 mg.
Zinc Gluconate*	25 mg.
Potassium Gluconate*	10 mg.
Ferrous Gluconate*	10 mg.
Magnesium Gluconate*	7 mg.
Manganese Gluconate*	6 mg.
Copper Gluconate*	0.5 mg.

*Natural mineral chelates in a base containing natural ingredients.

DOSAGE

One tablet daily.

SUPPLIED

Capsule shaped tablets in bottles of 30, 100 and 250.

For information on over-the-counter drugs, consult PDR For Nonprescription Drugs.

Consult 1999 PDR® supplements **DP2M2-0002906** 2000

of fibrin patients. These a 6-week over one available in adverse ns. s in eeks c week ration mg/day (=289) 6% 9% 6% 3% 5% 3% 3%

of fibrin patients. These a 6-week over one available in adverse ns. s in eeks c week ration mg/day (=289) 6% 9% 6% 3% 5% 3% 3%

Metabolic and Nutritional Disorders: *Frequent:* dehydration; *Infrequent:* gout, hypokalemia, increased creatine kinase, hyperglycemia, weight increase, increased lactate dehydrogenase.

Musculoskeletal System: *Frequent:* bone fracture; *Infrequent:* muscle weakness, muscle fasciculation.

Nervous System: *Frequent:* delusions, tremor, irritability, paresthesia, aggression, vertigo, ataxia, increased libido, restlessness, abnormal crying, nervousness, aphasia; *Infrequent:* cerebrovascular accident, intracranial hemorrhage, transient ischemic attack, emotional lability, neuralgia, coldness (localized), muscle spasm, dysphoria, gait abnormality, hypertonia, hypokinesia, neurodermatitis, numbness (localized), paranoia, dysarthria, dysphasia, hostility, decreased libido, melancholia, emotional withdrawal, nystagmus, pacing.

Respiratory System: *Frequent:* dyspnea, sore throat, bronchitis; *Infrequent:* epistaxis, post nasal drip, pneumonia, hyperventilation, pulmonary congestion, wheezing, hypoxia, pharyngitis, pleurisy, pulmonary collapse, sleep apnea, snoring.

Skin and Appendages: *Frequent:* pruritus, diaphoresis, urticaria; *Infrequent:* dermatitis, erythema, skin discoloration, hyperkeratosis, alopecia, fungal dermatitis, herpes zoster, hirsutism, skin striae, night sweats, skin ulcer.

Special Senses: *Frequent:* cataract, eye irritation, vision blurred; *Infrequent:* dry eyes, glaucoma, earache, tinnitus, blepharitis, decreased hearing, retinal hemorrhage, otitis externa, otitis media, bad taste, conjunctival hemorrhage, ear buzzing, motion sickness, spots before eyes.

Urogenital System: *Frequent:* urinary incontinence, nocturia; *Infrequent:* dysuria, hematuria, urinary urgency, metrorrhagia, cystitis, enuresis, prostate hypertrophy, pyelonephritis, inability to empty bladder, breast fibroadenosis, fibrocystic breast, mastitis, pyuria, renal failure, vaginitis.

Postintroduction Reports
Voluntary reports of adverse events temporally associated with ARICEPT® that have been received since market introduction that are not listed above, and that there is inadequate data to determine the causal relationship with the drug include the following: abdominal pain, agitation, cholecystitis, confusion, convulsions, hallucinations, hemolytic anemia, pancreatitis, and rash.

OVERDOSAGE
Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug.
As in any case of overdose, general supportive measures should be utilized. Overdosage with cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, collapse and convulsions. Increasing muscle weakness is a possibility and may result

cholinergics such as atropine as used as an antidote for ARICEPT® overdose. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response. Atypical responses in blood pressure and heart rate have been reported with other cholinomimetics when co-administered with quaternary anticholinergics such as glycopyrrolate. It is not known whether ARICEPT® and/or its metabolites can be removed by dialysis (hemodialysis, peritoneal dialysis, or hemofiltration).

Dose-related signs of toxicity in animals included reduced spontaneous movement, prone position, staggering gait, lacrimation, clonic convulsions, depressed respiration, salivation, miosis, tremors, fasciculation and lower body surface temperature.

DOSE AND ADMINISTRATION
The dosages of ARICEPT® shown to be effective in controlled clinical trials are 5 mg and 10 mg administered once per day.
The higher dose of 10 mg did not provide a statistically significantly greater clinical benefit than 5 mg. There is a suggestion, however, based upon order of group mean scores and dose trend analyses of data from these clinical trials, that a daily dose of 10 mg of ARICEPT® might provide additional benefit for some patients. Accordingly, whether or not to employ a dose of 10 mg is a matter of prescriber and patient preference.
Evidence from the controlled trials indicates that the 10 mg dose, with a one week titration, is likely to be associated with a higher incidence of cholinergic adverse events than the 5 mg dose. In open label trials using a 6 week titration, the frequency of these same adverse events was similar between the 5 mg and 10 mg dose groups. Therefore, because steady state is not achieved for 15 days and because the incidence of untoward effects may be influenced by the rate of dose escalation, treatment with a dose of 10 mg should not be contemplated until patients have been on a daily dose of 5 mg for 4 to 6 weeks.
ARICEPT® should be taken in the evening, just prior to retiring. ARICEPT® can be taken with or without food.

HOW SUPPLIED
ARICEPT® is supplied as film-coated, round tablets containing either 5 mg or 10 mg of donepezil hydrochloride. The 5 mg tablets are white. The strength, in mg (5), is debossed on one side and the medication code number (E 245) is debossed on the other side.
The 10 mg tablets are yellow and have the strength debossed on one side (10) and the medication code (E 246) on the other side.
5 mg (White) Bottles of 30 (NDC# 62856-245-30)
Unit Dose Blister Package 100 (10x10) (NDC# 62856-245-41)
10 mg (Yellow) Bottles of 30 (NDC# 62856-246-30)
Unit Dose Blister Package 100 (10x10) (NDC# 62856-246-41)
Storage: Store at controlled room temperature, 15°C to 30°C (59°F to 86°F).

Table 3. Adverse Events Reported in Controlled Clinical Trials in at Least 2% of Patients Receiving ARICEPT® and at a Higher Frequency than Placebo-treated Patients

Body System/Adverse Event	Placebo (n=355)	ARICEPT® (n=747)
Percent of Patients with any Adverse Event	72	74
Body as a Whole		
Headache	9	10
Pain, various locations	8	9
Accident	6	7
Fatigue	3	5
Cardiovascular System		
Syncope	1	2
Digestive System		
Nausea	6	11
Diarrhea	5	10
Vomiting	3	5
Anorexia	2	4
Hemic and Lymphatic System		
Eczymosis	3	4
Metabolic and Nutritional Systems		
Weight Decrease	1	3
Musculoskeletal System		
Muscle Cramps	2	6
Arthritis	1	2
Nervous System		
Insomnia	6	9
Dizziness	6	8
Depression	<1	3
Abnormal Dreams	0	3
Somnolence	<1	2
Urogenital System		
Frequent Urination	1	2

ARICEPT® is a registered trademark of Eisai Co., Ltd., Tokyo, Japan
Marketed by Eisai Inc., Teaneck, NJ 07666
Manufactured and Distributed/Marketed by Roerig Division of Pfizer Inc, New York, NY 10017
©1998 Eisai Inc.
Revised April, 1998
69-5210-00-3
Shown in Product Identification Guide, page 309

Available to physicians through Eisai Medical Sales Specialists, free of charge. All are available in Spanish also.
Understanding Alzheimers Disease Brochure
Managing Alzheimers Disease Brochure (both are disease specific brochures)
Know your Medicine Brochure (for patients on Aricept)
12 week patient diary (also for patients on Aricept)

Elkins-Sinn, Inc.
2 ESTERBROOK LANE
CHERRY HILL, NJ 08003-4099

Direct Inquiries to:
Professional Service
(610) 688-4400
For Emergency Medical Information Contact:
Day: (800) 934-5556 8:30 AM to 4:30 PM (Eastern Standard Time), Weekdays only
Night: (610) 688-4400 (Emergencies only; non-emergencies should wait until the next day)
For Medical/Pharmacy Inquiries on Marketed Products Call:
(800) 934-5556 8:30 AM to 4:30 PM (Eastern Standard Time), Weekdays only

Elkins-Sinn's DOSETTE® line offers a broad spectrum of injectable products in a variety of unit-of-use containers--DOSETTE® vials, DOSETTE® ampuls, DOSETTE® syringes, and DOSETTE® cartridge-needle units. Easily adaptable to any hospital pharmacy set-up, the DOSETTE® system combines easily identifiable, clearly printed product labeling with space-conserving packaging. Each DOSETTE® container is characterized by product name and strength in large, bold-faced type, important usage and storage data, lot identification number, and expiration date.
Elkins-Sinn also produces a vast number of multiple dose vials. Listed below are the major ESI products. For prescribing information on products listed, write to Professional Service, Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101, or contact your local Wyeth-Ayerst representative.

- AMIKACIN SULFATE INJECTION, USP
250 mg/mL 2 mL Dosette Vial
250 mg/mL 4 mL Vial
- AMINOCAPROIC ACID INJECTION, USP
250 mg/mL 20 mL Multiple Dose Vial
- ATROPINE SULFATE INJECTION, USP
400 mcg/mL 1 mL Dosette Vial
(0.4 mg, 1/150 gr)
- 400 mcg/mL 1 mL Dosette Ampul
(0.4 mg, 1/150 gr)
- 400 mcg/mL 20 mL Multiple Dose Vial
(0.4 mg, 1/150 gr)
- 1 mg/mL (1/60 gr) 1 mL Dosette Vial
- CHLORPROMAZINE HYDROCHLORIDE INJECTION, USP
25 mg/mL 1 mL Dosette Ampul
50 mg/2 mL 2 mL Dosette Ampul
- CYANOCOBALAMIN INJECTION, USP
1 mg/mL (1000 mcg) 1 mL Dosette Vial
1 mg/mL (1000 mcg) 10 mL Multiple Dose Vial
1 mg/mL (1000 mcg) 80 mL Multiple Dose Vial
- DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP
4 mg/mL 1 mL Dosette Vial
4 mg/mL 5 mL Multiple Dose Vial
10 mg/mL 1 mL Dosette Vial
10 mg/mL 10 mL Multiple Dose Vial
- DIAZEPAM INJECTION, USP®
5 mg/mL 1 mL Dosette Vial
5 mg/mL 10 mL Multiple Dose Vial
5 mg/mL 1 mL Dosette Syringe
10 mg/2 mL 2 mL Dosette Vial
10 mg/2 mL 2 mL Dosette Ampul
10 mg/2 mL 2 mL Dosette Syringe

Continued on next page

Consult 1999 PDR® supplements and future editions for revisions
DPEM2-0002907

Product Info. - Elkins-Sinn—Cont.

DIAZEPAM INJECTION, USP @
DOSETTE CARTRIDGE NEEDLE UNITS
 5 mg/mL 1 mL Dosette Cartridge
 10 mg/2 mL 2 mL Dosette Cartridge

DIGOXIN INJECTION, USP
 500 mcg/2 mL (0.5 mg) 2 mL Dosette Ampul

DIPHENHYDRAMINE HYDROCHLORIDE INJECTION, USP
 50 mg/mL 1 mL Dosette Vial

DOPAMINE HYDROCHLORIDE INJECTION, USP
 200 mg/5 mL 5 mL Dosette Ampul
 200 mg/5 mL 5 mL Single Use Vial
 400 mg/5 mL 5 mL Dosette Ampul
 400 mg/5 mL 5 mL Single Use Vial

DURAMORPH® (Morphine Sulfate Injection, USP) @ (Preservative-Free for Epidural & Intrathecal Administration)
 5 mg/10 mL (0.5 mg/mL) 10 mL Dosette Ampul
 10 mg/10 mL (1 mg/mL) 10 mL Dosette Ampul

EPINEPHRINE INJECTION, USP
 1 mg/mL (1:1000) 1 mL Dosette Ampul

FENTANYL CITRATE INJECTION, USP (Preservative-Free) @
 100 mcg/2 mL 2 mL Dosette Ampul
 (0.05 mg/mL)
 250 mcg/5 mL 5 mL Dosette Ampul
 (0.05 mg/mL)
 500 mcg/10 mL 10 mL Dosette Ampul
 (0.05 mg/mL)
 1000 mcg/20 mL 20 mL Dosette Ampul
 (0.05 mg/mL)
 1500 mcg/30 mL Single Dose Vial
 2500 mcg/50 mL Single Dose Vial

FUROSEMIDE INJECTION, USP (Preservative-Free)
 20 mg/2 mL 2 mL Dosette Ampul
 40 mg/4 mL 4 mL Dosette Ampul
 40 mg/4 mL 4 mL Single Use Vial
 100 mg/10 mL 10 mL Single Use Vial

GENTAMICIN SULFATE INJECTION, USP
 20 mg/2 mL 2 mL Dosette Vial
 (10 mg/mL—Pediatric)
 80 mg/2 mL 2 mL Dosette Vial
 (40 mg/mL)
 800 mg/20 mL 20 mL Multiple Dose Vial
 (40 mg/mL)

GENTAMICIN SULFATE INJECTION, USP
DOSETTE CARTRIDGE NEEDLE UNITS
 60 mg/1.5 mL 1.5 mL Dosette Cartridge
 80 mg/2 mL 2 mL Dosette Cartridge

HEPARIN SODIUM INJECTION, USP (Porcine Derived)
 1,000 Units/mL 1 mL Dosette Vial
 5,000 Units/mL 1 mL Dosette Vial
 5,000 Units/mL 10 mL Multiple Dose Vial
 10,000 Units/mL 1 mL Dosette Vial

HEPARIN SODIUM INJECTION, USP (Porcine Derived)
DOSETTE CARTRIDGE NEEDLE UNITS
 5,000 Units/0.5 mL 0.5 mL Dosette Cartridge
 5,000 Units/1 mL 1 mL Dosette Cartridge
 10,000 Units/1 mL 1 mL Dosette Cartridge

HEP-LOCK® (Heparin Lock Flush Solution, USP)
 10 Units/mL 1 mL Dosette Vial
 10 Units/mL 2 mL Dosette Vial
 10 Units/mL 10 mL Multiple Dose Vial
 10 Units/mL 30 mL Multiple Dose Vial
 100 Units/mL 1 mL Dosette Vial
 100 Units/mL 2 mL Dosette Vial
 100 Units/mL 10 mL Multiple Dose Vial
 100 Units/mL 30 mL Multiple Dose Vial

HEP-LOCK® (Heparin Lock Flush Solution, USP)
DOSETTE CARTRIDGE NEEDLE UNITS
 10 Units/1 mL 1 mL Dosette Cartridge
 25 Units/2.5 mL 2.5 mL Dosette Cartridge
 100 Units/1 mL 1 mL Dosette Cartridge
 250 Units/2.5 mL 2.5 mL Dosette Cartridge

HEP-LOCK® (Preservative-Free Heparin Lock Flush Solution, USP)
 10 Units/mL 1 mL Dosette Vial
 100 Units/mL 1 mL Dosette Vial

HYDROMORPHONE HYDROCHLORIDE INJECTION, USP @
 2 mg/mL 1 mL Dosette Vial
 2 mg/mL 20 mL Multiple Dose Vial

HYDROXYZINE HYDROCHLORIDE I.M. INJECTION, USP
 25 mg/mL 1 mL Dosette Vial
 50 mg/mL 1 mL Dosette Vial
 100 mg/2 mL 2 mL Dosette Vial
 50 mg/mL 10 mL Multiple Dose Vial

INFUMORPH® 200
 (Preservative-free Morphine Sulfate Sterile Solution) @
 For Use in Continuous Microinfusion Devices
 200 mg/20 mL (10 mg/mL) 20 mL Dosette Ampul

INFUMORPH® 500
 (Preservative-free Morphine Sulfate Sterile Solution) @
 For Use in Continuous Microinfusion Devices
 500 mg/20 mL (25 mg/mL) 20 mL Dosette Ampul

ISOPROTERENOL HYDROCHLORIDE INJECTION, USP
 (Refrigeration not required)
 0.2 mg/mL (1:5000) 5 mL Dosette Ampul

LEUCOVORIN CALCIUM FOR INJECTION (Lyophilized)
 50 mg Single Use Vial
 100 mg Single Use Vial

LIDOCAINE HYDROCHLORIDE INJECTION, USP
 (Preserved)
 1% (10 mg/mL) 30 mL Multiple Dose Vial
 1% (10 mg/mL) 50 mL Multiple Dose Vial
 2% (20 mg/mL) 30 mL Multiple Dose Vial
 2% (20 mg/mL) 50 mL Multiple Dose Vial

LIDOCAINE HYDROCHLORIDE INJECTION, USP
 (Preservative-Free, Single Use)
 1% (10 mg/mL) 5 mL Single Use Vial
 2% (20 mg/mL) 5 mL Single Use Vial

LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION, USP (1:100,000)
 (Refrigeration not required)
 1% (10 mg/mL) 30 mL Multiple Dose Vial
 2% (20 mg/mL) 30 mL Multiple Dose Vial

MEPERIDINE HYDROCHLORIDE INJECTION, USP @
 25 mg/mL 1 mL Dosette Vial
 25 mg/mL 1 mL Dosette Ampul
 50 mg/mL 1 mL Dosette Vial
 50 mg/mL 1 mL Dosette Ampul
 75 mg/mL 1 mL Dosette Vial
 75 mg/mL 1 mL Dosette Ampul
 100 mg/mL 1 mL Dosette Vial
 100 mg/mL 1 mL Dosette Ampul

MORPHINE SULFATE INJECTION, USP @
 1 mg/mL 60 mL Single Use Vial
 5 mg/mL (1/12 gr) 1 mL Dosette Vial
 8 mg/mL (1/3 gr) 1 mL Dosette Vial
 8 mg/mL (1/6 gr) 1 mL Dosette Ampul
 10 mg/mL (1/6 gr) 1 mL Dosette Vial
 10 mg/mL (1/6 gr) 10 mL Multiple Dose Vial
 15 mg/mL (1/4 gr) 1 mL Dosette Vial
 15 mg/mL (1/4 gr) 1 mL Dosette Ampul
 15 mg/mL (1/4 gr) 20 mL Multiple Dose Vial

NALOXONE HYDROCHLORIDE INJECTION, USP
 400 mcg/mL 1 mL Dosette Vial
 (0.4 mg/mL)
 400 mcg/mL 1 mL Dosette Ampul
 (0.4 mg/mL)
 400 mcg/mL 10 mL Multiple Dose Vial
 (0.4 mg/mL)

NEOSTIGMINE METHYLSULFATE INJECTION, USP
 1:1000 (1 mg/mL) 10 mL Multiple Dose Vial
 1:2000 (0.5 mg/mL) 10 mL Multiple Dose Vial

PANCURONIUM BROMIDE INJECTION
 1 mg/mL 10 mL Multiple Dose Vial
 2 mg/mL 2 mL Dosette Vial
 2 mg/mL 2 mL Dosette Ampul
 2 mg/mL 5 mL Dosette Ampul
 2 mg/mL 5 mL Single Use Vial

PHENOBARBITAL SODIUM INJECTION, USP @
 65 mg/mL (1 gr) 1 mL Dosette Vial
 130 mg/mL (2 gr) 1 mL Dosette Vial

PHENYLEPHRINE HYDROCHLORIDE INJECTION, USP
 10 mg/mL 1 mL Dosette Vial

PHENYTOIN SODIUM INJECTION, USP
 100 mg/2 mL (50 mg/mL) 2 mL Dosette Vial
 100 mg/2 mL (50 mg/mL) 2 mL Dosette Ampul
 250 mg/5 mL (50 mg/mL) 5 mL Single Use Vial

PROCAINAMIDE HYDROCHLORIDE INJECTION, USP
 100 mg/mL (1 gram/10 mL) 10 mL Multiple Dose Vial
 500 mg/mL (1 gram/2 mL) 2 mL Multiple Dose Vial

PROCHLORPERAZINE EDISYLATE INJECTION, USP
 10 mg/2 mL 2 mL Dosette Vial

PROMETHAZINE HYDROCHLORIDE INJECTION, USP
 25 mg/mL 1 mL Dosette Ampul
 50 mg/mL 1 mL Dosette Ampul

PROTAMINE SULFATE INJECTION, USP
 (Preservative-Free)
 (Refrigeration not required)
 50 mg/5 mL 5 mL Dosette Ampul
 250 mg/25 mL 25 mL Single Use Vial

SODIUM CHLORIDE INJECTION, USP (Preservative-Free, Single Use)
 0.9% 2 mL Dosette Vial
 0.9% 5 mL Dosette Ampul
 0.9% 10 mL Dosette Ampul

SODIUM CHLORIDE INJECTION, BACTERIOSTATIC, USP
 (Preserved with 0.9% Benzyl Alcohol)
 0.9% 30 mL Multiple Dose Vial
 0.9% 2 mL Dosette Cartridge

SOTRADECOL® (Sodium Tetracycl Sulfate Injection)
 1% 2 mL Dosette Ampul
 3% 2 mL Dosette Ampul

SUFENTANIL CITRATE INJECTION, USP
 500 mcg/mL 1 mL Dosette Ampul
 100 mcg/2 mL 2 mL Dosette Ampul
 250 mcg/5 mL 5 mL Dosette Ampul

SULFAMETHOXAZOLE & TRIMETHOPRIM CONCENTRATE FOR INJECTION, USP
 80 mg/mL Sulfamethoxazole 5 mL Dosette Ampul
 with 16 mg/mL Trimethoprim
 80 mg/mL Sulfamethoxazole 5 mL Single Use Vial
 with 16 mg/mL Trimethoprim
 80 mg/mL Sulfamethoxazole 10 mL Single Use Vial
 with 16 mg/mL Trimethoprim
 80 mg/mL Sulfamethoxazole 30 mL Multiple Dose Vial
 with 16 mg/mL Trimethoprim

THIAMINE HYDROCHLORIDE INJECTION, USP
 100 mg/mL 1 mL Dosette Vial

WATER FOR INJECTION, BACTERIOSTATIC, USP
 (Preserved with 0.9% Benzyl Alcohol)
 30 mL Multiple Dose Vial

AMIKACIN
 [a 'mi-cā-shū]
SULFATE INJECTION, USP

WARNINGS

Patients treated with parenteral aminoglycosides should be under close clinical observation because of the potential ototoxicity and nephrotoxicity associated with their use. Safety for treatment periods which are longer than 14 days has not been established.

Neurotoxicity, manifested as vestibular and permanent bilateral auditory ototoxicity, can occur in patients with preexisting renal damage and in patients with normal renal function treated at higher doses and/or for periods longer than those recommended. The risk of aminoglycoside-induced ototoxicity is greater in patients with renal damage. High frequency deafness usually occurs first and can be detected only by audiometric testing. Vertigo may occur and may be evidence of vestibular injury. Other manifestations of neurotoxicity may include numbness, skin tingling, muscle twitching and convulsions. The risk of hearing loss due to aminoglycosides increases with the degree of exposure to either high peak or high trough serum concentrations. Patients developing cochlear damage may not have symptoms during therapy to warn them of developing eighth-nerve toxicity, and total or partial irreversible bilateral deafness may occur after the drug has been discontinued. Aminoglycoside-induced ototoxicity is usually irreversible.

Aminoglycosides are potentially nephrotoxic. The risk of nephrotoxicity is greater in patients with impaired renal function and in those who receive high doses or prolonged therapy.

Neuromuscular blockade and respiratory paralysis have been reported following parenteral injection, topical instillation (as in orthopedic and abdominal irrigation or in local treatment of empyema) and following oral use of aminoglycosides. The possibility of these phenomena should be considered if aminoglycosides are administered by any route, especially in patients receiving anesthetics; neuromuscular blocking agents such as tubocurarine, succinylcholine, decamethonium; or in patients receiving massive transfusions of citrate-anticoagulated blood. If blockade occurs, calcium salts may reverse these phenomena, but mechanical respiratory assistance may be necessary.

Renal and eighth-nerve function should be closely monitored especially in patients with known or suspected renal impairment at the onset of therapy and also in those whose renal function is initially normal but who develop signs of renal dysfunction during therapy. Serum concentrations of amikacin should be monitored when feasible to assure adequate levels and to avoid potentially toxic levels and prolonged peak concentrations above 35 micrograms per mL. Urine should be examined for decreased specific gravity, increased excretion of proteins and the presence of cells or casts. Blood urea nitrogen, serum creatinine or creatinine clearance should be measured periodically. Serial audiograms should be obtained where feasible in patients old enough to be tested, particularly high risk patients. Evidence of ototoxicity (dizziness, vertigo, tinnitus, roaring in the ears and hearing loss) or nephrotoxicity requires discontinuation of the drug or dosage adjustment.

Concurrent and/or sequential systemic, oral or topical use of other neurotoxic or nephrotoxic products, particularly bacitracin, cisplatin, amphotericin B, cephaloridine, paromomycin, viomycin, polymyxin B, colistin, vancomycin or other aminoglycosides should be avoided. Other factors that may increase risk of toxicity are advanced age and dehydration.

The concurrent use of amikacin with potent diuretics (ethacrynic acid or furosemide) should be avoided since diuretics by themselves may cause ototoxicity. In some

DPEM2 00029



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.