

Pediazole®

erythromycin ethylsuccinate
and sulfisoxazole acetyl
for oral suspension

BRIEF SUMMARY:

Please see package enclosure for full prescribing information.

Indication

For treatment of ACUTE OTITIS MEDIA in children caused by susceptible strains of *Hemophilus influenzae*.

Contraindications

Known hypersensitivity to either erythromycin or sulfonamides.

Infants less than 2 months of age.

Pregnancy at term and during the nursing period, because sulfonamides pass into the placental circulation and are excreted in human breast milk and may cause kernicterus in the infant.

Warnings

Usage in Pregnancy (SEE ALSO: CONTRAINDICATIONS): The safe use of erythromycin or sulfonamides in pregnancy has not been established. The teratogenic potential of most sulfonamides has not been thoroughly investigated in either animals or humans. However, a significant increase in the incidence of cleft palate and other bony abnormalities of offspring has been observed when certain sulfonamides of the short, intermediate and long-acting types were given to pregnant rats and mice at high oral doses (7 to 25 times the human therapeutic dose).

Reports of deaths have been associated with sulfonamide administration from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias. The presence of clinical signs such as sore throat, fever, pallor, purpura or jaundice may be early indications of serious blood disorders. Complete blood counts should be done frequently in patients receiving sulfonamides.

The frequency of renal complications is considerably lower in patients receiving the most soluble sulfonamides such as sulfisoxazole. Urinalysis with careful microscopic examination should be obtained frequently in patients receiving sulfonamides.

Precautions

Erythromycin is principally excreted by the liver. Caution should be exercised in administering the antibiotic to patients with impaired hepatic function. There have been reports of hepatic dysfunction, with or without jaundice occurring in patients receiving oral erythromycin products.

Recent data from studies of erythromycin reveal that its use in patients who are receiving high doses of theophylline may be associated with an increase of serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

Surgical procedures should be performed when indicated.

Sulfonamide therapy should be given with caution to patients with impaired renal or hepatic function and in those patients with a history of severe allergy or bronchial asthma. In the presence of a deficiency in the enzyme glucose-6-phosphate dehydrogenase, hemolysis may occur. This reaction is frequently dose-related. Adequate fluid intake must be maintained in order to prevent crystalluria and renal stone formation.

Adverse Reactions

The most frequent side effects of oral erythromycin preparations are gastrointestinal, such as abdominal cramping and discomfort, and are dose-related. Nausea, vomiting and diarrhea occur infrequently with usual oral doses. During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted. The overall incidence of these latter side effects reported for the combined administration of erythromycin and a sulfonamide is comparable to those observed in patients given erythromycin alone. Mild allergic reactions such as urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis, have been reported with erythromycin.

The following untoward effects have been associated with the use of sulfonamides:

Blood dyscrasias: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia.

Allergic reactions: Erythema multiforme (Stevens-Johnson syndrome), generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis.

Gastrointestinal reactions: Nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis.

C.N.S. reactions: Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia.

Miscellaneous reactions: Drug fever, chills and toxic nephrosis with oliguria or anuria. Periarthritis nodosa and L.E. phenomenon have occurred.

The sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents. Goiter production, diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. Cross-sensitivity may exist with these agents.

Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides, and long-term administration has produced thyroid malignancies in the species.

Dosage and Administration

PEDIAZOLE SHOULD NOT BE ADMINISTERED TO INFANTS UNDER 2 MONTHS OF AGE BECAUSE OF CONTRAINDICATIONS OF SYSTEMIC SULFONAMIDES IN THIS AGE GROUP.

For Acute Otitis Media in Children: The dose of Pediazole can be calculated based on the erythromycin component (50 mg/kg/day) or the sulfisoxazole component (150 mg/kg/day to a maximum of 6 g/day). Pediazole should be administered in equally divided doses four times a day for 10 days. It may be administered without regard to meals.

The following approximate dosage schedule is recommended for using Pediazole:

Children: Two months of age or older.

Weight	Dose—every 6 hours
Less than 8 kg (less than 18 lb)	Adjust dosage by body weight
8 kg (18 lb)	1/2 teaspoonful (2.5 ml)
16 kg (35 lb)	1 teaspoonful (5 ml)
24 kg (53 lb)	1 1/2 teaspoonfuls (7.5 ml)
Over 45 kg (over 100 lb)	2 teaspoonfuls (10 ml)

How Supplied

Pediazole Suspension is available for teaspoon dosage in 100 ml (NDC 0074-8030-13) and 200-ml (NDC 0074-8030-53) bottles, in the form of granules to be reconstituted with water. The suspension provides erythromycin ethylsuccinate equivalent to 200 mg erythromycin activity and sulfisoxazole acetyl equivalent to 600 mg sulfisoxazole per teaspoonful (5 ml).

ROSS LABORATORIES
COLUMBUS, OHIO 43216
Division of Abbott Laboratories, USA

B131/2810

Books received

New books received by the Andrew Taylor Still Memorial Library are acknowledged below. Those of greatest interest to readers will be reviewed later.

Hamilton Bailey's Demonstrations of physical signs in clinical surgery. Edited by Allen Clain; ed. 17, p. 622, with illus.; PSG Publishing Co., Inc., 545 Great Road, Littleton, MA 01460, 1986, \$37.50 (paper).

Selfassessment questions and answers on clinical surgery. (Based on the seventeenth edition of Hamilton Bailey's Demonstrations of physical signs in clinical surgery.) By Allan Clain; ed. 2, pp. 227; PSG Publishing Co., Inc., 545 Great Road, Littleton, MA 01460, 1986, \$12.50 (paper).

Casarett and Doull's Toxicology. The basic science of poisons. Edited by Curtis D. Klaassen, Mary O. Amdur, and John Doull; Macmillan Publishing Co., 866 Third Ave., New York 10022, \$49.95.

Clinical hypertension. By Norman M. Kaplan; ed. 4, pp. 492, with illus.; Williams & Wilkins, 428 E. Preston St., Baltimore 21202, 1986, \$54.95.

Respiratory failure. (Written to provide clinicians with information to manage respiratory failure in patients of all age groups.) By Robert R. Kirby and Robert W. Taylor; pp. 665, with illus.; Year Book Medical Publishers, Inc., 35 E. Wacker, Chicago 60601, 1986, \$75.00.

A clinician's companion: A study guide for effective and humane patient care. (Directed primarily to young physicians, medical students, and house officers.) By Joseph S. Alpert and Stephen M. Wittenberg; pp. 207, with illus.; Little, Brown, and Co., 34 Beacon Street, Boston 02106, 1986, \$16.00 (paper).

1986 Year book of medicine. Edited by Rogers, et al.; pp. 839, with illus.; Year Book Medical Publishers, Inc., 35 E. Wacker, Chicago 60601, 1986, \$44.95.

Vertebral manipulation. (Discusses how to use the techniques of mobilization and other manipulative procedures on the different intervertebral levels; by an Australian physiotherapist.) By G.D. Maitland; ed. 5, pp. 390, with illus.; Butterworth Publishers, 80 Montvale Ave., Stoneham, MA 02180, 1986, \$24.95 (paper).

1986 Year book of plastic and reconstructive surgery. Edited by Frederick J. McCoy; pp. 349, with illus.; Year Book Medical Publishers, Inc., 35 E. Wacker, Chicago 60601, 1986, \$46.95

Atlas of endourology. (For urologic surgeons and radiologists.) By Kurt Amplatz and Paul Lange; pp. 344, with illus.; Year Book Medical Publishers, Inc., 35 E. Wacker, Chicago 60601, 1986, \$95.00.

1986 Year book of critical care medicine. Edited by Rogers et al.; pp. 510, with illus.; Year Book Medical Publishers, Inc., 35 E. Wacker, Chicago 60601, 1986, \$44.95.

Flint's Emergency treatment and management. By Harvey D. Cain; pp. 842, with illus.; W.B. Saunders Co., West Washington Square, Philadelphia 19105, 1985, \$34.95.

Brain matters. Stories of a neurologist and his patients. (Nonfiction.) By Bruce H. Dobkin; pp. 214; Crown Publishers, Inc., 225 Park Ave. South, New York 10003, 1986, \$17.95.

Anatomy of the temporal bone with surgical implications. (A practical presentation of ear anatomy for general practitioners and specialists including audiologists, neurologists, and otologic surgeons. Pocketed in the back of the book—nine reels of color stereoscopic transparencies.) By Harold F. Schuknecht and A. Julianna Gulya; pp. 350, with illus.; Lea & Febiger, 600 Washington Square, Philadelphia 19106-9982, 1986, \$125.00. Also available but separate from the book is a set of 159 full-color slides, 35-mm paper-mounted transparencies, each one matching a photomicrograph from the book for \$175.00

Emotional disorders in physically ill patients. (Divided into 3 sections—common problems encountered in primary care medicine, emotional problems in surgical patients, and the psychologic effects of chronic illness.) Edited by Robert L. Roessler and Norman Decker; pp. 269; Human Sciences Press, Inc., 72 Fifth Ave., New York 10011, \$26.95.

The secret strength of depression. (Self-help book written by a psychiatrist.) By Frederic F. Flach; pp. 221; Bantam Books, 666 Fifth Ave., New York 10103, 1986, \$3.95 (paper).

applications for membership

Buehrer, Betsy D., TCOM '81; 174 Prospect St., Portland, ME 04103

Cox, Donald R., MSUCOM '81; 2799 W. Grand Blvd., Dept. of Infectious Diseases, Detroit, MI 48202

Dalpra, Steven, MSUCOM '83; 5151 S. Main St., Suite D, Sylvania, OH 43560

Elliott, R. Kirk, UHSCOM '79; 5868 Fulton Dr., N.W., Canton, OH 44718

Ferguson, James L., PCOM '81; F.C.I., Staff House No. 4, Sandstone, MN 55072

Glassman, Paul S., UOMHS '61; 733 N.E. 167th St., North Miami Beach, FL 33162

Grimm, Peter D., CCOM '79; Swedish Hospital, Tumor Institute, 1221 Madison, Seattle, WA 98104

Hall, Donald W., UHSCOM '66; 2201 4th St., N., St. Petersburg, FL 33704

Higginbotham, Ronald S., CCOM '81; 214 Sunrise Dr., Mountain Home, ID 83647

Howlett, J. Maurice, CCOM '40; Rt. 1, Box 174-3, Brevard, NC 28712

Jassey, Marvin, UHSCOM '70; 255-44 Memphis Ave., Rosedale, NY 11422-2596

Kienitz, Ronald H., MSUCOM '80; 1276 Mokulua Dr., Kailua, HI 96734

Krouk, Marianne G., PCOM '84; Medical College of Pennsylvania, Eastern Pennsylvania Psychiatric Institute, Philadelphia, PA 19129

Nelson, Thomas D., UHSCOM '73; 3012 N. Beltline Rd., Irving, TX 75062

Peters, Jana M., WVSOM '84; Tanglewood Apt. No. 9, Princeton, WV 24740

Rajala, Bruce W., Capt., CCOM '82; Box 66, 2nd General Hospital, APO, New York, NY 09180

Ray, Scott L., CCOM '81; 2349 Sunset Point Rd., Suite 403, Clearwater, FL 33575

Reeder, Christopher A., NYCOM '83; 36-14 165th St., Apt. 2H-S, Flushing, NY 11358

Roberson, Andrea, COMP '83; 655 Camino De Los Mares, Suite 126, San Clemente, CA 92672

Schwartzman, Mitchell A., PCOM '76; 6122 Torresdale Ave., Philadelphia, PA 19135

Soifer, Neal E., PCOM '82; 323 Barton Run Blvd., Marlton, NJ 08053

Thompson, Ted B., UHSCOM '57; 1801 Staring Ln., Baton Rouge, LA 70810

March 7 - 14, 1987 MAUI, HAWAII

"Alternatives in OB-GYN"

54th Annual Convention of the American College of
Osteopathic Obstetricians and Gynecologists . . .

All physicians welcome.

Six-day program . . .
Two days of Wellness . . .
maternal-fetal medicine,
reproductive endocrinology,
and more . . .

•
The Maui Marriott
Lahaina, Maui, HI

•
For information, contact
ACOGG, 900 Auburn Road,
Pontiac, MI 48057; phone
(313) 332-6360

