

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 in 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 an overgrowth occurs, 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, hypoproliferative anemia 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).

Letters to the Editor



The Journal welcomes Letters to the Editor; if found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with journal style.

Reliability of Computerized Morbidity Data

To the Editor:

The article on reliability of computerized morbidity data (Fortinsky RH, Gutman JD: *A two-phase study of computerized data. J Fam Pract 13:229, 1981*) addresses an area of great importance to the discipline of family medicine, especially with the increase in the use of data systems to capture encounter and morbidity data. I believe that it is important to point out several features not explicitly highlighted in the article. The authors compared two methods of coding diagnoses: (1) the physicians coded their own diagnoses in the first period, and (2) a precoded encounter form was introduced in the second study period. It is important to point out that this study does not look at using front office coder(s) (billing clerk) to do the coding, as is the case in most practices. Moreover, it would have been helpful to know how many problems were noted per visit in each of the study periods and how many different codes were used, since precoded encounter forms might have the effect of forcing physicians to limit the scope of diagnoses used.

The exclusion of status-post diagnoses removed any statistical significance between the two methods. It might have been more useful to have presented the data from the perspective that there was no significant difference unless status-post diagnoses were included.

I would like to point out that there is a published conversion code from ICHPPC-1 to ICHPPC-2.¹

Ronald Schneeweiss, MD
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Reference

1. Becker LA, Boyle RM, Froom J, et al: A conversion code from ICHPPC-1 to ICHPPC-2. *J Fam Pract 12:707, 1981*

The preceding letter was referred to Dr. Fortinsky, who responds as follows:

The comments of Dr. Schneeweiss are appreciated. This response will hopefully serve to clarify the conduct and context of our study.

First, although the precoded encounter form was introduced as a medium for data collection in the second study period, the family practice residents remained responsible for recording all health problems on the form. The form did not simply replace physician effort but helped to alleviate the inconvenience of referring to the code book for every health problem. The code book still must be referred to when coding problems not on the encounter form. Therefore, the overall methods of coding diagnoses in each study period are not so different as Dr. Schneeweiss implies.

Second, we did not discuss the use of billing clerks as coders because billing is not currently a function of the Family Care Center data system. We did, however, Continued on page 826

Tenuate® (IV)
(diethylpropion hydrochloride USP)

Tenuate Dospan® (IV)
(diethylpropion hydrochloride USP)

controlled-release
AVAILABLE ONLY ON PRESCRIPTION

Brief Summary

INDICATION: Tenuate and Tenuate Dospan are indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use such as those described below.

CONTRAINDICATIONS: Advanced arteriosclerosis, hyperthyroidism, known hypersensitivity, or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states. Patients with a history of drug abuse. During or within 14 days following the administration of monoamine oxidase inhibitors. (hypertensive crises may result).

WARNINGS: If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly. When central nervous system active agents are used, consideration must always be given to the possibility of adverse interactions with alcohol. **Drug Dependence:** Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of abuse should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with varying degrees of psychological dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. **Use in Pregnancy:** Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential risks. **Use in Children:** Tenuate is not recommended for use in children under 12 years of age.

PRECAUTIONS: Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hypertension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of guanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.

ADVERSE REACTIONS: Cardiovascular: Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. **Central Nervous System:** Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache; rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. **Gastrointestinal:** Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. **Allergic:** Urticaria, rash, ecchymosis, erythema. **Endocrine:** Impotence, changes in libido, gynecostasia, menstrual upset. **Hematopoietic System:** Bone marrow depression, agranulocytosis, leukopenia. **Miscellaneous:** A variety of miscellaneous adverse reactions has been reported by physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.

DOSE AND ADMINISTRATION: Tenuate (diethylpropion hydrochloride): One 25 mg. tablet three times daily, one hour before meals, and in mid-evening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release: One 75 mg. tablet daily, swallowed whole, in mid-morning. Tenuate is not recommended for use in children under 12 years of age.

OVERDOSAGE: Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phenytoin (Regitine®) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

Product Information as of June, 1980

Reference: 1. Abramson R, Garg M, Cioffari A, and Rotman PA: An Evaluation of Behavioral Techniques Reinforced with an Anorectic Drug in a Double-Blind Weight Loss Study. *J Clin Psych* 41:234-237, 1980.

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LETTERS TO THE EDITOR

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note that additional errors are introduced at the phase of data entry in our setting. It is apparent that reliability is inversely related to the number of personnel included in the process of capturing morbidity data.

Third, it was not possible for us to calculate comparable problems per visit figures because, due to programming limitations, visit based information was not available for the first study period. We were, in fact, more interested in patient based and health problem based reliability because these units of analysis form the basis of such family practice research. We are currently reviewing data to determine whether those health problems on our encounter form now represent a larger proportion of all recorded problems than they did before the introduction of the form.

Finally, Dr. Schneeweiss' comment about status-post conditions is well taken. I would like to know the extent to which other settings attempt to collect such conditions in computerized data systems. While their clinical importance is obvious, it does not seem that their inclusion in computerized systems is common. I hope that researchers in family medicine continue to share such experiences, and I thank Dr. Schneeweiss for his insightful comments on our article.

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Method to Demonstrate the Sclera in the Newborn

To the Editor:

It is often desirable to examine the sclera of the newborn for

inflammation, hemorrhage, icterus, edema, and so on. The examiner, however, finds that the palpebral fissure of such patients is only large enough to show the cornea and none of the sclera is visible. In addition, the usually edematous eyelids are closed tightly when they are touched or when the infant is crying. The following method is suggested.

For good results, one must wait until the infant is not crying. Then, with one hand supporting the neck and occiput firmly, the other hand and the examiner's chest support the bottom half of the infant. It is best to hold the infant over a table. The infant may then open his eyes after a short quiet pause. If not, the infant may be raised up gently to a sitting position. This often causes the eyes to open. With infants of less than four days of age, swelling of the eyelids and crying may make these attempts unsuccessful, and one may then have to hold the eyelids apart with a thumb and index finger, the infant still being held against the chest or lying on a table. The following aid will still be successful.

When the eyes are open, the eyeballs move very little and the corneas will be centered straight ahead almost constantly. If now the infant's head is turned smoothly and quickly to the left, the eyeballs will continue to stare at the same point as before the movement. This causes the sclera to the left of each cornea to occupy about one fourth of the palpebral space, where it can be seen. Similarly, turning the head to the right causes the sclera to the right of each cornea to be visible in the palpebral fissure. Thus, all of the temporal and nasal portions of the sclera of each eye can be seen.

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