

PEDIAMYCIN® 400

ERYTHROMYCIN ETHYLSUCCINATE ORAL SUSPENSION

Mode of action: The mode of action of erythromycin is by inhibition of protein synthesis without affecting nucleic acid synthesis. Resistance to erythromycin of some strains of *Haemophilus influenzae* and staphylococci has been demonstrated. Culture and susceptibility testing should be done. If the Kirby-Bauer method of disc susceptibility is used, a 15 mm erythromycin disc should give a zone diameter of at least 18 mm when tested against an erythromycin-susceptible organism.

Oral administration: Erythromycin ethylsuccinate suspensions are readily and reliably absorbed. Pediamycin Chewable is readily and reliably absorbed when chewed. Comparable serum levels of erythromycin are achieved in the fasting and the nonfasting states.

Absorption: After absorption, erythromycin diffuses readily into most body fluids. In the absence of meningeal inflammation, low concentrations are normally achieved in the spinal fluid, but passage of the drug across the blood-brain barrier increases in meningitis. In the presence of normal hepatic function, erythromycin is concentrated in the liver and excreted in the bile; the effect of hepatic dysfunction on excretion of erythromycin by the liver into the bile is not known. After oral administration, less than 5 percent of the quantity of the administered dose can be recovered in the urine.

Erythromycin crosses the placental barrier but fetal plasma levels are generally low.

Indications: Erythromycin *pyogenes* (Group A beta-hemolytic streptococcus): Upper and lower respiratory tract, skin and soft tissue infections of mild to moderate severity.

Penicillate benzathine penicillin G is considered by the American Heart Association to be the drug of choice in the treatment and prevention of streptococcal pharyngitis and rheumatic fever. When oral medication is preferred for treatment of the above conditions, penicillin G V or erythromycin is the alternate drug of choice.

When oral medication is given, the importance of strict adherence by the patient to the prescribed dosage regimen must be stressed. A therapeutic dose should be administered for at least 10 days.

Anti-streptococcal streptococci (viridans group): Short-term prophylaxis of bacterial endocarditis prior to dental or other operative procedures in patients with a history of rheumatic fever or congenital heart disease who are hypersensitive to penicillin. Erythromycin is not suitable prior to genitourinary surgery where the organisms likely to lead to bacteremia are gram-negative bacilli or the enterococcus group of streptococci.

Staphylococcus aureus: Acute infections of skin and soft tissue of mild to moderate severity. Resistant organisms may emerge during treatment.

Diphtheria (Diplococcus) pneumoniae: Upper respiratory tract infections (e.g., sinusitis, otitis media, pharyngitis) and lower respiratory tract infections (e.g., pneumonia) of mild to moderate degree.

Legionella pneumoniae (Eaton agent, PPL0): For respiratory infections due to this organism.

Streptococcus pneumoniae: For upper respiratory tract infections of mild to moderate severity when used concomitantly with adequate doses of sulfonamides. Not all strains of this organism are susceptible to the erythromycin concentrations ordinarily achieved with appropriate sulfonamide labeling for prescribing information).

Streptococcus pyogenes: Erythromycin is an alternate choice of treatment for primary pharyngitis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid examinations should be done before treatment and as part of follow-up after therapy.

Streptococcus diphtheriae and C. minutissimum: As an adjunct to antitoxin, to prevent establishment of carriers, and to eradicate the organism in carriers. In the treatment of erythrasma.

Trichomonas histolytica: In the treatment of intestinal amebiasis only. Extra-enteric amebiasis requires treatment with other agents.

Streptococcus monocytogenes: Infections due to this organism.

Legionnaires' Disease: Although no controlled clinical efficacy studies have been conducted, *in vitro* and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' Disease.

Contraindications

Erythromycin is contraindicated in patients with known hypersensitivity to this antibiotic.

Pregnancy and lactation: The safety of erythromycin for use during pregnancy has not been established. Erythromycin crosses the placental barrier. Erythromycin also appears in breast milk.

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 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 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.

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 non-susceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted.

Mild allergic reactions such as urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis, have been reported.

Dosage and Administration

Erythromycin ethylsuccinate suspensions and chewable tablets may be administered with regard to meals.

For full therapeutic effect, Pediamycin Chewable tablets must be chewed. They should not be swallowed whole.

Children: Age, weight and severity of the infection are important factors in determining the proper dosage. In mild to moderate infections the usual dosage of erythromycin ethylsuccinate for children is 30 to 50 mg/kg/day in equally divided doses. For more severe infections this dosage may be doubled.

Adults: 400 mg erythromycin ethylsuccinate every 6 hours is the usual dose. Dosage may be increased up to 4 g per day according to the severity of the infections.

For twice-a-day dosage is desired in either adults or children, one-half of the total daily dose may be given every 12 hours. Doses may also be given three times daily if desired by administering one-third of the total daily dose every 8 hours.

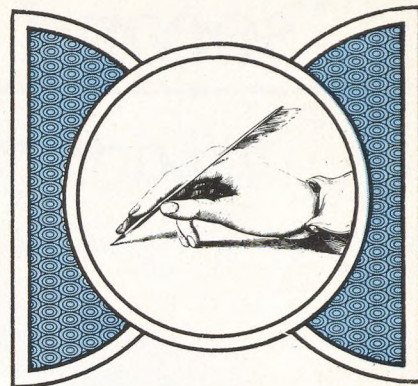
How Supplied

Pediamycin 400 (erythromycin ethylsuccinate oral suspension) is supplied in 1-pint (NDC 007-0211-16) and 100-ml bottles (NDC 007-0211-13). It provides erythromycin ethylsuccinate equivalent to 400 mg erythromycin per teaspoonful (5 ml).

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

221-B106

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.

Community Medicine in Family Practice

To the Editor:

Having been both a family medicine educator and a practicing family physician, I well appreciated the article "Community Medicine in the Training of Family Physicians" in the May issue of *The Journal* (Donsky J, Massad R. *J Fam Pract* 8:965, 1979). Their conceptualization of this as yet undefined area was exhaustive and profound from both an educational and clinical standpoint.

However, I am not at all sure that bringing about changes in social institutions falls within the jurisdiction of a family physician's professional activities. In a democratic society, allocation of resources and setting of priorities properly falls in the realm of political decision making, an area where physicians should be advocates as ordinary citizens, but not as spokesmen endowed with any pre-eminent powers.

I am further concerned that by intimating that political advocacy at this level may be part of a physician's day-to-day practice that Donsky and Massad further aggra-

vate the already present danger of overextension of the territory of family medicine. I do agree that knowledge of community structure, the means of assessing community problems and resources, and the means of bringing about change should be a part of the curriculum in family and community medicine. In this way, interfaces can be defined, interdisciplinary cooperation facilitated, and appropriate referrals made and evaluated. The same may be said about ophthalmology or neurosurgery; the family physician must learn something about them for the same reasons as stated above, though few will include these highly specialized areas in their practices to any significant degree.

At this stage in our development as a legitimate specialty/discipline, it is critical that family medicine not promote itself unrealistically as being all things to all people. Reasonable boundaries and limits of the territory must be set.

Jonathan F. Feinberg, MD
San Mateo, California

Continued on page 1001

AMOXIL® (amoxicillin)

For complete prescribing information consult Official Package Insert.

Indications: Amoxil® (amoxicillin) is similar to ampicillin in its bactericidal action against susceptible strains of Gram-negative organisms—*H. influenzae*, *E. coli*, *P. mirabilis* and *N. gonorrhoeae*, and Gram-positive organisms—*Streptococci* (including *Streptococcus faecalis*), *D. pneumoniae* and non-penicillinase-producing staphylococci. Culture and sensitivity studies should be obtained. Indicated surgical procedures should be performed.

Contraindications: A history of a previous hypersensitivity reaction to any of the penicillins is a contraindication.

Warning: Anaphylaxis may occur, particularly after parenteral administration and especially in patients with an allergic diathesis. Check for a history of allergy to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, discontinue amoxicillin and institute appropriate treatment. Serious anaphylactic reactions require immediate emergency treatment with epinephrine, oxygen, intravenous steroids and airway management.

Usage in Pregnancy: Safety for use in pregnancy is not established.

Precautions: Mycotic or bacterial superinfections may occur. Cases of gonorrhea with a suspected primary lesion of syphilis should have dark-field examinations before receiving treatment. In all other cases where concomitant syphilis is suspected, monthly serological tests should be performed for a minimum of four months. Assess renal, hepatic and hematopoietic functions intermittently during long-term therapy.

Adverse reactions: Untoward reactions include glossitis, nausea, vomiting and diarrhea, skin rashes, urticaria, exfoliative dermatitis, erythema multiforme and anaphylaxis (usually with parenteral administration). Although anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been noted, they are usually reversible and are believed to be hypersensitivity phenomena. Moderate elevations in SGOT have been noted.

Usual Dosage: Adults—250 to 500 mg orally q. 8h (depending on infection site and offending organisms); Children—20-40 mg/kg/day orally q. 8h (depending on infection site and offending organisms). Children over 20 kg should be given adult dose.

Gonorrhea, acute uncomplicated—3 Gms as a single oral dose (see PRECAUTIONS). Serious infections, such as meningitis or septicemia, should be treated with parenteral antibiotics.

Supplied:**Capsules—**

250 mg in bottles of 100's and 500's, unit-dose

cartons of 100.

500 mg in bottles of 50's and 500's, unit-dose

cartons of 100.

for Oral Suspension—

125 mg/5 ml and 250 mg/5 ml in 80 ml, 100 ml and

150 ml bottles.

Pediatric Drops for Oral Suspension—

50 mg/ml in 45 ml bottles with calibrated dropper.

Continued from page 997

Endoscopy in Family Practice To the Editor:

It is with great interest that I read the recent article by Dr. David M. Woodliff, "The Role of Upper Gastrointestinal Endoscopy in Primary Care" (*J Fam Pract* 8:715, 1979), which details the first-year endoscopic experience of a family physician in Michigan. I express admiration at the incentive and determination which he displays in attempting to make endoscopy readily available to his rural practice. However, I wonder if this is really in the best interests of his patients since he only completed a two-week preceptorship in endoscopy. It may be true that the fundamental skills of passing an endoscope and recognition of major anatomic landmarks could probably be acquired in an intensive two-week course. However, the endoscopist's interpretation of both obvious and not-so-obvious endoscopic features can be the key to many diagnoses, and I would seriously doubt this skill could be developed in a two-week training program.

If I remember my Michigan geography correctly, the town of Hastings is within 100 miles of several cities where fully trained endoscopists are available. It is not at all uncommon here in Missouri for patients to travel up to 200 miles to be evaluated for endoscopy.

Although mere numbers may not reflect clinical competence, the minimum criteria recommended by the American Society for Gastrointestinal Endoscopy in the pamphlet, "Guidelines for Training in Endoscopy" (*Sherlock P [ed], Boston, American Society Gastrointestinal Endoscopy, July 1978,*

unpublished) is that any would-be endoscopist should complete at least 50 supervised endoscopies prior to starting on his own. It would seem to me medicolegally that any physician, rural or urban, who is to perform elective endoscopy would at least meet these requirements.

One last question which Dr. Woodliff did not address is how the practice of endoscopy affected his malpractice insurance rates, if at all. I am sure your readers will find these questions thought provoking.

J. C. O'Laughlin, DO
Fellow in Gastroenterology
Department of Medicine
University of Missouri
Columbia

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

This letter is certainly of some interest to me because it is really the first negative response to what I was trying to demonstrate in my article. I am well aware of the minimum requirements of the American Society for Gastrointestinal Endoscopy since I am a member of its Michigan Chapter. I also readily admit that a two-week intensive course is not sufficient to fully prepare me for all of the subtle findings associated with upper gastrointestinal pathology.

However, I do feel that in-depth supplemental study and continued practice with this procedure based

Continued on next page

Continued from preceding page

on an excellent preceptorship can provide an acceptable framework. Because of my desire to demonstrate what can be done, I felt that it was my obligation to allow my work to be scrutinized publically in a journal of national reputation and circulation.

I did not make any claims in my article that anyone can do this procedure nor did I pretend that I was as good as a fully trained gastroenterologist. As a matter of fact, I specifically stated that I limit the examination to diagnosis, biopsies, and retrieval of foreign bodies. More specific diagnosis, further treatment, or more involved procedures are referred to a fully trained specialist in a city 35 to 40 miles away.

My main contention is nevertheless that certain useful procedures such as upper gastrointestinal endoscopy can be performed in less medically sophisticated settings with excellent results. This assumes that the physician is conscientious, gets special training, and knows his limits. It is also important to point out that this service can be provided on a local level not only for the patients and referring physician's convenience, but at a considerable cost savings.

I think that it is interesting to note that I have not only been supported in this endeavor by the gastroenterologists who conducted the preceptorship at the University of Wisconsin, but also by the gastroenterologists in my local 100 mile area and all of the physicians on the staff of my local hospital.

Finally, to answer Dr. O'Laughlin's last question regarding malpractice insurance, I have not had to pay any more than I

would as an active family physician. I am in the same class as any physician performing such procedures as surgical assists or routine labor and deliveries.

David M. Woodliff, MD
Hastings, Michigan

Pelvic Surgery and Chronic Pain

To the Editor:

Dr. Brennan and his colleagues deserve credit for an excellent article, "A Study of Hysterectomy in a Family Practice" (*J Fam Pract* 8:723, 1979). I could carry their findings just one step further as a result of our experience at Rancho Los Amigos, Problem Back Service.

Many of our multioperated back pain patients, those with 5 to 15 operations, started their search for surgical solutions to emotional problems with pelvic surgery. Very often it would be a piecemeal approach: an ovary, or tube and ovary, then a partial hysterectomy, perhaps exploration for adhesions, then total hysterectomy. This piecemeal approach suggests that indications were equivocal at best.

The pelvis empty, the patient still complaining of pain obtains her first laminectomy, then another, then fusion, then rhizotomy. The elusive pain either persists or shifts elsewhere. Perhaps an operation every year or two is the only way they can validate a pain career.

J. Blair Pace, MD
Residency Director
Santa Ana-Tustin
Community Hospital
Santa Ana, California

NTID

If You Suspect a Hearing Loss, Doctor. . . Please. . . Don't Wait

Even infants as young as six months who suffer a hearing loss can be helped. . . if they receive early treatment.

But the key is detection.

Please don't wait for time to confirm your suspicions. Refer your patient immediately to an otolaryngologist, otologist or audiologist. As the child matures, an ophthalmological exam may also be indicated.

The National Technical Institute for the Deaf, a part of Rochester Institute of Technology, prepares nearly 1,000 deaf college students annually for successful technical careers. Over the past decade some important facts have been discovered about the detection and treatment of hearing disorders. We'd be pleased to share them with you, just for the asking.

Write:



National Technical
Institute for the Deaf
Rochester Institute
of Technology

Room 200A
One Lomb Memorial Drive
Rochester, NY 14623