

PRESCRIBING INFORMATION

ERYTHRO-ES

Erythromycin (as the ethylsuccinate) Tablets USP

600 mg

Antibiotic

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THERAPEUTIC CLASSIFICATION

Antibiotic

PHARMACOLOGY:

Erythromycin inhibits protein synthesis by binding to the 50S ribosomal subunit. It is usually bacteriostatic but may be bactericidal in high concentrations or against highly susceptible organisms. Its spectrum of activity is similar to that of penicillin G. Resistance to erythromycin of some strains of *H. influenzae* and staphylococci has been demonstrated. If the Kirby-Bauer method of disc susceptibility is used, a 15 µg erythromycin disc should give a zone diameter of at least 18 mm when tested against an erythromycin susceptible organism.

Erythromycin ethylsuccinate is absorbed intact. Once absorbed, erythromycin ethylsuccinate is hydrolyzed to the active base. Approximately 28 - 35% of the total serum erythromycin is active after administration of erythromycin ethylsuccinate. In general, after absorption, erythromycin diffuses readily into most fluids. In the absence of meningeal inflammation low concentrations are normally achieved in the spinal fluid, but passage of erythromycins across the blood brain barrier increases in meningitis. In the presence of normal hepatic function, erythromycins are concentrated in the liver and excreted in the bile; the effect of hepatic dysfunction on excretion of erythromycins by the liver into the bile is not known. After oral administration, less than 5% of the administered dose can be recovered in the urine.

Erythromycin crosses the placental barrier but fetal plasma levels are low. It is also secreted in breastmilk.

INDICATIONS:

The treatment of the following infections when caused by susceptible strains of microorganisms: upper and lower respiratory tract infections; skin and soft tissue infections; gonorrhea; syphilis; short term prophylaxis of bacterial endocarditis in patients hypersensitive to penicillin.

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

Injectable 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 in long-term prophylaxis of rheumatic fever. When oral medication is preferred for treatment of the above conditions, penicillin G, V, or erythromycin are alternate drugs of choice.

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

Alpha-hemolytic 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.)

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

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

M. pneumoniae (Eaton agent, PPLO): For respiratory infections due to this organism.

H. influenzae: Upper and lower respiratory tract infections of mild to moderate severity. Not all strains of this organism are susceptible at the erythromycin concentrations ordinarily achieved with usual therapeutic doses.

N. gonorrhoeae and *T. pallidum*: Erythromycin is an alternate choice of treatment for gonorrhea and primary syphilis in patients allergic to the penicillins. Before treatment of gonorrhea, patients who are suspected of also having syphilis should have a microscopic examination for *T. pallidum* (by immunofluorescence or darkfield) before receiving erythromycin, and monthly serologic tests for a minimum of 4 months. In the treatment of primary syphilis, conduct spinal fluid examinations before treatment and as part of follow-up after therapy.

C. diphtheriae and *C. minutissimum*: As an adjunct to anti-toxin, to prevent establishment of carriers and to eradicate the organism in carriers.

Treatment of erythrasma.

C. tetani: In vitro, *C. tetani* is highly sensitive to erythromycin. When antibiotic therapy is indicated in prophylaxis (e.g. in persons with hypersensitivity to penicillin and to antitetanus serum) erythromycin is effective when given in the usually recommended doses for 5 days.

CONTRAINDICATIONS:

Erythromycin and its derivatives should not be used in patients with known hypersensitivity to these drugs or with infections that are resistant to the drug (primarily certain staphylococcal organisms).

PRECAUTIONS:

Erythromycin's safety for use in pregnancy has not been established. Although the antibiotic crosses the placental barrier and appears in breastmilk, fetal plasma concentrations are generally low.

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

Toxic reactions as a result of significant elevations of serum theophylline concentrations have been observed in patients after initiation of erythromycin treatment. Ensure that serum theophylline concentrations in such patients are monitored.

The possibility of superinfection caused by overgrowth of nonsusceptible bacteria or fungi should be kept in mind during prolonged or repeated therapy, especially when other antibacterial agents are simultaneously employed. In such instances, the drug should be withdrawn and appropriate treatment instituted.

ADVERSE EFFECTS:

Erythromycin administration has been associated with an infrequent occurrence of intrahepatic cholestasis. The risk seems to be higher in adults receiving the estolate salt, followed by adults receiving other salts or the base.

The most frequent adverse effects of erythromycin preparations given orally are gastrointestinal (e. g., abdominal cramping and discomfort) and are dose related. Nausea, vomiting, and diarrhea occur infrequently with usual doses.

Mild allergic reactions, such as urticaria and morbilliform skin rashes have occurred. Should a patient demonstrate signs of hypersensitivity, administer appropriate counter measures, such as epinephrine, corticosteroid and antihistamines, and withdraw the antibiotic. Serious adverse reactions, including anaphylaxis, have been reported.

OVERDOSAGE:

Symptoms: In oral doses of over 2 g/day, abdominal discomfort, nausea, diarrhea, cramping and vomiting may occur.

Treatment: No specific treatment for accidental overdosage exists.

DOSAGE:

Although erythromycin ethylsuccinate preparations may be administered regardless of meals, optimum blood concentrations are obtained when the antibiotic is administered immediately after meals.

Children:

In mild to moderate infections, the usual dosage of erythromycin ethylsuccinate for children (up to 32 kg in weight) is 30 to 50 mg/kg/day in equally divided doses. For more severe infections, this dosage may be doubled. If twice a day dosage is desired, one half of the total daily dose may be given every 12 hours.

In the treatment of streptococcal infections, administer a therapeutic dosage of erythromycin ethylsuccinate for at least 10 days.

Presurgical prophylaxis of endocarditis (see Alpha-hemolytic streptococci) in children: 30 to 50 mg/kg/day divided into 3 or 4 evenly spaced doses.

Adults:

600 mg, 3 times a day is the usual dosage. Dosage may be increased to 4 g or more/day according to the severity of the infection.

If dosage is desired on a twice a day schedule, one-half of the daily dose may be given every 12 hours.

In the treatment of streptococcal infections, a therapeutic dosage of erythromycin should be administered for at least 10 days. In continuous prophylaxis of streptococcal infections in persons with a history of rheumatic heart disease, the dose is 600 mg twice a day.

When used prior to surgery to prevent endocarditis (see Alpha-hemolytic streptococci), a recommended schedule for adults is: 600 mg before the procedure and 600 mg every 8 hours for 3 doses after the procedure.

Primary Syphilis: 48 to 64 g in divided doses over a period of 10 to 15 days.

Gonorrhea: 3 g daily in divided doses for 5 days.

SUPPLIED:

Each yellow, film-coated tablet contains erythromycin 600 mg (as the ethylsuccinate). Bottles of 100 tablets.