

**PRESCRIBING INFORMATION**

**ERYTHRO-S**  
**Erythromycin Stearate Tablets**  
**House Standard**  
**250 mg and 500 mg**

**Antibiotic**

**AA PHARMA INC.**  
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**DATE OF PREPARATION:**  
**July 8, 2010**

**Control Number: 139969**

**PRESCRIBING INFORMATION**

ERYTHRO-S

Erythromycin Stearate Tablets

House Standard

250 mg and 500 mg

**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. influenza 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 stearate dissociates in the duodenum to erythromycin base before absorption. Erythromycin stearate is acid labile and should be administered on an empty stomach. In general, 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 erythromycin across the blood brain barrier increased 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% of the administered dose can be recovered in the urine.

Erythromycin crossed the placental barrier but fetal plasma levels are low. It is also secreted in breast milk.

## **INDICATIONS:**

*S. pyogenes* (Group A beta hemolytic streptococcus): 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. A therapeutic dose should be administered 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 the 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): Primary atypical pneumonia, when due to this organism.

*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, spinal fluid examinations should be done before treatment and as part of follow up after therapy.

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

Treatment of erythrasma.

### **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). Erythromycin estolate is also contraindicated in persons with pre-existing liver disease or dysfunction.

### **PRECAUTIONS:**

The rare 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.

### **DRUG INTERACTIONS:**

Concomitant use of erythromycin and high doses of theophylline may be associated with increased theophylline serum concentration and possible toxicity. The dose of theophylline may have to be reduced while patients are taking erythromycin.

Safety for use in pregnancy has not been established.

**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 risk in children is low.

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 oral doses.

Serious allergic reactions to erythromycin have been extremely infrequent. Mild allergic reactions, such as urticaria and morbilliform skin rashes have occurred. Should a patient demonstrate signs of hypersensitivity, administer appropriate countermeasures such as epinephrine, corticosteroid and antihistamines, and withdraw the antibiotic.

**OVERDOSE:**

Symptoms: In oral doses of over 2 g per day, abdominal discomfort, nausea or diarrhea may occur.

Treatment: No specific treatment for accidental over dosage has been proposed.

**DOSAGE:****Oral:**

When given orally, erythromycin stearate is susceptible to inactivation by acid in the stomach. This can be reduced by administering before meals.

The recommended basic dose (Note: all doses expressed in term of erythromycin base) of erythromycin is 1 g daily (i.e. 500 mg every 12 hours or 250 mg every 6 hours) taken prior to meals. If the twice daily dosage regimen is employed in moderate to severe infections, it is recommended that a loading dose of 1 g be given initially, followed by 500 mg every 12 hours.

In the treatment of beta hemolytic streptococcal infections, adequate erythromycin dosage should be administered for a full 10 days to reduce the nonsuppurative complications of rheumatic fever and glomerulonephritis. In the presence of a well established history of rheumatic fever and clinical rheumatic heart disease, continuous prophylaxis with erythromycin may be achieved with 250 mg twice a day.

When erythromycin is used prior to surgery to prevent endocarditis caused by alpha hemolytic streptococci (viridans group), a recommended schedule for adults is 500 mg before the procedure and 250 mg every 8 hours for 4 doses afterward; for children, 30 to 50 mg/kg per day divided into 3 or 4 evenly spaced doses.

Primary Syphilis: 30 to 40 g given in divided doses over a period of 10 to 15 days.

Gonorrhea: Adults, 500 mg orally 4 times daily for 5 days.

**AVAILABILITY:**

Each pink, film-coated tablet contains erythromycin 250 and 500 mg as the stearate. Available in bottles of 100 tablets.