

# Etrocin®

Tablet/Suspension

## Description

Etrocin suspension is a preparation of Erythromycin Ethylsuccinate. Enteric coated Etrocin tablet is a preparation of Erythromycin USP.

**Antimicrobial Actions :** Its range of antimicrobial action is similar to that of penicillin. It is active against most Gram-positive and some Gram-negative bacteria including *Neisseria* species, *Haemophilus influenzae* and *Bordetella pertussis*, against spirochete and some rickettsiae and chlamydia. *Mycoplasma pneumoniae* is very sensitive to Erythromycin, *Streptococcus pneumoniae* and haemolytic streptococci are highly sensitive but streptococci (including those resistant to penicillin) are rather less sensitive. Although the Enterobacteriaceae are generally resistant to Erythromycin, some strains of *Escherichia coli* and *Klebsiella* species have been reported to be sensitive at an alkaline pH. The Gram-negative bacterium responsible for legionnaire's disease known as *Legionella pneumophila* is reported to be sensitive to Erythromycin.

## Indications

Etrocin is highly effective in the treatment of a great variety of clinical infections caused by Erythromycin sensitive organisms. *Upper respiratory tract infections :* Tonsillitis, peritonsillar abscess, pharyngitis, laryngitis, sinusitis, secondary infections in cold and influenza. *Lower respiratory tract infections :* Tracheitis, acute and chronic bronchitis, pneumonia (lobar pneumonia, broncho-pneumonia, primary atypical pneumonia), bronchiectasis, legionnaire's disease. *Ear infection :* Otitis media and otitis externa, mastoiditis. *Oral infection :* Gingivitis, Vincent's angina. *Eye infection:* Blepharitis. *Skin and soft tissue infections :* Boils and carbuncles, paronychia, abscesses, pustular acne, impetigo, cellulitis, erysipelas. *Gastro-intestinal infections :* Cholecystitis, staphylococcal enterocolitis. *Prophylactic use :* Pre and post-operative trauma, burns, rheumatic fever. *Other infections :* Osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever.

## **Dosage and Administration**

In case of suspension, optimum blood levels are obtained, when doses are given on an empty stomach. Eetrocin tablet can be given before, during or after meal.

*Adults and children over 8 years* : 250-500 mg every 6 hours or 0.5-1 g every 12 hours. This may be increased up to 4 g per day according to the severity of infection.

*Elderly* : Same as for adults.

*Children* : Age, weight and severity of infection are important factors in determining the correct dosage.

The usual regimen is 30-50 mg/kg/day in divided doses or as directed by the physician. For more severe infections this dosage may be doubled. If administration on a twice daily schedule is desirable, one half of the total daily dose may be given every 12 hours, one hour before meal.

*Amoebic dysentery* : Adult- 250-500 mg four times daily for 10 to 14 days. Children- 30-50 mg/kg/day in divided doses for 10-14 days.

*Pertussis* : Although optimum dosage and duration of treatment have not been established, doses of Erythromycin utilized in reported clinical studies were 40-50 mg/kg/day given in divided doses for 5-14 days.

*Streptococcal infections* : In the treatment of group A  $\beta$  haemolytic streptococcal infections, therapeutic dosage of Erythromycin should be administered for at least 10 days.

*Prophylaxis* : In continuous prophylaxis of streptococcal infections in persons with a history of rheumatic heart disease, the dosage is 250 mg twice daily.

When Eetrocin is used prior to surgery to prevent endocarditis caused by  $\alpha$  haemolytic streptococci, a recommended schedule for children- 20 mg/kg 1.5-2 hours pre-operatively and 10 mg/kg every six hours for eight doses post-operatively. For adults the dose is 1 g, 1.5-2 hours pre-operatively and 500 mg every six hours for eight doses post-operatively.

## **Contraindication**

It is contraindicated in patients hypersensitive to Erythromycin.

## **Precautions**

Since Erythromycin is metabolised principally by the liver, caution should be exercised in administering the antibiotic to patient with impaired hepatic function. There have been reports of hepatic dysfunction with or without jaundice occurring in patients taking oral Erythromycin.

The use of Erythromycin in patients who are receiving concomitant high doses of Theophylline may be associated with Theophylline toxicity due to increase level of the drug in the serum. If symptoms of toxicity develop, the dose of Theophylline should be reduced.

## **Side Effects**

Serious side effects are rare. The most frequent side effects of Erythromycin preparation are gastrointestinal (e.g., abdominal cramping and discomfort) and these are dose related. Nausea, vomiting and diarrhoea occur infrequently with usual oral doses.

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

## **Use in Special Population**

*Pregnancy and lactation* : Clinical and laboratory studies have no evidence of teratogenicity or toxicity. However, caution should be exercised when prescribing for the pregnant women. Erythromycin is readily excreted in breast milk.

## **Commercial Packs**

Etrocin® 250 Tablet : Box containing 100 enteric-coated tablets in 10 x 10's blister strips, each tablet contains 250 mg Erythromycin USP.

Etrocin® 500 Tablet : Box containing 50 enteric-coated tablets in 5 x 10's blister strips, each tablet contains 500 mg Erythromycin USP.

Etrocin® Suspension : Bottle containing dry powder for 100 ml suspension. After reconstitution each 5 ml contains Erythromycin Ethylsuccinate USP equivalent to 125 mg Erythromycin.