ERYTHROMYCIN STEARATE TABLETS BP
ERYCYN – 250

COMPOSITION: Each Film-coated tablet contains: Erythromycin BP 250mg

PHARMACOLOGICAL CATEGORY: Macrolide Antibiotic

PHARMACOLOGY: Erythromycin is primarily a bacteriostatic, by inhibition of bacterial protein synthesis. Also it can exert bactericidal action depending on the susceptibility of the organisms and concentration. Its activity increases with pH up to about 8.5. Active primarily against Gram-positive bacteria via *Staphylococci, Streptococci, Corynebacterium diphtheria* and some Gram-negative pathogens Viz *Bordetella pertussis, Neisseria spp.* highly effective against *Chlamydia, Mycoplasma, Ureaplasma* and *H. ducreyi.*

Pharmacokinetics: Acid stability and effect of food on absorption varies. Cmax varies with dose and type of salt/ester. Average range is 0.3 to 1.9 mcg/mL and means Tmax is 2 hours. Well distributed into body fluids and tissues. Protein binding is 65 to 90%. Crosses into foetal blood and breast milk. Metabolised in the liver and eliminated mainly into bile. Half-life is 1.9 to 2.1 hours for the base.

INDICATIONS & USES: Upper and lower respiratory tract infections; Mycoplasma and Chlamydial infections; Skin and soft tissue infections; Diphtheria; Legionnaires disease; Otitis media; Pertussis; Chancroids.

CONTRAINDICATIONS:
- Erythromycin is contraindicated in patients taking astemizole, terfenadine, domperidone, cisapride or pimozide
- Erythromycin should not be given to patients with a history of QT prolongation (congenital or documented acquired QT prolongation) or ventricular cardiac arrhythmia, including torsades de pointes (see "Warnings and Precautions")
- Erythromycin should not be given to patients with electrolyte disturbances (hypokalaemia, hypomagnesaemia due to the risk of prolongation of QT interval)

SIDE EFFECTS / ADVERSE REACTIONS:
Serious side-effects very rare except for cholestatic hepatitis, mild GI effects fairly common after large doses.
Cardiac arrest, ventricular fibrillation (frequency not known)

PRECAUTIONS AND WARNINGS: Hepatic dysfunction with or without jaundice has occurred. It may be accompanied by malaise, nausea, vomiting, abdominal colic, and fever. In some instances, severe abdominal pain may stimulate an abdominal surgical emergency. If the above findings occur, discontinue erythromycin promptly.

Cardiovascular Events
Prolongation of the QT interval, reflecting effects on cardiac repolarisation imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in patients treated with macrolides including erythromycin (see "Contraindications" and "Adverse Effects"). Fatalities have been reported.
Erythromycin should be used with caution in the following:
- Patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia
- Patients concomitantly taking other medicinal products associated with QT prolongation (see "Contraindications")
- Elderly patients may be more susceptible to drug-associated effects on the QT interval

Epidemiological studies investigating the risk of adverse cardiovascular outcomes with macrolides have shown variable results. Some observational studies have identified a rare short-term risk of arrhythmia, myocardial infarction and cardiovascular mortality associated with macrolides including erythromycin. Consideration of these findings should be balanced with treatment benefits when prescribing erythromycin.

Infantile hypertrophic pyloric stenosis
There have been reports of infantile hypertrophic pyloric stenosis (IHPS) occurring in infants following erythromycin therapy. Epidemiological studies including data from meta-analyses suggest a 2- to 3-fold increase in the risk of IHPS following exposure to erythromycin in infancy. This risk is highest following exposure to erythromycin during the first 14 days of life. Available data suggests a risk of 2.6% (95% CI: 1.5 - 4.2%) following exposure to erythromycin during this time period. The risk of IHPS in the general population is 0.1 - 0.2%. Since erythromycin may be used in the treatment of conditions in infants which are associated with significant mortality or morbidity (such as pertussis or chlamydia), the benefit of erythromycin therapy needs to be weighed against the potential risk of developing IHPS. Parents should be informed to contact their physician if vomiting or irritability with feeding occurs.

DRUG INTERACTIONS: Clinically important interactions with carbamazepine, cyclosporin, Warfarin, Xanthine's and interference with activity of Penicillins and chloramphenicol are reported.
Erythromycin should not be given with other ototoxic drugs.

USE IN PREGNANCY AND LACTATION: Erythromycin crosses the placenta but concentrations in foetal blood are low. There have been no reports of problems in humans. Still, the possible benefit and the potential risk should be weighed before the decision to give to pregnant women. Breast feeding; Erythromycin is excreted in significant amounts in the breast milk. But most of it may be destroyed by the acidity in the infant's stomach.

DOSAGE AND ADMINISTRATION: 250 mg 6 hrly; the dose may be doubled for severe infections.
Gonorrhoea: 500 mg 6 hrly for 6-7 days

Syphilis: 1gm 6hrly for 10-15 days (30days in late syphilis)
Prophylaxis against streptococci: 250mg 12 hrly.

OVERDOSE SYMPTOMS AND ANTIDOTE: The symptoms of acute over dosage are generally related to gastrointestinal tract - nausea, vomiting, abdominal pain or cramps and diarrhoea. Treatment is symptomatic and supportive.

STORAGE: Store at or below 30°C. Keep out of reach of children.

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Manufactured by:

MICRO LABS LIMITED
92, Sipcot Industrial Complex
HOSUR-635 126. INDIA.