Erythromycin Stearate Tablets BP

COMPOSITION

ERYKO-500

Each film coated tablet contains:

Erythromycin Stearate BP equivalent to Erythromycin .....500 mg

ERYKO-250

Each film coated tablet contains tablet contains:

Erythromycin Stearate BP equivalent to Erythromycin .....250 mg

THERAPEUTIC CLASSIFICATION:

Pharmacotherapeuticgroup: Macrolide, antibacterial.

ATC code: D02184

PHARMACODYNAMICS:

Mechanism of Action:

Erythromycin exerts its antimicrobial action by binding to the 50S ribosomal sub-unit of susceptible microorganisms and suppresses protein synthesis. Erythromycin may be either bacteriostatic or bactericidal, depending upon its serum concentration and the susceptibility of the micro-organism. The in-vitro antibacterial spectrum of pathogens usually sensitive to Erythromycin is as follows (In-vitro sensitivity does not necessarily imply in vivo efficacy):

Gram-positive aerobes: Listeria monocytogenes, Corynebacterium diphtheriae (as an adjunct to antitoxin), Staphylococci spp, Streptococci spp (including Enterococci).

Gram-negative aerobes: Haemophilus influenzae, Neisseria meningitidis, Neisseria gonorrhoeae, Legionella pneumophila, Moraxella (Branhamella) catarrhalis, Bordetella pertussis, Campylobacter spp.

Mycoplasma- Mycoplasma pneumoniae, Ureaplasma urealyticum.

Other organisms - Treponemapallidum, Chlamydia spp, Clostridia spp, L-forms, the agents causing trachoma and lymphogranuloma venereum.

PHARMACOKINETICS:

Peak plasma concentrations were achieved in 2 hours of oral dosing. The elimination half-life is approximately 5 hours. After absorption, erythromycin diffuses readily into most body fluids, including middle ear and prostatic fluid, but the highest concentrations arein the liver, bile and spleen. Erythromycin is highly plasma protein bound (70 to 90 %), with more than 90% of the drug metabolised in the liver and excreted in the bile. After oral administration, 2 to 5% is excreted renally. Erythromycin crosses the placenta, but concentrations in foetal plasma are low.

INDICATIONS:

ERYKO Tablets are indicated in treatment of susceptible infections in patients:

- oral infections
- respiratory tract infections (including legionnaires disease)
- whooping cough
-campylobacter enteritis
- syphilis
-non-gonococcal urethritis
- skin infections
- chronic prostatitis
- prophylaxis of diphtheria
-group A streptococcal infection
-acne vulgaris and rosacea

CONTRAINDICATIONS:

Known hypersensitivity to erythromycin or any other macrolides. Use is contraindicated in acute porphyria.

DOSAGE AND ADMINISTRATION:

- ADULT and CHILD over8 years

250-500mg every 6 hours or 0.5-1g every 12 hours upto 4g daily in

divided doses in severe infections

- Early syphilis: 500mg, 4 times daily for 14 days
- Uncomplicated genital chlamydia, non-gonococcal urethritis: 500mgtwicedaily for 14 days
- Lyme disease: 500mg4 times daily for 14-21 days
- Renal impairment: Max.1.5g daily

SIDE EFFECTS:

Common: Nausea, vomiting, diarrhea and abdominal discomfort.

Less common: Hepatotoxicity (including cholestatic jaundice) and rash.

Rare or Very Rare: Pancreatitis, antibiotic associated colitis, QT interval prolongation, arrhythmias, hearing loss (reversible), tinnitus, Stevens-Johnson syndrome, myasthenia like syndrome and toxic epidermal necrolysis.

DRUG-DRUG INTERACTIONS:

Erythromycin increases plasma concentration of alfentanil, disopyramide, dronedarone. Concurrent administration with erythromycin should be avoided due to increased risk of toxicity and side-effects. Erythromycin enhances plasma concentration of carbamazepine, loratadine, rupatadine, darifenacin, clozapine, quetiapine, buspirone, zopiclone, digoxin, cilostazole, everolimus, eplerenone, eletriptan, pravastatin, galantamine, sildenafil, sirolimus, tacrolimus, tadalafil, theophylline, vardenafil. Concomitant use should be avoided.

Erythromycin inhibits metabolism of mizolastine, midazolam, felodipine, ciclosporin, corticosteroids, avoid concomitant use. Plasma concentration of erythromycin increased by cimetidine and ritonavir. Concomitant use should be avoided Avoid use of Erythromycin with tolterodine, droperidol, amisulpride, pimozide, lercanidipine, colchicine, nilotinib, docetaxel, vinblastine, bromocriptine, cabergoline, ergotamine, methysergide, ivabradine, atorvastatin, simvastatin. Erythromycin possibly reducesanti-platelet effect of clopidogrel, increases toxicity of arsenic trioxide, reduces contraceptive effect of oestrogens and enhances anticoagulant effect of coumarins. Erythromycin reduces plasma concentration of Zafirlukast, rosuvastatin while plasma concentration of erythromycin are possibly increased by ritonavir. Dose regimens should be revised or monitored in case of concomitant use.

PRECAUTIONS & WARNINGS:

Erythromycin is excreted principally by the liver, so caution should be exercised in administering the antibiotic to patients with impaired hepatic function or concomitantly receiving potentially hepatotoxic agents.
ERYKO Tablets are not recommended for use in Neonates and Children below 8 years of age.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, and may range in severity from mild to life-threatening. Treatment with antibacterial agents alters the normal flora of the colon, which may lead to overgrowth ofC. difficile or other non-susceptible micro-organisms. There have been reports that erythromycin may aggravate the weakness of patients with myasthenia gravis. Rhabdomyolysis with or without renal impairment has been reported in seriously ill patients receiving erythromycin concomitantly with statins.

PREGNANCYAND LACTATION:

Erythromycin is reported to cross placental barrier in humans as well as it is excreted in breast milk. Although Erythromycin is reported not to be harmful in pregnant and nursing mothers, caution should be exercised when erythromycin is administered to a nursing and Pregnant mothers..

OVERDOSE:
Symptoms: hearing loss, severe nausea, vomiting and diarrhoea.

Treatment: gastric lavage, general supportive measures.

STORAGE:
Store below 30°C in a dry place. Protect from light and moisture.

PRESENTATION :
Blister of 10x10 Tabs
Jar of 100’s, 500's Tabs, 1000's Tabs.

PRESCRIPTION ONLY MEDICINE.
KEEP OUT OF SIGHT AND REACH OF CHILDREN.