pharmaniaga®

ERICIN FOR ORAL SUSPENSION

200MG/5ML

DESCRIPTION

Free flowing homogeneous powder, free from lumps and white to pinkish in colour.

After Reconstitution: Slightly viscous, free flowing homogeneous suspension and pink in colour.

Active Substance

Each 5ml of reconstituted suspension contains Erythromycin Ethylsuccinate is equivalent to 200mg of Erythromycin.

PHARMACODYNAMICS

Erythromycin is a bacteriostatic macrolide antibiotic and it maybe bactericidal in high concentrations or when used against highly susceptible organisms. It is thought to penetrate the bacterial cell membrane and reversibly binds to the 50S subunit of bacterial ribosomes or near the "P" or donor site so that binding of the t-RNA to the donor site is blocked. Translocation of peptides from the "A" or acceptor to the "P" or donor site is prevented and subsequently protein synthesis is inhibited. Erythromycin is effective only against actively dividing organisms.

PHARMACOKINETICS

Absorption**:** Due to instability in gastric acid so the absorption becomes variable and unreliable. Absorption of the base or the stearate may be reduced by food intake. Time to peak plasma concentration is 1-4 hours.

Distribution**:** Widely distributed into body tissues and fluids. Crosses the placenta and enters breast milk. Plasma protein binding: 70-75% (as the base), 95% (as the propionate ester.

Metabolism**:** Erythromycin Ethylsuccinate is hydrolyzed to free drug in the gastrointestinal tract and in the blood. The free drug is partially metabolised by demethylation in the liver to an inactive form.

Excretion**:** Through faeces and urine (as unchanged drug). Plasma half-life is between 1.5-2.5 hours.

INDICATIONS

Erythromycin is use in the treatment of various infections caused by susceptible microorganisms in the following diseases: respiratory tract infections (upper and lower) of mild to moderate degree, pertussis (whooping cough), as adjunct to antitoxin in infections due to *Corynebacterium diphtheriae*, in the treatment of infections due to *Corynebacterium minutissimum*, intestinal amebiasis caused by *Entamoeba histolytica*, acute pelvic inflammatory disease caused by *Neisseria gonorrhoeae*, skin and soft tissue infections of mild to moderate severity caused by *Streptococcus pyogenes* and *Staphylococcus aureus*, primary syphilis caused by *Treponema pallidum*, infections caused by *Chlamydia trachomatis*, nongonococcal urethritis caused by *Ureaplasma urealyticum*, and Legionnaires' disease caused by *Legionella pneumophila*.

RECOMMENDED DOSAGE

Usual Adult Dose: Antibacterial (Systemic)- Oral, the equivalent of Erythromycin: Up to 4g daily.

Note: Doses up to the equivalent of 8g of Erythromycin daily are apparently well tolerated.

Usual Paediatric Dose: Antibacterial (Systemic)- Oral, the equivalent of Erythromycin: 7.5 to 12.5mg per kg of body weight every 6 hours.

Note: Gonorrhea (disseminated) - Oral, the equivalent of Erythromycin: 20mL every 6 hours for 7 days.

Legionnaires' Disease- Oral, the equivalent of Erythromycin: 10mL to 25mL every 6 hours.

Streptococcal prophylaxis- Continuous prophylaxis of streptococcal infections in patients with a history of rheumatic heart disease and/or chorea: Oral, the equivalent of Erythromycin: 10mL every 12 hours.

Syphilis- Oral, the equivalent of Erythromycin: 20mL every 6 hours for 15 days (early syphilis) or for 30 days (late syphilis).

ROUTE OF ADMINISTRATION: Oral

CONTRAINDICATIONS

Erythromycin is contraindicated in:

- Patients with known hypersensitivity to this medicine, or any of the excipients in the formulation.
- Patients with severely impaired hepatic function
- Concurrent treatment with cisapride, ergotamine, dihydroergotamine or pimozide (see Interactions with other Medicaments).
- Patients who are hypersensitive to other antibiotics from the macrolide family.

WARNINGS & PRECAUTIONS

Erythromycin should be given with caution to patients with impaired liver function. Erythromycin may interfere with the following diagnostic test:

1) Urinary catecholamine determination may produce false elevations of urinary catecholamines.
2) Serum Alkaline Phosphatase concentrations, Serum Alanine Aminotransferase (SGPT), Serum Aspartate Aminotransferase concentrations (SGOT) and Serum Bilirubin concentrations - (may be increased).

Rare cases of serious cardiovascular adverse event including deaths, cardiac arrests, torsades de pointes and other ventricular arrhythmia have been observed when used in patients taking concomitant terfenadine.

In the event of severe acute hypersensitivity reactions such as anaphylaxis, severe cutaneous adverse reactions (SCARs) [e,g. Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) & acute generalized exanthematous pustulosis (AGEP)], Ericin for Oral Suspension 200mg/5ml should be discontinued immediately and appropriate treatment should be urgently initiated.

There have been reports of infantile hypertrophic pyloric stenosis (IHPS) occurring in infants following erythromycin therapy. In one cohort of 157 newborns who were given erythromycin for pertussis prophylaxis, seven neonates (5%) developed symptoms of non-bilious vomiting or irritability with feeding and were subsequently diagnosed as having IHPS requiring surgical pyloromyotomy. 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/HPS. Parents and caregivers should be informed to contact their physician if vomiting and/ or irritability with feeding occurs.

INTERACTIONS WITH OTHER MEDICAMENTS

Be alert for the possible drug interactions and their related problems, when used concurrently with:

Rhabdomyolysis with or without renal impairment with HMG-CoA reductase inhibitors (e.g. simvastatin). Increased risk of colchicine toxicity. Increased sedation with triazolobenzodiazepines and related benzodiazepines (e.g. alprazolam, midazolam).

Theophylline may decrease and cimetidine may increase erythromycin concentration. Hypotension, bradyarrhythmia and lactic acidosis with Calcium channel blockers (e.g. verapamil, amlodipine, diltiazem). Increased systemic exposure of sildenafil.

Increased or prolonged adverse effects with ciclosporin, carbamazepine, tacrolimus, alfentanil, disopyramide, rifabutin, quinidine, methylprednisolone, cilostazol, vinblastine and bromocriptine. Increased risk of digoxin toxicity and bleeding with oral anticoagulants.

May cause an excess of corticosteroids resulting in increased blood glucose due to the nature of erythromycin being a CYP3A4 inhibitor (CYP3A4 is an enzyme that metabolizes corticosteroids). If the combination is considered necessary, a lower dosage of corticosteroid may be required.

Potentially Fatal: QT prolongation, cardiac arrhythmias, ventricular tachycardia, ventricular fibrillation, torsades de pointes w/ cisapride, pimozide, astemizole or terfenadine. Acute ergot toxicity with ergotamine and dihydroergotamine.

PREGNANCY & LACTATION

There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% of diet) prior to and during mating, during gestation, and through weaning of two successive litters. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Erythromycin has been reported to cross the placental barrier in humans, but fetal plasma levels are generally low.

Erythromycin is excreted in breast milk. Caution should be exercised when erythromycin is administered to a nursing woman.

SIDE EFFECTS / ADVERSE REACTIONS

Abdominal pain and cramping, nausea, vomiting, diarrhoea, stomatitis, heartburn, anorexia, melaena, pruritus ani, reversible mild acute pancreatitis, hepatic dysfunction, prolongation of QT interval, ventricular arrhythmias, urticaria, skin eruptions, rash, bilateral hearing loss, tinnitus, vertigo, venous irritation, thrombophlebitis.

Potentially Fatal: Pseudomembranous colitis, infantile hypertrophic pyloric stenosis (IHPS), bacterial superinfection from prolonged use.

Skin and Subcutaneous Tissue Disorders

Frequency not known: severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) & acute generalized exanthematous pustulosis (AGEP).

Post-marketing Experience:

Gastrointestinal Disorders: infantile hypertrophic pyloric stenosis.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE Symptoms **:**

Refer to side effects/ adverse reactions above. Treatment **:**

Gastric lavage and general supportive measures.

PACKING SIZES

HDPE Bottles of 60mL and 100mL.

STORAGE CONDITIONS

Store below 30°C in a cool dry place; Protect from light and moisture. Keep in refrigerator after reconstituted (2°C to 8°C).

USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS

Reconstitution: Ericin for Oral Suspension 200mg/5ml:

For 60 mL bottle : Shake the bottle to loosen the powder. Add freshly boiled and cooled water and shake well. Make up the volume to 60mL. Use the reconstituted suspension within 7 days. Complete the prescribed course. Shake well.

For 100 mL bottle : Shake the bottle to loosen the powder. Add freshly boiled and cooled water and shake well. Make up the volume to 100mL. Use the reconstituted suspension within 7 days. Complete the prescribed course. Shake well.

Shake well the reconstituted suspension every time before use. Take this medicine on a full or empty stomach, with a full glass of water (240mL). Take this medicine on six hourly basis, do not miss any doses, and the prescribed course must be completed.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging

REGISTRATION NUMBER

MAL19860047AZ

CONTROLLED MEDICINE
UBAT TERKAWAL

KEEP MEDICINES OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

For further information, please consult your doctor or your pharmacist.

Revision Number	:	03
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Lt-091.04 Product Registration Holder and Manufacturer
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