ERYMYCIN DRY SYRUP 200

MAL19972482AZ

PRODUCT DESCRIPTION:
POWDER
Flavour : Orange
Colour : White (Orange suspension on adding water)

EACH 5 ML OF THE RECONSTITUTED SUSPENSION CONTAINS:
Erythromycin Ethylsuccinate equivalent to Erythromycin 200 mg
(Preservative: Sodium Benzoate 0.1% w/v)

PHARMACODYNAMICS:
Erythromycin is a macrolide antibiotic. It interferes with bacterial protein synthesis by binding to the 50S subunit of ribosomes. It is bacteriostatic or bactericidal depending on its concentration and the type of organism. Activity increases with increases in pH up to about pH 8.5. Its range of antimicrobial action is similar to that of penicillin. The minimum inhibitory concentrations of Erythromycin for sensitive microorganisms have been reported to range from less than 0.1 to about 2 mcg per ml.

PHARMACOKINETICS:
Erythromycin is well absorbed and may be given without regard to meals. 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 the drug across the blood-brain-barrier increases 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, <5% of the activity of the administered dose can be recovered in the urine. Erythromycin crosses the placental barrier but feotal plasma levels are low.

INDICATION:
Upper and lower respiratory tract infections; ear and eye infections; gastrointestinal infection; skin and soft tissue infections; gonorrhoea; syphillis and whooping cough.

RECOMMENDED DOSE:
For children, the recommended dosage are as below:

Body weight	Dosage
7 to 11 kg	100 mg (2.5 ml) 4 times daily.
11 to 23 kg	200 mg (5 ml) 4 times daily.
23 to 45 kg	300 mg (7.5 ml) 4 times daily.
Over 45 kg	400 mg (10 ml) 4 times daily.

For mild to moderately severe infections in adults, the usual dosage is 400 mg (10 ml) four times daily or 800 mg (20 ml) twice daily. For more severe infections, 2 to 4 grams may be given daily in divided doses.

ROUTE OF ADMINISTRATION:
FOR ORAL USE ONLY

CONTRAINDICATIONS:
Patient hypersensitive to Erythromycin.
Porphyria. Erythromycin was considered to be unsafe in patients with acute porphyria because it has been shown to be porphyrinogenic in vitro systems.

WARNINGS AND PRECAUTIONS:
Erythromycin is principally excreted by the liver. Caution should be exercised in administering the antibiotic to patients with impaired hepatic function. There have been reports of hepatic dysfunction, with or without jaundice, occurring in patients receiving oral Erythromycin products.
To avoid the ototoxicity of Erythromycin in patients with renal failure it is suggested that the daily dosage should not exceed 1.5 g in patients with serum creatinine above 180 μmol per liter.
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. Sincy 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 and caregivers should be informed to contact their physician if vomiting and/or irritability with feeding occurs.

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 generalised exanthematous pustulosis (AGEP)], **ERYMYCIN DRY SYRUP 200** should be discontinued immediately and appropriate treatment should be urgently initiated.

INTERACTIONS WITH OTHER MEDICAMENTS:
Recent data from studies of Erythromycin reveal that its use in patients who are receiving high dose of Theophylline may be associated with an increase of serum Theophylline level and potential Theophylline toxicity. In case of Theophylline toxicity and/ or elevated serum Theophylline levels, the dose of receiving concomitant Erythromycin therapy.
Erythromycin administration in children receiving Carbamazepine has been reported to cause increase blood levels of Carbamazepine with subsequent development of signs of Carbamazepine toxicity.
Erythromycin may decrease the clearance of Warfarin and thus potentiate the hypoprothrombinemic effects of Warfarin.
Erythromycin has been reported to decrease the clearance of cyclosporine causing elevated cyclosporine levels and associated increased serum creatinine. Renal function as well as serum concentration of cyclosporine should be closely monitored when both drugs are administered concomitantly.
An interaction between Erythromycin and Ergotamine has been reported to increase the vasospasm associated with Ergotamine.

PREGNANCY AND LACTATION:
Use in pregnancy: The safety of Erythromycin for use during pregnancy has not been established.
Lactation: Erythromycin crosses the placental barrier. Erythromycin also appears in breast milk.

SIDE EFFECTS:
The most frequent adverse effects of Erythromycin preparations are gastrointestinal, e.g. abdominal cramping and discomfort, and are dose-related. Nausea, vomiting and diarrhoea occurred infrequently with unusual oral doses. During prolonged or repeated therapy, there is a possibility of overgrowth of non-susceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted. Mild allergic reactions, e.g. urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis, have been reported. There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of Erythromycin.
Postmarkerting Experience:
Gastrointestinal Disorders: infantile hypertrophic pyloric stenosis.
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 generalised exanthematous pustulosis (AGEP).

SYMPTOMS AND TREATMENT OF OVERDOSE:
Symptoms of overdosage include gastrointestinal, e.g. abdominal cramping and discomfort, and nausea, vomiting and diarrhoea, mild allergic reactions, e.g. urticaria and other skin rashes.
In case of overdosage, Erythromycin should be discontinued. Overdosage should be handled with the prompt elimination of unabsorbed drug and all other appropriate measures. Erythromycin is not removed by peritoneal dialysis or haemodialysis.
Allergic reactions associated with acute overdosage should be handled in the usual manner, that is, by the administration of adrenaline, corticosteroids and antihistamines as indicated and the prompt elimination of unabsorbed drug, in addition to all needed supportive measures.

DIRECTION FOR MIXING:
Shake to loosen powder.
Add approximately 30 ml freshly boiled and cooled water and shake well. Add more water until 60 ml mark is reached and shake.
To be used within 7 days after mixing.

PACKING/PACK SIZE(S):
Plastic bottle of 60 ml.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN
SHAKE WELL BEFORE USE

MANUFACTURER/PRODUCT REGISTRATION HOLDER:
DYNAPHARM (M) SDN. BHD. (65683-V)
2497, Mk. 1, Lorong Perusahaan Baru 5,
Kawasan Perusahaan Perai 3,
13600 Perai, Pulau Pinang, MALAYSIA

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