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Barcode

EROGRAN GRANULES

VIERO02-var4

DESCRIPTION

Erogran granules 125 mg/5ml
White, cherry flavoured granules.

Erogran granules 200 mg/5ml
White, cherry flavoured granules.

COMPOSITION

Erogran granules 125mg/5ml: Erythromycin ethylsuccinate equivalent to 125 mg of erythromycin in 5 ml when reconstituted.

Erogran granules 200mg/5ml: Erythromycin ethylsuccinate equivalent to 200 mg of erythromycin in 5 ml when reconstituted.

ACTIONS AND PHARMACOLOGY

Erythromycin, a bacteriostatic antibiotic, may be bactericidal in high concentrations or when used against highly susceptible organisms. It is thought to penetrate the bacterial cell membrane and to reversibly bind to the bacterial ribosomes so that translocation of peptides is prevented and subsequent protein synthesis is inhibited. It is adequately absorbed orally and is excreted in the bile and urine.

INDICATIONS

Indicated in the treatment or prophylaxis of the following :

- Upper and lower respiratory tract infections.
- Skin and soft-tissue infections including erythrasma.
- Genitourinary tract infections including gonorrhoea and syphilis.
- Intestinal amoebiasis.
- Others include bacterial endocarditis, streptococcal pharyngitis, diphtheria, Legionnaires' disease and pertussis.

CONTRAINDICATIONS

- Avoid in patients known to be hypersensitive to erythromycins
- 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)

WARNINGS AND PRECAUTIONS

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 or astemizole.

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, my ocardial 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.

MAIN SIDE/ADVERSE EFFECTS

- Abdominal discomfort, diarrhoea, nausea, vomiting and ototoxicity (after high doses).
- Mild allergic reactions such as urticaria and other skin rashes.
- Serious allergic reactions including anaphylaxis.
- Hearing loss and/or tinnitus (patients with renal and hepatic insufficiency and on high dose).
- Cardiac arrest, ventricular fibrillation (frequency not known)

DRUG INTERACTIONS

- Concurrent use with aminophylline, oxtriphylline or theophylline may result in increased serum theophylline levels; dosage adjustments may be necessary.
- Co-administration of lincomycins or penicillins is not recommended since erythromycins may interfere with their effects.

OVERDOSAGE

Clinical features: Nausea, vomiting, diarrhoea, prostration.
Treat overdosage by emesis or gastric lavage, if appropriate; with the necessary symptomatic and supportive measures, if required.

DOSAGE AND ADMINISTRATION

Adults

- **Antibacterial**
  Oral, the equivalent of erythromycin 400 mg every 6 hours or 800 mg every 12 hours.
- **Antibacterial (streptococcal prophylaxis)**
  - Continuous prophylaxis of streptococcal infections in patients with a history of rheumatic heart disease and/or chorea.
  - Oral, the equivalent of erythromycin 400 mg every 12 hours.
- **Antiprotozoal**
  Oral, the equivalent of erythromycin 400 mg every 6 hours for ten to fourteen days.
- **Gonorrhoea (disseminated)**
  Oral, the equivalent of erythromycin 800 mg every 6 hours for seven days.
- **Legionaires' Disease**
  Oral, the equivalent of erythromycin 400 mg to 1 gram every 6 hours.
- **Syphilis**
  Oral, the equivalent of erythromycin 800 mg every 6 hours for 15 days (early syphilis) or for 30 days (late syphilis).

Usual adult prescribing limits
Antibacterial the equivalent of erythromycin up to 4 grams daily.

Note: Doses up to the equivalent of 8 grams of erythromycin daily are apparently well tolerated.

Children

- **Antibacterial**
  Oral, the equivalent of erythromycin 7.5 to 25 mg per kg of body weight every 6 hours or 15 to 50 mg per kg of body weight every 12 hours.
- **Antiprotozoal**
  Oral, the equivalent of erythromycin 7.5 to 12.5 mg per kg of body weight every 6 hours for 10 to 14 days.

Note: 1.17 grams of erythromycin ethylsuccinate are equivalent to approximately 1 gram of erythromycin.

To reconstitute, add cooled boiled water until well dispersed, then add water to the appropriate mark.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage:
Store below 25°C. Protect from moisture.
Refrigerate and use within 10 days after reconstitution.

Presentation/Packing:
Granules 125mg/5 ml x 60 ml, 100 ml.
Granules 200mg/5 ml x 60 ml, 100 ml.
(Not all strengths and presentations may be available locally)

Manufactured by: HOVID Bhd.
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