MERITRO

Instructions for the medicinal product

Trade name: Meritro.
International Nonproprietary Name: Erythromycin.
Dosage form: Film-coated tablets.
Composition: Each film coated tablet contains:
Erythromycin stearate BP eq. to Erythromycin 500 mg;
Approved colours used in coating.
Pharmacotherapeutic group: Macrolide antibiotic.
ATC Classification: J01FA01.
Pharmacologic property:
Pharmacodynamics:
Erythromycin is macrolide group of antibiotics. It is basic and readily forms salts with acids. The base, the stearate salt and the esters are poorly soluble in water. Erythromycin ethylsuccinate is an ester of erythromycin suitable for oral administration.
Erythromycin is usually active against most strains of the following organisms both *in vitro* and in clinical infections:
Gram positive bacteria - *Listeria monocytogenes, Corynebacterium diphtheriae* (as an adjunct to antitoxin), Staphylococci *spp,* Streptococci *spp* (including Enterococci*)*.
Gram negative bacteria - *Haemophilus influenzae, Neisseria meningitidis, Neisseria gonorrhoeae, Legionella pneumophila, Moraxella (Branhamella) catarrhalis, Bordetella pertussis*, Campylobacter spp.
Mycoplasma - *Mycoplasma pneumoniae, Ureaplasma urealyticum*.
Other organisms - *Treponema pallidum*, *Chlamydia spp, Clostridia spp, L-forms,* the agents causing trachoma and lymphogranuloma venereum.
Pharmacokinetics:
Erythromycin is very rapidly absorbed, and diffuses into most tissues and phagocytes. Due to the high concentration in phagocytes, erythromycin is actively transported to the site of infection, where, during active phagocytosis, large concentrations of erythromycin are released.
Most of erythromycin is metabolised by demethylation in the liver. Its main elimination route is in the bile. There is little renal excretion. Erythromycin's elimination half-life is 1.6 hours.
Indications for use:
For the prophylaxis and treatment of infections caused by erythromycin-sensitive organisms.
Erythromycin is highly effective in the treatment of a great variety of clinical infections such as:
• Upper Respiratory Tract infections: tonsillitis, peritonsillar abscess, pharyngitis, laryngitis, sinusitis, secondary infections in influenza and common colds
• Lower Respiratory Tract infections: tracheitis, acute and chronic bronchitis, pneumonia (lobar pneumonia, bronchopneumonia, primary atypical pneumonia), bronchiectasis, Legionnaire's disease
• Ear infection: otitis media and otitis externa, mastoiditis
• Oral infections: gingivitis, Vincent's angina
• Eye infections: blepharitis
• Skin and soft tissue infections: boils and carbuncles, paronychia, abscesses, pustular acne, impetigo, cellulitis, erysipelas
• Gastrointestinal infections: cholecystitis, staphylococcal enterocolitis
• Prophylaxis: pre- and post- operative trauma, burns, rheumatic fever
• Other infections: osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever
Contraindications:
• hypersensitivity to erythromycin or any macrolide antibiotic;
• contraindicated in patients taking astemizole, terfenadine, cisapride or pimozide.;
• preexisting liver disease (with estolate salt);
• epithelial herpes simplex keratitis;
Precautions: arrhythmia (anamnesis), prolongation of the interval QT; jaundice (anamnesis), hepatic failure, renal failure.
Pregnancy and lactation:
There is no evidence of teratogenicity or any other adverse effect on reproduction in pregnant women. However this drug should be used during pregnancy only if clearly needed.
Meritro is excreted in human milk. Caution should be exercised when Meritro is administered to a nursing woman.
Dosage and directions for use:
Set individually depending on the location and severity of the infection, the sensitivity of the pathogen.
For oral administration.
For adults and adolescents over 14 years - 250-500 mg, daily dosage - 1-2 g. Interval between doses - 6 hours. In severe infections the daily dosage may be increased to 4 g.
Children from 4 months to 14 years, depending on the age, body weight and severity of the infection - 30-50 mg / kg per day in 2-4 doses.
Children of the first 3 months of life - 20-40 mg / kg per day in the case of serious infections the dose may be doubled.
The treatment of diphtheria carrier - 250 mg 2 times a day.
Primary syphilis - 30 to 40 g given in divided doses over a period of 10 to 15 days.
Intestinal Amebiasis: Adults - 500 mg every 12 hours or 250 mg every 6 hours for 10 to 14 days. *Children* - 30 to 50 mg/kg/day in divided doses for 10 to 14 days.
Legionnaires' Disease - Although optimal dosage has not been established, doses utilized in reported clinical data were 1 to 4 g daily in divided doses, during 14 days.
Gonorrhoea - 500 mg every 6 hours for 3 days, then - 250 mg every 6 hours for 7 days.
Preoperative bowel preparation to the prevention of infectious complications - oral, 1 g per 19 h, 18 h and 9 h prior to surgery (total 3 g).
Prevention of streptococcal infection (tonsillitis, pharyngitis) - Adults - 20-50 mg / kg per day. Children - 20-30 mg / kg per day, the duration of the course - at least 10 days.
To prevent bacterial endocarditis patients with heart defects - 1 g for adults and 20 mg / kg - for children, for 1 hour before therapeutic or diagnostic procedure, 500 mg more - for adults and 10 mg / kg for children repeatedly after 6 hours.
Whooping cough - 40-50 mg / kg per day, given in divided doses for 5 to 14 days.
Pneumonia in children - 50 mg / kg per day in 4 divided doses, for at least 3 weeks.
Urogenital Infections During Pregnancy Due to Chlamydia trachomatis –500 mg 4 times per day for at least 7 days, or (if not tolerated this regimen) - a decreased dose of one 500 mg tablet orally every 12 hours or 250 mg a day should be used for at least 14 days.
For adults with uncomplicated chlamydia and tetracycline intolerance - 500 mg 4 times a day for at least 7 days.
Side-effects:
Blood and lymphatic system disorders: eosinophilia.
Cardiac disorders: QTc interval prolongation, torsades de pointes, palpitations, and cardiac rhythm disorders including ventricular tachyarrhythmias.
Ear and labyrinth disorders: deafness, tinnitus; there have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency or taking high doses.
Gastrointestinal disorders: the most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. Have been reported - upper abdominal discomfort, nausea, vomiting, diarrhoea, pancreatitis, anorexia, infantile hypertrophic pyloric stenosis.
General disorders and administration site conditions: chest pain, fever, malaise.
Hepatobiliary disorders: cholestatic hepatitis, jaundice, hepatic disfunction, hepatomegaly, hepatic failure, hepatocellular hepatitis.
Immune system disorders: allergic reactions ranging from urticaria and mild skin eruptions to anaphylaxis have occurred.
Investigations: increased liver enzyme values.
Nervous system disorders: there have been isolated reports of transient central nervous system side effects including confusion, seizures and vertigo; however, a cause and effect relationship has not been established.
Psychiatric disorders: hallucinations.
Renal and urinary disorders: interstitial nephritis
Skin and subcutaneous tissue disorders: skin eruptions, pruritus, urticaria, exanthema, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme.
Vascular disorders: hypotension.
Overdose:
Symptoms: hearing loss, severe nausea, vomiting and diarrhoea.
Treatment: gastric lavage, general supportive measures.
Drug interaction:
Increases in serum concentrations of the following drugs metabolised by the cytochrome P450 system may occur when administered concurrently with erythromycin: acenocoumarol, alfentanil, astemizole, bromocriptine, carbamazepine, cilostazol, cyclosporin, digoxin, dihydroergotamine, disopyramide, ergotamine, hexobarbitone, methylprednisolone, midazolam, omeprazole, phenytoin, quinidine, rifabutin, sildenafil, tacrolimus, terfenadine, theophylline, triazolam, valproate, vinblastine, and antifungals e.g. fluconazole, ketoconazole and itraconazole. Appropriate monitoring should be undertaken and dosage should be adjusted as necessary. Particular care should be taken with medications known to prolong the QTc interval of the electrocardiogram.
Antihistamine H1 antagonists: care should be taken in the coadministration of erythromycin with H1 antagonists such as terfenadine, astemizole and mizolastine due to the alteration of their metabolism by erythromycin.
Erythromycin significantly alters the metabolism of terfenadine, astemizole and pimozide whentaken concomitantly. Rare cases of serious, potentially fatal, cardiovascular events including cardiac arrest, torsade de pointes and other ventricular arrhythmias have been observed.
Anti-bacterial agents: Erythromycin antagonises the action of clindamycin, lincomycin and chloramphenicol. The same applies for streptomycin, tetracyclines and colistin.
Triazolobenzodiazepines (such as triazolam and alprazolam) and related benzodiazepines: erythromycin has been reported to decrease the clearance of triazolam, midazolam, and related benzodiazepines, and thus may increase the pharmacological effect of these benzodiazepines.
Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy. Oral erythromycin is given concurrently with theophylline there is a significant decrease in erythromycin serum concentrations. This decrease could result in sub-therapeutic concentrations of erythromycin.
There have been reports of colchicine toxicity with concomitant use of erythromycin and colchicine.
Hypotension, bradyarrhythmias and lactic acidosis have been observed in patients receiving concurrent verapamil, a calcium channel blocker.
Cimetidine may inhibit the metabolism of erythromycin which may lead to an increased plasma concentration.
Erythromycin has been reported to decrease the clearance of zopiclone and thus may increase the pharmacodynamic effects of this drug.
Cautions:
Caution should be exercised in patients with history of liver disease, yellowing of the skin or eyes, colitis, stomach problems, irregular heartbeat, blood disease porphyria and any allergy.
Avoid long-term use of this medication; otherwise it may cause secondary infection.
It may aggravate muscle weakness in patients with myasthenia gravis.
During prolonged therapy is necessary to monitor liver function, kidney function and complete blood cell.
The symptoms of cholestatic jaundice may develop within a few days after the start of therapy, but the risk increases after 7-14 days of continuous therapy.
Don't administrate Meritro with milk and dairy products.
Presentation:
2x10, PVC Blister in carton box, with instructions for use.
Storage:
Keep in dry place, protected from light at a temperature below 25°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Prescribed medicine.

BELINDA

Manufactured for:
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