Klatril®

Clarithromycin Tablets USP 500mg

Composition

Each film coated tablet contains:

Clarithromycin USP 500mg

Colour: Titanium Dioxide BP

Actions

Clarithromycin is a semi-synthetic macrolide antibiotic. Chemically it is 6-0 methylerythromycin. Like other macrolides, clarithromycin binds to the 50S subunit of the 70S ribosome, thereby blocking RNA-mediated bacterial protein synthesis. Clarithromycin can be bacteriostatic or bactericidal in action, depending on the concentration as well as the particular organism and its inoculum. The minimum inhibitory concentrations (MIC) of clarithromycin are generally two-fold lower than the MIC of erythromycin.

Indications

1. Highly potent against a wide variety of aerobic and anaerobic gram-positive and gram-negative organisms.
2. Respiratory tract infections.
3. Ear, nose and throat infections.
4. Community acquired pneumonia.
5. Disseminated mycobacterial infections due to Mycobacterium avium or Mycobacterium intracellular.
6. Prevention of disseminated Mycobacterium avium complex (MAC) disease in patients with advanced HIV infection.
7. Treatment of H. pylori infections in combination with other drugs such as lansoprazole, omeprazole, ranitidine, bismuth, amoxicillin etc.

Dosage

The usual dosage of clarithromycin is 250 mg twice daily. Although this may be increased to 500mg twice daily for unto 14 days in severe infections.

The recommended dose of clarithromycin for the prevention of disseminated Mycobacterium avium disease is 500 mg bid. Clarithromycin is recommended as the primary agent for the treatment of disseminated infection due to Mycobacterium avium

complex. In the treatment of Mycobacterium avium complex, clarithromycin should be used in combination with other antimycobacterial drugs. The recommended dose for mycobacterium infections in adults is 500 mg bid.

In children the dose is 7.5 mg to 15 mg/kg 12 hourly.

Clarithromycin may be administered without dosage adjustment in the presence of hepatic impairment if there is normal renal function. However, in the presence of severe renal impairment (creatinine clearance < 30 ml/min). with or without coexisting hepatic impairment, the dose should be halved or the dosing interval doubled.

Pregnancy and lactation

The safety of clarithromycin during pregnancy and beast-feeding of infants has not been established. Clarithromycin should thus not be used during pregnancy or location unless the benefit is considered outweigh the risk. Some animal studies have suggested an embryo toxic effect, but only at dose levels which are clearly toxic to mothers. Clarithromycin has been found in the milk of lactating animals and in human breast milk.

Effects on ability to Drive and use Machines

The medicine is unlikely to produce an effect.

Mutagenicity and Teratogenicity

No evidence of mutagenic potential of clarithromycin was seen during a range of in vitro and in vivo tests.

Pharmacokinetic Properties

Clarithromycin is rapidly and well absorbed from the gastro-intestinal tract after oral administration of clarithromycin. The microbiologically active metabolite 14-hydroxycalrithromycin is formed by first pass metabolism. Clarithromycin may be given without regard to meals as food does not affect the extent of bioavailability of clarithromycin. Food does slightly delay the onset of absorption of clarithromycin and formation of the 14-hydroxymelabolite. The pharmacokinetics of clarithromycin are non-linear; however, steady state is attained with 2days of dosing. At 250 mg bid daily 15-20% of unchanged drug is excreted in the urine. With 500mg bid daily dosing urinary excretion is greater (app.36%). The 14-hydroxclarithromycin is the major urinary metabolite and accounts for 10-15% of the dose. Most of the reminder of the dose is eliminated in the faces, primarily via the bile. 5-10% of the parent drug is recovered from the faeces. When clarithromycin 500 mg is given three times daily, the clarithromycin plasma concentration are increased with respect to the 500mg twice daily dosage.

Clarithromycin provides tissue concentrations that are several times higher than the circulating drug levels. Increased levels have been found in both tonsillar and lung tissue. Clarithromycin is 80% bound to plasma proteins at therapeutic levels. Clarithromycin also penetrates the gastric mucus. Level of clarithromycin in gastric acid mucus and gastric tissues are higher when clarithromycin is co-administered with omeprazole than when clarithromycin is administered alone. Clarithromycin penetrates into the middle ear fluid at concentrations greater than in the serum.

Side Effects

The majority of side effects observed in clinical trials were of mild and transient nature. Fever than 3%of adults of patients without mycobacterial infections and fewer than 2% of pediatric patients without mycobacterial infections discontinued therapy because of drug related side effects.

The most frequently reported events in adults were diarrhea, nausea, abnormal taste, dyspepsia, abdominal pain/discomfort, and headache. In paediatric patients, the most frequently reported events were diarrhea, vomiting abdominal pain, rash and headache. Most of these events were described as a mild or moderate in severity.

H. pylori organisms may develop resistance to clarithromycin in a small number of patients.

Contraindications

Clarithromycin is contraindicated with a known hypersensitivity to clarithromycin erythromycin, or any of the macrolide antibiotics. It is also contraindicated in pregnancy. Concomitant administration of clarithromycin with cisapride, pimozole, or tertenadine is contraindicated

Clarithromycin and ergot derivatives should not to be co-administered. Clarithromycin may potentiate the effects of carbamazepine due to a reduction in the rate of excretion.

Storage

Clarithromycin tablets have a shelf- life of 24 months when stored in Alu/PVC/PVDC blisters in a cool dry place. Do not store above 30^0c. Protect from light.

Presentation

Blister pack of 14 tablets.

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

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