KLARIBAC®

(Clarithromycin)

ACTION:

Clarithromycin is a macrolide antibiotic with in vitro activity against many gram-positive and gram-negative aerobic and anaerobic organisms. Clarithromycin exerts its antibacterial action by binding to the 50S ribosomal subunit of susceptible microorganisms resulting in inhibition of protein synthesis. Clarithromycin is active in vitro against the following microorganisms:- Gram-positive aerobes: Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes. Gram-negative aerobes: Haemophilus influenzae, Moraxella catarrhalis. Other aerobes: Mycoplasma pneumoniae. Clarithromycin exhibits in vitro minimum inhibitory concentrations of 2 µg/ml or less against the following microorganisms; Gram-positive aerobes: Listeria monocytogenes, Streptococcus agalactiae, Streptococcus viridans. Gram-negative aerobes:- Bordetella pertussis, Campylobacter jejuni, Legionella pneumophila, Neisseria gonorrhoea. Other aerobes: Chlamydia trachomatis. Gram-positive anaerobes: Clostridium perfringens, Propionibacterium acnes. Gram-negative anaerobes: Bacteroides melaninogenicus. Clarithromycin also has in vitro activity against Helicobacter pylori and has been clinically effective, when combined with PPI's, in the treatment of peptic ulcers. Clarithromycin is rapidly absorbed from the gastrointestinal tract following oral administration, and undergoes first-pass metabolism; the bioavailability of the parent drug is about 55%. Clarithromycin and the 14-Hydroxy clarithromycin metabolite distribute readily into body tissues and fluids, excluding the CNS. Because of high intracellular concentrations, tissue concentrations are higher than serum concentrations. The extent of absorption is relatively unaffected by the presence of food. Peak serum concentrations are attained within 2 hours after oral dosing. Steady-state peak serum concentrations are approximately 1 µg/ml with a 250 mg dose administered every 12 hours and 2 to 3 µg/ml with a 500 mg dose administered every 12 hours. With a 250 mg every 12 hours dosing, the principal metabolite, 14-Hydroxy clarithromycin, attains a peak steady-state concentration of about 0.6 µg/ml. Drug half-life appears to be dose dependent, high doses may produce increases in peak concentrations of the parent drug, due to saturation of the metabolic pathways. Approximately 40% of the dose of 250 mg given twice a day is excreted in the urine as clarithromycin.14-Hydroxy clarithromycin accounts for 10% of the dose excreted in the urine. It is excreted in faeces via the bile. Clarithromycin is 65% to 75% bound to plasma proteins.

INDICATIONS:

Klaribac is indicated in the treatment of infections caused by microorganisms sensitive to clarithromycin. Pharyngitis, tonsillitis, acute maxillary sinusitis, acute bacterial exacerbation of chronic bronchitis, bacterial pneumonia and atypical pneumonia, uncomplicated skin and skin structure infections. In children in addition to the previous indications, Klaribac is used for acute otitis media. Klaribac is given to eradicate Helicobacter pylori in the treatment regimens for peptic ulcer.

DOSAGE AND ADMINISTRATION:

Klaribac usual adult dose is 250 mg twice daily, increased to 500 mg twice daily if necessary in severe infections. A course is usually for 7 to 14 days .

Klaribac usual children dose: Infants up to 6 months of age: Safety and efficacy have not been established. Children 6 months of age and older: 7.5 mg per kg body weight twice daily. In patients with severe renal function impairment (creatinine clearance < 30 ml/min) dosage may need to be halved.

CONTRAINDICATIONS:

Clarithromycin is contraindicated in patients with a known hypersensitivity to clarithromycin, erythromycin or any of the macrolide antibiotics. Severe liver insufficiency. Clarithromycin is contraindicated in patients receiving terfenadine therapy who have preexisting cardiac abnormalities.

WARNINGS:
Safety and efficacy have not been established for infants up to 6 months of age.

PRECAUTIONS:
Clarithromycin is principally excreted via the liver and kidney , and so particular caution should be taken when administering it to patients with severely impaired liver function, in patients with severe renal impairment and to elderly patients.
Clarithromycin should not be given in case of pregnancy and breast feeding.

Drug interactions:
Administration of carbamazepine with clarithromycin has been shown to increase significantly the plasma concentration of carbamazepine. Carbamazepine serum levels should be monitored. Concurrent administration of digoxin with clarithromycin has been shown to increase serum digoxin concentrations. Monitoring of digoxin serum levels is recommended in patients receiving digoxin and clarithromycin concurrently. Clarithromycin can cause an increase in theophylline serum levels which needs monitoring in patients receiving high doses of theophylline . Similarly to other macrolides, interactions with warfarin, cyclosporines are possible.

SIDE EFFECTS:
G. I. disturbances: Diarrhea, nausea, dyspepsia, abdominal pain and discomfort. Headache. Rash. Transient increases of SGOT,SGPT is possible. Hepatic cholestasis with or without jaundice, has been reported exceptionally. As with other antibacterial agents, during treatment with clarithromycin, superinfections by resistant bacteria or fungi can rarely arise, which needs medical attention if they continue or are bothersome.

OVERDOSAGE:
In case high dosages of clarithromycin is ingested , G.I. disturbances may occur which needs gastric lavage and supportive treatment .

PRESENTATION:

Tablets:	
Klaribac® 250	Clarithromycin USP 250 mg
Klaribac® 500	Clarithromycin USP 500 mg
Susp:*	
Klaribac® 125	Clarithromycin USP 125 mg
Klaribac® 250	Clarithromycin USP 250 mg

* Per 5ml (teaspoonful) .

This is a medicament - Keep medicaments out of the reach of children.

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

إن هذا دواء - لا تترك الأدوية في متناول أيدي الأطفال.

- الدواء مستحضر يؤثر على صحتك واستهلاكه خلافاً للتعليمات يعرضك للخطر.
- اتبع بدقة وصفة الطبيب وطريقة الإستعمال المنصوص عليها وتعليمات الصيدلاني الذي صرفها لك.
- الطبيب والصيدلاني هما الخبيران بالدواء وبنفعة وضرره.
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك.
- لا تكرر صرف الدواء دون وصفة طبية.

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