KLARO-250/500

Clarithromycin Tablets USP

IDENTIFICATION:
KLARO-250: Yellow colour, capsule shape, plain on both side of film coated tablets
KLARO-500: Yellow colour, capsule shape, Break line on one side and plain on other side of film coated tablets.

COMPOSITION :
Each film coated tablet contains:
Clarithromycin USP 250 mg / 500 mg
Excipients Q.S.
Colour: Quinoline yellow & Titanium Dioxide

THERAPEUTIC CLASS:
Anti-bacterial

PHARMACOLOGICAL ACTIONS:
Pharmacodynamic:
Clarithromycin is a semi synthetic derivative of erythromycin-A and is active against wide variety of aerobic and anaerobic gram positive and gram negative bacterial strains. It binds to 50s ribosomal unit of susceptible bacteria and inhibiting protein synthesis. The metabolite 14-hydroxy clarithromycin is also active and synergistic with the parent compound.
Pharmacokinetics:
Clarithromycin is rapidly and well absorbed from the gastrointestinal tract after oral administration. The microbiologically active metabolite 14-hydroxyclarithromycin is formed by first pass metabolism. **KLARO** may be given without regard to meals as food does not affect the extent of bioavailability of clarithromycin. Food does slightly delays the onset of absorption of clarithromycin and formation of 14-hydroxymetabolite. The pharmacokinetics of clarithromycin are non linear; steady state is attained within 2 days of dosing. **KLARO-250** b.i.d. 15-20% of unchanged drug is excreted in urine. **KLARO-500** b.i.d. daily dosing urinary excretion is greater (approximately 36%). The 14-hydroxyclarithromycin is the major urinary metabolite and accounts for 10-15% of dose. Most of the remainder of the dose is eliminated in the faeces, primarily via the bile.

INDICATIONS:
- Lower respiratory tract infections for example, acute and chronic bronchitis, and pneumonia.
- Upper respiratory tract infections for example, sinusitis and Pharyngitis.
- Skin and soft tissue infections of mild to moderate severity.
- Eradication of *H.Pylori* in patients with duodenal ulcers

CONTRAINDICATIONS:
- Hypersensitivity to Clarithromycin or other macrolides or any of the Excipients
- In patients with hypokaliemia.

ADVERSE EFFECTS:
The majority of side effects observed were mild and transient in nature. The most frequently reported events were diarrhea, nausea, abnormal taste, dyspepsia, abdominal pain/discomfort and headache.

WARNING & PRECAUTIONS:
Clarithromycin should not be used in patients with congenital or documented acquired QT prolongation. H. pylori organisms may develop resistance to Clarithromycin. Prolonged or repeated used of Clarithromycin may result in an overgrowth of non-susceptible bacteria or fungi. If super-infection occurs, it should be discontinued and appropriate therapy instituted. Clarithromycin is principally excreted by the liver and kidney. So, caution should be exercised when administered in patients with impaired hepatic or renal function.
Pregnancy & lactation: The safety of clarithromycin during pregnancy and breast feeding of infants has not been established. Thus it is not be used during pregnancy or lactation unless the benefit is considered to outweigh the risk. Clarithromycin has been found human milk. So, caution should be exercised when it is administered to nursing women.

DOSAGE AND ADMINISTRATION:
Patients with respiratory infection/skin and soft tissue infection:
Adults: The usual dose is 250 mg twice daily for 7 days although this may be increased to 500 mg twice daily for up to 14 days in severe infections.
Children older than 12 years: As for adults
Children younger than 12 years: Use an appropriate clarithromycin paediatric preparation.
Eradication of H. Pylori in patients with duodenal ulcers (Adults):
Triple Therapy (7-14 days): Clarithromycin 500 mg b.i.d + Lansoprazole 30 mg b.i.d. + Amoxycillin 1000 mg b.i.d.
Triple Therapy (7 days): Clarithromycin 500 mg b.i.d + Lansoprazole 30 mg b.i.d. + Metronidazole 400 mg b.i.d.
Triple Therapy (7 days): Clarithromycin 500 mg b.i.d + Omeprazole 40 mg q.d. + Amoxycillin 1000 mg or Metronidazole 400 mg b.i.d.
Triple Therapy (10 days): Clarithromycin 500 mg b.i.d + Omeprazole 20 mg q.d. + Amoxycillin 1000 mg
Dual Therapy (14 days): Clarithromycin 500 mg t.i.d + Omeprazole 40 mg q.d.
Dosage in renal functional impairment:
Dosage adjustments are not usually required except in patients with severe renal impairment (Creatinine clearance < 30 ml/min). If adjustment is necessary, the total daily dosage should be reduced by half, e.g. 250 mg once daily or 250 mg twice daily in more severe infections.

DRUG INTERACTIONS:
As with other macrolide antibiotics the use of Clarithromycin in patients concurrently taking drugs metabolised by the cytochrome P450 system (e.g. Terfenadin, Astemizol, Alprazolam, Triazolam, Midazolam, Carbamazepine, Phenytoin, Hexobarbital, Pimozide, Disopyramide, Quinidine, Ergot alkaloids, Sildenafil, Lovastatin, Simvastatin, Ciclosporin, Tacrolimus, Methylprednisolone, Alfentanil, Omeprazole, Cisapride, Warfarin, Rifabutin, Vinblastine) may be associated with elevations in serum levels of these drugs. This may result in QT prolongation & cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation and Torsade de Points.

OVERDOSAGE:
Symptoms: gastrointestinal symptoms such as abdominal pain, vomiting, nausea and diarrhea. *Treatment:* It should be treated by the prompt elimination of unabsorbed drug and supportive measures.

EXCIPIENTS:
Microcrystalline Cellulose Powder (Avicel), Maize Starch, Povidone (P.V.P.K. 30), Isopropyl Alcohol, Sodium Starch Glycolate (Type-A), Croscarmellose Sodium, Purified Talc, Magnesium Stearate, Colour Quinoline Yellow SC-SP-2299, Dichloromethane.

PRESENTATION:
Alu /Alu-Blister Pack

STORAGE CONDITION:
Store under normal storage conditions (15°C - 30°C). Protect from light & moisture.

SHELF LIFE:
36 Months

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