CLARITHROMYCIN TABLETS USP

Clariwin

COMPOSITION:
Each film-coated tablet contains: Clarithromycin USP 250/500 mg

CHEMISTRY:
Erythromycin, 6-O-Methyl-6-O-Methylerythromycin

PHARMACOLOGICALCATEGORY:
Macrolide Antibiotic

PHARMACOLOGY:
Clarithromycin exerts its antibacterial action by binding to the 50S ribosomal subunit of susceptible organisms and inhibiting protein synthesis.
Microbiology: Clarithromycin is active in vitro against a variety of aerobic and anaerobic gram-positive and gram-negative organisms as well as most Mycobacterium avium complex (MAC) organisms.
Gram positive aerobes: Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes
Gram negative aerobes: Haemophilus influenzae, Moraxella (Branhamella) catarrhalis
Other aerobes: Mycoplasma pneumoniae
Mycobacteria: Mycobacterium avium complex (MAC) consisting of: Mycobacterium avium and Mycobacterium intracellulare

***Pharmacokinetics*:**
Clarithromycin is rapidly absorbed from the gastrointestinal tract after oral administration. The absolute bioavailability of 250 mg Clarithromycin tablets was approximately 50%. Food slightly delays both the onset of Clarithromycin absorption and the formation of the antimicrobially active metabolite, 14-OH Clarithromycin, but does not affect the extent of bioavailability. Therefore, Clarithromycin tablets may be given without regard to meals.

INDICATIONS & USES:
Clarithromycin is indicated in the treatment of upper & lower respiratory tract infections, pharyngitis/ tonsillitis due to Streptococcus pyogenes, acute maxillary sinusitis, acute bacterial exacerbation of chronic bronchitis, Pneumonia, uncomplicated skin & skin structure infections.

CONTRAINDICATIONS:
Clarithromycin is contraindicated in patients with known hypersensitivity to Clarithromycin, Erythromycin, or any of the macrolide antibiotics

SIDE EFFECTS / ADVERSE REACTIONS:
Diarrhoea, nausea, abnormal taste, dyspepsia, abdominal pain/ discomfort & headache.

PRECAUTIONS / WARNINGS:
General: In presence of severe renal impairment with or without coexisting hepatic impairment, decreased dosage or prolonged dosing intervals may be appropriate. Clarithromycin should not be used in pregnant women except in clinical circumstances where no alternative therapy is appropriate. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, and may range in severity from mild to severe.
Pediatric Use: Safety and effectiveness of Clarithromycin in children under 6 months of age have not been established.

Prolongation of the QT interval
Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with macrolides, therefore caution is required when treating:

- Patients with congenital or documented QT prolongation
- Patients currently receiving treatment with other active substances known to prolong QT interval such as antiarrhythmics of classes IA and III; antipsychotic agents; antidepressants; and fluoroquinolones
- Patients with electrolyte disturbance, particularly in cases of hypokalaemia and hypomagnesemia
- Patients with clinically relevant bradycardia, cardiac arrhythmia or cardiac insufficiency
- Elderly patients: elderly patients may be more susceptible to drug-associated effects on the QT interval

DRUG INTERACTIONS:
Clarithromycin use in patients who are receiving Theophylline may be associated with increase of serum Theophylline concentrations. Clarithromycin may increase Carbamazepine concentrations. Active metabolite of Terfenadine was three fold higher when coadministered with Clarithromycin. Concomitant administration of Erythromycin and Digoxin has been reported to result in elevated digoxin level.

USE IN PREGNANCY & LACTATION:
There are no adequate and well-controlled studies in pregnant women. Clarithromycin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Use in lactating mothers: It is not know whether Clarithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Clarithromycin is administered to a nursing woman.

DOSAGE & ADMINISTRATION:
Upper respiratory tract infections: 250mg-500mg for 10-14 days twice a day. Lower respiratory tract infections: 250mg for 7-14 days twice a day. Uncomplicated skin & skin structure infections: 250mg for 7-14 days twice a day.

OVERDOSAGE, SYMPTOMS & ANTIDOTE:
Studies on overdosage not available.

STORAGE:
Keep below 25°C in a dry place.

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