CLARIMAC®

250 MG & 500 MG **FILM COATED TABLETS**

COMPOSITION:
Tablets:
Each film coated tablet contains Clarithromycin (USP) 250 mg.
Each film coated tablet contains Clarithromycin (USP) 500 mg.

CLINICAL PHARMACOLOGY:
Clarithromycin is a semi-synthetic macrolide antibiotic. It is usually bacteriostatic and may be bactericidal in high concentration or against highly susceptible organisms. Clarithromycin inhibits protein synthesis in susceptible organisms by penetrating the cell wall and binding to 50s ribosomal subunits.
Clarithromycin is rapidly absorbed from gastrointestinal tract after oral administration. The extent of clarithromycin absorption is unaffected by concomitant ingestion of food.

INDICATIONS:
CLARIMAC is indicated for the treatment of the following infections when caused by susceptible organisms:
- Upper respiratory tract infections: sinusitis, pharyngitis, tonsillitis and acute otitis media due to Haemophilus influenza.
- Lower respiratory tract infections: bronchitis, bacterial pneumonia and atypical pneumonia.
- Mild to moderate skin and soft tissue infections: impetigo, erysipelas, folliculitis, furunculosis and septic wounds.

CLARIMAC is also indicated for the treatment of helicobacter pylori infection and duodenal ulcer when used in combination with amoxycillin and omeprazole as triple therapy.

CONTRAINDICATIONS:
- Hypersensitivity to macrolides or any component of the formulation.
- Clarithromycin and ergot derivatives should not be co-administered.
- Concomitant administration of clarithromycin with cisapride, pimozide and terfenadine is contraindicated.

PRECAUTIONS:
- Caution should be taken when given to patients with impaired liver function.
- Dosage should be reduced in patient with renal impairment.
- Caution should be taken in patients with prophyria.
- Pseudomembranous colitis diagnosed due to diarrhea may occur following administration of antibacterial agents including Clarithromycin.

ADVERSE REACTIONS:
Clarithromycin is generally well tolerated. The most frequently side effects reported include:
Gastrointestinal disturbances such as: nausea, abdominal pain, discomfort, diarrhea and dyspepsia.
Other side effects include headache, arthralgia, myalgia, allergic reactions and taste disturbances.
As with other macrolides, hepatic dysfunction including altered liver function tests, hepatitis and cholestasis with or without jaundice has been reported.

DRUG INTERACTIONS:
- Food delays absorption but does not affect extent of absorption.
- Concomitant administration of the following drugs causes an increase in their plasma level: Theophylline, carbamazepine, omeprazole, oral anticoagulants, digoxin and simvastatin.
- Concomitant administration of the following drugs should be avoided: Reboxetine, tolterodine, pimozide, terfenadine and mizolastine
- Ergotamine should be avoided due to risk of ergotism.
- Concomitant administration of clarithromycin with some antiviral agents, the following interactions have been reported:
  - Retonavir: increased plasma concentration of clarithromycin.
  - Efavirenz: increased risk of rash.
  - Zidovudine: reduced its absorption.

USE DURING PREGNANCY AND LACTATION:
- In pregnancy, clarithromycin should be used only when the potential benefits outweigh the possible risks (under medical supervision).
- Caution should be exercised when clarithromycin is administered to nursing women (consult your doctor).

DOSAGE:
- Usual dose in adults is 250 mg of CLARIMAC twice daily, increased if necessary in severe infections to 500 mg twice daily.
- A course is usually for 7 to 14 days.
- Children may be given 7.5 mg per kg body-weight twice daily for 5 to 10 days.

OVERDOSAGE:
In case high dosages of clarithromycin have been ingested, gastrointestinal disturbances can occur such as: nausea, vomiting, diarrhea, constipation, reversible pancreatitis, hearing loss with or without tinnitus or vertigo which need gastric lavage and supportive treatment.

STORAGE:
Store at room temperature (15-25) °C, protect from light.
Do not use the drug after the expiry date printed on the package.

PRESENTATION:
Tablets:
Packs contain (14) film coated tablets of CLARIMAC 250 mg.
Packs contain (14) film coated tablets of CLARIMAC 500 mg.
Hospital packs of CLARIMAC 250 mg & 500 mg film coated tablets.

This is a medicament

- 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 sold 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.

Keep medicaments out of the reach of children

Council of Arab Health Ministers Union of Arab Pharmacists

RIYADH PHARMA

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