

Maxpectra® XL

Clarithromycin Extended Release Tablets

Composition:

Each film coated tablet contains:

Clarithromycin 500 mg.

Excipients: Lactose, magnesium stearate, talc, hydroxypropyl methylcellulose, propylene glycol, sorbitan monooleate, vanillin, titanium dioxide (E171), quinoline yellow (E104).

Properties:

Clarithromycin is a semi-synthetic macrolide antibiotic. It is highly potent against a wide variety of aerobic and anaerobic gram positive and gram-negative micro-organisms in addition to atypical pathogens, it inhibits protein synthesis in susceptible micro-organisms by penetrating the cell wall and binding to 50S ribosomal subunits. Clarithromycin is rapidly absorbed from gastrointestinal tract after oral administration and rapidly diffuses in the majority of tissues, Clarithromycin penetrates into middle ear fluid of children with secretory otitis media.

Clarithromycin is metabolized in the liver to a microbiologically active metabolite, 14-hydroxy Clarithromycin which achieves peak plasma level after 2-4 hours from administration of 250 mg. Clarithromycin is eliminated by both renal and non-renal mechanisms.

Indications:

Maxpectra XL is indicated for the treatment of infections caused by susceptible microorganisms. These infections include upper respiratory tract as: Pharyngitis, tonsillitis, sinusitis and otitis media. Lower respiratory tract as: Acute bacterial exacerbation of chronic bronchitis, bacterial pneumonia and atypical pneumonia. Skin infections: Impetigo, erysipelas, folliculitis, furunculosis and septic wounds.

It is also indicated for the treatment of Helicobacter pylori infection when used in combination with amoxicillin and omeprazole as triple therapy.

Contraindications:

Maxpectra XL is contraindicated for patients with known hypersensitivity to any of its components, and for patients on cisapride, pimozide therapy.

Precautions:

Precautions should be taken in people with impaired hepatic or renal function, and when given to nursing mothers.

Interactions with other drugs:

Concomitant administration of the following drugs causes an increase in their plasma level: Theophylline, carbamazepine, ranitidine bismuth citrate, oral anticoagulants, digoxin, simvastatin.

Concomitant administration of fluconazole increases the plasma concentration of Clarithromycin.

Avoid concurrent use with: Disopyramide, phenytoin, cyclosporin.

Clarithromycin reduces absorption of zidovudine.

Warnings:

Clarithromycin should not be given to pregnant women, dosage adjustment required with severe renal impairment. Macrolide antibiotic (including Clarithromycin) have been associated with rare QT prolongation and ventricular arrhythmia.

Dosage and Administration:

Do not crush or chew the tablets.

Maxpectra XL tablets should be given within or after food.

In most infections include upper and lower respiratory tract infections, skin and soft tissue, the recommended dose ranges from 1-2 tablets once daily according to the severity of infection.

For the treatment of Helicobacter pylori infection, triple therapy of 500 mg Clarithromycin, 30 mg lansoprazole or 20 mg omeprazole and 1.0 g amoxicillin is suggested twice daily for 10 days.

Overdosage:

Symptoms of overdose include nausea, vomiting, diarrhea, constipation, reversible pancreatitis, hearing loss with or without tinnitus or vertigo.

Treatment includes symptomatic and supportive care.

Side Effects:

The most frequently reported side effects are: Diarrhea, nausea, abnormal taste, dyspepsia, abdominal pain/discomfort and headache, hepatitis, jaundice and hypoglycemia.

Consult your Physician or Pharmacist if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30°C).

Do not use beyond the expiry date or if the product shows any signs of deterioration.

Presentations:

Maxpectra XL: Pack of 7 Tablets.

® is a trademark.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow 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 medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



Manufactured by:

TABUK PHARMACEUTICAL MANUFACTURING COMPANY,
P.O. Box 3633, TABUK-SAUDI ARABIA.

March 09
44196/RO