

**CLAMYCIN®
250 mg Tablets**

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about CLAMYCIN

CLAMYCIN is an antibiotic of the macrolide group. It contains 250 mg of clarithromycin and the following excipients: lactose, microcrystalline cellulose, talc.

Clarithromycin is active against a variety of aerobic and anaerobic gram-positive and gram-negative bacteria, as well as against most mycobacterium species.

Clarithromycin has been shown to be active against most strains of *Helicobacter pylori*, the bacteria involved in the pathogenesis of gastro-duodenal ulcers.

CLAMYCIN is indicated in the treatment of mild to moderate infections caused by susceptible bacteria:

- Upper respiratory tract infections: pharyngitis/tonsillitis, acute maxillary sinusitis.
- Lower respiratory tract infections: acute bacterial exacerbation of bronchitis, community-acquired pneumonia.
- Skin infections.
- Treatment and prevention of disseminated mycobacterial infections.
- Gastro-duodenal ulcers caused by *Helicobacter pylori* as triple therapy in combination with proton pump inhibitor or anti-H₂ and other anti-infective agent.

The way to take CLAMYCIN

Take CLAMYCIN as prescribed by your doctor.

CLAMYCIN may be given with or without food.

The dosage of Clarithromycin depends on the type and severity of the infection. The recommended dose in adults is 250mg (1 tablet) 2 times daily for 7 to 14 days. In case of severe infections, dosage can be increased up to 500mg (2 tablets) twice daily.

For the treatment and prevention of mycobacterial infections in adults, the usual dose is 500mg (2 tablets) twice daily.

For gastro-duodenal ulcer associated with *H. pylori* infection, CLAMYCIN is given 500mg (2 tablets) twice daily as triple therapy in association with anti-ulcer and other anti-infective drugs for 10 to 14 days.

In patients with severe renal impairment (creatinine clearance less than 30 ml/min), the dosage of this drug should be reduced by one-half.

Duration of treatment

The duration of therapy will be decided by your doctor and will depend on the type and severity of the infection.

The usual duration of treatment is 7 to 14 days. Do not discontinue your treatment without consulting your doctor, even if you begin to feel better; your symptoms may start to improve before the infection is completely treated.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- Known hypersensitivity to clarithromycin or any of the macrolide antibiotics.
- Patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of clarithromycin.
- Patients with severe liver insufficiency.

Precautions

-This drug should be administered with caution in elderly patients, in case of hepatic or renal impairment and in patients with myasthenia gravis.

-Tell your doctor if severe diarrhea occurs during treatment; this can be a sign of pseudomembranous colitis subsequent to the administration of antibacterial agents.

-This drug should be used with care in patients with a history of ventricular arrhythmias, severe cardiac insufficiency, uncorrected hypokalemia and or hypomagnesaemia, bradycardia (<50 bpm), or during concomitant administration with other medicinal products with a QT-prolonging effect. It should not be used in patients with congenital or documented acquired QT prolongation.

-Inform your doctor before using this medication in case of pregnancy or lactation. This drug is not recommended for use during pregnancy and in nursing mothers.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

-This drug is contra-indicated with colchicine, cisapride, pimozone, terfenadine, astemizole, ergotamine and derivatives.

-This drug should be used with caution when taken with: theophylline, carbamazepine, phenytoin, hexobarbital, disopyramide, quinidine, sildenafil, tadalafil, vardenafil, inhibitor of (HMG-CoA) reductase, ciclosporin, tacrolimus, digoxin, methylprednisolone, oral anticoagulants, rifabutin, antivirals, verapamil, itraconazole.

Adverse reactions

The most common side effects include: diarrhea, nausea, vomiting, abdominal pain, abnormal taste, dyspepsia, headache, smell alteration, reversible tooth and tongue discoloration, stomatitis, glossitis.

Other less common side effects may include: immunity disorders, hepatobiliary disorders, cardiac troubles, ear disorders, neurological troubles.

Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (below 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

CLAMYCIN, Clarithromycin 250 mg, pack of 14 Tablets

Revision date: 10/2011

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