

**Clarem 250** Film-Coated Tablets 250 mg

**Clarem 500** Film-Coated Tablets 500 mg

**Please read carefully this leaflet before you start taking the medicine.**

- Keep this leaflet in a safe place. You may need to read it again.
- If you have any questions ask your doctor or your pharmacist.
- This medicine was prescribed for you personally and you should not pass it on to others. It can be harmful, even when their symptoms are the same as yours.

**Composition:**

*Active substance:* Clarithromycin

*Excipients:* Microcrystalline Cellulose, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate, Hypromellose, Macrogol 400, Titanium Dioxide, Talc, Quinoline Yellow E104, Orange flavour, Povidone.

**Marketing Licence Holder & Manufacturer:**

Remedica Ltd, Limassol Industrial Estate, Limassol, Cyprus, EU.

**Marketing Licence Number:**

Clarem 250 : 19180

Clarem 500 : 19181

**1. WHAT CLAREM IS AND WHAT ITS USES ARE**

Clarithromycin, the active substance of Clarem, belongs to the group of antibiotics called macrolides. It is used in the treatment of bacterial infections appearing in various parts of our body. By its action Clarithromycin kills the microbes or inhibits their development. It should not be administered in the common cold, influenza or other infections caused by viruses.

**Indications:**

Clarem is indicated for the treatment of infections caused by strains of susceptible bacteria.

- Respiratory tract infections: acute and chronic bronchitis, pneumonia, sinusitis and pharyngitis.
- Skin and soft tissue infections of mild to moderate severity. Clarem is also indicated for the eradication of the helicobacter pylori in patients with duodenal ulcer.

**2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE CLAREM**

**Be particularly careful with Clarem:**

Inform your doctor:

- if you are allergic to Clarithromycin or to any other macrolide antibiotic,
- if you are pregnant or if you intend to become pregnant or if you are breast-feeding,
- if you suffer from hepatic or renal insufficiency.

**Contra-Indications:**

Clarithromycin is contra-indicated in patients with known hypersensitivity to macrolide antibiotic drugs. Clarithromycin and ergot derivatives should not be co-administered.

Concomitant administration of clarithromycin and any of the following drugs is contra-indicated: cisapride, pimozone and terfenadine. Elevated cisapride, pimozone and terfenadine levels have been reported in patients receiving either of these drugs and clarithromycin concomitantly. This may result in QT prolongation and cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation and Torsade de Pointes. Similar effects have been observed with concomitant administration of astemizole and other macrolides.

**Interactions:**

A number of medicines interact with Clarithromycin and should not be used concomitantly with clarithromycin. However, a few of them can be used concomitantly under special precautions. In this case, your doctor can change the posology or take other precautions if needed. If you are about to take Clarithromycin it is important to inform your doctor or pharmacist if you are taking any other medications and in particular any of the following:

Theophylline, carbamazepine, midazolam, triazolam, alprazolam, sildenafil, quinidine, tacrolimus, warfarin, digoxin, ergotamine or dihydroergotamine, phenytoin, disopyramide, symvastatin or lovastatin, cyclosporine, zidovudine, rifabutin, ritonavir, ranitidine, colchicine, omeprazole, Maalox.

**Special precautions:**

Caution is necessary in patient with hepatic function disorders.

**Pregnancy:**

Clarithromycin should not be used during pregnancy.

Consult your doctor or pharmacist before taking any medicine.

**Lactation:**

It should be used cautiously during lactation as it is not known if it is excreted into human milk.

Consult your doctor or pharmacist before taking any medicine.

**Driving and operating machinery:**

Caution is required as Clarithromycin may cause dizziness.

**3. HOW TO TAKE CLAREM**

Follow your doctor's instructions.

Respiratory, skin and soft tissue infections:

*Adults:* 250mg twice daily for 7 days. The dose may be increased to 500mg twice daily for up to 14 days in severe infections.

*Children over 12 years old:* Same as adults

*H. pylori-associated infection with duodenal ulcer (Adults):*

Triple therapy (7-14 days)

500mg clarithromycin twice daily with lansoprazole 30mg twice daily should be given with 1000mg amoxicillin twice daily for 7 - 14 days.

Triple therapy (7 days)

500mg clarithromycin twice daily with lansoprazole 30mg twice daily should be given with metronidazole 400mg twice daily for 7 days.

Triple therapy (7 days)

500mg twice daily and omeprazole 40mg daily should be given with 1000mg amoxicillin twice daily for 7 days

Triple therapy (10 days)

500mg clarithromycin twice daily should be given with 1000mg amoxicillin twice daily and omeprazole 20mg daily for 10 days.

Dual therapy (14 days)

500mg clarithromycin 3 times daily for 14 days. Clarem should be administered with omeprazole 40mg once daily for 28 days.

*Elderly:* As for adults

*Renal impairment:* 250mg once daily or 250mg twice daily in more severe infections.

Clarem can be taken either with or without food.

**Duration of Treatment:**

For the complete eradication of the infection, continue taking the drug for the whole period of treatment prescribed by the doctor, even if you feel better after a few days. If you stop taking the medicine abruptly without completing the treatment the symptoms may recur.

Clarithromycin is more effective when there is a constant concentration in the blood. Therefore, you should not stop taking the doses at constant time intervals, day and night. If, for example, you are to take 2 doses per 24 hours, then there must be an interval of 12 hours between every dose. If this interferes with your sleep or your every day activities or if you need assistance for scheduling the time that you will take the medicine, then consult your doctor or pharmacist.

**If you take a dose of Clarem larger than normal:**

In case you have taken a dose larger than normal, contact your doctor immediately.

Overdosage symptoms: gastro-intestinal symptoms and rarely altered mental status, paranoid behaviour, hypokalemia and hypoxemia.

Adverse reactions accompanying overdosage should be treated by gastric lavage and supportive measures.

**What you should know if you forget to take a dose:**

If you have to take the medicine continuously and you miss taking a dose, take the missed dose as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take double doses. In case you missed more than one dose consult your doctor because it may be necessary for the treatment to start again.

**4. POSSIBLE UNDESIRABLE EFFECTS**

As with all medicines Clarem may cause undesirable effects.

Most usual are:

Nausea, vomiting, dyspepsia, intestinal upsets, diarrhoea, urticaria, rashes and other allergic reactions, loss of hearing following large doses which is reversible on withdrawal of the drug, cholestatic jaundice, hepatitis, headache, disorders in the sense of smell and taste, discolouration of teeth and tongue, stomatitis, glossitis, arthralgia, myalgia, dizziness, vertigo, tinnitus, agitation, insomnia, nightmares, confusion, psychosis, hypoglycaemia, Stevens-Johnson syndrome, tachycardia.

If you experience undesirable effects not mentioned above, please contact your doctor.

**5. STORAGE OF Clarem**

**Product expiry date:**

Shown on the inner and outer packaging. In case the expiry date has lapsed, do not use.

**Special precautions for storage of the product:**

It is stored below 25°C, away from light and moisture and in a safe place out of the reach of children.

**6. OTHER INFORMATION**

For any other information regarding this pharmaceutical product, contact the Marketing License Holder.

**Date of last revision of leaflet:**

March 2007.

**Legal Category:**

This medicine is dispensed only by medical prescription.