

## Package leaflet: Information for the user

### Clarithromycin 250 mg film-coated tablets Clarithromycin 500 mg film-coated tablets clarithromycin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

- 1. What Clarithromycin is and what it is used for**
- 2. What you need to know before you take Clarithromycin**
- 3. How to take Clarithromycin**
- 4. Possible side effects**
- 5. How to store Clarithromycin Contents of the pack and further information**

#### **1. What Clarithromycin is and what it is used for**

Clarithromycin is an antibiotic belonging to a group called the macrolides. Antibiotics stop the growth of bacteria (bugs) which cause infections.

Clarithromycin is used to treat infections such as:

- Chest infections such as bronchitis and pneumonia
- Throat and sinus infections
- Skin and soft tissue infections such as cellulitis, folliculitis or erysipelas
- Infections caused by certain types of bacteria called Mycobacteriae
- *Helicobacter pylori* infection associated with duodenal ulcer.

#### **2. What you need to know before you take Clarithromycin**

##### **Do not take Clarithromycin if you:**

- are **allergic** to clarithromycin or other macrolide antibiotics, such as erythromycin or azithromycin, or any of the other ingredients of this medicine (listed in section 6).
- have **liver** or **kidney** problems. If you develop symptoms of hepatic disease such as anorexia, yellowing of the skin (jaundice), dark urine, pruritus or tender abdomen, please stop taking Clarithromycin and inform your doctor immediately (see section 4 'Possible side effects').
- you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called 'long QT syndrome'.
- have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- are taking medicines called ergot alkaloids, for example ergotamine or dihydroergotamine tablets (for migraines) or using ergotamine inhalers. Consult your doctor for advice on alternative medicines.
- are taking cisapride or domperidone (for stomach disorders), pimozone (for some mental illnesses), terfenadine or astemizole (for hay fever or allergy), as combining these drugs with clarithromycin can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- are taking other medicines which are known to cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- are taking lovastatin or simvastatin (used to lower increased blood fats such as cholesterol and

triglycerides) as combining these drugs with clarithromycin can sometimes cause a muscular condition called rhabdomyolysis.

- are taking ticagrelor (a blood thinning medicine) or ranolazine (to treat angina).
- are taking colchicine (for gout).
- are taking oral midazolam (for epilepsy, anxiety or to help sleep).
- are taking a medicine containing lomitapide

**Clarithromycin tablets are not suitable for use in children under 12 years of age.**

### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Clarithromycin if you:

- have myasthenia gravis (a disorder which causes muscle weakness).
- are pregnant, may be pregnant or are breast-feeding.
- if you develop severe or prolonged diarrhoea during or after taking clarithromycin, tell your doctor **immediately**, as this could be a symptom of more serious conditions such as pseudomembranous colitis or clostridioides difficile associated diarrhoea.
- if you develop any symptoms of liver dysfunction such as anorexia (loss of appetite), yellowing of the skin or whites of the eyes, dark urine, itching or tender abdomen, stop taking Clarithromycin tablets and tell your doctor **immediately**.
- if you need to have intravenous or oromucosal (absorbed in the mouth) midazolam
- if you have heart problems

Long term use of Clarithromycin tablets may lead to infection with resistant bacteria and fungi.

### **Other medicines and Clarithromycin:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Clarithromycin tablets **must not** be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozone, ticagrelor, ranolazine, colchicine, some medicines for treating high cholesterol and medicines that are known to cause serious disturbances in heart rhythm (see under **Do not take Clarithromycin tablets**).

In particular tell your doctor or pharmacist if you are taking the following medicines:

- digoxin, quinidine or disopyramide (for heart problems). Your heart may need to be monitored (ECG test) or you may need to have blood tests if you take clarithromycin with some medicines used to treat heart problems.
- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (for thinning the blood). It may be necessary to have blood tests to check that your blood is clotting efficiently.
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy).
- simvastatin or lovastatin (for high cholesterol).
- omeprazole (used for the treatment of indigestion and gastric ulcers) unless your doctor has prescribed it for you to treat *Helicobacter pylori* infection associated with duodenal ulcer.
- theophylline (used in patients with breathing difficulties such as asthma).
- triazolam, alprazolam or midazolam (sedatives).
- cilostazol (for poor circulation).
- methylprednisolone (a corticosteroid).
- ibrutinib or vinblastine (for treatment of cancer).
- ciclosporin, tacrolimus or sirolimus (immune suppressant used for organ transplants and severe eczema).
- quetiapine or other antipsychotic medicines.
- rifabutin, rifampicin, rifapentine, fluconazole or itraconazole (treatments for infectious diseases).
- tolterodine (for overactive bladder).
- ritonavir, efavirenz, nevirapine, atazanavir, saquinavir, etravirine or zidovudine (anti-viral or anti-HIV drugs).

- sildenafil, vardenafil or tadalafil (for impotence in adult males or for treating high blood pressure in the blood vessels of the lung).
- insulin, repaglinide or nateglinide (medicines for the treatment of diabetes).
- a herbal remedy called St John's Wort, used to treat depression.
- verapamil, amlodipine or diltiazem (for high blood pressure)

### **Pregnancy and Breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine as its safety in pregnancy and breast-feeding is not known.

### **Driving and using machines**

Clarithromycin tablets may cause dizziness, vertigo, confusion and disorientation. If you are affected do not drive or use machines.

### **Clarithromycin contains glucose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Clarithromycin contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

## **3. How to take Clarithromycin**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### Adults and children over 12 years

The recommended dose is one 250 mg tablet in the morning and one in the evening. In severe infections, your doctor may increase the dose to 500 mg twice daily. The usual length of treatment is between 6 and 14 days.

### Patients with kidney problems

If you have kidney problems or certain infections, your doctor may give you a different dose.

### Children younger than 12 years

These tablets are not suitable for children under 12 years. Your doctor will prescribe another suitable medicine for your child.

### **For infections caused by certain types of bacteria called mycobacteria:**

The recommended dose is 500 mg twice daily. Your doctor may increase the dose to 1000 mg twice daily if no response is seen after 3-4 weeks. For the prevention of mycobacterial infections, the usual dose is 500 mg twice daily.

### **For the treatment of *Helicobacter pylori* infection associated with duodenal ulcers:**

There are a number of effective treatment combinations available in which Clarithromycin is taken together with one or two other drugs. These include the following:

- Triple Therapy (7 days)  
Clarithromycin 500 mg twice daily together with amoxicillin 1000 mg twice daily and a proton pump inhibitor at the recommended daily dose for 7 days.
- Triple Therapy (7 days)  
Clarithromycin 500 mg twice daily together with a proton pump inhibitor at the recommended daily dose and metronidazole 400 mg twice daily for 7 days.
- Triple Therapy (7-10 days)

Clarithromycin 500 mg twice daily together with amoxicillin 1000 mg twice daily and omeprazole 20 mg once daily for 7-10 days.

- **Dual Therapy (14 days)**

Clarithromycin 500 mg three times daily for 14 days together with omeprazole 40 mg once daily. The treatment combination which you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking, or for how long you should be taking them, please consult your doctor for advice.

**If you take more Clarithromycin Tablets than you should**

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. An overdose of Clarithromycin tablets is likely to cause vomiting and stomach pains.

**If you forget to take Clarithromycin**

If you forget to take a dose take another as soon as you remember, unless it is nearly time for the next dose. **Do not** take two doses at the same time to make up for forgotten individual doses.

**If you stop taking Clarithromycin**

Do not stop taking Clarithromycin because you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor immediately if the following side effects occur:**

- Allergic reactions including rashes have been reported with clarithromycin. Allergic rashes may range in severity from mild itchy skin eruptions to rarer more serious skin eruptions (such as Stevens-Johnson syndrome). Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). In very rare cases, difficulty in breathing, fainting and swelling of the face and throat can occur which may need emergency treatment.
- If you develop loss of appetite, yellowing of the skin (jaundice), dark urine, itching or tenderness in the abdomen, contact your doctor immediately as these may be signs of liver failure. Severe or prolonged diarrhoea, which may have blood or mucus in it, during or after taking Clarithromycin. These could be symptoms of more serious conditions such as pseudomembranous colitis or clostridioides difficile associated diarrhoea. Diarrhoea may occur over two months after treatment with clarithromycin.

**Common side effects** (between 1 and 10 in every 100 people are likely to get these):

- stomach problems such as feeling or being sick, stomach pain, indigestion or diarrhoea.
- changes in liver enzymes (as seen in blood tests).
- rash, increased sweating, flushing.
- difficulty sleeping.
- changes in sense of taste.
- headache.

**Uncommon side effects** (between 1 and 10 in every 1,000 people are likely to get these):

- 'thrush' in the mouth, skin or in the genital area (yeast infections).
- change in the level of white blood cells in the blood (which can make infections more likely)
- change in the levels of blood platelets in the blood (increased risk of bruising, bleeding or blood clots)
- allergic reaction
- loss of appetite (anorexia).
- feeling of restlessness and agitation (anxiety).

- fainting, dizziness, drowsiness, tremors, involuntary movement of the tongue, face, lips or limbs.
- ‘ringing’ in the ears, hearing loss or balance problems (vertigo).
- irregular heart beat (arrhythmias) and palpitations.
- breathing problems (asthma), nosebleed
- blood clot in the lungs
- digestive problems such as constipation, belching, heartburn, abdominal distension (bloating), wind or anal pain.
- sore or dry mouth, swollen tongue.
- inflammation of the lining of the stomach or oesophagus (the tube connecting your mouth with your stomach).
- increased amounts of certain substances in the blood (transaminases, alkaline phosphatase and lactate dehydrogenase).
- liver disorders (hepatitis and cholestasis) which may cause yellowing of the skin (jaundice), pale stools or dark urine.
- itching (pruritus), hives (urticaria) and inflammation of the skin.
- fever, feeling unwell (asthenia), feeling tired, pain in the chest and feeling cold (chills).
- stiffness, aches or spasms in the muscles.
- kidney problems such as raised levels of protein normally excreted by the kidneys or raised levels of kidney enzymes.
- abnormal blood test results

**Frequency not known** (cannot be estimated from the available data):

- severe inflammation of the bowel (pseudomembranous colitis) linked to antibiotic use.
- severe skin infections (erysipelas).
- swelling of the skin around the face and the throat. This may cause difficulty in breathing (angioedema)
- a dangerous drop in a type of white blood cells. (agranulocytosis); a drop in the number of platelets (thrombocytopenia).
- psychotic disorder, hallucinations (seeing things), abnormal dreams, confusion, loss of sense of reality, depression, loss of bearings (disorientation), manic episodes.
- convulsions.
- loss of ability to taste and smell things.
- loss of hearing.
- accelerated (tachycardia) or irregular heart beat (Torsades de Pointes, ventricular fibrillation).
- haemorrhage (bleeding).
- inflammation of the pancreas (acute pancreatitis).
- teeth and tongue becoming discoloured.
- hepatic failure and jaundice (yellowing of the skin).
- rare allergic skin reactions such as AGEP (which causes a red, scaly rash with bumps under the skin and blisters), Stevens-Johnson syndrome or toxic epidermal necrolysis (which cause severe illness with ulceration of the mouth, lips and skin), DRESS (which causes severe illness with rash, fever and inflammation of internal organs) muscular problems like rhabdomyolysis, myopathy and myasthenia gravis (a condition in which the muscles become weak and tire easily).
- kidney problems (nephritis) and kidney failure.
- paraesthesia (tingling and burning sensation in the skin, numbness, ‘pins and needles’ sensation)

Clarithromycin may worsen the symptoms of myasthenia gravis (a condition in which the muscles become weak and tire easily) in patients who already suffer from this condition.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs

Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Clarithromycin**

Keep this medicine out of the sight and reach of children. Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton and blister foil after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Clarithromycin contains**

The active substance is clarithromycin. Each tablet either contains 250 mg or 500 mg of the active ingredient.

The other ingredients are: microcrystalline cellulose (E460), colloidal anhydrous silica, croscarmellose sodium, povidone, stearic acid, talc, magnesium stearate (E470), sorbitan monooleate (E494), hypromellose (E464), propylene glycol, vanilla dry flavour (contains artificial vanilla flavouring, glucose, palm oils and coconut oils), titanium dioxide (E171), quinoline yellow (E104), hyprollose (E463) and sorbic acid (E200-E201).

### **What Clarithromycin looks like and contents of the pack**

Film-coated tablets.

250 mg tablets: Yellow, oval-shaped, convex film-coated tablets scored on one side.

500 mg tablets: Yellow, oval-shaped, film-coated tablets.

Clarithromycin 250 mg and 500 mg film-coated tablets are packed in blisters with 14 tablets.

### **Marketing Authorisation Holder**

Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland.

### **Manufacturer**

Medochemie Ltd, Factory AZ, 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol, P.O. Box 51409, Cyprus

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