

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 any further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Clarithromycin Tablets are and what they are used for
2. What you need to know before you take Clarithromycin Tablets
3. How to take Clarithromycin Tablets
4. Possible side effects
5. How to store Clarithromycin Tablets
6. Contents of the pack and other information

1. What Clarithromycin Tablets are and what they are used for

The name of your medicine is Clarithromycin Tablets.

Clarithromycin belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria that cause infections.

Clarithromycin is used in the treatment of the following infections:

- Chest infections such as bronchitis and pneumonia
- Throat and sinus infections
- Mild to moderate skin and tissue infections
- Helicobacter pylori infection associated with duodenal ulcer.

Clarithromycin Tablets are indicated in adults and children 12 years and older.

2. What you need to know before you take Clarithromycin Tablets

Do not take clarithromycin if you:

- know that 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).
- are taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers for migraine.
- are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach problems) or pimozide (for mental health problems) as combining these drugs 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.
- are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).
- are taking oral midazolam (a sedative).
- have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- have severe liver disease with kidney disease.
- or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsade de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.
- are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina)
- are taking colchicine (usually taken for gout).
- 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 before taking clarithromycin:

- if you have liver or kidney problems– your doctor may need to adjust the dose (see also under “Do not take clarithromycin).
- if you have *H. pylori* infection – follow your doctor’s advice strictly, because careless use of clarithromycin may result in drug-resistant organisms.
- if you have or have had an allergic reaction to certain other antibiotics (**lincomycin** and **clindamycin**). There is a risk of an allergic reaction to clarithromycin as well (cross-hypersensitivity).
- if you have heart problems (e.g. heart disease, heart failure, an unusually slow/or irregular heart rate, coronary vessel disease or a weak heart) have low blood values of potassium and/or magnesium. The rhythm of heartbeat may become affected in such cases.
- if you have myasthenia gravis (a disease affecting muscle functions), symptoms may become more severe if clarithromycin is used.
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you are taking colchicines (medicine used for the treatment of gout).
- if you are pregnant or breast feeding

If you have any of the following conditions (now or in the past,) speak to your doctor before using clarithromycin:

- Tell your doctor immediately if you suffer from severe or prolonged diarrhoea during or after use of clarithromycin. Clarithromycin may cause a serious inflammation of the large intestine (pseudomembranous colitis) in very rare cases.
- Tell your doctor immediately if you suspect that during prolonged or repeated use of clarithromycin you (or your child) have developed a new infection. This may be a superinfection by micro-organisms which are not susceptible to clarithromycin.

Children

Do not give these tablets to children under 12 years. Your doctor will prescribe another suitable medicine for your child.

Other medicines and Clarithromycin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should not take clarithromycin if you are taking any of the following medicines (see section ‘Do not take clarithromycin if’):

- cisapride (gastric medicine), pimozide (antipsychotic), astemizole, terfenadine (antiallergic)
- ergot alkaloids e.g. ergotamine or dihydroergotamine (used for migraine)
- oral Midazolam (hypnotic)
- lovastatin or simvastatin (statins, medicines to lower cholesterol)
- ticagrelor (for stroke or heart attack)
- ranolazine (for chest pain)
- colchicine (to treat gout)

If your doctor has specifically recommended you take clarithromycin while taking any of the medicines mentioned below, your doctor may need to monitor you more closely, as your dose may need to be changed or you may need to have regular tests performed.

- digoxin, quinidine or disopyramide (heart medicines)
- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (for thinning the blood)
- carbamazepine, phenytoin, valproate (medicines to treat epilepsy)
- atorvastatin, rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins and used to lower levels of cholesterol (a type of fat in the blood)). Statins can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (used to lower blood glucose levels)
- gliclazide or glimepiride (sulphonylureas used in the treatment of type II diabetes)
- theophylline (used in patients with breathing difficulties such as asthma)
- triazolam, alprazolam, or intravenous or oromucosal midazolam (sedatives)
- cilostazol (for poor circulation)
- methylprednisolone (a corticosteroid)
- cyclosporine, sirolimus and tacrolimus (immune suppressants)
- etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral drugs used in the treatment of HIV)
- rifabutin, rifampicin, rifapentine, fluconazole (used in the treatment of certain bacterial infections)
- itraconazole (medicine to treat fungal infections)
- tolterodine (for overactive bladder)
- verapamil, amlodipine, diltiazem (for high blood pressure)
- sildenafil, vardenafil and tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- St John’s Wort (a herbal product used to treat depression)
- quetiapine or other antipsychotic medicines
- other macrolide medicines
- omeprazole (gastric medicine)
- vinblastine (for treatment of cancer)
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as clarithromycin may increase the chance of you getting side effects that affect your heart.

Clarithromycin Tablets with food and drink

Clarithromycin can be taken with or without food.

The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water).

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 before taking this medicine as the safety of clarithromycin tablets in pregnancy and breast-feeding is not known.

Driving and using machines

Clarithromycin Tablets may make you feel dizzy or drowsy. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

Clarithromycin Tablets contains lactose and sodium

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

Do not give these tablets to children under 12 years.

Always take Clarithromycin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Dosage in adults and adolescents (children over 12 years old):

The recommended dose is 250 mg twice daily.

Your doctor may increase the dose to 500 mg twice daily in severe infections. Treatment will last for between 6 and 14 days. Your doctor will decide the duration of your treatment.

Use in H. pylori infections:

In adult patients with gastro-duodenal ulcers due to H. pylori infection, clarithromycin as part of the "first line triple therapy" is given in a dosage of 500 mg twice daily.

Patients with kidney problems:

If you have severe kidney problems your doctor may need to reduce your dose by half, i.e. once daily and restrict treatment to 14 days at the most.

If you have the impression that the effect of clarithromycin is too strong or too weak, talk to your doctor or pharmacist.

If you take more Clarithromycin Tablets than you should

If you (or someone else) swallow a lot of the tablets all together, contact your nearest hospital casualty department or your doctor immediately.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

An overdose is likely to cause vomiting and stomach pains.

If you forget to take Clarithromycin Tablets

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet. Take the remaining doses at the correct time.

If you stop taking Clarithromycin Tablets

Do not stop taking your medicine even if 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.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

If you or your child suffer from any of the following at any time during your treatment STOP TAKING your tablets and contact your doctor immediately:

- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor.
- a rash, difficulty breathing, fainting or swelling of the lips, eyes, face and throat, itchy, red skin, skin eruption, inflammation of the tongue, mouth and lips and dizziness to shock (drop of blood pressure, restlessness, weak rapid pulse, clammy skin, reduced consciousness). This is a sign that you may have developed an allergic reaction.
- severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome: skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth/toxic epidermal necrolysis).
- rare allergic skin reactions which cause severe illness with ulceration of the mouth, lips and skin which causes severe illness with rash, fever and inflammation of internal organs (DRESS).
- inflammation of the skin characterized by the presence of the bullae which are filled with fluid, itchy and painful rash.
- yellowing of the skin (jaundice), skin irritation/itchiness, pale stools, dark urine, tender abdomen or loss of appetite. These are signs that the levels of products made by the liver are changed, there is an inflammation of the liver or that your liver may not be working properly.
- pain in your lower back, have difficulty passing urine, stop passing urine or if you have blood in your urine which may be signs of kidney problems.
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).
- chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat.
- asthma: lung disease associated with tightening of air passages, making breathing difficult.

Contact your doctor straight away if you or your child experience:

- nausea, vomiting, abdominal pain and back pain (pancreatitis).
- reduction in blood cells (thrombocytopenia) with bruises and tendency to bleed.
- ringing in the ears (tinnitus), hearing loss (usually reversible on withdrawal of treatment).

Other possible side effects:

Common side effects (may affect up to 1 in 10 people) include:

- difficulty sleeping
- changes in sense of taste
- headache

- widening of blood vessels
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion
- a change in the way the liver works
- increased sweating

Uncommon side effects (may affect up to 1 in 100 people) include:

- high temperature
- oral or vaginal 'thrush' (a fungal infection)
- inflammation of the stomach and intestines
- decrease of the levels of blood platelets (blood platelets help stop bleeding)
- decrease in white blood cells (leukopenia)
- decrease in neutrophils (neutropenia)
- stiffness
- chills
- increase of eosinophils (white blood cells involved in immunity)
- exaggerated immune response to a foreign agent
- lack or loss of appetite
- anxiety, nervousness
- drowsiness, tiredness, dizziness or shaking
- involuntary muscle movements
- vertigo
- nose bleed
- blood clot that causes sudden blockage in a lung artery (pulmonary embolism)
- inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- anal pain
- bloating, constipation, wind, burping
- dry mouth
- situation where the bile (fluid made by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis)
- inflammation of the liver
- muscle spasms, muscle pain or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily), clarithromycin may worsen these symptoms.
- raised abnormal kidney and liver function blood test and raised blood tests
- feeling weak, tired and having no energy

Not known (frequency cannot be estimated from the available data)

- inflammation of the colon
- bacterial infection of the outer layers of the skin
- confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares and mania (feeling of elation or over-excitement)
- convulsion (fits)
- paraesthesia, more commonly known as 'pins and needles'
- loss of taste or smell or inability to smell properly
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- loss of blood (haemorrhage)
- inflammation of the pancreas
- discolouration of the tongue or teeth
- acne

- change in the levels of products produced by the kidney, inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

Malta: ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

Ireland: HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clarithromycin Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Clarithromycin Tablets contain

- The active substance is clarithromycin.

Each Clarithromycin 250 mg Tablet contains 250 mg of clarithromycin.

Each Clarithromycin 500 mg Tablet contains 500 mg of clarithromycin.

- The other ingredients are lactose monohydrate, cellulose microcrystalline, sodium starch glycolate (Type A), hydroxypropyl cellulose, silica (colloidal anhydrous), talc, magnesium stearate and Opadry Y-1-7000 white which contains hypromellose, macrogol 400 and titanium dioxide.

What Clarithromycin Tablets looks like and contents of the pack

Each Clarithromycin Tablet is a white to off white, oval shaped, film coated tablet.

Clarithromycin 250 mg Tablets are debossed with 'W954' on one side and plain on the other side.

Clarithromycin 500 mg Tablets are debossed with 'W949' on one side and plain on the other side.

Both 250 mg and 500 mg Clarithromycin Tablets are available in the following packs:

PVC-PVdC blister packs containing 14 tablets.

The blisters are packaged in a carton.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder in Ireland and Malta**

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer:

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

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