

Package leaflet: Information for the patient

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 symptoms 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 the 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

Each Clarithromycin tablet contains 250 mg or 500 mg of the active ingredient clarithromycin. Clarithromycin belongs to a group of medicines called macrolide antibiotics.

Antibiotics stop the growth of bacteria (bugs) which cause infections. Clarithromycin Tablets are used in adults and children 12 years and older to treat infections such as:

- Bacterial pharyngitis
- Mild to moderate community acquired pneumonia
- Acute bacterial sinusitis (adequately diagnosed)
- Acute exacerbation of chronic bronchitis
- Skin infections and soft tissue infections of mild to
- Moderate severity

Clarithromycin Tablets are also used to treat *Helicobacter pylori* associated ulcers in adults (in appropriate combination with antibacterial therapeutic regimens and appropriate ulcer healing agent).

2. What you need to know before you take Clarithromycin Tablets**Do not take Clarithromycin Tablets if you**

- are **allergic** to clarithromycin, 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 or domperidone (for stomach disorders) 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).
- are taking a medicine containing lomitapide
- 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 torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.
- are taking medicines called ticagrelor, ivabradine or ranolazine (for angina or to reduce the chance of heart attack or stroke)
- are taking colchicine (usually taken for gout)

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Clarithromycin tablets;

- if you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate)
- if you have any liver or kidney problems
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you are pregnant or breast feeding

Children and Adolescents

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

Other medicines and Clarithromycin Tablets

You should **not** take this medicine if you are taking any of the other medicines listed in the section above “Do not take Clarithromycin Tablets if you;”

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as your dose may need to be changed or you may need to have regular tests performed:

- digoxin, quinidine or disopyramide (for heart problems)
- ibrutinib (for cancer treatment)
- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to thin your blood).
- carbamazepine, valproate, phenobarbital or phenytoin (for 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)
- methadone (used in the treatment of opioid addiction)
- vinblastine (for treatment of cancer)
- ciclosporin, 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, itraconazole (used in the treatment of certain bacterial 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)
- aminoglycosides (a group of antibiotic to treat certain bacteria for example gentamicin, neomycin) and other medicines that may be toxic to the ear.
- 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 getting abnormal heart rhythms and other serious side effects that affect your heart.
- corticosteroids (e.g. methylprednisolone), given by mouth, by injection or inhaled (used to help suppress the body’s immune system - this is useful in treating a wide range of conditions).
- quetiapine or other antipsychotic medicines.
- other macrolide medicines
- lincomycin and clindamycin (lincosamides—a type of antibiotic)

Please tell your doctor if you are taking oral contraceptive pills and diarrhoea or vomiting occurs, as you may need to take extra contraceptive precautions such as using a condom.

Clarithromycin Tablets with food, drink and alcohol

Clarithromycin can be taken with or without food.

Pregnancy, breast-feeding and fertility

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 this medicine in pregnancy and breast-feeding is not known.

Driving and using machines

This medicine 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 monohydrate

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

Information on sodium content

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

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

For chest infections, throat or sinus infections and skin and soft tissue infections:

Usual dose of this medicine for adults including the elderly and adolescents (children aged 12 years and over) is 500mg tablet once a day or 250 mg twice daily for 6 to 14 days, e.g. one 250 mg tablet in the morning and one in the early evening. Your doctor may increase the dose to 500 mg twice daily in severe infections.

Clarithromycin tablets should be swallowed with at least half a glass of water.

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

For adults including elderly, there are a number of effective combinations available to treat *H. pylori* in which this medicine are taken together with one or two other drugs.

Dual Therapy

This combination includes the following and are usually taken for 14 days: One Clarithromycin 500 mg tablet taken thrice a day along with omeprazole 40 mg once a day.

Triple Therapy

These combinations include the following and are usually taken for 6 to 14 days:

- a) One Clarithromycin 500 mg tablet taken twice a day along with amoxicillin 1000 mg twice a day and lansoprazole 30 mg twice a day.
- b) One Clarithromycin 500 mg tablet taken twice a day along with metronidazole 400 mg twice a day and lansoprazole 30 mg twice a day.
- c) One Clarithromycin 500 mg tablet taken twice a day along with amoxicillin 1000 mg twice a day or metronidazole 400 mg twice a day and omeprazole 40 mg once a day.
- d) One Clarithromycin 500 mg tablet taken twice a day along with amoxicillin 1000 mg twice a day and omeprazole 20 mg taken once a day.

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The treatment combination that 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 how long you should be taking them for, please consult your doctor for advice.

Clarithromycin Tablets should be taken with food and must be swallowed whole and not chewed.

Patients with kidney problems: If you have severe kidney problems, your doctor may need to reduce your dose by half, i.e. 250 mg once daily, or 250 mg twice daily in more severe infections and restrict treatment to 14 days at the most.

If you take more Clarithromycin than you should

If you accidentally take more of this medicine in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor or nearest hospital emergency department immediately. An overdose of this medicine is likely to cause vomiting and stomach pains.

If you forget to take Clarithromycin

If you forget to take a dose of this medicine, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Clarithromycin

Do not stop taking this 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, pharmacist or nurse.

4. Possible side effects

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

If you 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 face, tongue, lips, eyes and throat. This is a sign that you may have developed an allergic reaction.
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These are signs that your liver may have inflammation and not be working properly.
- severe skin reactions such as painful blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- a red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous

pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

- 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).
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)

These are very serious but rare side effects. You may need urgent medical attention or hospitalization.

The following side effects have been reported at the approximate frequencies shown:

Other side effects

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

- difficulty sleeping
- changes in sense of taste
- headache
- widening of blood vessels
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- increased sweating
- skin rash
- a change in the way the liver works

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

- high temperature
- swelling, redness or itchiness of the skin
- 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, tremor or shaking
- involuntary muscle movements
- vertigo
- ringing in the ears or hearing loss
- 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

- nosebleed
- inflammation of the mouth or tongue
- 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
- rectal pain
- bloating, constipation, wind, burping, heartburn
- dry mouth
- joint pain
- 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 skin characterized by the presence of the bullae which are filled with fluid, itchy and painful rash
- muscle spasms, muscle pain or loss of muscle tissue. If your child suffers 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
- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- 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
- leaking of blood from blood vessels (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)
- a change in the levels of products made by the liver, inflammation of the liver or an inability of the liver to function properly (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin).
- Deafness
- Low blood sugar levels

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 tablet contains 250 mg or 500 mg clarithromycin. The other ingredients are microcrystalline cellulose (E 460), croscarmellose sodium, colloidal anhydrous silica, powdered cellulose (E 460), magnesium stearate, hypromellose (E 464), titanium dioxide (E 171), macrogol and lactose monohydrate.

What Clarithromycin Tablets look like and content of the pack

Clarithromycin 250 mg film-coated tablets are white, oblong, biconvex film-coated tablets with ‘K’ and ‘250’ debossed on one side and plain on the other side.

Clarithromycin 500 mg film-coated tablets are white, oblong, biconvex, film-coated tablets with ‘K’ and ‘500’ debossed on one side and plain on the other side.

Clarithromycin tablets are available in blister packs containing 7, 14, 21, 28 or 56 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Clarithromycin 250 mg film-coated tablets; PL 17907/0690

Clarithromycin 500 mg film-coated tablets; PL 17907/0691

This leaflet was last revised in June 2025

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V 10 24-06-25 D0