

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 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
6. Contents of the pack and other information.

1. What Clarithromycin is and what it is used for

Clarithromycin belongs to a group of medicines called macrolide antibiotics. 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 tissue infections,
- *Helicobacter pylori* infection associated with duodenal ulcers.

This medicine is indicated in adults and children 12 years and older.

2. What you need to know before you take Clarithromycin

Do not take Clarithromycin 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).
- you are taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers for migraine.
- you have **severe** liver disease with kidney disease
 - you 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.
- you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- you 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).
- you are taking oral midazolam (a sedative).
- you have abnormally low levels of **potassium or magnesium** in your blood (hypokalaemia or hypomagnesaemia)
- you 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".
- you are taking colchicine (usually taken for gout),
- you are taking medicines called ticagrelor, ivabradine or ranolazine (for heart attack, chest pain or angina).
- you are taking a medicine containing lomitapide.
- you are taking a medicine called ivabradine due to the risk of Torsade de Pointes

Consult your doctor and take this medicine if any of the above cases apply to you, or that in the past.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clarithromycin;

- 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

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

Other medicines and Clarithromycin

You should not take Clarithromycin tablets if you are taking any of the medicines listed in the section above "Do not take Clarithromycin if;"

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 (for blood thinning)
- 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 glibenclamide (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)
- 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)
- 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)
- quetiapine or other antipsychotic medicines.
- other macrolide medicines
- lincomycin and clindamycin (lincosamides – a type of antibiotic)
- 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.

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.

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 for advice before taking this medicine as the safety of Clarithromycin tablets in pregnancy and breast-feeding is not known

Driving and using machines

Clarithromycin 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 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

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

Always take this medicine exactly as your doctor has told you. You should 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 Clarithromycin tablets for adults and children over 12 years is 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:

There are a number of effective treatment combinations available to treat *Helicobacter pylori* in which Clarithromycin tablets are taken together with one or two other drugs. These combinations include the following and are usually taken for 6 to 14 days:

- a. One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- b. One Clarithromycin 500 mg tablet taken twice a day together with metronidazole, 400 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- c. One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day or metronidazole, 400 mg taken twice a day plus omeprazole, 40 mg a day.

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- d. One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus omeprazole, 20 mg taken once a day.

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.

If you take more Clarithromycin than you should

If you accidentally take more Clarithromycin tablets 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 Clarithromycin, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Clarithromycin

Do not stop taking Clarithromycin tablets, even if you feel better. It is important that you take your medicine 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.

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).

Other side effects:

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

- difficulty sleeping
- headache
- changes in sense of taste
- widening of blood vessels
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- increased sweating

Uncommon (may affect 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 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
- 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 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
- 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)

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 Yellow Card Scheme at: 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

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 blister and 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 contains

- The active substance is clarithromycin. Each film-coated tablet contains 250 mg of clarithromycin. Each film-coated tablet contains 500 mg of clarithromycin
- The other ingredients are: Microcrystalline cellulose, croscarmellose sodium, silica, colloidal anhydrous, magnesium stearate, povidone, hypromellose, propylene glycol, titanium dioxide (E 171), hydroxypropyl cellulose, vanillin, sorbic acid and iron oxide yellow (E 172).

What Clarithromycin looks like and contents of the pack

Film-coated tablet

Clarithromycin 250 mg film-coated tablets: Light yellow coloured, oval shaped, biconvex film-coated tablets, with 'D' debossed on one side and '62' on the other side. The size is 15.1 mm x 7.1 mm

Clarithromycin 500 mg film-coated tablets: Light yellow coloured, oval shaped, biconvex film-coated tablets, with 'D' debossed on one side and '63' on the other side. The size is 18.5 mm x 8.1 mm

Clarithromycin 250 mg & 500 mg tablets are available in clear PVC/PVDC/Aluminium blister packs of 7, 12, 14 and 21 film-coated tablets.

Not all pack sizes may be marketed.

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