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Package leaflet: Information for the patient

Clarithromycin 250 mg and 500 mg Film-coated Tablets

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 or your pharmacist.
- 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 or pharmacist. 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 Tablet is and what it is 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 to treat infections such as:
1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and tissue infections
4. *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 Tablets if you;
- know that you are **allergic** to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the tablets.
- are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.
- are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride (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).
- have **severe** liver disease with kidney disease.
- or someone in your family has a history of heart rhythm disorders (ventricular cardia arrhythmia, including torsades 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
- have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)

Warnings and precautions
Talk to your doctor or pharmacist 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
Clarithromycin tablets are not suitable for use in children under 12 years of age.

Other medicines and Clarithromycin Tablets
You should not take clarithromycin tablets if you are taking any of the 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 test performed:
- digoxin, quinidine or disopyramide (for heart problems)
- ibrutinib (for cancer treatment)
- warfarin, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (for thinning the 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 rhabdomyolosis (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) 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)
- methadone (used in the treatment of opioid addiction)
- 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 you getting 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 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 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. Your doctor will prescribe another suitable medicine for your child.
Always take Clarithromycin tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Clarithromycin may be given with or without food.
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 amoxycillin, 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 amoxycillin, 1000 mg taken twice a day or metronidazole, 400 mg taken twice a day plus omeprazole, 40 mg a day.
d) One Clarithromycin 500 mg tablet taken twice a day together with amoxycillin, 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 tablets 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 clarithromycin tablets is likely to cause vomiting and stomach pains.

If you forget to take Clarithromycin tablets
If you forget to take a clarithromycin tablet, take one as soon as you remember. Do not take more tablets in one day than your doctor has told you to.

If you stop taking Clarithromycin tablets
Do not stop taking clarithromycin tablets, 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, clarithromycin tablets 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 may be 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 side effects of (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, diarrhoea
- increased sweating

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

- high temperature
- swelling, redness or itchiness of the skin, oral or vaginal 'thrush' (a fungal infection)
- inflammation of the stomach and intestines
- decrease in the level 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
- 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 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 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 side effects (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)
- convulsions (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 Tablets
Keep this medicine out of the sight and reach of children

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

This medicinal product does not require any special storage condition.

Do not throw away any medicines via wastewater or household water. 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
Each clarithromycin 250 mg and 500 mg film-coated tablet contain clarithromycin as active ingredient.

Core ingredients: cellulose microcrystalline, croscarmellose sodium, povidone, colloidal anhydrous silica, stearic acid, talc, magnesium stearate.

Coating Ingredients: Hypromellose, hydroxypropyl cellulose, titanium dioxide, propylene glycol, sorbitan monooleate, talc, sorbic acid and vanillin.

What clarithromycin Tablets looks like and contents of the pack
250 mg: White capsule shaped, film coated tablets embossed with 'C1' on one side and plain on other side.

500 mg: White capsule shaped, film coated tablets embossed with 'C2' on one side and plain on other side.

Blister pack of Alu/PVC/PVDC containing 7, 14 and 21 tablets.

HDPE bottle packs of 500's and 1000's tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Rudipharm Limited
Unit 6, Salbrook Road Industrial Estate
Salbrook Road, Redhill, Surrey, RH1 5GJ, UK

Manufacturer:
Rudipharm Limited
Oak House, Reeds Crescent,
Watford, WD24 4QP, UK

POM

To listen to or request a copy of this leaflet in Braille, large print or audio please call,

01293 827819 (UK only)

Please be ready to give the following information:

Product name	Reference number
Clarithromycin 250mg Film-coated Tablets	PL 49565/0029
Clarithromycin 500mg Film-coated Tablets	PL 49565/0030

This leaflet was last revised in February 2026.

Clarithromycin 250/500 mg Tablets - PIL
Dimension: 150 x 285 mm

Clarithromycin Tablets

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Headings: 9pt (Bold)
Sub-Heading: 7pt (Bold)
Normal Text: 7pt (Roman)

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