

Clarithromycin 250 mg & 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 is an antibiotic which belongs to the group of macrolide antibiotics. It stops the growth of certain bacteria. Clarithromycin is used to treat:

- Infections of the respiratory tract (nose, throat and lungs) such as pneumonia, bronchitis, sinusitis and pharyngitis.
- Mild to moderate skin and soft tissue infections.
- It can also be used, in combination with other antibacterials and appropriate ulcer healing agents, to eradicate *H. pylori* infections.

2 What you need to know before you take Clarithromycin

Do not take Clarithromycin

- if you are **allergic** to clarithromycin, other macrolide antibiotics or any of the other ingredients of this medicine (listed in section 6).
- if you or someone in your family has a history of **heart rhythm disorders** (ventricular arrhythmia, including torsades de pointes) or abnormality of electro-cardiogram (ECG, electrical recording of the heart) called "long QT syndrome".
- if you suffer from severe liver failure and **kidney** problems **at the same time**
- if you have abnormally low levels of **potassium or magnesium** in your blood (hypokalaemia or hypomagnesaemia)
- if you are taking
 - **ticagrelor** (to prevent blood clotting)
 - **ranolazine** (used to treat angina pectoris)
 - **ivabradine** (for heart attack, chest pain or angina)
 - **ergotamine, dihydroergotamine** (medicines to treat migraine)
 - **cisapride and domperidone** (gastric medicine)
 - **pimozide** (antipsychotic)
 - **terfenadine or astemizole** (hay fever, antiallergics)
 - **lovastatin, simvastatin** (medicines to lower cholesterol)
 - a medicine containing **lomitapide**
 - **colchicine** (to treat gout).
 - other medicines which are known to cause serious disturbances in heart rhythm

Warnings and precautions

Talk to your doctor or pharmacist before taking Clarithromycin

- if you have **reduced liver or kidney** function.
- if you develop severe or prolonged diarrhoea (pseudomembranous colitis) during or after taking Clarithromycin, consult your doctor immediately. Inflammation of the colon (Pseudomembranous colitis) has been reported with nearly all antibacterial medicines including clarithromycin.
- if you have, or have had, heart problems or
- if you have used clarithromycin before on several occasions or for a long time.

Other medicines and Clarithromycin

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

Certain other medicines may affect the effectiveness of Clarithromycin or vice-versa. Such medicines include:

Clarithromycin may increase the effect of the following medicines:

- Astemizole, terfenadine (antiallergic), pimozide (antipsychotic), cisapride and domperidone (gastric medicine), ergotamine, dihydroergotamine (migraine medicines), ibuprofen (chronic lymphocytic leukemia, lovastatin, simvastatin (medicines to lower cholesterol), ticagrelor (to prevent blood clotting), ranolazine (used to treat angina pectoris), colchicine (to treat gout) (see "Do not take Clarithromycin")
- Alprazolam, triazolam, midazolam (hypnotics)
- Digoxin, verapamil, amlodipine, diltiazem (heart medicines)
- Theophylline (antiasthmatic)
- Warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (used to thin your blood)
- Atorvastatin, rosuvastatin (cholesterol lowering agents)
- Cyclosporine, sirolimus, tacrolimus (immunosuppressants)
- Carbamazepin, phenytoin, valproate (medicines to treat epilepsy)

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- Cilostazol (used to improve circulation in the legs)
- Insulin and other medicines for the treatment of diabetes (such as nateglinide or repaglinide)
- Methylprednisolone (a cortisone to treat inflammation)
- Omeprazole (gastric medicine)
- Sildenafil, tadalafil, vardenafil (medicines to treat erectile dysfunction)
- Tolterodine (to treat overactive bladder syndrome)
- Vinblastine (medicine for cancer therapy)
- Medicines with the risk to affect hearing, especially aminoglycosides, such as gentamicin or neomycin (group of antibiotics)

This is also important if you are taking medicines called:

- 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, 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)

Both, the effect of Clarithromycin and the effect of the following medicines may be increased when taken together:

- Atazanavir, saquinavir (medicines to treat HIV)
- Itraconazole (medicine to treat fungal infections)

If your doctor has specifically recommended to take Clarithromycin and any of the above mentioned medicines at the same time, your doctor may need to monitor you more closely.

The following medicines may weaken the effect of Clarithromycin:

- Rifampicin, rifabutin, rifapentine (antibiotics)
- Efavirenz, etravirine, nevirapine (medicines to treat HIV)
- Phenytoin, carbamazepine, phenobarbitone (antiepileptic)
- St John's Wort

Please note

Ritonavir (antiviral) and **fluconazole** (medicine to treat fungal infections) may increase the effect of Clarithromycin.

Clarithromycin may weaken the effect of **zidovudine** (antiviral). In order to avoid this you should leave a 4 hour interval between taking these medicines.

The use of Clarithromycin at the same time as **digoxin, quinidine, disopyramide or verapamil** (heart medicines) or **other macrolide antibiotics** may cause cardiac arrhythmia.

Taking Clarithromycin with food and drink

Clarithromycin can be taken before, with or after 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 for advice before taking this medicine.

There is no data available on the effect of clarithromycin on fertility in humans. In the rat, fertility studies have not shown any evidence of harmful effects.

Driving and using machines

Clarithromycin has generally no effect on the ability to drive or use machines but may cause side effects such as dizziness, confusion and disorientation. If you feel affected you should not drive, operate machinery or take part in activities where you may put yourself or others at risk. Visual impairment and blurred vision may have an effect on a patient's ability to drive or operate machinery.

Clarithromycin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, 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. The dispensing label will tell you how much of this medicine you should take and how often you should take it. Please read it carefully. The dose your doctor prescribes depends on the type of infection and how bad the infection is. It also depends on how your kidneys are working. Your doctor will explain this to you.

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Adults and children over 12 years:

The usual dose is one 250 mg tablet twice a day for 6 to 14 days. For some infections, you may be instructed to take two 250 mg tablets or one 500 mg tablet twice a day.

For *Helicobacter Pylori* Infections:

One 500 mg tablet (or two 250 mg tablets) twice a day in combination with 1000 mg amoxicillin and 20 mg omeprazole twice a day for 7 days.

Patients with kidney problems:

Depending on your kidney function, your doctor may need to give you a lower dose than the normal adult dose.

Children (under 12 years old):

Clarithromycin Tablets are not recommended. Clarithromycin Suspension will usually be given.

If you take more of this medicine than you should

If you have taken too many Clarithromycin tablets, or if someone else has taken your Clarithromycin tablets, you/they should contact your doctor or your nearest hospital accident and emergency department immediately. Please take any remaining medicine with you in the carton in which it came so that the doctor or hospital staff will know what has been taken.

If you forget to take this medicine

Take it as soon as you remember. Then continue as before. Do not take any more tablets in one day than your doctor has prescribed.

If you stop taking this medicine

Do not stop taking Clarithromycin before the end of the course, even if you think the infection is better. Stopping early can mean that the infection quickly comes back. If you are not sure about anything, ask your doctor or pharmacist.

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.

Serious side effects

If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital.

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

- fever, sore throat or mouth ulcers due to infections (signs of low level of white blood cells)
- rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening, facial/throat swelling, blue discoloration of the lips, tongue or skin (signs of severe allergic reaction)
- irregular heart-beat (change in the electrical activity of the heart)
- yellow skin and eyes, nausea, loss of appetite, dark urine

Serious side effects with unknown frequency (frequency cannot be estimated from the available data):

- diarrhoea, abdominal pain, fever (signs of inflammation of the colon)
- severe pain in the abdomen and back, caused by pancreas inflammation
- high or low urine output, drowsiness, confusion, and nausea caused by kidney inflammation
- severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs
- unusual bruising or bleeding caused by low blood platelets
- fast or irregular heart beat
- severe bleeding
- abnormal breakdown of muscle, causing pain, fever, red-brown urine
- severely decreased urine output
- dermatitis bullous, rash, fever, blood alterations (which may be a sign of hypersensitivity syndrome, called DRESS), a red, scaly rash with bumps under the skin and blisters (acute generalised exanthematous pustulosis).

These are all serious side effects. You may need urgent medical attention.

Other possible side effects

Tell your doctor if any of the following side effects bother you.

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

- difficulty falling asleep
- headache
- changes in the senses of taste (for example metallic or bitter taste)
- abdominal pain, feeling or being sick, diarrhoea, indigestion, heart burn
- abnormal liver function test results
- rash
- excessive sweating.
- widening of blood vessels.

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

- yeast infections (candidiasis)
- infections of the vagina
- low levels of white blood cells, increased number of certain white blood cells
- decrease in neutrophils (neutropenia)
- loss or reduction of appetite
- anxiety

- dizziness, drowsiness, tremor, somnolence, shaking
- involuntary muscle movements
- impaired hearing
- spinning sensation
- ringing in the ears (tinnitus)
- inflammation of the stomach lining, constipation, wind, dry mouth, belching, swelling or bloating of the abdomen
- increase of liver enzymes in the blood
- generally feeling unwell, weakness, tiredness
- chest pain
- chills
- 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
- anal pain
- 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)
- raised abnormal kidney and liver function blood test and raised blood tests
- abnormal blood test result - high level of an enzyme called alkaline phosphatase in the blood that gives information about the health of bones or high level of an enzyme called blood lactate dehydrogenase in the blood that gives information about the health of certain organs

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

- nightmares, loss of bearings, confusion, disorientation, hallucinations (seeing things that are not there), psychosis (loss of contact with reality), a feeling of loss of identity, mania (feeling of elation or over-excitement), depression
- convulsions, loss of sense of taste or smell, tingling and numbness of the skin
- deafness
- certain bacterial infections of the skin and underlying tissues
- disturbed sense of smell, loss of sense of smell or taste
- tongue discolouration, tooth discoloration
- hemorrhage
- acne
- pain or weakness in muscles
- abnormal blood test results - prolonged blood clotting time
- urine colour abnormal.
- Problems with your eye sight (blurred vision)
- Impairment of vision

Clarithromycin may also affect some laboratory tests. If you have to go to hospital or doctors for a blood test it is important that you tell the doctor or nurse that you are taking clarithromycin.

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 (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. Store in the original package in order to protect from moisture. 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.

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 film-coated tablets contain:

The active substance is clarithromycin. Each film-coated tablet contains 250 mg or 500 mg clarithromycin.

The other ingredients are: croscarmellose sodium, microcrystalline cellulose, povidone, magnesium stearate, colloidal anhydrous silica, talc, hypromellose, propylene glycol, titanium dioxide (E171), hydroxypropylcellulose, sorbitan monooleate, quinoline yellow (E104), vanillin.

What Clarithromycin Tablets look like and the contents of the pack

Clarithromycin 250 mg film-coated tablets are dark yellow, film-coated capsule-shaped, tablets and are available in PVC/PVDC/Aluminium blister Pack sizes: 8, 10, 12, 14, 15, 16, 20, 21, 24, 49, 50, 100, 100x1.*

Clarithromycin 500 mg film-coated tablets are light yellow, film-coated, oval shaped tablets and are available in PVC/PVDC/Aluminium blister Pack sizes: 5, 6, 7, 8, 10, 12, 14, 15, 16, 20, 21, 30, 42, 50, 60, 100, 100x1, 140. Not all pack sizes may be marketed.

Marketing Authorisation Holders and Manufacturer

The marketing authorisation holder is: Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, United Kingdom

The manufacturer is: Novartis Pharmaceuticals S.R.L., Livenzeni Street no 7A, Targu Mures, RO – 540472, Romania.

Sandoz GmbH, Biochemiestraße 10, 6050 Kundl, Austria
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