

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 medicine called macrolide antibiotics. Antibiotics stop the growth of bacteria which cause infections.

Clarithromycin is used to treat following infections:

- Chest infections such as bronchitis and pneumonia,
- Throat and sinus infections,
- Skin and soft tissue infections,
- Helicobacter pylori infections associated with duodenal ulcers.

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).
- you have a history of certain abnormal **heart rhythms** (ventricular arrhythmia, including torsades de pointes) or changes in the heart activity as measured in the electro-cardiogram called "QT prolongation",
- you suffer from **severe** liver failure and kidney problems at the same time,
- You are taking medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride or pimozone tablets 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 have abnormally low levels of **potassium** in your blood (**hypokalaemia**)
 - 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 any of the following medicines
- **ergotamine, dihydroergotamine** (medicines to treat migraine)
- **lovastatin, simvastatin** (medicines to lower cholesterol),
- **colchicines** (medicine to treat gout),
- **ticagrelor or ranolazine** (medicines to prevent stroke or heart attack).

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 are allergic to lincomycin or clindamycin
- if you have reduced liver or kidney function,
- if you have, or have had, heart problems
- if you are pregnant (see section "Pregnancy, breast-feeding and fertility")
- if your blood magnesium level have previously been low.
- 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 used clarithromycin before on several occasions or for a long time.
- Patients should be advised to stop treatment and contact their doctor if signs and symptoms of anorexia, jaundice, dark urine, pruritus, or tender abdomen.
- if you take combination a combination of clarithromycin and benzodiazepines, such as alprazolam, triazolam and midazolam (see section "Other medicines and Clarithromycin")
- if you take other drugs which affect your auditory function. Loss of hearing will be checked during and after treatment.
- In the event of severe acute hypersensitivity reactions, such as anaphylaxis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, clarithromycin therapy should be discontinued immediately and appropriate treatment should be urgently initiated.

- Concomitant use of clarithromycin with lovastatin or simvastatin is contraindicated (see section "Do not take Clarithromycin if"). Caution should be exercised when using clarithromycin with other statins. If you also use oral anticoagulants besides clarithromycin. There is a risk of serious bleeding.

If any of these apply to you, consult your doctor before taking Clarithromycin tablets.

Other medicines and Clarithromycin

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

Clarithromycin may increase the effect of the following medicines:

- astemizole, terfenadine (antiallergic), pimozone (antipsychotic), cisapride (gastric medicine), ergotamine, dihydroergotamine (migraine medicines), lovastatin, simvastatin (medicines to lower cholesterol) (see "Do not take Clarithromycin")
- alprazolam, triazolam, midazolam (hypnotics)
- atorvastatin, rosuvastatin (cholesterol lowering agents)
- warfarin, phenprocoumon (blood thinners): concomitant use may increase the risk of bleeding. Checking of the blood clotting should be more frequent if Clarithromycin used concomitantly.
- Nateglinide, repaglinide or insulin (antidiabetics)
- carbamazepin, phenytoin, valproate (medicines to treat epilepsy)
- cilostazol (used to improve circulation in the legs)
- colchicine (to treat gout)
- cyclosporine, sirolimus, tacrolimus (immunosuppressants)
- digoxin, verapamil, quinidine, disopyramide (heart medicines), concomitant use of clarithromycin and these agents may cause cardiac arrhythmias..
- methylprednisolone (a cortisone to treat inflammation)
- omeprazole (gastric medicine)
- rifabutin (antibiotic)
- sildenafil, tadalafil, vardenafil (medicines to treat erectile dysfunction)
- theophylline (antiasthmatic)
- tolterodine (to treat overactive bladder syndrome)
- vinblastine (medicine for cancer therapy)
- medicines with the risk to affect hearing, especially aminoglycosides (group of antibiotics that are given to vein)
- atypical antipsychotics (e.g. quetiapine)

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.

Clarithromycin may weaken the effect of following medicines:

- zidovudine ((used to treat HIV infection). In order to avoid this you should leave a 4 hour interval between taking these medicines.

The following medicines may weaken the effect of Clarithromycin:

- rifampicin, rifabutin, rifapentine (antibiotics)
- efavirenz, nevirapine, etravirine (medicines to treat HIV)
- phenytoin, carbamazepine, phenobarbitone (antiepileptic)
- St John's Wort (a herbal product used to treat depression)

The following medicines may strengthen the effect of Clarithromycin:

- ritonavir (antiviral)
- fluconazole (medicine to treat fungal infections)

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

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

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.

If you are pregnant or breast-feeding do not take Clarithromycin before consulting your doctor.

Driving and using machines

Clarithromycin has generally no effect on the ability to drive or use machines. However, if side effects, such as dizziness, confusion and disorientation, your reaction may be adversely affected. Use caution when driving or operating machinery until you know how you react to this medicine.

3. How to take Clarithromycin

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

Clarithromycin may be taken with or without food

Clarithromycin 500 mg film-coated tablet is not suitable for doses below 500 mg. There are other options for this strength available on the market.

The recommendations for the usual doses are given below:

Adults including the elderly and adolescents (children over 12 years)

The usual dose is 250 mg twice a day. The usual dose is 250 mg twice daily. In severe infections, your doctor may increase the dose to 500 mg twice daily. The treatment takes 7-14 days and should last at least two days after the disappearance of the symptoms.

Use in infections with H. pylori:

In adult patients with ulcers of stomach and duodenum by infection with H. Pylori, as a part of triple combination therapy administered usual dose is 500 mg twice a day.

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.

Children under 12 years

Use of Clarithromycin tablets for children under the age of 12 years (under 30 kg bodyweight) is not recommended. Your doctor will prescribe another medication that is appropriate for your child.

For children with a body weight of more than 30 kg, the same dose as for adults is used.

If you feel that the effect of this medicine is too strong or too weak? Please contact your doctor or pharmacist.

If you take more Clarithromycin than you should

If you have taken too much of Clarithromycin, contact your doctor or nearest hospital emergency department as soon as possible. Overdose can cause gastrointestinal discomfort and possibly other complaints.

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

It is important that you take your medicine in accordance with the doctor's instructions. Do not suddenly stop using Clarithromycin without discussing it first with your doctor. Otherwise symptoms may return.

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:

- allergic reactions such as sudden difficulty in breathing, speaking and swallowing
- extreme dizziness or fainting
- severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs

Take as soon as possible, contact your doctor if the following symptoms develop:

- diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation. Your doctor may discontinue treatment. Do not take medicines that reduce bowel movements.
- Liver function with following possible symptoms
- loss of appetite
- yellowing of the skin or whites of the eyes (jaundice),
- pale stools, dark urine
- Itchy rash
- Abdominal pain
- Palpitations or irregular heartbeat
- severe pain in the abdomen and back, caused by pancreas inflammation

**Other possible side effects:**

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

- difficulty sleeping
- headache
- changes in sense of taste
- abdominal pain, nausea, vomiting, diarrhoea, indigestion
- abnormal liver function test results
- skin rash
- excessive sweating.

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

- yeast infections (candidiasis) (Eg: in the mouth)
- infections of the vagina
- reduction in the level of certain white blood cells, which can make infections more likely (leucopenia and neutropenia)
- increased number of certain white blood cells (eosinophilia)
- loss of appetite
- anxiety, dizziness, difficulty sleeping, chills
- spinning sensation
- impaired hearing, ringing in the ears (tinnitus)
- palpitations
- inflammation of the stomach, mouth and tongue
- Flatulence, constipation and indigestion
- dry mouth
- cholestasis
- increase of liver enzymes in the blood
- itching, hives
- muscle pain
- generally feeling unwell
- weakness
- chest pain
- chills
- fatigue

Frequency not known [frequency cannot be estimated from the available data]:

- Inflammation of the gut with severe diarrhoea called Pseudomembranous colitis,
- Saint Anthony's fire (erysipelas), acne
- severe reduction of white blood cells associated with sudden high fever, severe sore throat and mouth ulcers (agranulocytosis)
- unusual bruising or bleeding caused by low blood platelets
- Serious allergic reaction which causes swelling of the face or throat (angioedema)
- psychosis, a feeling of loss of identity
- confusion, change in sense of reality or panicking,
- depression, nightmares, disorientation, hallucinations, mania

- convulsions
- disturbed sense of smell, loss of sense of smell or taste
- deafness
- tingling or numbness in the hands or feet
- difficulty with your blood clotting
- discoloration of the teeth and tongue
- acne
- pain or weakness in muscles
- Inflammation of the kidneys, renal failure
- abnormal urine colour.

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).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

The United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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.

Marketing Authorisation Holder

UK_ Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

MT_ Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta
Waterfront
Floriana FRN 1913
Malta

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Cyprus	Clarithromycin Aurobindo 500 mg επικαλυμμένο με λεπτό υμένιο δισκία
Czech Republic	Clarithromycin Aurovitas
Denmark	Clarithromycin "Aurobindo"
France	CLARITHROMYCINE ARROW LAB 250 mg/ 500 mg, comprimé pelliculé
Malta	Clarithromycin 250 mg/ 500 mg film-coated tablets
Netherlands	Clarithromycine Aurobindo 250 mg/ 500 mg, filmomhulde tabletten
Romania	Claritromicină Aurobindo 250 mg/500 mg comprimat filmat
Spain	CLARITROMICINA AUROVITAS 500 mg comprimidos recubiertos con película EFG
Sweden	Clarithromycin Aurobindo 250 mg/ 500 mg filmdragerade tabletter
United Kingdom	Clarithromycin 250 mg/ 500 mg film-coated tablets

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