

Package leaflet: Information for the patient

Klariger 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 Klariger is and what it is used for
2. What you need to know before you take Klariger
3. How to take Klariger
4. Possible side effects
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1. What Klariger is and what it is used for

Klariger belongs to a group of medicines called macrolide antibiotics and is used to treat a variety of different infections in adults and children aged 12 years and older. These include infections of the skin and soft tissue or the respiratory system (nose, throat, chest, lungs).

Klariger can also be used (along with other medicines) to treat the infection *Helicobacter pylori* (*H. pylori*) in patients with duodenal ulcers.

2. What you need to know before you take Klariger

Do not take Klariger if you

- are allergic to clarithromycin or any similar macrolide antibiotic such as erythromycin, or any of the other ingredients of this medicine (listed in section 6)
- are already taking any of the following medicines:
 - ergot alkaloids (e.g. ergotamine or dihydroergotamine) (for migraine)
 - oral midazolam (a sedative)
 - lovastatin or simvastatin (statins, for high cholesterol)
 - colchicine (for gout)
 - ticagrelor, ivabradine or ranolazine (for angina or to reduce the chance of heart attack or stroke)
- are taking medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride (for stomach disorders) or domperidone (for nausea (feeling sick) and vomiting (being sick)) or pimozide (for psychiatric conditions) as combining these medicines can sometimes cause serious disturbances in heart rhythm
- are taking other medicines which are known to cause serious disturbances in heart rhythm
- have a history of heart rhythm disorders (ventricular cardiac arrhythmia, including Torsades de pointe) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called 'long QT syndrome'

- have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- have severe liver failure in combination with kidney problems
- you are taking a medicine containing lomitapide

Warnings and precautions

Talk to your doctor or pharmacist before taking Klariger if you:

- have kidney or liver problems
- have coronary heart disease, severe cardiac insufficiency or bradycardia (slow heart beat)

Other medicines and Klariger

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially any of the following:

- digoxin, quinidine, verapamil, amlodipine, diltiazem or disopyramide (heart drugs)
- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to thin your blood)
- ergotamine or dihydroergotamine (for migraine)
- carbamazepine, phenobarbital, valproate or phenytoin (drugs for epilepsy)
- theophylline (helps breathing)
- terfenadine or astemizole (for hay fever or allergy)
- domperidone (for nausea (feeling sick) and vomiting (being sick))
- triazolam, alprazolam or intravenous or oromucosal midazolam (sedatives)
- ibrutinib (an anti-cancer drug)
- statins (e.g. atorvastatin, rosuvastatin, cerivastatin for high cholesterol)
- cisapride (for stomach disorders)
- ciclosporin, sirolimus or tacrolimus (immune suppressant)
- pimozide, quetiapine or other medicines for psychiatric conditions
- zidovudine, ritonavir, atazanavir, saquinavir, etravirine, nevirapine or efavirenz (anti-viral drugs used to treat HIV infections)
- rifabutin, rifapentine or rifampicin (for treatment of some infections)
- fluconazole or itraconazole (antifungal)
- St John's wort (for depression)
- other antibiotics such as erythromycin
- colchicine (usually taken for gout)
- insulin or oral anti-diabetic drugs such as nateglinide or repaglinide (to reduce blood sugar levels)
- cilostazol (to improve blood circulation)
- methylprednisolone (anti-inflammatory)
- sildenafil, tadalafil or vardenafil (for erectile dysfunction)
- vinblastine (an anti-cancer drug)
- tolterodine (for urinary incontinence)

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).

Pregnancy and breast-feeding

Klariger **should not** be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby.

Do not breast-feed your baby, as small amounts of clarithromycin can pass into breast milk.

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.

Driving and using machines

Do not drive or operate machinery if you feel dizzy, confused or disorientated while taking this medicine.

Klariger 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 Klariger

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

- The tablets should be swallowed whole with some liquid.
- Tablets can be taken with or without food
- 500 mg tablets **should not** be halved

The recommended dose is:

To treat a respiratory, skin or soft tissue infection

Adults, elderly and children aged 12 years and older

The recommended dose is 250 mg twice a day. For severe infections your doctor may increase the dose to 500 mg twice a day. Treatment normally lasts for 6 to 14 days.

Use in children (under 12 years old)

Do not give this medicine to children under 12 years old.

To treat *Helicobacter pylori* infection in adults with duodenal ulcers

Klariger is usually combined with other medicines to treat *H. pylori* infection in adults with duodenal ulcers. The dose and how often you take it will depend on the other medicines your doctor gives you. It is important to take your medicine as advised by your doctor.

If you take more Klariger than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Signs of overdose include feeling or being sick, diarrhoea, indigestion or stomach pains.

If you forget to take Klariger

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Klariger

Keep taking your medicine until the course is finished. Do not stop taking your medicine just because you feel better. If you stop too soon the infection may come back again.

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 any of the following happen, stop taking Klariger and tell your doctor immediately or go to your nearest hospital emergency department:

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

- allergic reaction with symptoms that include severe itchy skin rash or swelling of the face, lips, tongue and/or throat which may cause difficulty breathing or swallowing
- signs of infection, such as fever, shivering, sore throat, tiredness, swollen glands, which may be a sign of low white blood cell count
- changes to the rhythm of your heart, such as a faster or irregular heartbeat
- liver problems, which may cause dark urine, pale stools, yellowing of the skin or whites of the eyes (jaundice), feeling sick, weight loss, which can lead to liver failure

Not known (frequency cannot be estimated from the available data):

- severe pain in the abdomen and back caused by inflammation of the pancreas
- severe diarrhoea with blood in the stools
- severe skin reactions, including widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) and with extensive peeling of the skin to more than 30% of the body surface (toxic epidermal necrolysis)
- a delayed allergic reaction with symptoms that include rash, swelling of the face, fever, swollen glands and abnormal blood results (drug reaction with eosinophilia and systemic symptoms)
- changes in how often or how much you urinate, maybe blood in the urine, possibly with lower back pain, rash, fever, feeling tired or weak, feeling or being sick (may be signs of problems with your kidneys)
- fast heartbeat with chest pain and shortness of breath
- red, swollen skin cause by bacterial infection
- loss of hearing
- bleeding or bruising more easily or more often than usual, may be signs of low platelet levels in the blood
- muscle weakness, tenderness or pain with dark urine

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).

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

Other possible side effects

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

- feeling sick (nausea), being sick, diarrhoea, indigestion, stomach pains
- swollen, painful, sore mouth or tongue (e.g. ulcers, cold sores)
- headache
- changes to your sense of taste, i.e. metallic or bitter taste
- difficulty sleeping
- rash
- increased sweating

- altered liver function tests, which would be seen in a blood test
- changes to the levels of some chemicals in the blood, which may be used to measure how your body is working and would be seen in a blood test

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

- vaginal infection
- feeling dizzy, vertigo, feeling anxious, shaking, drowsiness
- lack or loss of appetite, constipation, dry mouth, flatulence, feeling bloated, burping
- inflammation of the stomach (gastritis) with symptoms that include pain, feeling sick (nausea), vomiting, vomiting blood, blood in the stools
- itching
- itchy rash with red bumps (hives)
- weakness, fatigue, chills, chest pain, generally feeling unwell
- oral or vaginal thrush
- ringing in the ears, reduced hearing

Very rare (may affect up to 1 in 10,000 people):

- numbness, prickling or tingling sensation in arms and legs (pins and needles)
- nightmares

Not known (frequency cannot be estimated from the available data):

- mental health problems
- hallucinations (seeing or hearing things that are not real), abnormal dreams, depression, convulsions, feeling disorientated, confused or disconnected from yourself or your actions
- over active, excited behaviour
- change in urine colour
- acne
- change in colour of tongue or teeth
- changes to or loss of sense of smell
- loss of sense of taste by the tongue
- painful joints or muscles

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Klariger

Keep the medicine out of the sight and reach of children.

Do not use Klariger 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 Klariger contains

The active substance is clarithromycin. Each tablet contains 500 mg clarithromycin.

The other ingredients are microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium (See section 2 “Clarithromycin contains sodium”), povidone, colloidal anhydrous silica, stearic acid, magnesium stearate. The coating includes hypromellose (E464), hydroxypropyl cellulose (E463), titanium dioxide (E171), macrogol (E1520), vanillin, Quinoline yellow (E104).

What Klariger looks like and contents of the pack

Your medicine comes as a yellow, oval shaped, film coated tablet. The 500 mg tablets are marked ‘C500’ on one side and ‘G’ on the other.

Klariger is available in blisters and plastic bottles containing 4, 6, 7, 8, 10, 12, 14, 20, 21, 24, 28, 30, 42, 50, 60, 100, 250 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viartis Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland.

Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary.

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Ireland Klariger

This leaflet was last revised in 03/2025