

Package leaflet: Information for the patient

Clarithromycine Sandoz® 250 mg, filmomhulde tabletten Clarithromycine Sandoz® 500 mg, filmomhulde tabletten

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 [Nationally completed name] is and what it is used for
2. What you need to know before you take [Nationally completed name]
3. How to take [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Contents of the pack and other information

1. What [Nationally completed name] 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.

[Nationally completed name] is used in adults and adolescents (12 years and older) to treat infections caused by bacteria which are sensitive to clarithromycin, for example:

- **throat** and **sinus** infections
- **chest** infections, such as bronchitis and pneumonia
- **skin** and **soft-tissue** infections
- **gastric ulcers** caused by the bacterium *Helicobacter pylori*.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]

- 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 certain abnormal **heart rhythms disorders** (ventricular arrhythmia, including torsades de pointes) or abnormality of electro-cardiogram (ECG, electrical recording of the heart) called “longQT syndrome”,
- if you suffer from severe **liver** failure and **kidney** problems **at the same time**,
- if you have abnormally low level 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)
 - **ergotamine, dihydroergotamine** (medicines to treat migraine)
 - **oral midazolam** (for anxiety or to help sleep)
 - **cisapride** and **domperidone** (gastric medicine),
 - **pimozide** (antipsychotic),
 - **terfenadine, 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 are pregnant or if you think you may be pregnant or are planning to have a baby
- if you have reduced **liver** or **kidney function**,
- if you have **diabetes**
- if you develop **severe or prolonged diarrhoea** (pseudomembranous colitis) during or after taking [nationally completed name], consult your doctor immediately. Inflammation of the colon (Pseudomembranous colitis) has been reported with nearly all antibacterial medicines including clarithromycin.
- if you have **heart problems**

Other medicines and [Nationally completed name]

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

[Nationally completed name] must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozide, ticagrelor, ranolazine, colchicine, some medicines for treating high cholesterol and medicines that are known to cause serious disturbances in heart rhythm (see under **Do not take [nationally completed name]**).

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

[Nationally completed name] may increase the effect of the following medicines:

- Ibrutinib (chronic lymphocytic leukemia),

- Alprazolam, triazolam, intravenous or buccal (oromucosal) midazolam (for anxiety or to help sleep)
- Digoxin, quinidine, disopyramide, verapamil, amlodipine, diltiazem (heart medicines)
- Theophylline (antiasthmatic)
- Warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (used to thin your blood)
- Other Statins (not being contraindicated lovastatin and simvastatin) like atorvastatin, rosuvastatin (cholesterol lowering agents)
- Cyclosporine, sirolimus, tacrolimus (immunosuppressants)
- Carbamazepin, phenytoin, valproate (medicines to treat epilepsy)
- Cilostazol (used to improve circulation in the legs)
- Insulin and other medicines for the treatment of diabetes (such as nateglinide, pioglitazone, rosiglitazone 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)

Both, the effect of [Nationally completed name] and the effect of the following medicines may be increased when taken together:

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

If your doctor has specifically recommended to take [Nationally completed name] 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 [Nationally completed name]:

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

Please note:

- **Ritonavir** (antiviral) and **fluconazole** (medicine to treat fungal infections) may increase the effect of [Nationally completed name].
- [Nationally completed name] may weaken the effect of **zidovudine** (medicine to treat HIV). In order to avoid this you should leave a 4 hour interval between taking these medicines.
- The use of [Nationally completed name] at the same time as **digoxin, quinidine, disopyramide** or **verapamil** (heart medicines), or **other macrolide antibiotics** may cause cardiac arrhythmia.
- The use of [Nationally completed name] at the same time as **disopyramide** may cause low blood sugar levels (*hypoglycaemia*).

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 for advice before taking this medicine.

Driving and using machines

[Nationally completed name] 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.

[Nationally completed name] 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 [Nationally completed name]

The doctor will prescribe the individual dosage which is appropriate for you. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Adults and adolescents (12 years and older)

The recommended dose is 1 [Nationally completed name] 250 mg film-coated tablet twice daily. The dosage may be increased to 2 [Nationally completed name] 250 mg film-coated tablets twice daily or 1 [Nationally completed name] 500 mg film-coated tablet twice daily.

Gastric ulcers caused by the bacterium *Helicobacter pylori*:

2 [Nationally completed name] 250 mg film-coated tablets twice daily or 1 [Nationally completed name] 500 mg film-coated tablet twice daily in combination with suitable antibiotics and medicines which are used for the treatment of excess gastric acid production.

Children (younger than 12 years):

Use for children under the age of 12 years is not recommended.

For these patients other pharmaceutical forms e.g. suspensions are available.

Severe kidney failure

Your doctor will lower the dose.

Method of use

For oral use.

Take a glass of water with the medicine.

The medicine may be taken with or without food.

Duration of treatment

- The duration of treatment is generally 6–14 days. Treatment should continue for at least 2 days after the symptoms have disappeared.
- In the case of streptococcal infections the minimum duration of therapy should be 10 days.
- Treatment of gastric ulcer due to *Helicobacter pylori* should be continued for 7 days.

If you take more [Nationally completed name] than you should

If you have taken too much [Nationally completed name], contact your doctor or hospital as soon as possible. Symptoms of overdosage may be gastrointestinal symptoms.

If you forget to take [Nationally completed name]

If you forget to take [Nationally completed name], continue treatment following the normal dosage, recommended by your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking [Nationally completed name]

It is important that you take your medicine in accordance with the doctor's instructions. Do not suddenly stop using [Nationally completed name] 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:

Contact your doctor or the **casualty department** at your nearest hospital **immediately** if you have any of the following symptoms of a **severe allergic reaction**:

- Sudden difficulty in breathing, speaking and swallowing, swelling of the lips, face and neck
- Extreme dizziness or collapse
- Severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs.
- **Severe** and persistent **diarrhoea** during or after treatment, sometimes bloody-slimy and/or with cramp-like abdominal pain. This can be a sign of a serious bowel inflammation. Your doctor may discontinue treatment. Do not take medicines that reduce bowel movements.
- **Liver problems** with possible signs such as
 - loss of appetite,
 - yellowing of your skin or whites of your eyes (jaundice),
 - unusually dark urine, pale stools,
 - itching of the skin,
 - abdominal pain.
- Feeling your **heart beat** or irregular heart beat
- Inflammation of the pancreas, which causes **severe pain in the abdomen and back**.
- a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis)

Other side effects:

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

- Sleeplessness
- Headache
- Changes in the senses of taste or bad taste in the mouth (for example metallic or bitter taste)
- Stomach-ache, feeling sick, vomiting, diarrhea, digestive disorders
- Abnormal liver function tests results
- Rash
- Sweating
- Widening of blood vessels

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

- Yeast infections (candidiasis) for example in the mouth
- Infections of the vagina
- Reduced number of white blood cells (leucopenia, neutropenia)
- Increased number of certain white blood cells (eosinophilia)
- Allergic reactions
- Anorexia, loss of appetite
- Anxiety, dizziness, sleepiness, trembling
- Spinning sensation
- Impaired hearing, ringing in the ears (tinnitus)
- Changes in the heart activity as measured in the ECG called “QT prolongation”
- Feeling your heart beat
- Inflammation of the stomach, mouth and tongue
- Wind, constipation, belching, an inflated stomach/belly
- Dry mouth
- Failure of bile flow
- Inflammation of the liver
- Increase of liver enzymes in the blood
- Itching, hives
- Malaise
- Generally feeling unwell
- Weakness
- Chest pain
- Chills
- Tiredness
- Fainting
- Dermatitis bullous (see “Serious side effects” above)

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

- Inflammation of the bowel, from mild to severe (see “Serious side effects” above)
- Certain infections of the skin and underlying tissues (erysipelas)
- Severe decrease of certain white blood cells (agranulocytosis)

- Reduced number of blood platelets: signs may be unusual bruising and bleeding
- Severe allergic reaction (anaphylactic reaction; see “Serious side effects” above)
- Psychosis, a feeling of loss of identity
- A feeling of not being yourself, confusion
- Depression, abnormal dreams, disorientation, hallucinations, mania
- Fits
- Changes in the senses of smell, loss of sense of smell and taste
- Tingling or numbness
- Deafness
- Heart rhythm disturbances including life-threatening cases (ventricular arrhythmia, torsades de pointes; see “Serious side effects” above)
- Prolongation of the blood clotting time
- Acute inflammation of the pancreas (see “Serious side effects” above)
- Discoloration of the teeth and tongue
- Severe liver failure including life-threatening cases (see “Serious side effects” above)
- Yellowing of your skin or whites of your eyes (jaundice)
- Severe skin diseases with discomfort, redness, flaking and swelling (Stevens-Johnson syndrome, toxic epidermal necrolysis, DRESS; see “Serious side effects” above)
- Acne
- Pain or weakness in muscles
- Inflammation of the kidneys, kidney failure
- Urine color abnormal
- Problems with your eye sight (blurred vision)
- Impairment of vision.

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 [national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [\[Nationally completed name\]](#)

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 medicine does not require any special temperature storage conditions.
Store in the original carton in order to protect from light.

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 [Nationally completed name] 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:

Tablet core: croscarmellose sodium (E 468), microcrystalline cellulose (E 460), povidone, magnesium stearate (E 572), colloidal anhydrous silica (E 551), talc (E 553b).

Film-coating: hypromellose (E 464), propylene glycol (E 1520), titanium dioxide (E 171), hydroxypropylcellulose (E 463), sorbitan monooleate (E 494), quinoline yellow (E 104), vanillin.

What [Nationally completed name] looks like and contents of the pack

250 mg film-coated tablets: dark yellow, film-coated, capsule shaped tablets (15.6 x 7.9 mm).

500 mg film-coated tablets: light yellow, film-coated, oval shaped tablets (18.8 x 8.8 mm).

PVC/PVDC aluminium blister

Pack sizes:

250 mg film-coated tablets: 7, 10, 12, 14 or 21 film-coated tablets.

500 mg film-coated tablets: 7, 10, 14 or 21 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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MA-numbers:

RVG 107886
RVG 107902

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

The Netherlands	Claritromycine Sandoz 250 mg, 500 mg, filmomhulde tabletten
Belgium	Clarithromycine Sandoz 250 mg, 500 mg, filmomhulde tabletten
Bulgaria	Lekoklar 250 mg, 500 mg, film-coated tablets
Greece	Clarithromycin/Sandoz, 250 mg, 500 mg, επικαλυμμένα με λεπτό υμένιο δισκία
Spain	Claritromicina Sandoz 250 mg, 500 mg, comprimidos recubiertos con película EFG
Lithuania	Lekoklar 500 mg plėvele dengtos tabletės
Poland	Lekoklar mite Lekoklar forte
Romania	Lekoklar 250 mg, 500 mg, comprimate filmate
Slovakia	LEKOKLAR 250 mg, 500 mg, filmom obalené tablety

Deze bijsluiter is voor het laatst goedgekeurd in juni 2021