Package leaflet: Information for the patient

Claritromycine Sandoz® 125 mg/5 ml, granulaat voor orale suspensie
Claritromycine Sandoz® 250 mg/5 ml, granulaat voor orale suspensie
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

Clarithromycin is an antibiotic which belongs to the group of macrolide antibiotics. It stops the growth of certain bacteria.

[Nationally completed name] is used to treat:
- Throat and sinus infections
- Middle ear infections in children
- 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 **heart rhythm disorders** (ventricular arrhythmia, including torsades de pointes) or abnormality of the electrocardiogram (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)
    - **ergotamine, dihydroergotamine** (medicines to treat migraine)
    - **oral midazolam** (for anxiety or to help sleep)
    - **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 [Nationally completed name]
- if you have **reduced liver** or **kidney function**
- 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 suffer from **myasthenia gravis**, a rare disease which causes muscle weakness
- if you have **diabetes**
- 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 [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 [Nationally completed name] or vice-versa.

Such medicines include:

[Nationally completed name] may increase the effect of the following medicines:
- ibrutinib (a medicine to treat chronic lymphocytic leukemia),
- Alprazolam, triazolam, intravenous or buccal (oromucosal) midazolam (for anxiety or to help sleep)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)
- 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)

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 (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, phenobarbitone (antiepileptic)
- St John's Wort

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** (antiviral). 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 for advice before taking this medicine.

Driving and using machines
[Nationally completed name] has generally no effect on the ability to drive and 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 sucrose and sodium
This medicine contains 2.4 g sucrose per 5 ml ready-for-use suspension. This should be taken into account in patients with diabetes mellitus.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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]

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. 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 well the kidneys are working. Your doctor will explain this to you.

Adults and adolescents:
The usual dose is 250 mg twice a day.
For severe infections or gastric ulcers caused by Helicobacter pylori the usual dose is 500 mg twice a day.

Children 6 months to 12 years:
The daily amount is worked out according to the weight of the child.

The following table provides a guide to usual doses:

125 mg/5 ml granules for oral suspension:

Body weight (in kg)	Age (years)	Dosage (in ml) given twice daily
8 – 11	1 – 2	2.5
12 – 19	2 – 4	5
20 – 29	4 – 8	7.5
30 – 40	8 – 12	10

250 mg/5 ml granules for oral suspension:

Body weight (in kg)	Age (years)	Dosage (in ml) given twice daily
12 – 19	2 – 4	2.5
20 – 29	4 – 8	3.75
30 – 40	8 – 12	5

Children who weigh less than 8 kg should be given a dose of 7.5 mg/kg twice a day.

Duration of treatment
Your doctor will tell you how long [Nationally completed name] should be used, normally between 5 and 14 days. Do not stop treatment on your own decision, e.g. because you or your child feels better. If the use is stopped too early, the infection may return.

Method of use
Usually this medicine is given twice a day, once in the morning and again in the early evening.
You may take this medicine with or without food.
This medicine can cause a bitter aftertaste when remaining in the mouth. This can be avoided by eating or drinking something immediately after the intake of the suspension.

How to measure the dose
A 5 ml syringe marked at 2.5, 3.75 and 5 ml is provided with this medicine. It comes with an adaptor which fits onto the bottle. To measure the medicine:
- Shake the bottle
- Put the adaptor into the mouth of the bottle
- Put the end of the syringe into the adaptor
- Turn the bottle upside-down
- Pull the plunger to measure the dose you need
- Turn the bottle upright, remove the syringe, leave the adaptor on the bottle and close the bottle

Always remember to shake the bottle before measuring out each dose.

Giving the medicine using the syringe:
- Make sure the child is supported in an upright position.
- Put the tip of the syringe carefully into the child's mouth. Point the tip of the syringe towards the inside of the cheek.
- Slowly push down the plunger of the syringe: Do not squirt it out quickly.
- Allow the child time to swallow the medicine.

Alternatively, empty the measured dose from the pipette onto a spoon for your child to take the medicine from.

How to prepare this medicine
A doctor or pharmacist will prepare this medicine for you. To open the medicine bottle, you need to press the childproof top down and then turn it.

If you need to prepare this medicine yourself, you should fill the bottle with cold water to just under the measurement line marked on the bottle. Shake it well as soon as you have done that.

Then put more water in right up to the measurement line marked on the bottle and shake it again.

You only need to prepare the suspension once, at the beginning of your course.

If you take more [Nationally completed name] than you should
If you have taken too much of this medicine, 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 this medicine, 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 this medicine 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:

Uncommon serious side effects (may affect up to 1 in 100 people):
- allergic reactions such as sudden difficulty in breathing, speaking and swallowing, swelling of the lips, face and neck, extreme dizziness or collapse, itchy, raised skin rash
- irregular heart-beat (change in the electrical activity of the heart)
- risk of blood clotting, caused by a high level of blood platelets
- dermatitis bullous

Serious side effect with unknown frequency:
- fever, sore throat, more frequent infections, caused by a serious shortage of white blood cells (agranulocytosis)
- rash, fever, blood alterations (which may be a sign of hypersensitivity syndrome, called DRESS).
- yellowing of the skin and eyes, nausea, loss of appetite, abnormal liver blood test results (signs of liver disorders)
- 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
- 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
- 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):
- headache
- changes in the senses of taste (for example metallic or bitter taste)
- abdominal pain, feeling or being sick, diarrhoea, indigestion
- difficulty in sleeping
- abnormal liver function test results
- rash
- excessive sweating
- widening of blood vessels

Uncommon (may affect up to 1 in 100 people):
- low level of white blood cells
- inflammation of the stomach and intestines
- increase of liver enzymes in the blood
- decrease in neutrophils (neutropenia)
- increase of eosinophils (white blood cells involved in immunity)
- yeast infections (candidiasis)
- infections, for example of the vagina
- loss or reduction of appetite
- anxiety, nervousness, screaming
- involuntary muscle movements
- drowsiness, dizziness, tremor, somnolence, shaking, fainting
- spinning sensation, impaired hearing, ringing in the ears (tinnitus)
- chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat
- feeling your heart beat
- inflammation of the stomach lining, constipation, wind, dry mouth, belching
- itching, hives, red raised rush
- muscle spasms
- fever, weakness
- 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)
- inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- raised abnormal kidney and liver function blood test and raised blood tests

Frequency not known (frequency cannot be established from available data):
- discoloration of the teeth and tongue
- certain bacterial infections of the skin and underlying tissues
- disturbed sense of smell, loss of sense of smell or taste
- deafness
- acne
- depression
- pain or weakness in muscles
- abnormal urine colour
- nightmares, loss of bearings, confusion, disorientation, seeing feeling or hearing things that are not there, loss of contact with reality, a feeling of loss of identity, mania (feeling of elation or over-excitement)
- convulsions, tingling and numbness of the skin
- bleeding
- impairment of vision
- problems with your eye sight (blurred 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 carton and bottle after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.
After reconstitution: Do not store above 25°C.

The suspension must be used within 14 days after preparation.

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.
  - After reconstitution 1 ml oral suspension contains 25 mg of clarithromycin, 5 ml oral suspenstion contain 125 mg of clarithromycin.
  - After reconstitution 1 ml oral suspension contains 50 mg of clarithromycin, 5 ml oral suspenstion contain 250 mg of clarithromycin.
- The other ingredients are poloxamer 188, povidone K30 (E 1201), hypromellose(E 464), macrogol 6000, titanium dioxide (E 171), methacrylic acid – ethyl acrylate copolymer (1:1), triethyl citrate (E 1505), glycerol monostearate, polysorbate 80 (E 433), sucrose, maltodextrin, potassium sorbate (E 202), colloidal anhydrous silica (E 551), xanthan gum (E 415), fruit punch flavouring (natural and artificial flavouring substances including maltodextrin, modified starch, sodium and maltol).

What [Nationally completed name] looks like and contents of the pack
Granules for oral suspension.
60 ml, 120 ml and 240 ml white to beige granules in HDPE bottles with child resistant PP-screw closures and oral PE/PP-measuring syringe (5 ml) with filling marks at 2.5 ml, 3.75 ml and 5.0 ml and/or a PE/PP-measuring spoon with filling marks at 1.25 ml, 2.5 ml and 5.0 ml.

NL/H/2099/001
Pack sizes:
1 bottle contains 34.1 g granules for oral suspension for 50 ml ready-for-use suspension (required water amount: 29.5 ml) or
41.0 g granules for oral suspension for 60 ml ready-for-use suspension (required water amount: 35.4 ml) or
54.6 g granules for oral suspension for 80 ml ready-for-use suspension (required water amount: 47.2 ml) or
68.3 g granules for oral suspension for 100 ml ready-for-use suspension (required water amount: 59.0 ml) or
81.9 g granules for oral suspension for 120 ml ready-for-use suspension (required water amount: 70.8 ml).

NL/H/2099/002
Pack sizes:
1 bottle contains 34.1 g granules for oral suspension for 50 ml ready-for-use suspension (required water amount: 28.5 ml) or
41.0 g granules for oral suspension for 60 ml ready-for-use suspension (required water amount: 34.2 ml) or
54.6 g granules for oral suspension for 80 ml ready-for-use suspension (required water amount: 45.6 ml) or
68.3 g granules for oral suspension for 100 ml ready for use suspension (required water amount: 57.0 ml).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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MA-number:
Claritromycine Sandoz 125 mg/5 ml, granulaat voor orale suspensie: RVG 108099
Claritromycine Sandoz 250 mg/5 ml, granulaat voor orale suspensie: RVG 108098

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

Belgium	Clarithromycin Sandoz 250 mg / 5 ml, 125 mg / 5 ml, granulaat voor orale suspensie
Bulgaria	Lekoklar
Estonia	Lekoklar
Greece	Clarithromycin/Sandoz
Italy	Claritromicina Sandoz GmbH
Netherlands	Claritromycine Sandoz 250 mg/5 ml, 125 mg/5 ml, granulaat voor orale suspensie
Poland	Lekoklar
Romania	Lekoklar 250 mg/5 ml, granule pentru suspensie orală
Slovak Republic	LEKOKLAR 250 mg/5 ml, 125 mg/5 ml, granulát na perorálnu suspenziu
Lithuania	Lekoklar 125 mg/5 ml, granulės geriamajai suspensijai

Deze bijsluiter is voor het laatst goedgekeurd in juni 2021

The following information is intended for healthcare professionals only:

NL/H/2099/001
For the preparation of the suspension fill the bottle with the following amount of water:
- For 50 ml bottle add 29.5 ml of water
- For 60 ml bottle add 35.4 ml of water
- For 80 ml bottle add 47.2 ml of water
- For 100 ml bottle add 59.0 ml of water
- For 120 ml bottle add 70.8 ml of water

NL/H/2099/002
For the preparation of the suspension fill the bottle with the following amount of water:
- For 50 ml bottle add 28.5 ml of water
- For 60 ml bottle add 34.2 ml of water
- For 80 ml bottle add 45.6 ml of water
- For 100 ml bottle add 57.0 ml of water

Shake the bottle well as soon as you have filled it with water. After reconstitution with water the medicinal product results in a white to beige suspension.