

Clarithromycin Sandoz®

Clarithromycin (kla-ree-thro-MY-sin) tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Clarithromycin Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking Clarithromycin Sandoz against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

WHAT CLARITHROMYCIN SANDOZ IS USED FOR

Clarithromycin Sandoz is used to treat certain bacterial infections, including the following:

- respiratory tract infections (throat, airways and lungs)
- ear infections
- skin infections
- peptic ulcer

Clarithromycin Sandoz is also used to prevent a specific bacterial infection associated with HIV infection.

Clarithromycin Sandoz is an antibiotic that belongs to the group of medicines called macrolides.

These medicines work by killing or

stopping the growth of bacteria which cause infections. It contains the active ingredient clarithromycin.

Your doctor, however, may have prescribed Clarithromycin Sandoz for another purpose. Ask your doctor if you have any questions about why Clarithromycin Sandoz has been prescribed for you.

Clarithromycin Sandoz will not work against infections caused by viruses, such as colds or flu.

Clarithromycin Sandoz to treat peptic ulcer

Peptic ulcers are associated with an infection in the intestine and stomach by a bacteria called *Helicobacter pylori* (*H. pylori*). Nearly all patients with peptic ulcers are infected with this bacteria.

The *H. pylori* infection can be treated with a combination of Clarithromycin Sandoz (clarithromycin), another appropriate antibiotic and stomach acid control treatments.

However, the best combination of tablets to treat *H. pylori* infection is yet to be determined. Your doctor will determine the best combination for you.

If your symptoms return, consult your doctor. It is possible that Clarithromycin Sandoz may no longer be effective in treating the *H. pylori* infection and a different antibiotic may be needed.

There is no evidence that Clarithromycin Sandoz is addictive. Clarithromycin Sandoz is only available with a doctor's prescription.

BEFORE YOU TAKE CLARITHROMYCIN SANDOZ

When you must not take it

Do not take Clarithromycin Sandoz if you have an allergy to:

- medicines containing clarithromycin, the active ingredient or to any of the other ingredients mentioned at the end of this leaflet under Product Description.
- other antibiotics from the macrolide family, such as, erythromycin, roxithromycin or azithromycin.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing or swallowing.

Do not take Clarithromycin Sandoz if you have any of the following medical conditions:

- severe liver problems
- poor kidney function
- cardiac arrhythmia (irregular heartbeat)
- heart condition called long QT syndrome (or QT prolongation)
- hypokalaemia (low potassium levels in blood).

Do not take Clarithromycin Sandoz if you are currently also taking the medicines:

- astemizole or terfenadine (commonly used to treat allergy symptoms – these medicines may be available without a prescription)

- cisapride (used to relieve certain stomach problems)
- domperidone (used for nausea)
- pimozide (used to treat schizophrenia)
- ergotamine or dihydroergotamine (used to treat headaches)
- lovastatin or simvastatin (used to treat high cholesterol)
- ticagrelor or ranolazine (used to prevent blood clotting)
- colchicine (used to treat gout)
- midazolam tablets or syrup (used to treat sleeplessness and anxiety).

Taking Clarithromycin Sandoz with any of the above medicines may cause serious side effects.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as Clarithromycin Sandoz
- any other substances, including foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking Clarithromycin Sandoz when pregnant.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking Clarithromycin Sandoz when breastfeeding.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems, including slow heart rate
- liver problems
- poor kidney function
- myasthenia gravis, a condition which the muscles become weak and tire easily
- intolerance to sugars
- low magnesium or any other electrolyte imbalances.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking Clarithromycin Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Clarithromycin Sandoz may interfere with each other. These include the medicines already listed under "When you must not take Clarithromycin Sandoz" (see above) and the following medicines

- digoxin, quinidine, disopyramide (used to treat heart failure)
- warfarin and other anticoagulants (used to prevent blood clotting)
- phenytoin, carbamazepine, phenobarbital (phenobarbitone), sodium valproate (used to treat epilepsy)
- theophylline (used to treat asthma)
- triazolam, alprazolam, midazolam (used to treat sleeplessness and anxiety)
- cilostazol (use to treat poor circulation)

- statins such as rosuvastatin, atorvastatin (used to treat high cholesterol)
- methylprednisolone (a corticosteroid)
- vinblastine (used to treat cancer)
- sildenafil, tadalafil or vardenafil (used to treat erectile dysfunction in adult males)
- ciclosporin, tacrolimus (medicines affecting the immune system)
- medicines used to treat HIV infection
- rifabutin, rifapentine, rifampicin (used to treat some infections)
- repaglinide, nateglinide, pioglitazone, rosiglitazone (used to treat diabetes)
- insulin (used to treat diabetes)
- calcium channel blockers such as verapamil, amlodipine, diltiazem (used to treat high blood pressure)
- fluoxetine (used to treat depression)
- omeprazole (used to treat stomach problems)
- aminoglycosides (used to treat infections)
- fluconazole and itraconazole (used to treat fungal infections)
- tolterodine (used to treat bladder symptoms)
- herbal medicines such as St John's Wort
- quetiapine (used in psychotic disorders)
- ibrutinib (used in cancer therapy)

These medicines may be affected by Clarithromycin Sandoz, or may affect how well it works. You may need to use different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE CLARITHROMYCIN SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The dose of Clarithromycin Sandoz will depend on the infection to be treated.

For respiratory tract infections and skin infections, the usual adult dose is one Clarithromycin Sandoz 250mg tablet twice a day.

For more severe infections, the dose can be increased to two Clarithromycin Sandoz 250mg tablets twice a day.

Your doctor will adjust the amount or frequency of your doses according to the infection being treated and the severity of your condition.

How to take it

Clarithromycin Sandoz tablets should be swallowed whole with a glass of water.

If you need to break Clarithromycin Sandoz, hold tablet with both hands and snap along break line.

When to take it

Take Clarithromycin Sandoz at about the same time each day.

This will allow your medicine to have the best effect and help you remember to take it.

How long to take it

Keep taking Clarithromycin Sandoz until you finish the pack or for as long as your doctor tells you. If you are being treated for an infection,

Clarithromycin Sandoz is usually taken for one or two weeks.

Do not stop taking Clarithromycin Sandoz, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

Check with your doctor if you are not sure how long you should be taking Clarithromycin Sandoz.

If you forget to take your dose

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Clarithromycin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include severe gastrointestinal symptoms, liver problems, or allergic reactions.

WHILE YOU ARE USING CLARITHROMYCIN SANDOZ

Things you must do

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Clarithromycin Sandoz.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Clarithromycin Sandoz.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are taking Clarithromycin Sandoz for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea, tell your doctor or pharmacist immediately.

Do this even if it occurs several weeks after stopping Clarithromycin Sandoz. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicine to stop your diarrhoea without first checking with your doctor.

Tell your doctor immediately if you experience any heart palpitations, changes in heartbeat, dizziness or fainting while taking Clarithromycin Sandoz.

If you have to take any urine tests, tell your doctor you are taking Clarithromycin Sandoz as it may affect the results of some laboratory tests.

Things you must not do

Do not stop taking Clarithromycin Sandoz without your doctor's permission.

Do not use Clarithromycin Sandoz to treat any other complaints unless your doctor says so.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Clarithromycin Sandoz affects you.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Clarithromycin Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach cramps and pains
- nausea, vomiting and severe diarrhoea
- oral thrush (sore white mouth or tongue) or vaginal thrush (vaginal itching or discharge)
- change in taste sensation
- headache
- asthma, shortness of breath
- muscle weakness, pain or spasms
- conjunctivitis
- chills
- fatigue
- eructation
- stomach distension
- flatulence

These are the more common side effects of Clarithromycin Sandoz. Mostly, these are mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- yellowing of the eyes or skin (jaundice)
- feeling generally unwell and having poor appetite
- hearing disturbances
- chest pain
- dizziness, confusion, hallucinations, convulsions
- fainting, irregular heart beat
- any type of skin rash, itching, hives
- severe diarrhoea, especially if bloody
- severe upper stomach pain, with nausea and vomiting (pancreatitis)

This above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking Clarithromycin Sandoz and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse. These are symptoms of an allergic reaction.

This above list includes very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After you have finished taking Clarithromycin Sandoz

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Clarithromycin Sandoz.

- severe stomach or abdominal cramps

- watery and severe diarrhoea, which may also be bloody (this may occur several weeks after you stop taking Clarithromycin Sandoz)
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel and you may need urgent medical care.

Do not take any diarrhoea medicine without first checking with your doctor.

Other side effects not listed above may also occur in some patients. Ask your doctor or pharmacist for more information about side effects, as they have a more complete list of side effects. Inform your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking Clarithromycin Sandoz even if it is not on this list.

AFTER TAKING CLARITHROMYCIN SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Clarithromycin Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

This leaflet was revised in April 2019.

Australian Register Numbers

Clarithromycin Sandoz 250 mg tablet: AUST R 101265 (blisters)

PRODUCT DESCRIPTION

What Clarithromycin Sandoz looks like

Clarithromycin Sandoz 250 mg film-coated tablet: white, oblong, convex tablet scored on both faces.

Available in blister packs of 14 tablets.

Ingredients

Active Ingredient:

Each Clarithromycin Sandoz 250 mg tablet contains 250 mg clarithromycin.

Inactive Ingredients:

Each Clarithromycin Sandoz tablet also contains:

- microcrystalline cellulose
- magnesium stearate
- croscarmellose sodium
- powdered cellulose
- colloidal anhydrous silica
- lactose monohydrate
- hypromellose
- macrogol 4000
- titanium dioxide

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369