

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
- 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 antibiotic (amoxicillin) and another medicine called omeprazole (used to control the acidity of the stomach).

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 (such as EES®, Erythrocin®, Eryc®, E-mycin®, EMU-V), roxithromycin (such as Rulide®, Biaxig® Roxar) or azithromycin (such as Zithromax®, Azith, Zedd).

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

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, cisapride (used to relieve certain stomach problems such as Prepulsid®), pimozide (used to treat schizophrenia used to treat headaches such as Orap®), ergotamine (such as Cafergot®), dihydroergotamine (such as Dihyergot®), astemizole or terfenadine (antihistamine drugs), statins (cholesterol lowering drugs), ticagrelor or ranolazine (used to prevent blood clotting),

Colchicine (used to treat gout), midazolam tablets or syrup (used to cause drowsiness before certain procedures or surgery).

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.

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 or are breast-feeding.

Your doctor will discuss the risks and benefits involved.

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

- kidney problems
- liver problems
- heart disease.

Tell your doctor if you have myasthenia gravis, a condition in which the muscles become weak and tire easily.

If you have not told your doctor 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.

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

- cisapride (such as Prepulsid®), a medicine used to treat stomach disorders
- pimozide (such as Orap®), a medicine used to treat psychotic disorders
- ergotamine (such as Cafergot®), used to treat migraines
- dihydroergotamine (such as Dihyergot®), used to treat migraines
- astemizole and terfenadine (antihistamine drugs).

Some medicines and Clarithromycin Sandoz may interfere with each other. These include:

- cyclosporin, tacrolimus; (medicines affecting the immune system)
- warfarin, used to prevent blood clotting (such as Coumadin®, Marevan®)
- phenytoin (such as Dilantin®), carbamazepine (such as Tegretol®) or hexobarbital, used to treat epilepsy
- theophylline (such as Nuelin®), used to treat asthma
- digoxin (such as Lanoxin®), used to treat heart failure
- triazolam (such as Halcion®) or midazolam (such as Hypnovel®), used to treat sleeplessness
- cilostazol (use to treat poor circulation)
- zidovudine (such as Retrovir®), ritonavir (such as Norvir®), indinavir (such as Crixivan®) or saquinavir (such as Invirase®), used to treat HIV infection
- methylprednisolone, a corticosteroid
- vinblastine, a medicine used to treat cancer
- sildenafil, tadalafil or vardenafil (such as Viagra®), used to treat erectile dysfunction in adult males
- ciclosporin, tacrolimus (medicines affecting the immune system)
- quinidine, used to treat heart arrhythmias
- disopyramide (such as Rythmodan®), used to treat heart arrhythmias
- alprazolam (such as Kalma®, Xanax®), used to treat anxiety
- sodium valproate (such as Epilim®, Valpro®), used to control epilepsy
- repaglinide (such as NovoNorm®) for treatment of diabetes
- colchicine used for the relief of pain in acute attacks of gout
- statins such as rosuvastatin, atorvastatin (cholesterol lowering drugs)
- quetiapine (used to treat antipsychotic)

- ototoxic drugs (especially aminoglycosides)
- efavirenz and nevirapine (to treat HIV), rifampicin (to treat meningococcal disease) and rifabutin (to treat tuberculosis)
- oral hypoglycemic agents or insulin (used for diabetics)
- macrolide drugs (antibiotics) especially lincomycin and clindamycin
- atazanavir (antiretroviral drug)
- tolterodine (used to treat bladder symptoms)
- itraconazole (used to treat fungal infections)
- verapamil (used to treat high blood pressure)
- herbal medicines such as St John's Wort.

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 have 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.

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.

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.

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 or vaginal thrush
- change in taste sensation
- headache.
- asthma, shortness of breath

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, sleeplessness
- 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)
- muscle pain
- unusual dream patterns.

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 or throat 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
- 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.

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.

PRODUCT DESCRIPTION

What Clarithromycin Sandoz looks like

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

Available in blister packs of 14 tablets.

Ingredients

Active Ingredient:

Each Clarithromycin Sandoz 250mg tablet contains 250mg clarithromycin.

Inactive Ingredients:

Each Clarithromycin Sandoz tablet also contains: cellulose-microcrystalline, magnesium stearate, croscarmellose sodium, cellulose - powdered, silica - colloidal anhydrous, lactose monohydrate, hypromellose, macrogol 4000 and titanium dioxide.

Supplier

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Australian Register Numbers

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