

Ciprofloxacin Sandoz®

ciprofloxacin hydrochloride tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Ciprofloxacin 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 risks of you taking this medicine against the benefits they expect it will 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 need to read it again.

WHAT CIPROFLOXACIN SANDOZ IS USED FOR

This medicine is used to treat infections of the lungs, skin, bones and joints, kidney and bladder, prostate and bowel.

Ciprofloxacin Sandoz tablets contains the active ingredient ciprofloxacin hydrochloride, which is an antibiotic belonging to a group of medicines called quinolone antibiotics. These antibiotics work by killing the bacteria that are causing your infection.

Ciprofloxacin Sandoz will not work against infections caused by viruses such as colds or the flu.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE CIPROFLOXACIN SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- ciprofloxacin hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- other medicines belonging to the quinolone chemical family (e.g. moxifloxacin, norfloxacin, nalidixic acid).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are also taking a medicine called tizanidine, a muscle relaxant used to treat spasticity associated with multiple sclerosis, injury or diseases of the spinal cord.

Ciprofloxacin Sandoz can interfere with tizanidine and can lead to undesirable side effects.

Ciprofloxacin Sandoz is not recommended in children under 18 years of age.

Do not take this medicine after the expiry date printed on the pack and blister.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging 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, foods, preservatives or dyes.

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

- suffer from epilepsy (seizures, convulsions), have had a stroke, or have kidney or liver disease
- have arrhythmias (fast or irregular heartbeats). Ciprofloxacin Sandoz may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels
- have previously taken corticosteroids. You may be at increased risk of swelling of the tendons. Symptoms include

- pain, tenderness and sometimes restricted movement
- have myasthenia gravis, a condition where the muscles become weak. Ciprofloxacin Sandoz can worsen the symptoms of this condition
- have a history of tendon problems associated with quinolone antibiotics (e.g. moxifloxacin, norfloxacin, nalidixic acid)
- have or have had a mental illness
- have diabetes.

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

Ciprofloxacin Sandoz is not recommended if you are pregnant but your doctor will assess the benefit if required. Medicines similar to Ciprofloxacin Sandoz have caused joint disease in immature animals.

Tell your doctor if you are breastfeeding.

Ciprofloxacin is excreted into the breast milk. Your doctor will tell you whether you should take it and temporarily stop breastfeeding while you are taking the tablets.

Ciprofloxacin Sandoz should be used with caution in elderly patients as they are more prone to side effects.

If you have not told your doctor about any of the above, tell him/her before you start taking Ciprofloxacin 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 may be affected by Ciprofloxacin Sandoz. These include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)

- theophylline, a medicine used to treat asthma
- oral anticoagulants, warfarin and it's derivatives, medicines used to stop blood clots
- phenytoin, a medicine used to treat epilepsy
- oral antidiabetic agents
- didanosine, a medicine used to treat viral infections
- ciclosporin, a medicine used to suppress the immune system
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to treat pain, arthritis and other inflammatory conditions
- methotrexate, a medicine used to treat certain types of cancers, severe psoriasis or severe rheumatoid arthritis
- duloxetine, a medicine used to treat depression, anxiety, and nerve pain in people with diabetes
- clozapine, a medicine used to treat schizophrenia
- ropinirole, a medicine used to treat Parkinson's disease and restless legs syndrome
- the local anaesthetic lidocaine, a medicine used to numb pain or cause loss of sensation
- oxpentifylline, a medicine used to treat circulation disorders
- sildenafil, a medicine used to treat erectile dysfunction
- agomelatine, a medicine used to treat depression
- zolpidem, a medicine used to treat sleep disorders.

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

Some medicines may interfere with the absorption of Ciprofloxacin Sandoz. These include:

- multivitamins, mineral supplements, antacids (used for indigestion) and other medicines containing iron, zinc,

- magnesium, aluminium or calcium
- sucralfate, a medicine used to treat duodenal or stomach ulcers
- medicines used to treat HIV infection
- probenecid, a medicine used to treat gout
- omeprazole, a medicine used to treat stomach ulcers and other conditions where the stomach produces too much acid
- sevelamer, a medicine used to treat high blood levels of phosphorus in patients with kidney disease who are on dialysis
- metoclopramide, a medicine used to relieve nausea, vomiting and stomach pain.

You can still take these medicines while you are taking Ciprofloxacin Sandoz. However, you must take Ciprofloxacin Sandoz at least 2 hours before or 2 hours after taking any of these medicines.

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

HOW TO TAKE CIPROFLOXACIN 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

Your doctor or pharmacist will tell you how much and how often you should take Ciprofloxacin Sandoz. This will depend on the type of infection and any medical conditions you may have.

The usual adult dosage for most infections is one tablet twice daily for 7 to 14 days.

You may need to take your tablets for a longer period of time for some types of infections.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Ciprofloxacin Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

When to take Ciprofloxacin Sandoz

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take your medicine preferably on an empty stomach, for example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of this medicine.

However, they can be taken with or without food.

If you need to take an antacid, multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium, take it at least 2 hours before or 2 hours after your dose of Ciprofloxacin Sandoz.

Your doctor and pharmacist will have more information on medicines to avoid while taking this medicine.

How long to take Ciprofloxacin Sandoz

Continue taking your medicine until you finish the pack or for as long as your doctor tells you.

Do not stop taking your tablets because you are feeling better. If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you forget to take it

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 that 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 to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

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 that you or anyone else may have taken too much Ciprofloxacin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING CIPROFLOXACIN SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ciprofloxacin Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Tell your doctor if you need to have a surgical or dental procedure that you are taking this Ciprofloxacin Sandoz.

If you develop diarrhoea, tell your doctor or pharmacist immediately.

Do this even if it occurs several weeks after you have stopped taking this medicine. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Do not take any medications for diarrhoea without checking with your doctor or pharmacist.

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

Drink plenty of water while you are taking Ciprofloxacin Sandoz. This helps to stop crystals forming in your urine.

Ciprofloxacin may affect the results of laboratory tests.

If you are about to have any tests, tell your doctor that you are taking this medicine.

Tell your doctor immediately, if you experience symptoms of depression or self-endangering behaviour.

Ciprofloxacin Sandoz should be discontinued immediately.

Tell your doctor immediately if you develop pain, burning, tingling, numbness or weakness in any part of the body.

Ciprofloxacin Sandoz should be discontinued immediately.

Things you must not do

Do not take Ciprofloxacin Sandoz to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine because you are feeling better, unless your doctor told you to do so.

If you do not complete the full course prescribed by your doctor, some of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear up completely or it may return.

Things to be careful of

Avoid excessive exposure to direct sunlight.

Your skin may become more prone to sunburn. If such a reaction occurs, stop taking Ciprofloxacin Sandoz immediately and tell your doctor.

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

This medicine may cause dizziness in some patients, especially after the first few doses. Your ability to drive and/or operate machinery may be impaired.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness and light-headedness may be worse.

Ciprofloxacin Sandoz may increase the stimulatory effects of caffeine.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of

the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of 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:

- feeling sick (nausea)
- diarrhoea

These are the common side effects of the medicine, and are usually mild and short-lived.

Tell your doctor immediately, or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:

- severe skin rashes, peeling of the skin and/or mucosal reactions
- signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing
- fainting
- severe, watery or bloody diarrhoea, even if it occurs several weeks after stopping this medicine
- fits (seizures or convulsions)
- confusion, nightmares, hallucinations, and psychotic reaction (even progressing to self-endangering behaviour)
- yellowing of the skin and/or eyes, also called jaundice
- fast or irregular heart beats
- visual disturbances (eyesight problems)
- ringing in the ear, loss of hearing
- abdominal pain/ cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue

- pain, burning, tingling, numbness and/or weakness in your limbs

These serious side effects are rare. If you have them, you may require urgent medical attention.

In isolated instances, some serious side effects may be long-lasting (>30 days) and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbance of senses.

Photosensitivity (getting sunburnt very easily) can occasionally occur with Ciprofloxacin Sandoz. However, it is temporary and staying out of direct sunlight while on Ciprofloxacin Sandoz tablets will prevent it from happening.

Rarely, there can be a worsening of the symptoms of myasthenia gravis. This is a condition in which the muscles become weak and tire easily, causing drooping eyelids, double vision, difficulty speaking and swallowing, and/or muscle weakness in the arms or legs.

Rarely, the Achilles tendon (extending from the calf to the heel of the foot) or other tendons have been torn after ciprofloxacin therapy.

This may occur even within the first 48 hours of treatment and up to several months after completing treatment with ciprofloxacin. This risk of tendon damage may be increased in elderly patients, during strenuous physical activity, if you are currently being treated with a type of medicine called corticosteroids, if you have reduced kidney function or have received solid organ transplants.

Tell your doctor immediately if you feel any discomfort, pain or inflammation of a tendon.

Rarely, you may experience hyperglycaemia (high blood sugar) or hypoglycaemia (low blood sugar). Symptoms of hyperglycaemia include increased

thirst, appetite and urination. Symptoms of hypoglycaemia include weakness, shaking, sweating, light headedness, headache, behavioural changes, confusion, numbness/pins and needles in the lips, fingers or toes, irritability and hunger. Tell your doctor if you experience these symptoms.

If you experience any of these symptoms during treatment with Ciprofloxacin Sandoz tablets, tell your doctor or pharmacist immediately. Ciprofloxacin Sandoz may need to be discontinued.

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

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

AFTER TAKING CIPROFLOXACIN 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 Ciprofloxacin 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 it looks like

Ciprofloxacin Sandoz comes in three types of tablets:

Ciprofloxacin Sandoz 250 mg - white, round, biconvex film-coated tablets with a breaking notch on one side, embossed with 'cip 250' on the other.

Ciprofloxacin Sandoz 500 mg - white, oblong, biconvex film-coated tablets with a breaking notch on both sides, embossed with 'cip 500'.

Ciprofloxacin Sandoz 750 mg - white, oblong, biconvex film-coated tablets with a breaking notch on both sides, embossed with 'cip 750'.

Available in blisters of 14 tablets.

Ingredients

Active ingredients:

- Ciprofloxacin Sandoz 250 mg – 250 mg ciprofloxacin (as ciprofloxacin hydrochloride)
- Ciprofloxacin Sandoz 500 mg – 500 mg ciprofloxacin (as ciprofloxacin hydrochloride)
- Ciprofloxacin Sandoz 750 mg – 750 mg ciprofloxacin (as ciprofloxacin hydrochloride).

Inactive ingredients:

- colloidal anhydrous silica
- povidone
- magnesium stearate
- microcrystalline cellulose
- stearic acid
- sodium starch glycollate type A
- croscarmellose sodium
- hypromellose
- macrogol 6000
- purified talc
- titanium dioxide.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Ciprofloxacin Sandoz is supplied in Australia by:

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

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Australian Register Numbers

250 mg film-coated tablets: AUST R 81460 (blisters)

500 mg film-coated tablets: AUST R 81461 (blisters)

750 mg film-coated tablets: AUST R 81462 (blisters)