

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICATION****PATIENT MEDICATION INFORMATION**

**Pr Sandoz Ciprofloxacin  
ciprofloxacin hydrochloride tablets**

**Pr Ciprofloxacin Injection USP**

**Pr Ciprofloxacin Intravenous Infusion BP  
Ciprofloxacin injection**

**Read this carefully before you start taking Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP and each time you get a refill. This leaflet is a summary and will not tell you everything about these drugs. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP.**

**Serious Warnings and Precautions**

- Quinolone antibiotics, like Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP, are related to disabling and possibly long lasting effects such as:
  - inflamed tendon (tendonitis), tendon rupture.
  - nerve damage (peripheral neuropathy).
  - problems in the brain such as:
    - convulsions
    - nervous breakdown
    - confusion
    - and other symptoms
- Quinolone antibiotics, like Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP:
  - have lengthened the heartbeat (QT prolongation)
  - have led to serious allergic reactions, including death
  - may be related to increased tendonitis (inflamed tendon)
  - may worsen myasthenia gravis (a muscle disease)
  - may lead to seizures and nervous breakdowns. Tell your doctor if you have brain or spinal cord problems (such as epilepsy)
  - may cause liver injury which may lead to death
- For further information and symptoms see:
  - the “To help avoid side effects and ensure proper use,…” section
  - the “What are possible side effects from using Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP?” section

Talk to your doctor to see if Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP is right for you.

**What are Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP used for?**

Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP are used to treat certain types of bacterial infections.

Antibacterial drugs like Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP should be taken exactly as directed. Misuse or overuse of Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP could lead to the growth of bacteria that will not be killed by Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP (resistance). This means that Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP may not work for you in the future. Do not share your medicine.

**How does Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP work?**

Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP are antibiotics that kill the bacteria causing the infection.

**What are the ingredients in Sandoz Ciprofloxacin tablets?**

Medicinal ingredients: ciprofloxacin as ciprofloxacin hydrochloride.

Non-medicinal ingredients: croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, silica colloidal anhydrous, sodium starch glycolate, stearic acid, talc, titanium oxide.

**What are the ingredients in Ciprofloxacin Injection USP?**

Medicinal ingredients: ciprofloxacin.

Non-medicinal ingredients: lactic acid (3.72 mg/mL), sodium hydroxide and/or hydrochloric acid to adjust pH and water for injection.

**What are the ingredients in Ciprofloxacin Intravenous Infusion BP (mini-bag)?**

Medicinal ingredients: ciprofloxacin.

Non-medicinal ingredients: Each mL contains 2 mg of ciprofloxacin in ready-to-use mini-bags of 100 mL and 200 mL.

	<b>100 mL mini-bag</b>	<b>200 mL mini-bag</b>
Ciprofloxacin, EP	200 mg	400 mg
Dextrose Monohydrate, EP	5.5 g	11.0 g
Lactic Acid solution, EP	64 mg	128 mg
1 N Hydrochloric Acid	pH to 3.5-4.6	pH to 3.5-4.6
Water for Injection ,EP	qs to 100 mL	qs to 200 mL

**Sandoz Ciprofloxacin tablets comes in the following dosage forms:**

Sandoz Ciprofloxacin 250 mg tablet: White round film-coated tablet with breaking notch on one side. Embossed "cip" on top and "250" on the bottom of the breaking notch. Bottles of 100.

Sandoz Ciprofloxacin 500 mg tablet: White oblong film-coated tablet with breaking notch on both sides. Embossed "cip" on one side of breaking notch and "500" on the other side, on one side of the tablet only. Bottles of 100.

Sandoz Ciprofloxacin 750 mg tablet: White oblong film-coated tablet with breaking notch on both sides. Embossed "cip" on one side of breaking notch and "750" on the other side, on one side of the tablet only. Bottles of 50.

**Ciprofloxacin Injection USP comes in the following dosage forms:**

Ciprofloxacin Injection USP: is available in 20 mL and in 40 mL single use vials, each format package in boxes of 10.

**Ciprofloxacin Intravenous Infusion BP (mini-bag) comes in the following dosage forms:**

Ciprofloxacin Intravenous Infusion BP (mini-bag): the mini-bags are made of polyvinylchloride (PVC) and an overpouch to protect from moisture. The 100 mL and 200 mL mini-bags are supplied in boxes of 10.

**Do not use Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP if:**

- you are allergic to ciprofloxacin or other quinolone antibiotics
- you are allergic to any other ingredient in these products (see “What are the ingredients in Sandoz Ciprofloxacin tablets?”, “What are the ingredients in Ciprofloxacin Injection USP?” and “What are the ingredients in Ciprofloxacin Intravenous Infusion BP (mini-bag)?”).
- you are taking tizanidine (ZANAFLEX®). Side effects such as drowsiness, sleepiness and low blood pressure may occur.
- you are currently taking agomelatine<sup>a</sup>. Agomelatine concentrations may increase and may cause further side effects such as liver toxicity.

<sup>a</sup>Currently not marketed in Canada

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP. Talk about any health conditions or problems you may have, including if you:**

- have a family history of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase deficiency as Ciprofloxacin Intravenous Infusion BP contains dextrose.
- have a history of seizures.
- have an irregular heart rhythm (such as QT prolongation).
- have low potassium blood levels.
- have liver or kidney disease or damage.
- are pregnant, planning to become pregnant, breast feeding or planning to breast feed.
- are less than 18 years of age.
- have a history of tendon problems (such as pain, swelling or rupture of a tendon) related to the use of a quinolone antibiotic.
- have myasthenia gravis (a muscle disease).

**Other warnings you should know about:**

**Blood Sugar Changes**

Medicines like Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP can cause blood sugar levels to rise and drop in patients with diabetes. Serious cases of hypoglycemia (low blood sugar levels) that caused coma or death have been seen with medicines like Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP. If you have diabetes, check your blood sugar levels often while taking Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP.

While taking Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP:

- Avoid too much sunlight or artificial ultraviolet light (such as sunlamps).

- Contact your doctor if a sunburn or rash occurs.
- Do not drive or use machinery if you feel dizzy or lightheaded.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP:**

- Theophylline or didanosine chewable/buffered tablets or pediatric powder. **Serious and fatal reactions have been reported in patients receiving ciprofloxacin, including Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP, and theophylline.**
- Antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron or zinc (see “How to take Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP:”).
- Antidiabetic agents (such as glyburide, glibenclamide, glimepiride, insulin); the combination of any of these agents with ciprofloxacin may cause lower blood sugar.
- Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)
- Caffeine (such as coffee) and other xanthine derivatives (such as pentoxifylline).
- Certain heart medications known as antiarrhythmics (such as quinidine, procainamide, amiodarone, sotalol).
- Other medications including:
  - oral anticoagulants (like warfarin and acenocoumarol),
  - phenytoin, duloxetine, methylxanthines, sevelamer,
  - sucralfate, clozapine, ropinirole, lidocaine, sildenafil, probenecid,
  - methotrexate, metoclopramide, cyclosporine, lanthanum carbonate, zolpidem.

**How to take Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP:**

- Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP should be taken as prescribed at almost the same times each day with food or on an empty stomach.
- Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone; however, Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP may be taken with a meal that contains these products (see “The following may interact with Sandoz Ciprofloxacin, Ciprofloxacin Injection USP and Ciprofloxacin Intravenous Infusion BP”).
- You should avoid excessive caffeine consumption while taking Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP.
- You should drink lots of water while taking Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP.
- Swallow the Sandoz Ciprofloxacin tablets whole, with water as needed. **DO NOT SPLIT, CRUSH, OR CHEW THE TABLET.**
- If you are taking the following medicines, take them at least 2 hours before or 6 hours after Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP;
  - antacids or mineral supplements containing magnesium or aluminium
  - sucralfate
  - supplements containing iron or zinc
  - any product (supplement or food) with more than 800 mg calcium
- Do not use Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP for another condition or give it to others.

You should take Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP for as long as your doctor prescribes it, even after you start to feel better. Stopping an antibiotic too early may result in failure to cure your infection.

**Usual dose:**

Your doctor (health care provider) will tell you how much of the medicine to take and for how long.

This information does not take the place of discussions with your doctor or health care professional about your medication or treatment.

**Overdose:**

If you think you have taken too much Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP, contact your health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

Should you forget to take it at the usual time, you may take your dose later in the day. Do not take more than two doses of Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP per day, even if you missed a dose.

**What are possible side effects from using Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP?**

All medicines, including Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP, can cause side effects, although not everyone gets them.

These are not all the possible side effects you may feel when taking Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP. If you have any side effects not listed here or if conditions worsen or do not improve then:

- contact your health care professional.
- see the “To help avoid side effects and ensure proper use...” section.

Stop taking Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP and contact your doctor if:

- a) you have symptoms of an allergic reaction such as:
  - rash, hives, blistering or other skin reaction
  - swelling of the face, lips, tongue or throat
  - difficulty breathing
  - irregular or rapid heartbeat, or fainting spells
- b) you have sunburn-like skin reaction when exposed to sunlight or ultraviolet light
- c) you have pain, swelling or rupture of a tendon. You should:
  - rest
  - avoid physical exercise
- d) you have neuropathy (damage to the nerves) with symptoms such as:
  - pain, burning, tingling, numbness or weakness
- e) you have severe diarrhea (bloody or watery) with or without:
  - fever
  - stomach pain or tenderness

You may have Clostridium difficile colitis (bowel inflammation). See your doctor right away.
- f) you have mental problems such as:
  - confusion, headache, shaking
  - hallucinations, depression, agitation
  - difficulty sleeping, anxiety, nervousness, suicidal thoughts

Contact your doctor if you have suicidal thoughts.

Other side effects include:

- your eyesight worsens or changes. See your doctor or eye specialist right away.
- nausea, dizziness, unsteady walk

- gas, cramping, feeling unwell,
- loss of hearing, problems of smell and taste, loss of appetite
- migraine, sweating
- worsening of myasthenia gravis (a muscle disease) with symptoms such as:
  - weakness
  - difficulty walking, swallowing, drooping eyelids

Do not use Sandoz Ciprofloxacin, Ciprofloxacin Injection USP or Ciprofloxacin Intravenous Infusion BP if you have this condition.

Self-Limiting Side Effects:

- feeling lightheaded
- insomnia (difficulty sleeping)
- nightmares

**If any of these affect you severely, tell your doctor or pharmacist.**

Serious Side Effects and What to do About Them				
Symptom / Effect		Talk to your health care professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
<b>Rare</b>	<b>Allergic Reaction:</b> <ul style="list-style-type: none"> <li>• rash</li> <li>• hives (skin eruptions),</li> <li>• swelling of the face, lips, tongue or throat,</li> <li>• difficulty swallowing or breathing,</li> <li>• rapid heartbeat</li> </ul>			✓
	<b>Mental Health Problems:</b> <ul style="list-style-type: none"> <li>• anxiety</li> <li>• confusion,</li> <li>• depression,</li> <li>• feeling agitated</li> <li>• restless or nervous</li> <li>• suicidal thoughts or actions</li> <li>• hallucinations,</li> <li>• inability to think clearly or pay attention</li> <li>• memory loss</li> <li>• paranoia or loss of touch with reality</li> </ul>			✓
	<b>Neurological Problems:</b> <ul style="list-style-type: none"> <li>• seizures (convulsions)</li> <li>• tremors</li> </ul>		✓	
	<b>Rise in the pressure within your skull:</b> <ul style="list-style-type: none"> <li>• blurred or double vision</li> <li>• headaches</li> <li>• nausea</li> </ul>		✓	
	<b>Photo-sensitivity Reaction:</b> Sensitivity to light, blistering of skin			✓
	<b>Tendon pain, inflammation, or rupture</b>			✓

Serious Side Effects and What to do About Them			
Symptom / Effect	Talk to your health care professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Increased Blood Sugar:</b> <ul style="list-style-type: none"> <li>• Frequent urination,</li> <li>• thirst,</li> <li>• hunger,</li> <li>• tiredness,</li> <li>• blurred vision,</li> <li>• headache,</li> <li>• trouble concentrating</li> </ul>	✓		
<b>Hypoglycemia (low blood sugar):</b> <ul style="list-style-type: none"> <li>• change in mood,</li> <li>• change in vision,</li> <li>• confusion,</li> <li>• dizziness,</li> <li>• fast heartbeat,</li> <li>• feeling faint,</li> <li>• headache,</li> <li>• hunger,</li> <li>• shaking,</li> <li>• sweating,</li> <li>• weakness,</li> </ul>		✓	
<b>Unknown</b>	<b>Severe Bowel Disorder (Clostridium difficile colitis):</b> <ul style="list-style-type: none"> <li>• persistent diarrhea,</li> <li>• bloody or watery diarrhea,</li> <li>• abdominal or stomach pain/cramping,</li> <li>• blood/mucus in stool</li> </ul>		✓
	<b>Nerve Disorder (Neuropathy):</b> Pain, burning, tingling, numbness, weakness		✓
	<b>Liver Disorder:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, pale stools		✓
	<b>Heart Disorder (QT Prolongation):</b> Irregular heartbeat		✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

**Tablets:** Store between 15 and 30°C.

**Vial:** Store between 15 and 30°C. Protect from light. Protect from freezing. Discard unused portion. Latex-free stoppers - Stoppers contain no dry natural rubber.

**Mini-bags:** Store between 15°C and 25°C (56°F and 77°F). Protect from light, excessive heat and freezing. Use promptly when pouch is opened.

As with all parenteral drug products, injections/intravenous admixtures should be inspected visually for clarity, particulate matter, precipitate, discolouration and leakage prior to administration, whenever solution and container permits. Solutions showing haziness, particulate matter, precipitate or leakage should not be used. Discard unused portion.

**Keep out of reach and sight of children.**

**If you want more information about Sandoz Ciprofloxacin, Ciprofloxacin Injection USP, and Ciprofloxacin Intravenous Infusion BP:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website <http://www.sandoz.ca>, or by calling 1-800-361-3062.

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