

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICATION**PATIENT MEDICATION INFORMATION****^{Pr}CIPROFLOXACIN
Ciprofloxacin Hydrochloride Tablets**

Read this carefully before you start taking CIPROFLOXACIN and each time you get a refill. This leaflet is a summary and will not tell you everything about CIPROFLOXACIN. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about CIPROFLOXACIN.

Serious Warnings and Precautions

- Fluoroquinolone antibiotics, like CIPROFLOXACIN, 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
- Fluoroquinolone antibiotics, like CIPROFLOXACIN:
 - 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 CIPROFLOXACIN?” section

Talk to your doctor to see if CIPROFLOXACIN is right for you.

What is CIPROFLOXACIN used for?

CIPROFLOXACIN is used to treat certain types of bacterial infections.

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

How does CIPROFLOXACIN work?

CIPROFLOXACIN is an antibiotic that kills the bacteria causing the infection.

What are the ingredients in CIPROFLOXACIN tablets?

Medicinal ingredients: ciprofloxacin as ciprofloxacin hydrochloride.

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

CIPROFLOXACIN comes in the following dosage forms:

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.

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.

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.

Do not use CIPROFLOXACIN if:

- you are allergic to ciprofloxacin or other fluoroquinolone antibiotics
- you are allergic to any other ingredient in these products (see “What are the ingredients in CIPROFLOXACIN tablets?”).
- you are taking tizanidine (ZANAFLEX®). Side effects such as drowsiness, sleepiness and low blood pressure may occur.
- you are currently taking agomelatine^a. Agomelatine concentrations may increase and may cause further side effects such as liver toxicity.

^aCurrently not marketed in Canada

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CIPROFLOXACIN. 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 fluoroquinolone antibiotic.
- have myasthenia gravis (a muscle disease).
- have an aortic aneurysm which is an abnormal bulge in a large blood vessel called the aorta.
- have or if anyone in your family has a condition called aneurysm disease which is an abnormal bulge in any large blood vessel in the body.
- have an aortic dissection which is a tear in the wall of the aorta.
- have any of the following conditions: Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis or Behcet’s disease.
- have high blood pressure.
- have atherosclerosis, which is a hardening of your blood vessels.

Other warnings you should know about:

Blood Sugar Changes

Medicines like CIPROFLOXACIN 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 CIPROFLOXACIN. If you have diabetes, check your blood sugar levels often while taking CIPROFLOXACIN.

While taking CIPROFLOXACIN:

- 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.

Quinolones, including CIPROFLOXACIN have been associated with an enlargement or “bulge” of a large blood vessel called the aorta (aortic aneurysm) and a tear in the aorta wall (aortic dissection)

- The risk of these problems is higher if you:
 - are elderly
 - have or anyone in your family has had aneurysm disease
 - have an aortic aneurysm or an aortic dissection
 - have any of the following conditions: Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis or giant cell arteritis or Behcet’s disease
 - have high blood pressure or atherosclerosis
- If you experience sudden, severe pain in your abdomen, chest or back, a pulsating sensation in your abdomen, dizziness or loss of consciousness, get immediate medical help.

Tendon problems can happen within the first 48 hours of treatment.

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 CIPROFLOXACIN:

- Theophylline or didanosine chewable/buffered tablets or pediatric powder. **Serious and fatal reactions have been reported in patients receiving ciprofloxacin, including CIPROFLOXACIN and theophylline.**
- Antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron or zinc (see “How to take CIPROFLOXACIN”).
- 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 CIPROFLOXACIN:

- CIPROFLOXACIN should be taken as prescribed at almost the same times each day with food or on an empty stomach.
- CIPROFLOXACIN should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone; however, CIPROFLOXACIN may be taken with a meal that contains these products (see “The following may interact with CIPROFLOXACIN”).
- You should avoid excessive caffeine consumption while taking CIPROFLOXACIN.

- You should drink lots of water while taking CIPROFLOXACIN.
- Swallow the 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 CIPROFLOXACIN;
 - 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 CIPROFLOXACIN for another condition or give it to others.

You should take CIPROFLOXACIN 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 CIPROFLOXACIN, contact your health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Take the normal dose as soon as possible and then continue as prescribed. Do not take a double dose to make up for a forgotten dose. If you are unsure about what to do, consult your healthcare professional.

What are possible side effects from using CIPROFLOXACIN?

All medicines, including CIPROFLOXACIN, can cause side effects, although not everyone gets them.

These are not all the possible side effects you may feel when taking CIPROFLOXACIN. 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 CIPROFLOXACIN 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. These side effects may last more than 30 days. 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
- These side effects may last more than 30 days.
Contact your doctor if you have suicidal thoughts.

Other side effects include:

- your eyesight worsens or changes. These side effects may last more than 30 days. 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. These side effects may last more than 30 days.
- migraine, sweating
- worsening of myasthenia gravis (a muscle disease) with symptoms such as:
 - weakness
 - difficulty walking, swallowing, drooping eyelids
 Do not use CIPROFLOXACIN, 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	
Rare	Allergic Reaction: <ul style="list-style-type: none"> • rash • hives (skin eruptions), • swelling of the face, lips, tongue or throat, • difficulty swallowing or breathing, • rapid heartbeat 			✓
	Mental Health Problems: <ul style="list-style-type: none"> • anxiety • confusion, • depression, • feeling agitated • restless or nervous • suicidal thoughts or actions • hallucinations, • inability to think clearly or pay attention • memory loss • paranoia or loss of touch with reality • (These side effects may last more than 30 days) 			✓

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	
Neurological Problems: <ul style="list-style-type: none"> • seizures (convulsions) • tremors 		✓	
Rise in the pressure within your skull: <ul style="list-style-type: none"> • blurred or double vision • headaches • nausea 		✓	
Photo-sensitivity Reaction: Sensitivity to light, blistering of skin			✓
Tendon pain, inflammation, or rupture (These side effects may last more than 30 days)			✓
Increased Blood Sugar: <ul style="list-style-type: none"> • frequent urination, • thirst, • hunger, • tiredness, • blurred vision, • headache, • trouble concentrating 	✓		
Hypoglycemia (low blood sugar): <ul style="list-style-type: none"> • change in mood, • change in vision, • confusion, • dizziness, • fast heartbeat, • feeling faint, • headache, • hunger, • shaking, • sweating, • weakness 		✓	
Unknown Aortic aneurysm (abnormal bulge in a large blood vessel called the aorta) /Aortic dissection (tear in the wall of the aorta): <ul style="list-style-type: none"> • dizziness • loss of consciousness pulsating sensation in the abdomen sudden, severe pain in abdomen, chest or back			✓
Severe Bowel Disorder (Clostridium difficile colitis): <ul style="list-style-type: none"> • persistent diarrhea, • bloody or watery diarrhea, • abdominal or stomach pain/cramping, • blood/mucus in stool 			✓
Nerve Disorder (Neuropathy): Pain, burning, tingling, numbness, weakness			✓

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	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, pale stools		✓	
Heart Disorder (QT Prolongation): 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:

Store between 15°C and 30°C.

Keep out of reach and sight of children.

If you want more information about CIPROFLOXACIN:

- 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://produits-sante.canada.ca/dpd-bdpp/index-fra.jsp>); or by calling 1-855-788-3153.

or at: www.sivem.ca

This leaflet was revised by:
Sivem Pharmaceuticals ULC
4705 Dobrin Street
Saint-Laurent, Quebec, Canada
H4R 2P7

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