

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

**Pr PRO-CIPROFLOXACIN**  
**ciprofloxacin tablets**  
**250 mg and 500 mg Ciprofloxacin Hydrochloride**

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

**Serious Warnings and Precautions**

- Quinolone antibiotics, like PRO-CIPROFLOXACIN is 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 PRO-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 PRO-CIPROFLOXACIN?” section

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

**What are PRO-CIPROFLOXACIN, used for?**

PRO-CIPROFLOXACIN is used to treat certain types of bacterial infections.

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

**How does PRO-CIPROFLOXACIN, work?**

PRO-CIPROFLOXACIN is antibiotics that kill the bacteria causing the infection.

**What are the ingredients in PRO-CIPROFLOXACIN tablets?**

Medicinal ingredients: ciprofloxacin as ciprofloxacin hydrochloride.

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

**PRO-CIPROFLOXACIN tablets come in the following dosage forms:**

PRO-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.

PRO-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.

**Do not use PRO-CIPROFLOXACIN, 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 PRO-CIPROFLOXACIN tablets?").
- you are taking tizanidine (ZANAFLEX<sup>®</sup>). 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 PRO-CIPROFLOXACIN. Talk about any health conditions or problems you may have, including if you:**

- 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:**

While taking PRO-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.

**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 PRO-CIPROFLOXACIN:**

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

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

You should take PRO-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 PRO-CIPROFLOXACIN, 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 PRO-CIPROFLOXACIN per day, even if you missed a dose.

**What are possible side effects from using PRO-CIPROFLOXACIN?**

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

These are not all the possible side effects you may feel when taking PRO-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 PRO-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. 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 PRO-CIPROFLOXACIN if you have this condition.

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	<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>Central Nervous System Disorders:</b> <ul style="list-style-type: none"> <li>• Seizures/ convulsions,</li> <li>• confusion,</li> <li>• tremors,</li> <li>• hallucinations,</li> <li>• depression,</li> <li>• suicidal thoughts or psychotic reactions</li> </ul>			✓
	<b>Photo-sensitivity Reaction:</b> Sensitivity to light, blistering of skin			✓
	Tendon pain, inflammation, or rupture			✓
	<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>Low Blood Sugar:</b> <ul style="list-style-type: none"> <li>• dizziness,</li> <li>• weakness,</li> <li>• headache,</li> <li>• sweating,</li> <li>• hunger</li> </ul>	✓		
Unknown	<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.

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

### If you want more information about PRO-CIPROFLOXACIN:

- a. Talk to your healthcare professional.
- b. This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Pro Doc Ltée Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca)

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