

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

# Pr PRO-CIPROFLOXACIN ciprofloxacin hydrochloride tablets

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**

- Fluoroquinolone antibiotics, like PRO-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
- Fluoroguinolone 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 is PRO-CIPROFLOXACIN used for?

PRO-CIPROFLOXACIN is used to treat certain types of bacterial infections. It does not treat viral infections such as the common cold.

PRO-CIPROFLOXACIN is used to treat infections caused by bacteria. These include infections of the:

- Respiratory tract
- Urinary tract

- Prostate
- Skin and soft tissues
- Bone and joint
   It is also used to remove meningococci (a type of bacteria) from the nasopharynx (upper throat area) in patients not infected with meningitis.

It is also used to treat the following conditions:

- Diarrhea caused by bacterial infections
- Typhoid fever
- Uncomplicated gonorrhea

#### How does PRO-CIPROFLOXACIN work?

PRO-CIPROFLOXACIN are 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, polyethyelene glycol, povidone, silica colloidal anhydrous, sodium starch glycolate, stearic acid, talc, titanium oxide.

# PRO-CIPROFLOXACIN tablets comes 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®), a medication that relaxes muscles. Side effects such as drowsiness, sleepiness and low blood pressure may occur.
- you are currently taking agomelatine<sup>a</sup>, a type of medication used to treat depression.
   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:

PRO-Ciprofloxacin Page 2 of 14

- have a history of seizures or have any other medical conditions or are taking medicines that could cause seizures.
- have an irregular heart rhythm (such as QT prolongation).
- you are taking medications that can affect your heart rhythm such as class IA or III antiarrhythmics that can cause QT prolongation
- have hypokalemia (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 fluoroguinolone antibiotics.
- have myasthenia gravis (a muscle disease).
- have an aortic aneurysm (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 (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:

Using PRO-CIPROFLOXACIN for too long or not long enough may cause the bacteria to become resistant, and your infection may not be resolved. Your doctor will tell you exactly how long you should be taking PRO-CIPROFLOXACIN for.

#### **Blood Sugar Changes**

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

PRO-CIPROFLOXACIN can make your skin more sensitive to the sun. While taking PRO-CIPROFLOXACIN:

- Avoid too much sunlight or artificial ultraviolet light (such as sunlamps).
  - Stop taking PRO-CIPROFLOXACIN and contact your doctor if a sunburn or rash occurs.
- Do not drive or use machinery if you feel dizzy or lightheaded.

Quinolones, including PRO-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:
  - o are elderly
  - o have or anyone in your family has had an aneurysm
  - o 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

o have high blood pressure or atherosclerosis

PRO-Ciprofloxacin Page 3 of 14

- Get immediate help If you experience:
  - sudden, severe pain in your abdomen, chest or back,
  - a pulsating sensation in your abdomen,
  - dizziness or loss of consciousness.

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

# Clostridium difficile-associated disease (CDAD)

PRO-CIPROFLOXACIN can cause infections of the colon caused by a bacteria called clostridium difficile. These infections can vary in severity from mild diarrhea to fatal colitis (inflammation of the colon). If you experience diarrhea or other symptoms of colitis, talk to your doctor. Symptoms of colitis can include stomach pain or cramping, rectal bleeding, urgency or inability to pass stool, fatigue, weight loss and fever.

# Allergic Reactions

Serious allergic reactions can happen from taking PRO-CIPROFLOXACIN. Stop taking PRO-CIPROFLOXACIN and talk to your doctor if you experience any of the following allergic reactions:

- severe hypotension (low blood pressure)
- seizure
- loss of consciousness
- tingling
- angioedema (swelling of the deeper layers of the skin including swelling of the tongue, throat or face)
- shortness of breath
- hives, itching, rashes and other skin reactions.

### Psychiatric (Mental) Adverse Reactions

Psychiatric (mental) adverse reactions can happen from taking PRO-CIPROFLOXACIN. Stop taking PRO-CIPROFLOXACIN and talk to your doctor if you experience any of the following adverse reactions:

- psychosis, hallucinations, paranoia (see, hear, or believe things that are not real)
- depression or suicidal thoughts
- anxiety, agitation, restlessness, or nervousness
- confusion, disorientation, or disturbances in attention
- insomnia or nightmares
- problems with your memory

#### **Ophthalmic (Eye) Problems**

If you experience any problems with your vision while taking PRO-CIPROFLOXACIN, contact an eye doctor immediately.

#### Peripheral Neuropathy (damaged nerves outside of the brain and spinal cord)

Nerve damage can happen from taking PRO-CIPROFLOXACIN. Stop taking PRO-CIPROFLOXACIN and talk to your doctor if you experience any of the following symptoms:

- pain, burning, tingling, numbness, weakness in your hands or feet
- decreased sensation of light touch, pain, temperature, position sense, vibration, and/or motor strength

PRO-Ciprofloxacin Page 4 of 14

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 didanosine chewable/buffered tablets or pediatric powder. Serious and fatal reactions have been reported in patients receiving ciprofloxacin, including PRO-CIPROFLOXACIN, and theophylline.
- 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, tizanidine, duloxetine, methylxanthines, sevelamer,
  - sucralfate, omeprazole, clozapine, ropinirole, lidocaine, sildenafil, probenecid,
  - ferrous sulfate, calcium-fortified products (including food and dairy products),
  - histamine H2-receptor antagonists
  - methotrexate, metoclopramide, cyclosporine, lanthanum carbonate, zolpidem.

#### How to take PRO-CIPROFLOXACIN:

- Take PRO-CIPROFLOXACIN as prescribed by your doctor at almost the same times each day. Take PRO-CIPROFLOXACIN with food or on an empty stomach.
- Do not take PRO-CIPROFLOXACIN with dairy products (like milk or yogurt) or calciumfortified juices alone. However, you may take PRO-CIPROFLOXACIN with a meal that contains these products (see "The following may interact with PRO-CIPROFLOXACIN").
- Do not take PRO-CIPROFLOXACIN with antacids that contain magnesium or aluminum.
- 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.
- After treatment has been completed, any remaining PRO-CIPROFLOXACIN should not be reused.
- 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 aluminum
  - sucralfate
  - didanosine chewable/buffered tablets or pediatric powder
  - 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.

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

PRO-Ciprofloxacin Page 5 of 14

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.

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, or a person you are caring for, have taken too much PRO-CIPROFLOXACIN, contact a health care professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

#### Missed Dose:

If you forget to take PRO-CIPROFLOXACIN and it is:

- 6 hours or more until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
- Less than 6 hours until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.

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 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, tell your healthcare professional.

Stop taking PRO-CIPROFLOXACIN and contact your doctor if:

you have sunburn-like skin reaction when exposed to sunlight or ultraviolet light

Self-Limiting Side Effects:

- feeling lightheaded
- insomnia (difficulty sleeping)
- nightmares

PRO-Ciprofloxacin Page 6 of 14

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

Serious side effects and what to do about them  Talk to your healthcare  Stop taking				
Symptom / effect	_	Talk to your healthcare professional		
	Only if severe	In all cases	drug and get immediate medical help	
UNCOMMON				
Digestive:				
<ul> <li>vomiting</li> <li>gastro-intestinal and abdominal pa (stomach-ache)</li> <li>flatulence (gas)</li> <li>dyspepsia(indigestion/heartburn)</li> <li>decreased appetite and food intak</li> </ul>		<b>√</b>		
Hemic and Lymphatic:				
<ul> <li>eosinophilia (a high concentration eosinophils, a type of white blood cell)</li> </ul>	of	✓		
Musculoskeletal:			<b>√</b>	
<ul><li>arthralgia (joint pain)</li></ul>			ν	
Skin:				
<ul><li>pruritis (itching),</li><li>urticaria (hives and/or skin eruptions)</li></ul>			✓	
Urogenital:				
<ul> <li>renal impairment (abnormal/poor kidney function)</li> </ul>		<b>√</b>		
RARE				
Allergic Reaction:				
<ul> <li>rash,</li> <li>bleeding diathesis (easy to bleed of bruise),</li> <li>Alopecia (hair loss patches),</li> <li>hyperpigmentation,</li> <li>exfoliative dermatitis (peeling skin)</li> <li>purpura (blood or purple spots on skin)</li> <li>Allergic edema or angioedema (swelling of the face, lips, tongue, throat or mucous membranes)</li> <li>difficulty swallowing or breathing, bronchospasm (wheezing),</li> <li>tachycardia (irregular or rapid heartbeat), or fainting spells</li> </ul>			✓	
Cardiovascular:				
<ul> <li>angina pectoris (chest pain), cardi arrest (sudden loss of heart function), cerebrovascular disorde</li> </ul>			✓	

PRO-Ciprofloxacin Page 7 of 14

Serious side effects a	nd what to do	about them	
	Talk to your healthcare		Stop taking
Symptom / effect	professional		drug and get
Symptom/ enect	Only if severe	In all cases	imme diate me dical help
<ul> <li>(disorders that affect blood supply to the brain), myocardial infarct (heart attack), cardiac murmur (heart murmur), cardiopulmonary arrest (loss of heart function and respiration), cardiovascular collapse (loss of consciousness due to loss of blood flow to the brain)</li> <li>pulmonary embolism (blockage of artery in lung)</li> <li>phlebitis (inflammation of the veins), thrombophlebitis (inflammation in vein due to blood clot), cerebral thrombosis (blood clot of a cerebral vein in the brain), pericarditis (inflammation of the sac surrounding heart)</li> <li>vasodilation (expansion of blood vessels, hot flashes), hypotension (low blood pressure), postural hypotension (low blood pressure/light-headedness when standing)</li> </ul>			
• dry mouth, dysphagia (difficulty swallowing), moniliasis (yeast infection of the mouth and throat), gastrointestinal moniliasis (yeast infection in the gut), cholestatic jaundice, hepatomegaly (enlarged liver) enlarged abdomen, stomatitis (swelling of the mouth or lips), stomatitis and ulcerative stomatitis (ulcers in the mouth), tooth discoloration  • esophagitis (irritation or inflammation of the esophagus), glossitis (swelling of the tongue), ileus (intestinal obstruction), increased appetite, intestinal perforation (hole in wall of stomach), constipation  • melena(black or tarry stools), tenesmus (cramping rectal pain), toxic megacolon (unable to pass)		<b>✓</b>	

PRO-Ciprofloxacin Page 8 of 14

Serious side effects and what to do about them				
O was to see to ffe at	Talk to your healthcare professional		Stop taking drug and get	
Symptom / effect	Only if severe	In all cases	imme diate me dical help	
gas or feces from colon), gastrointestinal bleeding or hemorrhage  • pseudomembranous colitis or antibiotic associated colitis (inflammation of the bowel linked to antibiotic use), can be fatal in very rare cases  • lipase increased (higher level of lipase in blood				
<ul> <li>Hemic and Lymphatic:         <ul> <li>leukopenia, anemia, leukocytosis (changes to white blood cell count) thrombocytopenia or thrombocytemia (changes in platelet levels)</li> <li>abnormal prothrombin (a clotting factor) level or increased amylase (increased levels of the enzyme amylase), acidosis (increased acidity in blood and body tissues)</li> <li>kidney vasculitis (inflammation of the walls of blood vessels in kidneys), haemorrhagic bullae and small nodules (papular rash) with crust formation showing vascular involvement</li> </ul> </li> </ul>		✓		
<ul> <li>liver disorder: jaundice (yellowing of the skin or eyes), dark urine, abdominal pain, nausea, vomiting, loss of appetite, pale stools</li> <li>liver damage,</li> <li>abnormal liver function tests,</li> <li>hepatic impairment (liver disorders), jaundice, non-infective hepatitis</li> </ul>			✓	
<ul> <li>Hyperglycemia (Increased Blood Sugar):</li> <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>	✓			

PRO-Ciprofloxacin Page 9 of 14

Serious side effects a	nd what to do	about them			
Symptom / officet	Talk to your healthcare professional				drug and get
Symptom / effect	Only if severe	In all cases			
Hypoglycemia (low blood sugar):					
change in mood					
change in vision					
<ul> <li>confusion</li> </ul>					
<ul> <li>dizziness,</li> </ul>					
fast heartbeat		✓			
feeling faint		,			
headache,					
<ul><li>hunger</li></ul>					
shaking					
• sweating,					
weakness					
Mental Health:					
anxiety					
confusion, delirium					
depression,					
feeling agitated					
restless or nervous, difficulty					
sleeping					
<ul> <li>suicidal thoughts or actions and self injurious behaviour,</li> </ul>					
<ul> <li>hallucinations, manic reaction</li> </ul>					
(mental disturbances)			✓		
<ul> <li>inability to think clearly or pay</li> </ul>					
attention					
disorientation					
memory loss					
phobia					
<ul> <li>paranoia or loss of touch with reality</li> </ul>					
<ul> <li>unresponsiveness</li> </ul>					
(These side effects may last more than 30					
days)					
Musculoskeletal:					
<ul> <li>pain in extremities, achiness, joint</li> </ul>					
disorder (joint swelling or stiffness),					
arthritis (inflammation of the joints),					
gout (flare up of arthritis)			✓		
<ul> <li>myalgia (muscular pain), increased</li> </ul>			·		
muscle tone and cramping,					
myoclonus (muscle spasms),					
rhabdomyolysis (breakdown and					
leakage of muscle fibres)					
Neurological:			✓		
seizures (convulsions)					

PRO-Ciprofloxacin Page 10 of 14

Serious side effects and what to do about them				
	Talk to your healthca		Stop taking	
Symptom / effect		ssional	drug and get	
Symptom/ enect	Only if severe	In all cases	imme diate me dical help	
• tremors				
shaking				
<ul><li>headache</li></ul>				
dysphasia (language disorder)				
Photosensitivity Reaction: Sensitivity to			✓	
light, blistering of skin				
Rise in the pressure within your skull:				
blurred vision or diplopia (double				
vision)		✓		
headache				
• nausea				
Special Senses:				
Eyes: your eyesight worsens or				
changes (These side effects may				
last more than 30 days), visual disturbances (flashing lights,				
changes in colour perception,				
overbrightness of lights),				
chromatopsia (abnormal vision				
colour), colour blindness,				
conjunctivitis (pink eye), corneal			✓	
opacity (scarring and clouding over				
cornea), eye pain, nystagmus				
(uncontrolled eye movements)				
<ul> <li>Ears: ear pain, hearing loss, tinnitus</li> </ul>				
(loss of hearing),				
<ul> <li>problems of smell and taste, loss of</li> </ul>				
appetite (These side effects may				
last more than 30 days).				
Symptoms of an Infection:				
fever, chills, drowsiness		<b>✓</b>		
• drug fever				
Tendon pain, inflammation, or rupture				
(these side effects may last more than 30			<b>v</b>	
days)				
<ul><li>Urogenital:</li><li>blood creatinine increased, acute</li></ul>				
kidney failure, albuminuria				
(increased albumin in urine), dysuria				
(pain during urination), urinary		✓		
retention,				
leukorrhea (changes in vaginal				
discharge), vaginitis (inflammation				
of the vagina) or vaginal moniliasis,				

PRO-Ciprofloxacin Page 11 of 14

Serious side effects a	nd what to do	about them	
	Talk to your healthcare		Stop taking
Symptom / effect	professional		drug and get
	Only if severe	In all cases	immediate medical help
candiduria (yeast urinary infection),			
urethral bleeding (blood in urine),     frequent using tion			
frequent urination <ul><li>renal failure (kidney failure),</li></ul>			
hematuria (blood in the urine),			
crystalluria (crystals in the urine) or			
tubulointerstitial nephritis (a type of			
urinary tract inflammation),			
electrolyte abnormality (loss of			
bodily fluids), hypercalcemia (increased calcium in blood),			
hypocalcemia (decreased calcium in			
blood), hemorrhagic cystitis			
(inflammation of the bladder),			
polyuria (frequent urination), renal			
calculi (kidney stones)			
VERY RARE Digestive:			
<ul><li>pancreatitis (inflammation of the</li></ul>		<b>✓</b>	
pancreas)			
Hemic and Lymphatic:			
<ul> <li>hemolytic anemia (a special type of</li> </ul>			
reduced red blood cell count),			
granulocytopenia, agranulocytosis			
(decrease in a type of white blood cells), or pancytopenia (an extreme			
drop in all blood cell counts) which		✓	
may be life- threatening; or bone			
marrow depression, which may also			
be life- threatening			
vasculitis (inflammation of the walls			
of the blood vessels)  Hepatic:			
<ul><li>Liver necrosis very rarely</li></ul>			
progressing to life-threatening			
hepatic failure (death of liver cells			✓
very rarely leading to life-			
threatening liver failure)			
Hypersensitivity:			
<ul> <li>petechiae (small, pin-point bleeding rash under the skin),</li> </ul>			
<ul><li>erythema multiforme, erythema</li></ul>			<b>✓</b>
nodosum (various skin eruptions,			
blisters, peeling or rashes),			
Stevens-Johnson syndrome, toxic			

PRO-Ciprofloxacin Page 12 of 14

Serious side effects a	nd what to do	about them	
Or word a mark a fife and	Talk to your healthcare professional		Stop taking drug and get
Symptom / effect	Only if severe	In all cases	imme diate me dical help
epidermal necrolysis which may be life-threatening (severe allergic skin reactions)  • serum sickness-like reaction (an allergic reaction)			
<ul><li>Mental Health:</li><li>toxic psychosis (substance-induced psychosis)</li></ul>			✓
Musculoskeletal:  • worsening of myasthenia gravis (a muscle disease) with symptoms such as: weakness, difficulty walking, swallowing, drooping eyelids (Do not use CIPRO if you have this condition)			✓
Neurological:  • migraine		✓	
UNKNOWN			
Acute generalized exanthematous pustulosis (AGEP) (pustular rash) Aortic aneurysm (abnormal bulge in a large blood vessel called the aorta) /Aortic dissection (tear in the wall of the aorta):  dizziness loss of consciousness pulsating sensation in the abdomen sudden, severe pain in abdomen, chest or back			✓
Clostridium difficile colitis (severe bowel disorder):  • persistent diarrhea, • bloody or watery diarrhea with or without fever and stomach pain or tenderness, • abdominal or stomach pain/cramping, • blood/mucus in stool  Epistaxis (acute haemorrhage from nose			✓
or nosebleed)		✓	
<b>Gynecomastia</b> (swelling of breast tissue in males)		✓	
Lymphade nopathy (swollen lymph nodes)		✓	
Neuropathy (nerve disorder): peripheral			✓

PRO-Ciprofloxacin Page 13 of 14

Serious side effects and what to do about them				
Community on Lastin at	Talk to your healthcare professional		Stop taking drug and get	
Symptom / effect	Only if severe	In all cases	immediate medical help	
neuropathy and polyneuropathy (troubles associated with the nervous system such as pain, burning, tingling, numbness, weakness in your hands and feet				
QT Prolongation (heart disorder) and other cardiovascular effects: Irregular heartbeat, ventricular arrhythmia or Torsades de Pointes (abnormal heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm)			✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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
   (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a> ) 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:

- 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 (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html</a>); or by contacting Pro Doc Ltée at 1-800-361-8559, <a href="https://www.prodoc.gc.ca">www.prodoc.gc.ca</a> or <a href="mailto:info@prodoc.gc.ca">info@prodoc.gc.ca</a>.

This leaflet was prepared by Pro Doc Ltée.

Last revised: January 05, 2023

PRO-Ciprofloxacin Page 14 of 14