

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICATION

PATIENT MEDICATION INFORMATION

^{Pr} CIPROFLOXACIN INJECTION USP

Read this carefully before you start taking CIPROFLOXACIN INJECTION USP 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 CIPROFLOXACIN INJECTION USP.

Serious Warnings and Precautions

- Quinolone antibiotics, like CIPROFLOXACIN INJECTION USP, 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 CIPROFLOXACIN INJECTION USP:
 - 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 INJECTION USP?” section

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

What is CIPROFLOXACIN INJECTION USP used for?

CIPROFLOXACIN INJECTION USP is used to treat certain types of bacterial infections in patients over 18 years of age and is administered by the healthcare professional. Antibacterial drugs like CIPROFLOXACIN INJECTION USP treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, CIPROFLOXACIN INJECTION USP should be taken exactly as directed. Misuse or overuse of CIPROFLOXACIN INJECTION USP could lead to the growth of bacteria that will not be killed by CIPROFLOXACIN INJECTION USP (resistance). This means that CIPROFLOXACIN INJECTION USP may not work for you in the future. Do not share your medicine.

How does CIPROFLOXACIN INJECTION USP work?

CIPROFLOXACIN INJECTION USP is an antibiotic that kills bacteria causing infection. You should contact your doctor if your condition has not improved or if it has worsened while taking CIPROFLOXACIN INJECTION USP.

What are the ingredients in CIPROFLOXACIN INJECTION USP?

Each mL of CIPROFLOXACIN INJECTION USP contains 2 mg of ciprofloxacin. The other ingredients are dextrose monohydrate, lactic acid solution, hydrochloric acid to adjust pH and water for injection.

CIPROFLOXACIN INJECTION USP comes in the following dosage forms:

CIPROFLOXACIN INJECTION USP is available in ready-to-use minibags of 100 mL or 200 mL, Each mL contains 2 mg of ciprofloxacin.

Do not use CIPROFLOXACIN INJECTION USP if:

- you are allergic to any other ingredient in these products (see “What are the ingredients in CIPROFLOXACIN INJECTION USP?”).
- you have ever had a severe reaction to any of the ingredients contained within this medication or to the group of antibiotics known as “quinolones.” Before taking this medication, tell your doctor if you have a history of seizures.
- you are taking tizanidine for the management of spasticity. Tizanidine concentrations may increase and cause further side effects such as drowsiness, sleepiness and low blood pressure.
- you are currently taking agomelatine^a. Agomelatine concentrations may increase and may cause further side effects such as liver toxicity.

^a Currently not marketed in Canada

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

- have a family history of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase deficiency as CIPROFLOXACIN INJECTION USP contains sucrose.
- have a history of seizures or epilepsy.

- 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 quinolone antibiotics.
- have myasthenia gravis (a muscle disease).

Other warnings you should know about:

While taking CIPROFLOXACIN INJECTION USP:

- 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 CIPROFLOXACIN INJECTION USP:

- Theophylline or didanosine chewable/buffered tablets or pediatric powder.
Serious and fatal reactions have been reported in patients receiving ciprofloxacin, including CIPROFLOXACIN INJECTION USP, and theophylline.
- Antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron or zinc (see “How to take CIPROFLOXACIN INJECTION USP:”).
- 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).
- Foods fortified with calcium and dairy products
- Other medications including:
 - oral anticoagulants (like warfarin and acenocoumarol),
 - phenytoin, duloxetine, methylxanthines, caffeine, sevelamer,
 - sucralfate, clozapine, ropinirole, lidocaine, sildenafil, pentoxifylline, probenecid,
 - methotrexate, metoclopramide, cyclosporine, lanthanum carbonate, zolpidem.

How to take CIPROFLOXACIN INJECTION USP:

CIPROFLOXACIN INJECTION USP can be prescribed only by a licensed physician. Your doctor has prescribed CIPROFLOXACIN INJECTION USP only for you. Your healthcare professional will give you CIPROFLOXACIN INJECTION USP by injection into a vein.

Usual dose:

CIPROFLOXACIN INJECTION USP will be administered according to your doctor's instructions, usually for 7-14 days, depending on the infection.

Stopping an antibiotic too early may result in failure to cure your infection.

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 INJECTION USP, contact your healthcare 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 CIPROFLOXACIN INJECTION USP per day, even if you missed a dose.

What are possible side effects from using CIPROFLOXACIN INJECTION USP?

- All medicines, including CIPROFLOXACIN INJECTION USP, can cause side effects, although not everyone gets them. These are not all the possible side effects you may feel when taking CIPROFLOXACIN INJECTION USP. Ciprofloxacin Injection USP is generally well-tolerated. The most common side effects, which are usually mild, include nausea and diarrhea. Antibiotics of the quinolone class may also cause vomiting, rash, and abdominal pain/discomfort. If these symptoms persist, call your health care professional. If you have any side effects not listed here or if conditions worsen or do not improve then:contact your healthcare professional.
- see the “To help avoid side effects and ensure proper use,...” section.

Stop taking CIPROFLOXACIN INJECTION USP 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 CIPROFLOXACIN INJECTION USP 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 healthcare 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 			✓
Central Nervous System Disorders: <ul style="list-style-type: none"> • seizures/ convulsions, • confusion, • tremors, • hallucinations, • depression, • suicidal thoughts or psychotic reactions 			✓
Photosensitivity Reaction: Sensitivity to light, blistering of skin			✓
Tendon pain, inflammation, or rupture			✓
Increased Blood Sugar: <ul style="list-style-type: none"> • frequent urination, • thirst, • hunger, • tiredness, • blurred vision, • headache, • trouble concentrating 	✓		

Serious Side Effects and What to do About Them			
Symptom/ Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Low Blood Sugar: <ul style="list-style-type: none"> • dizziness, • weakness, • headache, • sweating, • hunger 	✓		
Unknown			
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			✓
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 Suspected 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:

Keep out of reach and sight of children.

Protect from light, excessive heat and freezing. Store at 20°C to 25°C. Use promptly when container is opened. Single use, discard unused portion.

As with all parenteral drug products, intravenous admixtures should be inspected visually for clarity, particulate matter, precipitate, discoloration and leakage prior to administration, whenever solution and container permits.

If you want more information about CIPROFLOXACIN INJECTION USP:

- 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; the manufacturer's website www.pfizer.ca or by calling **1-800-463-6001**.

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