

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

### PATIENT MEDICATION INFORMATION

## Pr **CIPRO<sup>®</sup> XL**

(Ciprofloxacin hydrochloride and ciprofloxacin extended release tablets)

Read this carefully before you start taking **CIPRO XL** 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 **CIPRO XL**.

### Serious Warnings and Precautions

- Quinolone antibiotics, like CIPRO XL, 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 CIPRO XL:
  - 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 CIPRO XL?](#)” section

Talk to your doctor to see if this medication is suitable for you.

### **What is CIPRO XL used for?**

CIPRO XL is used to treat bacterial urinary tract infections and inflammation of the kidneys.

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

### **How does CIPRO XL work?**

CIPRO XL is an antibiotic that kills the bacteria causing infection in the urinary tract.

### **What are the ingredients in CIPRO XL?**

Medicinal ingredients: ciprofloxacin

Non-medicinal ingredients: crospovidone, hypromellose, magnesium stearate, polyethylene glycol, silica colloidal anhydrous, succinic acid, and titanium dioxide.

### **CIPRO XL comes in the following dosage forms:**

extended release tablets: 500 mg and 1000 mg.

CIPRO XL tablets are nearly white to slightly yellowish, film-coated, oblong-shaped tablets.

### **Do not use CIPRO XL if:**

- you are allergic to ciprofloxacin or other quinolone antibiotics.
- you are allergic to any other ingredient in this product (see “[What are the ingredients in CIPRO XL?](#)”).
- you are taking tizanidine (ZANAFLEX<sup>®</sup>). Side effects such as drowsiness, sleepiness and low blood pressure may occur.
- 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 CIPRO XL. 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 quinolone antibiotics.
- have as myasthenia gravis (a muscle disease).

**Other warnings you should know about:**

While taking CIPRO XL:

- 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 CIPRO XL:**

- Theophylline or VIDEX<sup>®</sup> (didanosine) chewable/buffered tablets or pediatric powder. **Serious and fatal reactions have been reported in patients receiving ciprofloxacin, including CIPRO XL and theophylline.**
- Antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron or zinc (see “How to take CIPRO XL” section).
- Antidiabetic agents (such as glyburide, glibenclamide, glimepiride, insulin); the combination of ciprofloxacin with any of these agents 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 CIPRO XL:**

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

**Usual dose:**

Urinary tract infections: One tablet once a day for 3 days as prescribed.

Inflammation of the kidneys: One tablet once a day for 7 to 14 days as prescribed.

You should take CIPRO XL 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.

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 CIPRO XL, 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 one dose of CIPRO XL per day, even if you missed a dose.

**What are possible side effects from using CIPRO XL?**

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

These are not all the possible side effects you may feel when taking CIPRO XL. 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 CIPRO XL 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 CIPRO XL if you have this condition.

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

<b>Serious Side Effects and What to do About Them</b>			
Symptom/ Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Common</b>			
<b>Vaginal Yeast Infection:</b> Itching, burning, thick white discharge		✓	
<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>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>Photosensitivity Reaction:</b> Sensitivity to light, blistering of skin			✓

<b>Serious Side Effects and What to do About Them</b>			
Symptom/ Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Tendon pain, inflammation, or rupture			✓
<b>Increased Blood Sugar:</b> <ul style="list-style-type: none"> <li>• frequent urination,</li> <li>• thirst and 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>	✓		
<b>Unknown</b>			
<b>Severe Bowel Disorder</b> (Clostridium difficile colitis): <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		✓	

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	
<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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### 3 ways to report:

- Online at [MedEffect](http://www.healthcanada.gc.ca/medeffect) (www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect).

*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 at 15°C to 30°C (56-86°F).

Keep out of reach and sight of children.

### If you want more information about CIPRO XL:

- 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 <http://www.bayer.ca> or by contacting Bayer Medical Information at 1-800-265-7382 or [canada.medinfo@bayer.com](mailto:canada.medinfo@bayer.com).



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