

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

### PATIENT MEDICATION INFORMATION

Pr **CIPRO**<sup>®</sup>

(Ciprofloxacin tablet USP)

Pr **CIPRO**<sup>®</sup> **ORAL SUSPENSION**

(Ciprofloxacin oral suspension)

Read this carefully before you start taking **CIPRO** and **CIPRO ORAL SUSPENSION** 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** and **CIPRO ORAL SUSPENSION**.

#### Serious Warnings and Precautions

- Quinolone antibiotics, like CIPRO, 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:
  - 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 and CIPRO ORAL](#)” section

## **SUSPENSION?” section**

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

### **What are CIPRO and CIPRO ORAL SUSPENSION used for?**

CIPRO and CIPRO ORAL SUSPENSION are used to treat certain types of bacterial infections.

Antibacterial drugs like CIPRO and CIPRO ORAL SUSPENSION treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, CIPRO and CIPRO ORAL SUSPENSION should be taken exactly as directed.

Misuse or overuse of CIPRO and CIPRO ORAL SUSPENSION could lead to the growth of bacteria that will not be killed by CIPRO and CIPRO ORAL SUSPENSION (resistance). This means that CIPRO and CIPRO ORAL SUSPENSION may not work for you in the future. Do not share your medicine.

### **How does CIPRO and CIPRO ORAL SUSPENSION work?**

CIPRO and CIPRO ORAL SUSPENSION are antibiotics that kill the bacteria causing the infection.

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

Medicinal ingredients: ciprofloxacin as ciprofloxacin hydrochloride.

Non-medicinal ingredients: crospovidone, hypromellose, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, silica colloidal anhydrous and titanium dioxide.

### **What are the ingredients in CIPRO ORAL SUSPENSION?**

Medicinal ingredients: ciprofloxacin

Non-medicinal ingredients: hypromellose, magnesium stearate, medium chain triglycerides, poly acrylate dispersion, polysorbate 20, polyvidone 25, soy-lecithin, strawberry flavouring, sucrose and water.

**CIPRO Tablets come in the following dosage forms:**

CIPRO tablets: 250 mg, 500 mg and 750 mg.

The 250 mg tablets are round and white to slightly yellow in colour. One side is engraved with “CIP 250” and a score-line, and the other side has the Bayer cross.

The 500 mg tablets are oblong and white to slightly yellow in colour. One side is engraved with “CIP 500” and a score-line, and “BAYER” on the other side.

The 750 mg tablets are oblong and white to slightly yellow in colour. One side is engraved with “CIP 750” and “BAYER” on the other.

**CIPRO ORAL SUSPENSION comes in the following dosage forms:**

CIPRO ORAL SUSPENSION: 10 g/100 mL

**Do not use CIPRO and CIPRO ORAL SUSPENSION 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 CIPRO Tablets?](#)” and “[What are the ingredients in CIPRO ORAL SUSPENSION?](#)”).
- you are taking tizanidine (ZANAFLEX®). 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 and CIPRO ORAL SUSPENSION. 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 CIPRO ORAL SUSPENSION contains sucrose.
- 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 myasthenia gravis (a muscle disease).

**Other warnings you should know about:**

While taking CIPRO and CIPRO ORAL SUSPENSION:

- 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 and CIPRO ORAL SUSPENSION:**

- 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 and CIPRO ORAL SUSPENSION, and theophylline.**
- Antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron or zinc (see “[How to take CIPRO and CIPRO ORAL SUSPENSION:](#)”).
- 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 CIPRO and CIPRO ORAL SUSPENSION:**

- CIPRO or CIPRO ORAL SUSPENSION should be taken as prescribed at almost the same times each day with food or on an empty stomach.
- CIPRO and CIPRO ORAL SUSPENSION should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone; however, CIPRO or CIPRO ORAL SUSPENSION may be taken with a meal that contains these products (see “[The following may interact with CIPRO and CIPRO ORAL SUSPENSION:](#)”).

- You should avoid excessive caffeine consumption while taking CIPRO and CIPRO ORAL SUSPENSION.
- You should drink lots of water while taking CIPRO or CIPRO ORAL SUSPENSION.
- Swallow the CIPRO tablets whole, with water as needed. **DO NOT SPLIT, CRUSH, OR CHEW THE TABLET.**
- **Shake** CIPRO ORAL SUSPENSION vigorously each time before use for approximately 15 seconds. Swallow the prescribed amount of suspension. Do not chew the microcapsules. Reclose the bottle completely after use and store it in an upright position.
- After use the graduated measuring spoon should be cleaned under running water with detergent and dried thoroughly afterwards.
- If you are taking the following medicines, take them at least 2 hours before or 6 hours after CIPRO:
  - 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 or CIPRO ORAL SUSPENSION for another condition or give it to others.

You should take CIPRO or CIPRO ORAL SUSPENSION 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 (healthcare 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 CIPRO or CIPRO ORAL SUSPENSION, 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 CIPRO or CIPRO ORAL SUSPENSION per day, even if you missed a dose.

## **What are possible side effects from using CIPRO and CIPRO ORAL SUSPENSION?**

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

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

**If any of these affect 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>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,</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>	✓		
<b>Unknown</b>			
<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		✓	



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:

**Tablets:** Store below 30°C (86°F).

**Oral Suspension:** Can be kept for 14 days when stored in the refrigerator or at room temperature (5°C-25°C). Store in an upright position.

Keep out of reach and sight of children.

**If you want more information about CIPRO and CIPRO ORAL SUSPENSION:**

- 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).

This leaflet was prepared by:



Bayer Inc.  
2920 Matheson Blvd East,  
Mississauga, Ontario  
L4W 5R6  
Canada

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