

PART III: CONSUMER INFORMATION**Pr CIPROFLOXACIN**
Ciprofloxacin Tablets, USP

This leaflet is part III of a three-part "Product Monograph" published when CIPROFLOXACIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CIPROFLOXACIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat the medication is used for:

CIPROFLOXACIN is intended to treat infections in males or females over 18 years of age.

CIPROFLOXACIN should not be used to treat other infections.

What it does:

CIPROFLOXACIN is an antibiotic in the quinolone class that contain the active ingredient ciprofloxacin. CIPROFLOXACIN is formulated to be taken twice daily to kill bacteria causing infection. You should contact your doctor if your condition has not improved or if it has worsened while taking CIPROFLOXACIN.

When it should not be used:

- You should not take CIPROFLOXACIN if you are currently taking tizanidine (Zanaflex®) for the management of spasticity. Tizanidine concentrations may increase and cause further side effects such as drowsiness, sleepiness and low blood pressure.
- You should not take CIPROFLOXACIN if 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" (see What the non-medicinal ingredients are).

What the medicinal ingredient is:

Ciprofloxacin Hydrochloride USP

What the nonmedicinal ingredients are:

CIPROFLOXACIN tablets contain the following non-medicinal ingredients: colloidal silicon dioxide, corn starch, crospovidone, magnesium stearate, microcrystalline cellulose, polyethyleneglycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.

What dosage forms it comes in:

250 mg, 500 mg, and 750 mg tablets.

WARNINGS AND PRECAUTIONS

BEFORE you use CIPROFLOXACIN talk to your doctor or pharmacist if any of the following apply to you:

- If you have a history of seizures;
- CIPROFLOXACIN is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown. If you are pregnant or plan to become pregnant while taking CIPROFLOXACIN, talk to your doctor before taking this medication.
- CIPROFLOXACIN is not recommended for persons less than 18 years of age.

INTERACTIONS WITH THIS MEDICATION

It is important to let your health care professional know of all the medicines and supplements that you are using including the following:

- Theophylline or Videx®(didanosine) chewable/buffered tablets or pediatric powder
- Other medications including vitamin K antagonists like warfarin and acenocoumerol, glyburide, phenytoin, duloxetine, tizanidine, methylxanthines, caffeine, sevelamer, sucralfate, clozapine, ropinirole, lidocaine, sildenafil, pentoxifylline and certain heart medications known as antiarrhythmics which may interact with CIPROFLOXACIN
- antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron, or zinc all of which can interfere with the absorption of CIPROFLOXACIN and may prevent them from working. You should take CIPROFLOXACIN either 2 hours before or 6 hours after taking these products.
- Avoid excessive caffeine intake (e.g. coffee)

PROPER USE OF THIS MEDICATION

CIPROFLOXACIN should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone; however CIPROFLOXACIN may be taken with a meal that contains these products.

You should avoid excessive caffeine consumption while taking CIPROFLOXACIN.

Do not give it to other people even if they have a similar condition. If you have any concerns about your condition or your medicine, ask your doctor. Only your doctor can determine if CIPROFLOXACIN is right for you.

Usual dose:

CIPROFLOXACIN should be taken twice a day, twelve hours apart at approximately the same times each day with food or on an empty stomach.

Swallow the CIPROFLOXACIN tablets whole. **DO NOT SPLIT, CRUSH, OR CHEW THE TABLET.**

You should take 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.

Overdose:

Symptoms of ciprofloxacin overdose may include urination problems, joint pain, and muscle pain.

In case of drug overdose, contact a health care practitioner, 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 per day, even if you missed a dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

CIPROFLOXACIN 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 experience symptoms such as severe diarrhea (watery or bloody), fever, abdominal pain, you may have clostridium difficile colitis (bowel inflammation). If this happens, stop taking CIPROFLOXACIN and call your healthcare professional immediately.

You should be careful about driving or operating machinery until you are sure CIPROFLOXACIN is not causing dizziness.

Rare cases of allergic reactions have been reported in patients receiving quinolones, including ciprofloxacin, even after just one dose. If you develop hives, difficulty breathing, swelling of the tongue, throat, face, itching, serious skin reactions or other symptoms of a severe allergic reaction, seek emergency treatment right away. If you develop a skin rash, you should stop taking CIPROFLOXACIN and call your health care professional.

Some patients taking quinolone antibiotics may become more sensitive to sunlight or ultraviolet light such as that used in tanning salons. You should avoid excessive exposure to sunlight or ultraviolet light while you are taking CIPROFLOXACIN.

Quinolones, a class of antibiotics including CIPROFLOXACIN, have been rarely associated with inflammation of the tendons. If you experience pain, swelling or rupture of a tendon, you should stop taking CIPROFLOXACIN, rest, avoid physical exercise and call your health care professional.

Treatment with a quinolone antibiotic, including CIPROFLOXACIN, may worsen muscle weakness in persons with myasthenia gravis. If you have myasthenia gravis, do not use CIPROFLOXACIN.

Neuropathy (problems in the nerves) has been reported in patients receiving quinolones, including CIPROFLOXACIN. If neuropathy symptoms occur such as pain, burning, tingling, numbness or weakness, you should stop taking CIPROFLOXACIN and contact your doctor immediately.

Seizures have been reported in patients receiving quinolone antibiotics including ciprofloxacin. If you have experienced seizures in the past, be sure to let your physician know that you have a history of seizures. Quinolones, including ciprofloxacin, have been rarely associated with other central nervous system events including confusion, tremors, headache, hallucinations, depression, agitation, insomnia, anxiety, nervousness and rarely, suicidal thoughts.

If you notice any side effects not mentioned in this section, or if you have concerns about side effects you may be experiencing, please inform your health care professional.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect | | Stop taking drug and seek immediate emergency medical attention |
|------------------|--|---|
| Uncommon | Body: <ul style="list-style-type: none"> back, chest, pain, pain in extremities | ✓ |
| | Cardiovascular <ul style="list-style-type: none"> rapid or irregular heart beat, inflamed veins Hypotension Chest pain, cardiac arrest (heart attack), cerebrovascular disorder, hot flashes, hypertension, | ✓ ✓ ✓ |
| | Digestive <ul style="list-style-type: none"> Abdominal pain, anorexia, dry mouth, dyspepsia enlarged abdomen, bowel inflammation, diarrhea (watery or bloody) vomiting | ✓ ✓ ✓ |
| | Hypersensitivity <ul style="list-style-type: none"> Rash Allergic reactions, hepatitis Shock, pruritic rash, fever Photosensitivity | ✓ ✓ ✓ ✓ |
| | Metabolic <ul style="list-style-type: none"> Edema (face) | ✓ |
| | Musculoskeletal <ul style="list-style-type: none"> Achiness, joint pain or swelling, tendon rupture, tendonitis, muscle pain. | ✓ |
| | Nervous System <ul style="list-style-type: none"> Agitation, confusion, convulsion, dizziness, hallucinations, head ache, tremor Paresthesia, depression, sleep disorder, migraine. | ✓ ✓ |
| | Other <ul style="list-style-type: none"> Asthenia (general feeling of weakness) | ✓ |
| | Respiratory System <ul style="list-style-type: none"> Shortness of breath | ✓ |
| | Special Senses <ul style="list-style-type: none"> Abnormal vision, taste perversion | ✓ |
| | Urogenital system <ul style="list-style-type: none"> Blood in urine | ✓ |

This is not a complete list of side effects. For any unexpected effects while taking CIPROFLOXACIN, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting:

Sanis Health Inc. at 1-866-236-4076
or via email at quality@sanis.com

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