

PART III: CONSUMER INFORMATION

Pr LEVOFLOXACIN
(Levofloxacin tablets)

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

Before you start to take your medicine, please read this leaflet carefully, all the way through, as it contains important information.

Retain this leaflet for the duration of your treatment.

Remember to consult your doctor if you feel that LEVOFLOXACIN is not helping you get better, or if you feel worse.

ABOUT THIS MEDICATION

What the medication is used for:

LEVOFLOXACIN is from a group of antibiotics known as quinolones. LEVOFLOXACIN is used to treat adults with certain lung, sinus, skin and urinary tract infections caused by certain germs called bacteria.

What it does:

Levofloxacin has been shown, in a large number of clinical trials, to be effective for the treatment of bacterial infections. LEVOFLOXACIN interferes with bacterial enzymes to prevent bacterial growth, thereby killing many types of bacteria that can infect the lungs, sinus, skin, and urinary tract.

Sometimes, viruses rather than bacteria may infect the lungs and sinuses (for example, the common cold). LEVOFLOXACIN, like other antibiotics, does not kill viruses.

When it should not be used:

You should not take LEVOFLOXACIN if you have had an allergic reaction to any of the group of antibiotics known as quinolones, or to any of the nonmedicinal ingredients (see What the nonmedicinal ingredients are). This includes antibiotics such as ofloxacin, ciprofloxacin, moxifloxacin hydrochloride, gatifloxacin and norfloxacin. If you have had any reaction to quinolones, you should discuss this with your doctor.

You should not take LEVOFLOXACIN if you have had tendinitis or tendon rupture while taking quinolone

antibiotics.

What the medicinal ingredient is:

Levofloxacin (as levofloxacin hemihydrate).

What the nonmedicinal ingredients are:

Colloidal silicon dioxide, croscarmellose sodium, ferric oxide yellow, ferric oxide red, glycerol dibehenate, hypromellose, hydroxypropyl cellulose, lactose monohydrate, polyethylene glycol, povidone, sodium starch glycolate, talc, titanium dioxide.

What dosage forms it comes in:

LEVOFLOXACIN tablets are peach coloured for the 500 mg tablet.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- LEVOFLOXACIN has been shown to lengthen the heartbeat on an electrocardiogram test (QT interval prolongation).
- Serious hypersensitivity (allergic) reactions, sometimes fatal, have been reported in some patients receiving quinolone therapy, including levofloxacin.
- Seizures may occur with quinolone therapy. Tell your doctor if you have any central nervous system problems (i.e., epilepsy). Your doctor will determine whether you should use this medication.
- Fluoroquinolones, including LEVOFLOXACIN, may worsen muscle weakness in persons with myasthenia gravis. **Do not use LEVOFLOXACIN if you have or have had myasthenia gravis.**
- Fluoroquinolones, including LEVOFLOXACIN, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants.

See SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

BEFORE you use LEVOFLOXACIN talk to your doctor or pharmacist if:

- you have decreased kidney function.
- you have epilepsy or have a history of seizures (convulsions).
- you have had any problems with your heart rhythm, heart rate, or problems with low potassium.
- you are taking anti-diabetic medications as LEVOFLOXACIN may interfere with blood sugar levels.
- you have a disease that causes muscle weakness (myasthenia gravis).
- you experience any symptoms of muscle weakness, including breathing difficulties (e.g., shortness of breath).

INTERACTIONS WITH THIS MEDICATION

Before taking LEVOFLOXACIN, make sure you tell your doctor and pharmacist all the medications you are taking. Do not start a new medicine without first consulting a doctor or pharmacist.

It is important to let your doctor know all of the medicines you are using including some medications for arthritis (non-steroidal anti-inflammatory drugs), blood sugar medicines, drugs for any heart condition, and non-prescription drugs, because LEVOFLOXACIN may react with certain medications.

Taking warfarin and LEVOFLOXACIN together can further predispose you to the development of bleeding problems. If you take warfarin, be sure to tell your doctor.

Many multivitamin/mineral combinations and antacids, containing calcium, magnesium, aluminum, iron, zinc and sucralfate may interfere with the absorption of levofloxacin and may prevent it from working properly. You should take LEVOFLOXACIN either two hours before or two hours after taking these products.

Some medicines such as erythromycin, clarithromycin, quinidine, procainamide, amiodarone, sotalol, cisapride*, antipsychotics, tricyclic antidepressants, and other medications may produce an effect on the electrocardiogram test. The risk of developing abnormal heartbeat may be increased when LEVOFLOXACIN is taken with any of these medications. Do not take any of these medications with LEVOFLOXACIN unless your doctor tells you that it is alright.

* no longer marketed in Canada

PROPER USE OF THIS MEDICATION

Usual Adult Dose:

LEVOFLOXACIN tablets should be taken once a day for 3, 5, 7, 10, 14 or 28 days depending on your condition.

Each tablet should be swallowed whole and may be taken with or without food. Try to take the tablet at the same time each day and drink fluids liberally, to maintain a hydrated condition.

You may begin to feel better quickly; however, in order to make sure that you are getting the full, sustained benefits from your medication so that your infection does not return, **you should complete the full course of medication.**

Overdose:

In case of drug overdose, contact a healthcare practitioner (e.g., doctor), hospital emergency department, or regional poison control centre, even if there are no symptoms.

Missed dose:

Do not take more than the prescribed dose of LEVOFLOXACIN tablets even if you missed a dose by mistake. You should not take a double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

LEVOFLOXACIN tablets are generally well tolerated. The most common side effects caused by LEVOFLOXACIN, which are usually mild, include nausea, vomiting, diarrhea, abdominal pain, constipation, dizziness, flatulence, rash, headache, difficulty in sleeping, and vaginitis in women. However, allergic reactions have been reported in patients receiving quinolones, including LEVOFLOXACIN tablets, even after just one dose. If you develop hives, itching, skin rash, difficulty breathing or swallowing, swelling in the face, tongue or throat, or other symptoms of an allergic reaction, you should stop taking this medication and call your doctor.

LEVOFLOXACIN may be associated with dizziness. You should know how you react to this drug before you operate an automobile, or machinery, or perform other activities requiring mental alertness or co-ordination.

Pain, swelling and tears of shoulder, hand, or Achilles tendons have been reported in patients receiving quinolones, including LEVOFLOXACIN. The risk of tendon effects is higher if you are over 65 years old, and especially if you are taking corticosteroids. If you develop pain, swelling, or rupture of a tendon you should stop taking LEVOFLOXACIN, rest, avoid exercise and strenuous use of the affected area and contact your doctor.

Convulsions have been reported in patients receiving quinolone antibiotics including LEVOFLOXACIN. If you have experienced convulsions in the past, be sure to let your physician know that you have a history of convulsions.

Quinolones, including LEVOFLOXACIN, may also cause central nervous system stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia and, rarely, suicidal thoughts or acts. If you have suicidal thoughts, contact your doctor.

Neuropathy (problems in the nerves) has been reported in patients receiving quinolones, including LEVOFLOXACIN tablets. Peripheral neuropathy may be irreversible. If neuropathy symptoms occur such as pain, burning, tingling, numbness, weakness, or other alterations of sensation

(including feelings of vibration, temperature or touch sensitivity), you should stop taking LEVOFLOXACIN tablets and contact your doctor immediately.

Sun sensitivity (photosensitivity), which can appear as skin eruption or severe sunburn, can occur in some patients taking quinolone antibiotics after exposure to sunlight or artificial ultraviolet (UV) light (e.g., tanning beds). Levofloxacin has been infrequently associated with phototoxicity. You should avoid excessive exposure to sunlight or artificial ultraviolet light while you are taking LEVOFLOXACIN. Use sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your doctor.

If you have diabetes and you develop a hypoglycemic reaction (low blood sugar) while taking LEVOFLOXACIN tablets, you should stop taking LEVOFLOXACIN tablets and call your doctor. Hypoglycemic coma has been observed in diabetic patients and deaths have occurred. Hyperglycemic and hypoglycemic (high and low blood sugar, respectively) reactions have also been reported in patients without diabetes. Common symptoms of hyperglycemia (high blood sugar) include excessive thirst or excessive urination. Common symptoms of hypoglycemia (low blood sugar) include dizziness, excessive hunger, lack of coordination, headache, fatigue, or fainting. You should call your doctor if you experience any of these symptoms.

Problems with the liver, including fatal cases, have been reported in patients taking LEVOFLOXACIN. The symptoms of hepatic impairment are non-specific and include nausea, vomiting, stomach pain, fever, weakness, abdominal pain or tenderness, loss of appetite, itching, unusual or unexplained tiredness, light coloured bowel movements and dark coloured urine. In more severe cases, these symptoms are followed by jaundice (yellowing of the skin) and/or icterus (yellowing of the eyes). Call your doctor if you experience these symptoms.

Some quinolones have been associated with lengthening of the heart beat on an electrocardiogram test, and with abnormal heart rhythm. Very rare cases of abnormal heart beat have been reported in patients while on levofloxacin, but these reports generally involved patients who had conditions that predisposed them to abnormal heart beat, or who have been taking other medicines that increase the risk of developing abnormal heart beat. If you develop heart palpitations (fast beating) or have fainting spells, you should stop taking LEVOFLOXACIN and call your doctor.

Eye abnormalities and abnormal vision have been reported in patients being treated with quinolones. The relationship of the drugs to these events has not been established.

Diarrhea that usually ends after treatment is a common problem caused by antibiotics. A more serious form of diarrhea can occur during or up to 2 months after the use of

antibiotics. This has been reported with all antibiotics including with levofloxacin tablets. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your doctor as soon as possible.

Fluoroquinolones like LEVOFLOXACIN may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. If you have or have had myasthenia gravis, do not use LEVOFLOXACIN.

These are not all the side effects that have been reported with LEVOFLOXACIN. If you notice any side effects not mentioned in this leaflet, or you have concerns about the side effects you are experiencing, please inform your doctor.

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

Symptom/Effect	Talk to your doctor or pharmacist	Stop taking drug and call your doctor or pharmacist
Rare		
Heart palpitations (fast beating) or fainting spells		√
Tendon pain, swelling or rupture		√
Worsening muscle weakness or breathing problems		√
Symptoms of allergic reaction • skin rash • hives • itching • difficulty breathing or swallowing • swelling of face, tongue or throat		√
Symptoms of neuropathy • pain • burning • tingling • numbness • weakness		√
If you have diabetes and you develop a hypoglycemic reaction		√
Symptoms of hypoglycemia • dizziness • excessive hunger • lack of coordination	√	

<ul style="list-style-type: none"> • headache • fatigue • fainting 		
Symptoms of hyperglycemia <ul style="list-style-type: none"> • excessive thirst • excessive urination 	√	
Symptoms of liver problems <ul style="list-style-type: none"> • yellowing of the skin and/or eyes • nausea • vomiting • loss of appetite • itching 	√	

MORE INFORMATION

This document, plus the full product monograph prepared for health professionals, can be obtained by contacting the Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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

HOW TO STORE IT

LEVOFLOXACIN tablets should be stored in a well closed container between 15°C and 30°C. Protect from moisture. Keep out of reach of children.

Do not use after the expiry date. Generally, all expired medications should be returned to your pharmacist.

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, ON 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.