

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrLEVOFLOXACIN (Levofloxacin tablets)

Read this carefully before you start taking Levofloxacin 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 Levofloxacin.

Serious Warnings and Precautions

Talk to your doctor, if you:

- Have serious allergic reaction to levofloxacin or similar antibiotics such as ciprofloxacin, moxifloxacin, and others.
- Have seizures (convulsions). Tell your doctor if you have any problems in the brain, including epilepsy. Your doctor will tell you whether you should use this medication.
- Have muscle problems (e.g. weakness, joint problems). **Do not use Levofloxacin if you have or have had myasthenia gravis.**
- Have previous history of inflamed tendon (fiber that connects bones to muscles in the body) and tendon rupture. Your risk for tendon problem is greater, if you are over 60 years of age, and if you are taking steroid medication, or if you have had kidney, heart or lung transplant.
- Have family history of long QT syndrome (prolongation of the heartbeat on an electrocardiogram test).

What is Levofloxacin used for?

Levofloxacin is used to treat bacterial infections in the:

- Skin.
- Kidneys.
- Urinary tract (bladder or prostate).
- Sinuses.
- Lungs.

How does Levofloxacin work?

Levofloxacin is in a group of antibiotics called quinolones (kwin-o-lones) that:

- Stop growth of bacteria.
- Kill the bacteria.
- Reduce the infection.

Some infections are caused by viruses, such as the common cold. Levofloxacin **does not** kill viruses.

What are the ingredients in Levofloxacin?

Medicinal ingredients: Levofloxacin (levofloxacin hemihydrate).

Non-medicinal ingredients: 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.

Levofloxacin comes in the following dosage forms:

Levofloxacin tablets are peach coloured for the 500 mg tablet.

Do not use Levofloxacin:

- you have allergic reaction to this drug or to other quinolone antibiotics (such as ciprofloxacin, moxifloxacin)
- you have a history of tendinitis (inflammation of tendon or tendon rupture). This condition causes pain and tenderness just outside of joint in shoulders, elbows, wrists, knees, heels, etc.

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

- have kidney problems.
- have epilepsy.
- have or have had seizures (convulsions).
- have had any problems with your heart rhythm, heart rate, or problems with low potassium.
- have diabetes and are taking anti-diabetic medications (it may interfere with blood sugar levels).
- have a disease that causes muscle weakness (myasthenia gravis).
- experience any symptoms of muscle weakness, including breathing difficulties (e.g., shortness of breath).
- have a history of tendon problems associated with antibiotics.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. Talk to your doctor about how to feed your baby while you are taking Levofloxacin.

- Have an aortic aneurysm which is an abnormal bulge in a large blood vessel called the aorta.
- Have or if anyone in your family has a condition called aneurysm disease which is an abnormal bulge in any large blood vessel in the body.
- Have an aortic dissection which is a tear in the wall of the aorta.
- Have any of the following conditions: Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis or Behcet's disease.
- Have high blood pressure.
- Have atherosclerosis, which is a hardening of your blood vessels.

Other warnings you should know about:

Blood Sugar Changes

Medicines like Levofloxacin can cause blood sugar levels to rise and drop in patients with diabetes. Serious cases of hypoglycemia (low blood sugar levels) that caused coma or death have been seen with medicines like Levofloxacin. If you have diabetes, check your blood sugar levels often while taking Levofloxacin.

If you have diabetes, you may develop a **hypoglycemic reaction** (low blood sugar) with common symptoms such as:

- Dizziness.
- Excessive hunger.
- Lack of coordination.
- Headache.
- Fatigue.
- Fainting.

Or a hyperglycemic reaction (high blood sugar) with common symptoms such as:

- Excessive thirst.
- Excessive urination.

- Quinolones, including Levofloxacin, have been associated with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm) and aortic dissection (a tear in the aorta wall)
 - The risk of these problems is higher if you:
 - are elderly
 - have or anyone in your family has had aneurysm disease
 - have an aortic aneurysm or an aortic dissection
 - have any of the following conditions: Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis or giant cell arteritis or Behcet's disease
 - have high blood pressure or atherosclerosis
 - If you experience sudden, severe pain in your abdomen, chest or back, a pulsating sensation in your abdomen, dizziness or loss of consciousness, get immediate medical help.

What are possible side effects (from using Levofloxacin)?

Self-Limiting Side Effects

- Feeling lightheaded
- Insomnia (difficulty sleeping)
- Nightmares

You should call your doctor if you experience any of these symptoms.

Allergic reaction:

If you develop one of the following:

- Hives.
- Itching.
- Skin rash.
- Difficulty breathing or swallowing.
- Swelling in the face, tongue or throat.
- Other symptoms of an allergic reaction.

You should stop taking this medication and call your doctor.

Operating Heavy Machinery:

You should know that use of Levofloxacin may cause dizziness. Please make sure that you know how to react if you are:

- driving a car.
- operate any machinery at working place.
- perform work that needs mental alertness or coordination.

Exposure to sunlight:

You should not expose yourself to sunlight or artificial ultraviolet light while you are taking Levofloxacin. Use sunscreen and wear protective clothing if out in the sun

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 Levofloxacin:

- antacids, multi-vitamins, or products containing metals (such as aluminium, calcium, iron, magnesium or zinc). See How to take Levofloxacin.
- medicines used for ulcers (such as sucralfate). See How to take Levofloxacin.
- medicines used for heartburn or gout (such as probenecid, cimetidine, etc).
- medicines used for treatment of asthma or chronic obstructive pulmonary disease (COPD) (such as theophylline)
- medications for arthritis (nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen).
- blood sugar medicines (such as metformin, gliclazide, insulin, etc).
- medicines used for any heart conditions.
- blood thinner medications (such as warfarin, etc.) that used to thin the blood and prevent clots – may predispose you to the development of bleeding problems.

This medication may interfere with certain laboratory tests (such as urine screening for opiates), possibly causing false test results.

How to take Levofloxacin:

You should swallow the whole tablet with or without food.

Try to take the tablet at the same time and drink plenty of fluids while taking this medicine unless otherwise directed by your doctor.

Do not share your medicine with anyone.

Antibacterial drugs like Levofloxacin treat only bacterial infections. They do not treat viral infections. Although you may feel better early in the treatment, Levofloxacin should be used exactly as directed. Misuse or overuse of Levofloxacin could lead to the growth of bacterial that will not be killed by Levofloxacin (resistance). This means that Levofloxacin may not work in the future.

Ask your pharmacist about the other products you take. Some medicines will affect the way that your body absorbs Levofloxacin. Take Levofloxacin at least 2 hours before or 2 hours after taking these medicines. Some examples include: vitamins/minerals (including iron and zinc supplements), and products containing magnesium, aluminum, or calcium (such as antacids, calcium supplements).

Usual Adult Dose:

You should take this medication by mouth as directed by your doctor.

The dosage and length of the treatment depends on your kidney function, medical condition, and response to treatment. It may last for 3, 5, 7, 10, 14 or 28 days depending on your condition.

Tell your doctor if your condition does not improve.

Overdose:

If you think you have taken too much Levofloxacin, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.
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Symptoms of overdose may include: severe dizziness.

Missed dose:

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

What are possible side effects from using Levofloxacin?

These are not all the possible side effects you may feel when taking Levofloxacin. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them			
Symptom/Effect	Talk to your doctor or pharmacist		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Nausea	√		
Headache	√		
Diarrhea (have slightly soft to watery stool)	√		
Insomnia (lack of sleep)	√		
Dizziness (drowsiness, light headedness)	√		
Constipation (hard to pass stool)	√		
COMMON			
Abdominal or stomach pain or discomfort	√		
Vomiting	√		
Dyspepsia (discomfort or pain in the upper abdomen)	√		
Dyspnea (shortness of breath)	√		
Moniliasis (yeast infection of the mouth and throat)	√		
Skin rash	√		
Pruritus (itching)	√		
Vaginal itching and discharge	√		
Edema (swelling caused by excess fluid in your body)	√		
Chest pain	√		
RARE			
Stomach cramps or pain (severe)		√	
Agitation (purposeless movements)		√	
Blisters		√	
Confusion		√	
Diarrhea (watery and severe) which may also be bloody		√	
Feeling that others can hear your thoughts or control your behavior		√	
Fever		√	
Pain, inflammation, or swelling in the calves of the legs, shoulders, or hands, including tendon rupture or swelling of the tendon (tendinitis)		√	

Serious side effects and what to do about them			
Symptom/Effect	Talk to your doctor or pharmacist		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Redness and swelling of the skin		√	
Seeing, hearing, or feeling things that are not there		√	
Sensation of burning on the skin		√	
Severe mood or mental changes		√	
Neuropathy (problems in the nerves such as pain, burning, tingling, numbness or weakness)		√	
Skin rash, itching, or redness – sun sensitivity (photosensitivity), which can appear as skin eruption or severe sunburn		√	
Trembling		√	
Unusual behavior		√	
Severe/persistent headache			√
Vision changes			√
Shaking (tremors), seizures (convulsions)			√
Severe dizziness, fainting			√
Fast/irregular heartbeat			√
<u>Mental Health Problems:</u> <ul style="list-style-type: none"> • Anxiety • Confusion • Depression • Feeling agitated • Restless or nervous • Suicidal thoughts or actions • Hallucinations • Inability to think clearly or pay attention • Memory loss • Paranoia or loss of touch with reality 		√	
<u>Neurological Problems:</u> <ul style="list-style-type: none"> • Seizures (convulsions) • Tremor 		√	
<u>Rise in the pressure within your skull:</u> <ul style="list-style-type: none"> • Blurred or double vision • Headaches • Nausea 		√	

Serious side effects and what to do about them			
Symptom/Effect	Talk to your doctor or pharmacist		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<u>Hypoglycemia (Low blood sugar):</u> <ul style="list-style-type: none"> • Change in mood • Change in vision • Confusion • Dizziness • Fast heartbeat • Feeling faint • Headache • Hunger • Shaking • Sweating • Weakness 		√	
Signs of liver problems (such as persistent nausea/vomiting, stomach abdominal pain, unusual tiredness, yellowing eyes/skin, dark urine)			√
Aortic aneurysm (abnormal bulge in a large blood vessel called the aorta) /Aortic dissection (tear in the wall of the aorta): dizziness, loss of consciousness, pulsating sensation in the abdomen, sudden, severe pain in abdomen, chest or back.			√

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 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:

Levofloxacin tablets should be stored in a well-closed container between 15°C and 30°C. Protect from moisture.

Keep out of reach and sight of children.

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

If you want more information about Levofloxacin:

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

This leaflet was prepared by

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