

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

LEVOFLOXACIN IN 5% DEXTROSE INJECTION

Levofloxacin 5 mg / mL Sterile solution for intravenous infusion

Read this carefully before you start taking **LEVOFLOXACIN IN 5% DEXTROSE INJECTION** 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 IN 5% DEXTROSE INJECTION**.

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.
- Fluoroquinolones, including levofloxacin, may worsen muscle weakness in persons with myasthenia gravis. Do not use LEVOFLOXACIN IN 5% DEXTROSE INJECTION if you have or have had myasthenia gravis.
- Fluoroquinolones, including levofloxacin, are associated with disabling and long lasting effects such as:
 - tendonitis (inflamed tendon), tendon rupture
 - peripheral neuropathy (problems in the nerves)
 - problems in the brain such as seizures, psychoses, confusion and other symptoms.

See **What are possible side effects from using LEVOFLOXACIN IN 5% DEXTROSE** of the **PATIENT MEDICATION INFORMATION** section for further information and symptoms.

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

What is LEVOFLOXACIN IN 5% DEXTROSE INJECTION used for?

LEVOFLOXACIN IN 5% DEXTROSE INJECTION is used to treat bacterial infections in the:

- Skin
- Urinary tract (bladder)
- Sinuses
- Lungs

How does LEVOFLOXACIN IN 5% DEXTROSE INJECTION work?

LEVOFLOXACIN IN 5% DEXTROSE INJECTION 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 IN 5% DEXTROSE INJECTION does not kill viruses.

What are the ingredients in LEVOFLOXACIN IN 5% DEXTROSE INJECTION?

Medicinal ingredients: levofloxacin

Non-medicinal ingredients: dextrose, water for injection

Solutions of hydrochloric acid and/or sodium hydroxide may have been added to adjust the pH.

LEVOFLOXACIN IN 5% DEXTROSE INJECTION comes in the following dosage forms:

Single-use flexible containers containing a premixed, ready-to-use levofloxacin solution in D₅W in the following formats:

- Containers of 100 mL capacity containing 50 or 100 mL of premixed solution.
- Containers of 250 mL capacity containing 150 mL of premixed solution.

Do not use LEVOFLOXACIN IN 5% DEXTROSE INJECTION 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 are the ingredients in LEVOFLOXACIN IN 5% DEXTROSE INJECTION**, Non-medicinal ingredients). 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 have had tendinitis or tendon rupture while taking quinolone antibiotics. 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 IN 5% DEXTROSE INJECTION. Talk about any health conditions or problems you may have, including if you:

- 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 problems with the valves inside your heart (also known as leaky valves) or have had a heart infection (infective endocarditis)
- Have any of the following conditions: Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis or Behcet's disease, Turner syndrome, rheumatoid arthritis, Sjögren's syndrome
- Have high blood pressure
- Have atherosclerosis, which is a hardening of your blood vessels
- Have decreased kidney function
- Have a history of seizures
- Have a history of tendon problems associated with the use of quinolone antibiotics
- Have had any problems with your heart rhythm, heart rate, or problems with low potassium
- Have a disease that causes muscle weakness (myasthenia gravis)

- Experience any symptoms of muscle weakness, including breathing difficulties (e.g., shortness of breath)
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed. Levofloxacin can be transferred to your baby through breastmilk. Talk to your doctor about how to feed your baby while taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION.

Other warnings you should know about:

Joint Pain, Swelling or Inflammation

If you experience pain, swelling or inflammation around your joints, stop taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION immediately. LEVOFLOXACIN IN 5% DEXTROSE INJECTION has been linked to tendinitis and tendon rupture, which may require surgery. This may happen while you are taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION or up to several months afterwards. If you experience symptoms of tendinitis and tendon rupture, rest and avoid strenuous activity until you've talked to your healthcare professional. The risk of tendon effects is higher if you are over 60 years old, if you are taking corticosteroids, if you've had a kidney, heart or lung transplant, or if you have any joint related issues (rheumatoid arthritis).

Aortic Aneurism and Dissection

Quinolones, including LEVOFLOXACIN IN 5% DEXTROSE INJECTION, 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). A tear in a blood vessel is more common if you are also taking corticosteroids. 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 heart valve regurgitation/incompetence
- have any of the following conditions: Marfan syndrome, vascular Ehler-Danlos syndrome, Takayasu arteritis or giant cell arteritis or Behcet's disease, Turner syndrome, rheumatoid arthritis, Sjögren's syndrome
- 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, sudden trouble breathing, sudden fast heartbeat, or swelling in your legs or your trunk, get immediate medical help.

Blood Sugar Changes

Medicines like LEVOFLOXACIN IN 5% DEXTROSE INJECTION 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 IN 5% DEXTROSE INJECTION. If you have diabetes, check your blood sugar levels often while taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION. Hyperglycemic and hypoglycemic (high and low blood sugar respectively) reactions have also been reported in patients without diabetes.

Driving or Operating Machinery

LEVOFLOXACIN IN 5% DEXTROSE INJECTION may cause light-headedness or dizziness. Wait to see how you react to LEVOFLOXACIN IN 5% DEXTROSE INJECTION before starting activities that may require you to be coordinated or alert.

Sensitivity to Light

Sun sensitivity (photosensitivity) can occur in some patients taking quinolone antibiotics after exposure to sunlight or artificial ultraviolet (UV) light (e.g., tanning beds). You should avoid excessive exposure to sunlight or artificial ultraviolet light while you are taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION. Use sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your doctor.

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 IN 5% DEXTROSE INJECTION:

- Antidiabetic agents
- Digoxin used to treat heart conditions
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) used to relieve pain, reduce inflammation or reduce fevers
- Probenecid[¶] used to treat gout
- Cimetidine used to treat heartburn and ulcers
- Theophylline used to treat asthma and other lung diseases
- Warfarin used to prevent blood clots (blood thinner)
- Some medicines such as erythromycin, clarithromycin, quinidine, procainamide, amiodarone, sotalol, cisapride[¶], antipsychotics, tricyclic antidepressants, and other medications may increase the risk of developing abnormal heartbeat when taken with LEVOFLOXACIN IN 5% DEXTROSE INJECTION. Do not take any of these medications with LEVOFLOXACIN unless your doctor tells you that it is alright.
- Many multi-vitamin/mineral combinations and antacids, containing calcium, magnesium, aluminum, iron, zinc and sucralfate may prevent LEVOFLOXACIN IN 5% DEXTROSE INJECTION from working properly. You should take LEVOFLOXACIN IN 5% DEXTROSE INJECTION either two hours before or two hours after taking these products.
- LEVOFLOXACIN IN 5% DEXTROSE INJECTION may affect the results of tuberculosis or opioid urine screening tests. Tell your healthcare professional that you are taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION if you are being tested for tuberculosis or screened for opioids.

[¶] No longer marketed in Canada

How to take LEVOFLOXACIN IN 5% DEXTROSE INJECTION:

- Antibacterial drugs like LEVOFLOXACIN IN 5% DEXTROSE INJECTION treat only bacterial infections. They do not treat viral infections.
- Although you may feel better early in the treatment, LEVOFLOXACIN IN 5% DEXTROSE INJECTION should be used exactly as directed. Talk to your doctor if your infection gets worse while taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION.
- Misuse or overuse of LEVOFLOXACIN IN 5% DEXTROSE INJECTION could lead to the growth of bacteria that will not be killed by LEVOFLOXACIN IN 5% DEXTROSE INJECTION (resistance). This means that LEVOFLOXACIN may not work in the future.

- Drink plenty of fluids while you are being given LEVOFLOXACIN IN 5% DEXTROSE INJECTION. It is important to stay hydrated while taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION.

Usual adult dose:

LEVOFLOXACIN IN 5% DEXTROSE INJECTION is to be administered intravenously by your healthcare provider.

Overdose:

If you think you, or a person you are caring for, have taken too much LEVOFLOXACIN IN 5% DEXTROSE INJECTION, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Do not take more than the prescribed dose of LEVOFLOXACIN IN 5% DEXTROSE INJECTION even if you missed a dose by mistake. You should not take a double dose.

What are possible side effects from using LEVOFLOXACIN IN 5% DEXTROSE INJECTION?

These are not all the possible side effects you may have when taking LEVOFLOXACIN IN 5% DEXTROSE INJECTION. If you experience any side effects not listed here, tell your healthcare professional.

Side Effects Include:

- abdominal pain
- constipation
- difficulty in sleeping
- dizziness
- flatulence
- headache
- nausea
- nightmares
- rash
- vaginitis in women
- vomiting

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	
RARE			
Clostridium difficile colitis (Bowel inflammation): Symptoms include severe (watery or bloody) diarrhea, fever, abdominal pain or tenderness. If you are currently taking or have recently taken antibiotics and you			√

develop diarrhea, contact your doctor, even if the diarrhea is relatively mild.			
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.			√
Heart palpitations (fast beating) or fainting spells			√
Tendon pain, swelling or rupture			√
Worsening muscle weakness or breathing problems			√
Allergic reaction: skin rash, hives, itching, difficulty breathing or swallowing, swelling of face, tongue or throat			√
Kounis syndrome (serious heart condition caused by an allergic reaction): chest pain, chest discomfort when swallowing, shortness of breath, faintness, headache, a general feeling of being unwell, nausea, vomiting, itchy skin, fainting			√
Neuropathy (problems with your nerves): pain, burning, tingling, numbness, weakness			√
If you have diabetes and you develop a hypoglycemic reaction			√
Hypoglycemia (low blood sugar): thirst, frequent urination, hunger, nausea and dizziness, fast heartbeat, tingling, trembling, nervousness, sweating, low energy		√	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		√	
Liver problems: yellowing of your skin and eyes (jaundice), stomach pain or swelling, nausea or vomiting, unusual dark urine,			√

unusual tiredness, unexplained loss of appetite			
Mental Health Problems: 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		√	
Neurological Problems: seizures (convulsions), tremors			√
Encephalopathy (rise in the pressure within your skull): blurred or double vision, headaches, nausea		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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.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 IN 5% DEXTROSE INJECTION should be stored at 20-25°C and may also be stored in a refrigerator, 2-8°C.

Brief exposure up to 40°C does not adversely affect the product. Avoid excessive heat and protect from freezing and light. Store with protective overwrap and use immediately once removed from the overwrap.

Keep out of reach and sight of children.

If you want more information about LEVOFLOXACIN IN 5% DEXTROSE INJECTION:

- 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.pfizer.ca>, or by calling 1-800-463-6001.

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