



Levofloxacin Injection

(lee voo flox' a sin)

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IMPORTANT WARNING:

Using levofloxacin injection increases the risk that you will develop tendinitis (swelling of a fibrous tissue that connects a bone to a muscle) or have a tendon rupture (tearing of a fibrous tissue that connects a bone to a muscle) during your treatment or for up to several months afterward. These problems may affect tendons in your shoulder, your hand, the back of your ankle, or in other parts of your body. Tendinitis or tendon rupture may happen to people of any age, but the risk is highest in people over 60 years of age. Tell your doctor if you have or have ever had a kidney, heart, or lung transplant; kidney disease; a joint or tendon disorder such as rheumatoid arthritis (a condition in which the body attacks its own joints, causing pain, swelling, and loss of function); or if you participate in regular physical activity. Tell your doctor and pharmacist if you are taking oral or injectable steroids such as dexamethasone (Decadron, Dexpak), methylprednisolone (Medrol), or prednisone (Sterapred). If you experience any of the following symptoms of tendinitis, stop using levofloxacin injection, rest, and call your doctor immediately: pain, swelling, tenderness, stiffness, or difficulty in moving a muscle. If you experience any of the following symptoms of tendon rupture, stop using levofloxacin injection and get emergency medical treatment: hearing or feeling a snap or pop in a tendon area, bruising after an injury to a tendon area, or inability to move or to bear weight on an affected area.

Talk to your doctor about the risks of using levofloxacin injection.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with levofloxacin injection. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs>) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Levofloxacin injection is used to treat infections such as pneumonia; chronic bronchitis; and sinus, urinary tract, kidney, prostate (a male reproductive gland), and skin infections. Levofloxacin injection is also used to prevent anthrax (a serious infection that may be spread on purpose as part of a bioterror attack) in people who may have been exposed to anthrax germs in the air. Levofloxacin injection is in a class of antibiotics called fluoroquinolones. It works by killing bacteria that cause infections. Antibiotics will not work for colds, flu, or other viral infections.

How should this medicine be used?

Levofloxacin injection comes as a solution (liquid) to be given through a needle or catheter placed in your vein. It is usually infused (injected slowly) intravenously (into a vein) over a period of 60 or 90 minutes, once every 24 hours. The length of your treatment depends on the type of infection you have. Your doctor will tell you how long to use levofloxacin injection.

You may receive levofloxacin injection in a hospital or you may use the medication at home. If you are using levofloxacin injection at home, use it at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or other healthcare provider to explain any part you do not understand. Use levofloxacin injection exactly as directed. Do not infuse it more quickly than directed. Do not use more or less of it or use it more often than prescribed by your doctor.

If you will be using levofloxacin injection at home, your healthcare provider will show you how to infuse the medication. Be sure that you understand these directions, and ask your healthcare provider if you have any questions. Ask your healthcare provider what to do if you have any problems infusing levofloxacin injection.

You should begin feeling better during the first few days of your treatment with levofloxacin injection. If your symptoms do not improve, or if they get worse, call your doctor.

Use levofloxacin injection until you finish the prescription, even if you feel better. Do not stop using levofloxacin injection unless you experience the symptoms of tendinitis or tendon rupture described in the IMPORTANT WARNING section or the symptoms of allergic reaction described in the SIDE EFFECTS section. If you stop using levofloxacin injection too soon or if you skip doses, your infection may not be completely treated and the bacteria may become resistant to antibiotics.

Other uses for this medicine

Levofloxacin injection is also sometimes used to treat endocarditis (infection of the heart lining and valves), tuberculosis (TB), and plague (a serious infection that may be spread on purpose as part of a bioterror attack). Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using levofloxacin injection,

- tell your doctor and pharmacist if you are allergic or have had a severe reaction to levofloxacin; any other quinolone or fluoroquinolone antibiotic such as ciprofloxacin (Cipro), gatifloxacin (Tequin) (not available in the US), gemifloxacin (Factive), lomefloxacin (Maxaquin) (not available in the US), moxifloxacin (Avelox), nalidixic acid (NegGram), norfloxacin (Noroxin), ofloxacin (Floxin), and sparfloxacin (Zagam) (not available in the US); or any other medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); certain antidepressants; antipsychotics (medications to treat mental illness); cyclosporine (Gengraf, Neoral, Sandimmune); diuretics ('water pills'); insulin; oral medications for diabetes such as glyburide (DiaBeta, in Glucovance, Micronase, others); certain medications for irregular heartbeat such as amiodarone (Cordarone), procainamide (Procanbid), quinidine, and sotalol (Betapace, Betapace AF, Sorine); nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Motrin, others) and naproxen (Aleve, Naprosyn, others); tacrolimus (Prograf); or theophylline (Elixophyllin, Theo-24, Uniphyl, others). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you or anyone in your family has or has ever had prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death) or an irregular heartbeat and if you have or have ever had nerve

problems; a low level of potassium in your blood; cerebral arteriosclerosis (narrowing of blood vessels in or near the brain that can lead to stroke or mini-stroke); seizures; slow heartbeat; chest pain; or liver disease.

- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using levofloxacin injection, call your doctor.
- you should know that levofloxacin injection may cause confusion, dizziness, lightheadedness, and tiredness. Do not drive a car, operate machinery, or participate in activities requiring alertness or coordination until you know how this medication affects you.
- plan to avoid unnecessary or prolonged exposure to sunlight or ultraviolet light (tanning beds and sunlamps) and to wear protective clothing, sunglasses, and sunscreen. Levofloxacin injection may make your skin sensitive to sunlight or ultraviolet light. If your skin becomes reddened, swollen, or blistered, like a bad sunburn, call your doctor.

What special dietary instructions should I follow?

Make sure you drink plenty of water or other fluids every day while you are using levofloxacin injection.

What should I do if I forget a dose?

Infuse the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not infuse a double dose to make up for a missed one.

What side effects can this medication cause?

Levofloxacin injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- stomach pain
- constipation
- heartburn
- diarrhea
- headache
- vaginal itching and/or discharge
- irritation, pain, tenderness, redness, warmth, or swelling at the injection spot

Some side effects can be serious. If you experience any of these symptoms, or those mentioned in the IMPORTANT WARNING section, stop using levofloxacin injection, and call your doctor immediately:

- severe diarrhea (watery or bloody stools) that may occur with or without fever and stomach cramps (may occur up to 2 months or more after your treatment)
- rash or blisters
- hives
- itching
- tingling or swelling of the face, neck, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- difficulty breathing or swallowing
- hoarseness or throat tightness
- fainting
- rapid, irregular, or pounding heartbeat
- chest pain
- joint or muscle pain
- fever

- unusual bruising or bleeding
- extreme tiredness
- lack of energy
- loss of appetite
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- dark urine
- pale stools
- flu-like symptoms
- seizures
- dizziness
- confusion
- nervousness
- restlessness
- anxiety
- not trusting others or feeling that others want to hurt you
- difficulty falling asleep or staying asleep
- nightmares or abnormal dreams
- hallucinations (seeing things or hearing voices that do not exist)
- depression
- thoughts about dying or killing yourself
- uncontrollable shaking of a part of the body
- pain, burning, tingling, numbness, and/or weakness in a part of the body

Levofloxacin injection may cause problems with bones, joints, and tissues around joints in children. Levofloxacin injection should not normally be given to children younger than 18 years old unless they have been exposed to anthrax in the air. If your doctor prescribes levofloxacin injection for your child, be sure to tell the doctor if your child has or has ever had joint-related problems. Call your doctor if your child develops joint problems, such as pain or swelling, while using levofloxacin injection or after treatment with levofloxacin injection. Talk to your child's doctor about the risks of giving levofloxacin injection to your child.

Levofloxacin injection may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

What storage conditions are needed for this medicine?

Your healthcare provider will tell you how to store your medication. Store your medication only as directed. Make sure you understand how to store your medication properly. Throw away any medication that is outdated or no longer needed. Talk to your healthcare provider about the proper disposal of your medication.

Keep your supplies in a clean, dry place that is out of the reach of children when you are not using them. Your healthcare provider will tell you how to throw away used needles, syringes, tubing, and containers to avoid accidental injury.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to levofloxacin injection.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are using levofloxacin injection.

Do not let anyone else use your medication. Your prescription is probably not refillable. If you still have symptoms of infection after you finish using levofloxacin injection, call your doctor.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Levaquin®

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