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Levofloxacin Injection, for Intravenous Use (LEE-voe-FLOX-a-sin)

MEDICATION GUIDE
Read this Medication Guide before you start taking Levofloxacin Injection and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Levofloxacin Injection?

Levofloxacin, a fluoroquinolone antibiotic, can cause serious side effects. Some of these serious side effects could result in death.

If you have any of the following serious side effects while you take Levofloxacin Injection, you should stop taking Levofloxacin Injection immediately and get medical help right away.

1. Tendon rupture or swelling of the tendon (tendinitis).

   - Tendon problems can happen in people of all ages who take Levofloxacin Injection. Tendons are tough cords of tissue that connect muscle to bones. Some tendon problems include pain, swelling, tears, and swelling of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites.
   - The risk of getting tendon problems while you take levofloxacin is lower if you:
     - are over 60 years of age
     - are taking steroids (corticosteroids)
     - have had a kidney, heart, or lung transplant
   - Tendon problems can happen in people who do not have the above risk factors when they take levofloxacin.
   - Other reasons that can increase your risk of tendon problems can include:
     - physical activity or exercise
     - kidney failure
     - tendon problems in the past, such as in people with rheumatoid arthritis (RA)
   - Stop taking Levofloxacin Injection immediately and get medical help right away if you get any of the following signs or symptoms of a tendon rupture:
     - hear or feel a snap or pop in a tendon area
     - bruising right after an injury in a tendon area
     - unable to move the affected area or bear weight

2. Changes in sensation and possible nerve damage (Peripheral Neuropathy).

   - Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including Levofloxacin Injection. Stop taking Levofloxacin Injection immediately and talk to your healthcare provider right away if you get any of the following symptoms of peripheral neuropathy in your arms, hands, legs, or feet:
     - pain
     - burning
     - tingling
     - numbness
     - weakness
   - The nerve damage may be permanent.

3. Central Nervous System (CNS) effects.

   - Seizures have been reported in people who take fluoroquinolone antibacterial medicines, including Levofloxacin Injection. Tell your healthcare provider if you have a history of seizures before you start taking Levofloxacin Injection. CNS side effects may happen as soon as after taking the first dose of Levofloxacin Injection. Stop taking Levofloxacin Injection immediately and talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:
     - seizures
     - hear voices, see things, or sense things that are not there (hallucinations)
     - feel restless
     - tremors
     - feel anxious or nervous
     - confusion
     - depression
     - trouble sleeping
     - nightmares
     - feel lightheaded or dizzy
     - feel more suspicious (paranoia)
     - suicidal thoughts or acts
     - headaches that will not go away, with or without blurred vision

4. Worsening of myasthenia gravis (a problem that causes muscle weakness).

   - Fluoroquinolones like levofloxacin may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Tell your healthcare provider if you have a history of myasthenia gravis before you start taking Levofloxacin Injection. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

What is Levofloxacin Injection?

Levofloxacin Injection is a fluoroquinolone antibiotic medicine used in adults 18 years or older to treat certain infections caused by certain germs called bacteria. These bacterial infections include:

- nosocomial pneumonia
- community-acquired pneumonia
- acute sinus infection
- acute worsening of chronic bronchitis
- skin infections, complicated and uncomplicated
- chronic prostate infection
- urinary tract infections, complicated and uncomplicated
- acute kidney infection (pyelonephritis)
- inhalation anthrax
- plague

Studies of Levofloxacin Injection for use in the treatment of plague and anthrax were done in animals only, because plague and anthrax could not be studied in people.

Levofloxacin Injection should not be used in patients with uncomplicated urinary tract infections, acute bacterial exacerbation of chronic bronchitis, or acute bacterial sinusitis if there are other treatment options available.

Levofloxacin Injection is also used to treat children who are 6 months of age or older and may have breathed in anthrax germs, have plague, or been exposed to plague germs.

It is not known if Levofloxacin Injection is safe and effective in children under 6 months of age.

The safety and effectiveness in children treated with Levofloxacin Injection for more than 14 days is not known.

Who should not take Levofloxacin Injection?

Do not take Levofloxacin Injection if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to levofloxacin or any of the ingredients in Levofloxacin Injection. See the end of this leaflet for a complete list of ingredients in Levofloxacin Injection.

What should I tell my healthcare provider before taking Levofloxacin Injection?

Before you take Levofloxacin Injection, tell your healthcare provider if you:

- have tendon problems; Levofloxacin Injection should not be used in patients who have a history of tendon problems
- have a problem that causes muscle weakness (myasthenia gravis); Levofloxacin Injection should not be used in patients who have a known history of myasthenia gravis
- have central nervous system problems such as seizures (epilepsy)
- have nerve problems; Levofloxacin Injection should not be used in patients who have a history of a nerve problem called peripheral neuropathy
- have or anyone in your family has an irregular heartbeat, especially a condition called QT prolongation
- have low blood potassium (hypokalemia)
- have bone problems
- have joint problems including rheumatoid arthritis (RA)
- have kidney problems. You may need a lower dose of Levofloxacin Injection if your kidneys do not work well.
- have liver problems
- have diabetes or problems with low blood sugar (hypoglycemia)
- are pregnant or plan to become pregnant. It is not known if Levofloxacin Injection will harm your unborn child.
- are breastfeeding or plan to breastfeeding. You and your healthcare provider should decide if you will take Levofloxacin Injection or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Levofloxacin Injection and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:

- a steroid medicine
- an anti-psychotic medicine
- a tricyclic antidepressant
- a water pill (diuretic)
- a blood thinner (warfarin, Coumadin, Jantoven)
- an oral anti-diabetes medicine or insulin
- an NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take Levofloxacin Injection or other fluoroquinolones may increase your risk of central nervous system effects and seizures.
- theophylline (Theo-24®, Elixophyllin®, Theo-Chron®, Unigyl®, Theolair®)
- a medicine to control your heart rate or rhythm (antiarrhythmics)

Ask your healthcare provider if you are not sure if any of your medicines are listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take Levofloxacin Injection?

- Take Levofloxacin Injection exactly as your healthcare provider tells you to take it.
- Take Levofloxacin Injection at about the same time each day.
- Drink plenty of fluids while taking Levofloxacin Injection.
- Do not skip any doses of Levofloxacin Injection or stop taking it, even if you begin to feel better, until you finish your prescribed treatment, unless:
  - you have tendon problems. See “What is the most important information I should know about Levofloxacin Injection?”
  - you have a nerve problem. See “What are the possible side effects of Levofloxacin Injection?”
  - you have a central nervous system problem. See “What are the possible side effects of Levofloxacin Injection?”
  - you have a serious allergic reaction. See “What are the possible side effects of Levofloxacin Injection?”
  - your healthcare provider tells you to stop taking Levofloxacin Injection.
Taking all of your Levofloxacin Injection doses will help make sure that all of the bacteria are killed. Taking all of your Levofloxacin Injection doses will help you lower the chance that the bacteria will become resistant to levofloxacin. If your infection does not get better while you take Levofloxacin Injection, it may mean that the bacteria causing your infection may be resistant to levofloxacin. If your infection does not get better, call your healthcare provider. If your infection does not get better, Levofloxacin Injection and other similar antibiotic medicines may not work for you in the future.

- If you take too much Levofloxacin Injection, call your healthcare provider or get medical help right away.

**What should I avoid while taking Levofloxacin Injection?**

- Levofloxacin can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how Levofloxacin Injection affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Levofloxacin Injection can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while taking Levofloxacin Injection, call your healthcare provider right away. You should use a sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

**What are the possible side effects of Levofloxacin Injection?**

**Levofloxacin Injection can cause serious side effects, including:**

- See “What is the most important information I should know about Levofloxacin Injection?”
- **Serious allergic reactions.** Allergic reactions can happen in people taking fluoroquinolones, including Levofloxacin Injection, even after only 1 dose. Stop taking Levofloxacin Injection and get emergency medical help right away if you have any of the following symptoms of a severe allergic reaction:
  - hives
  - trouble breathing or swallowing
  - swelling of the lips, tongue, face
  - throat tightness, hoarseness
  - rapid heartbeat
  - faint
  - skin rash

Skin rash may happen in people taking Levofloxacin Injection, even after only 1 dose. Stop taking Levofloxacin Injection at the first sign of a skin rash and immediately call your healthcare provider. Skin rash may be a sign of a more serious reaction to Levofloxacin Injection.

- **Liver damage (hepatotoxicity):** Hepatotoxicity can happen in people who take Levofloxacin Injection. Call your healthcare provider right away if you have unexplained symptoms such as:
  - nausea or vomiting
  - stomach pain
  - fever
  - weakness
  - abdominal pain or tenderness
  - itching
  - unusual tiredness
  - loss of appetite
  - light colored bowel movements
  - dark colored urine
  - yellowing of your skin or the whites of your eyes

Stop taking Levofloxacin Injection and tell your healthcare provider right away if you have yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to Levofloxacin Injection (a liver problem).

- **Intestine infection (Pseudomembranous colitis)**
  Pseudomembranous colitis can happen with many antibiotics, including Levofloxacin Injection. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may have stomach cramps and a fever. Pseudomembranous colitis can happen 2 or more months after you have finished your antibiotic.

- **Serious heart rhythm changes (QT prolongation and torsade de points)**
  Tell your healthcare provider right away if you have a change in your heart beat (a fast or irregular heartbeat), or if you faint. Levofloxacin Injection may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this happening are higher in people:
  - who are elderly
  - with a family history of prolonged QT interval
  - with low blood potassium (hypokalemia)
  - who take certain medicines to control heart rhythm (antiarhythmics)

- **Joint Problems**
  Increased chance of problems with joints and tissues around joints in children can happen. Tell your child's healthcare provider if your child has any joint problems during or after treatment with Levofloxacin Injection.

- **Changes in blood sugar**
  People who take Levofloxacin Injection and other fluoroquinolone medicines with oral anti-diabetes medicines or with insulin can get low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia). Follow your healthcare provider’s instructions for how often to check your blood sugar. If you have diabetes and you get low blood sugar while taking Levofloxacin Injection, stop taking Levofloxacin Injection and call your healthcare provider right away. Your antibiotic medicine may need to be changed.

- **Sensitivity to sunlight (photosensitivity)**
  See “What should I avoid while taking Levofloxacin Injection?” The most common side effects of Levofloxacin Injection include:
  - nausea
  - headache
  - diarrhea
  - insomnia
  - constipation
  - dizziness

In children 6 months and older who take Levofloxacin Injection to treat anthrax disease or plague, vomiting is also common.

Low blood pressure can happen when Levofloxacin Injection is given too fast by IV injection. Tell your healthcare provider if you feel dizzy or faint during a treatment with Levofloxacin Injection.

Levofloxacin Injection may cause false-positive urine screening results for opiates when testing is done with some commercially available kits. A positive result should be confirmed using a more specific test.

These are not all the possible side effects of Levofloxacin Injection. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store Levofloxacin Injection?**

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. However, brief exposure up to 40°C (104°F) does not adversely affect the product. Avoid excessive heat and protect from freezing and light.

**Keep Levofloxacin Injection and all medicines out of the reach of children.**

**General information about the safe and effective use of Levofloxacin Injection**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Levofloxacin Injection for a condition for which it is not prescribed. Do not give Levofloxacin Injection to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Levofloxacin Injection. If you would like more information about Levofloxacin Injection, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Levofloxacin Injection that is written for healthcare professionals.

For more information, go to www.akorn.com or call 1-800-932-5676.

**What are the ingredients in Levofloxacin Injection?**

Levofloxacin Injection in Single-dose Vials:
- Active ingredient: levofloxacin

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

Rx only

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