

MEDICATION GUIDE
LEVOFLOXACIN TABLETS
250 mg, 500 mg and 750 mg

Read the Medication Guide that comes with levofloxacin before you start taking it 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 tablets?

Levofloxacin belongs to a class of antibiotics called fluoroquinolones. Levofloxacin can cause side effects that may be serious or even cause death. If you get any of the following serious side effects, get medical help right away. Talk with your healthcare provider about whether you should continue to take levofloxacin.

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

- **Tendon problems can happen in people of all ages who take levofloxacin tablets.**
Tendons are tough cords of tissue that connect muscles to bones.
 - Some tendon problems include pain, swelling, tears, and inflammation 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 tablets are higher 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 tablets. 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).
- **Call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation.** Stop taking levofloxacin tablets until tendinitis or tendon rupture has been ruled out by your healthcare provider. Avoid exercise and using the affected area. The most common area of pain and swelling is the Achilles tendon at the back of your ankle. This can also happen with other tendons.
- **Talk to your healthcare provider about the risk of tendon rupture with continued use of levofloxacin tablets.** You may need a different antibiotic that is not a fluoroquinolone to treat your infection.
- **Tendon rupture can happen while you are taking or after you have finished taking levofloxacin tablets.** Tendon ruptures have happened up to several months after patients have finished taking their fluoroquinolone.
- **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. Worsening of myasthenia gravis (a disease that causes muscle weakness).

Fluoroquinolones like levofloxacin tablets may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

See the section **“What are the possible side effects of levofloxacin tablets?”** for more information about side effects.

What is Levofloxacin?

Levofloxacin is a fluoroquinolone antibiotic medicine used in adults, 18 years or older, to treat certain infections caused by certain germs called bacteria.

Children have a higher chance of getting bone, joint, or tendon (musculoskeletal) problems such as pain or swelling while taking levofloxacin tablets.

In children 6 months and older who have breathed the anthrax bacteria germ:

- Levofloxacin tablets are used to prevent anthrax disease (inhalation anthrax).
- It is not known if it is safe to use levofloxacin tablet in children for more than 14 days.

It is not known if levofloxacin tablets are safe and works in children under the age of 6 months.

Sometimes infections are caused by viruses rather than by bacteria. Examples include viral infections in the sinuses and lungs, such as the common cold or flu. Antibiotics, including levofloxacin, do not kill viruses.

Call your healthcare provider if you think your condition is not getting better while you are taking levofloxacin tablets.

Who should not take levofloxacin tablets?

Do not take levofloxacin tablets if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to any of the ingredients in levofloxacin tablets. Ask your healthcare provider if you are not sure. See the list of the ingredients in levofloxacin tablets at the end of this Medication Guide.

What should I tell my healthcare provider before taking levofloxacin tablets? See “What is the most important information I should know about levofloxacin tablets?”

Tell your healthcare provider about all your medical conditions, including if you:

- have tendon problems
- have a disease that causes muscle weakness (myasthenia gravis)
- have central nervous system problems (such as epilepsy)
- have nerve problems
- have or anyone in your family has an irregular heartbeat, especially a condition called “QT prolongation.”
- have low blood potassium (hypokalemia)
- have a history of seizures
- have bone and joint problems
- have kidney problems. You may need a lower dose of levofloxacin tablets if our kidneys do not work well.
- have liver problems
- have rheumatoid arthritis (RA) or other history of joint problems
- are pregnant or planning to become pregnant. It is not known if levofloxacin tablets will harm your unborn child.
- are breast-feeding or planning to breast-feed. Levofloxacin is thought to pass into breast milk. You and your healthcare provider should decide whether you will take levofloxacin tablets or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal and dietary supplements. Levofloxacin tablets and other medicines can affect each other causing side effects. Especially tell your healthcare provider if you take:

- an NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take levofloxacin tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See **“What are the possible side effects of levofloxacin tablets?”**
- an oral anti-diabetes medicine or insulin
- a blood thinner (warfarin, Coumadin, Jantoven)
- a medicine to control your heart rate or rhythm (antiarrhythmics). See **“What are the possible side effects of levofloxacin tablets?”**
- an anti-psychotic medicine
- a tricyclic antidepressant
- a water pill (diuretic)
- a steroid medicine. Corticosteroids taken by mouth or by injection may increase the chance of tendon injury. See **“What is the most important information I should know about levofloxacin tablets?”**.
- theophylline (Theo-24[®], Elixophyllin[®], Theochron[®], Uniphyll[®], Theolair[®])
- Certain medicines may keep levofloxacin tablets from working correctly. Take levofloxacin tablets either 2 hours before or 2 hours after taking these products:
 - an antacid, multivitamin, or other product that has magnesium, aluminum, iron, or zinc.
 - sucralfate (Carafate[®])
 - didanosine (Videx[®], Videx[®] EC)

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 tablets?

- Take levofloxacin tablets exactly as prescribed by your healthcare provider.
- Take levofloxacin tablets at about the same time each day.
- Drink plenty of fluids while taking levofloxacin tablets.
- Levofloxacin tablets can be taken with or without food.
- If you miss a dose of levofloxacin tablets, take it as soon as you remember. Do not take more than one dose in one day.
- Do not skip any doses, or stop taking levofloxacin tablets even if you begin to feel better, until you finish your prescribed treatment, unless:
 - you have tendon effects (see “What is the most important information I should know about levofloxacin tablets?”),
 - you have a serious allergic reaction (see “What are the possible side effects of levofloxacin tablets?”), or
 - your healthcare provider tells you to stop.
- This will help make sure that all of the bacteria are killed and lower the chance that the bacteria will become resistant to levofloxacin tablets. If this happens, levofloxacin tablets and other antibiotic medicines may not work in the future.

If you take too much, call your healthcare provider or get medical help immediately.

If you have been prescribed levofloxacin tablets after being exposed to anthrax:

- Levofloxacin tablets have been approved to lessen the chance of getting anthrax disease or worsening of the disease after you are exposed to the anthrax bacteria germ.
- Take levofloxacin tablets exactly as prescribed by your healthcare provider. Do not stop taking levofloxacin tablets without talking with your healthcare provider. If you stop taking levofloxacin tablets too soon, it may not keep you from getting the anthrax disease.
- Side effects may happen while you are taking levofloxacin tablets. When taking levofloxacin tablets to prevent anthrax infection, you and your healthcare provider should talk about whether the risks of stopping your medicine too soon are more important than the risks of side effects with levofloxacin tablets. It is not known if it is safe to use levofloxacin tablets for more than 28 days in adults and for more than 14 days in children 6 months of age and older.
- If you are pregnant, or plan to become pregnant while taking levofloxacin tablets, you and your healthcare provider should decide whether the benefits of taking levofloxacin tablets for anthrax are more important than the risks.

What should I avoid while taking levofloxacin tablets?

- Levofloxacin tablets 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 tablets affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Levofloxacin tablets 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 tablets, 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 tablets?

Levofloxacin tablets can cause side effects that may be serious or even cause death.

See “What is the most important information I should know about levofloxacin tablets?”

Other serious side effects of levofloxacin tablets include:

- **Liver damage (hepatotoxicity):** Liver damage (hepatotoxicity) can happen in people who take levofloxacin tablets. 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 or yellowing of your skin or the whites of your eyes.
- **Central Nervous System Effects.** Seizures have been reported in people who take fluoroquinolone antibiotics including levofloxacin tablets. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking levofloxacin tablets will change your risk of having a seizure.

Central Nervous System (CNS) side effects may happen as soon as after taking the first dose of levofloxacin tablets. 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
- feel more suspicious (paranoia)
- suicidal thoughts or acts
- persistent headache with or without blurred vision.
- **Serious allergic reactions.**
Allergic reactions can happen in people taking fluoroquinolones, including levofloxacin, even after only one dose. Stop taking levofloxacin tablets and get emergency medical help right away if you get 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
 - Yellowing of the skin or eyes. Stop taking levofloxacin tablets and tell your healthcare provider right away if you get 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 tablets (a liver problem).

- **Skin rash**
Skin rash may happen in people taking levofloxacin tablets, even after only one dose. Stop taking levofloxacin tablets at the first sign of a skin rash and call your healthcare provider. Skin rash may be a sign of a more serious reaction to levofloxacin tablets.

- **Intestine infection (Pseudomembranous colitis)**
Pseudomembranous colitis can happen with most antibiotics, including levofloxacin tablets. 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.

- **Changes in sensation and possible nerve damage (Peripheral Neuropathy)** Damage to the nerves in arms, hands, legs, or feet can happen in people taking fluoroquinolones, including levofloxacin. Talk with 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

Levofloxacin tablets may need to be stopped to prevent permanent nerve damage.

- **Serious heart rhythm changes** (QT prolongation and torsades de pointes) 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 tablets 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 (antiarrhythmics)

- **Changes in blood sugar [low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia)]**

People who take levofloxacin tablets 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 tablets, stop taking levofloxacin tablets 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 tablets?”

- **Joint Problems**

Increased chance of problems with joints and tissues around joints in children. Tell your child's healthcare provider if your child has any joint problems during or after treatment with levofloxacin tablets.

The most common side effects of levofloxacin tablets include:

- dizziness
- headache
- constipation
- nausea
- diarrhea

In children 6 months and older who take levofloxacin tablets to prevent anthrax disease, vomiting is also common.

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

Levofloxacin tablets 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 tablets. 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 tablets?

Store at 20-25°C (68°-77°F) [see USP Controlled Room Temperature]. Keep the container closed tightly.

Keep levofloxacin tablets and all medicines out of the reach of children.

General Information about levofloxacin tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use levofloxacin tablets for a condition for which it is not prescribed. Do not give levofloxacin tablets 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 tablets. If you would like more information about levofloxacin tablets, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about levofloxacin tablets that is written for healthcare professionals. For more information you can also call 1-800-346-6854.

What are the ingredients in levofloxacin tablets?

- 250 mg Levofloxacin Film-Coated Tablets:
 - Active ingredient: levofloxacin.
 - Inactive ingredients: colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, propylene glycol, sodium starch glycolate, titanium dioxide and iron oxide red.
- 500 mg Levofloxacin Film-Coated Tablets:
 - Active ingredient: levofloxacin.
 - Inactive ingredients: colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, propylene glycol, sodium starch glycolate, titanium dioxide, iron oxide yellow and iron oxide red.
- 750 mg Levofloxacin Film-Coated Tablets:
 - Active ingredient: levofloxacin.
 - Inactive ingredients: colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, propylene glycol, sodium starch glycolate and titanium dioxide.

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