

MEDICATION GUIDE

Levofloxacin (lee" voe flox' a sin) Tablets, USP

What is the most important information I should know about levofloxacin tablets? Levofloxacin, a fluoroquinolone antibiotic, can cause serious side effects. Some of these serious side effects can happen at the same time and could result in death.

If you have any of the following serious side effects while you take levofloxacin tablets, **you should stop taking levofloxacin tablets 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 tablets.** Tendons are tough cords of tissue that connect muscles 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 tablets is 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).
- Stop taking levofloxacin tablets immediately and get medical help right away at the first sign of tendon pain, swelling or inflammation. 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. 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 can happen within hours or days of taking levofloxacin tablets and have happened up to several months after people have finished taking their fluoroquinolone.
- Stop taking levofloxacin tablets 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

The tendon problems may be permanent.

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. Stop taking levofloxacin tablets 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
- numbness
- burning
- weakness
- tingling

The nerve damage may be permanent.

3. Central Nervous System (CNS) effects. Mental health problems and seizures have been reported in people who take fluoroquinolone antibacterial medicines, including levofloxacin. Tell your healthcare provider if you have a history of mental health problems, including depression, or have a history of seizures before you start taking levofloxacin tablets. CNS side effects may happen as soon as after taking the first dose of levofloxacin. Stop taking levofloxacin tablets 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 or agitated
- tremors
- feel anxious or nervous
- confusion
- depression
- reduced awareness of surroundings
- 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
- memory problems
- false or strange thoughts or beliefs (delusions)

The CNS changes may be permanent.

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 tablets. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

What are levofloxacin tablets?

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

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

Studies of levofloxacin 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 tablets should not be used in people with uncomplicated urinary tract infections, acute bacterial exacerbation of chronic bronchitis, or acute bacterial sinusitis if there are other treatment options available.

Levofloxacin tablets are also used to treat children who weigh at least 66 pounds (or at least 30 kilograms) and may have breathed in anthrax germs, have plague, or been exposed to plague germs.

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

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

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 levofloxacin or any of the ingredients in levofloxacin tablets. See the end of this leaflet for a complete list of ingredients in levofloxacin tablets.

Before you take levofloxacin tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have tendon problems. levofloxacin should not be used in people who have a history of tendon problems.
- have a problem that causes muscle weakness (myasthenia gravis). levofloxacin should not be used in people who have a known history of myasthenia gravis.
- have a history of mental health problems, including depression.
- have central nervous system problems such as seizures (epilepsy).
- have nerve problems. levofloxacin should not be used in people 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 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 will harm your unborn child.
- are breastfeeding or plan to breastfeed. Levofloxacin passes into your breast milk. You should not breastfeed during treatment with levofloxacin and for 2 days after taking your last dose of levofloxacin. You may pump your breast milk and throw it away during treatment with levofloxacin and for 2 days after taking your last dose of levofloxacin. If you are taking levofloxacin for inhalational anthrax, you and your healthcare provider should decide whether you can continue breastfeeding while taking levofloxacin.

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

Levofloxacin 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).
- certain medicines may keep levofloxacin from working correctly. Take levofloxacin tablets either 2 hours before or 2 hours after taking these medicines or supplements:
 - an antacid, multivitamin, or other medicines or supplements that have magnesium, aluminum, iron, or zinc
 - sucralfate (Carafate®)
 - didanosine (Videx®, Videx® EC)
- 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 or other fluoroquinolones may increase your risk of central nervous system effects and seizures.
- theophylline (Theo-24®, Elixophyllin®, Theochron®, Uniphyll®, 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 tablets?

- Take levofloxacin tablets exactly as your healthcare provider tells you to take it.
- Take levofloxacin tablets at the same time each day.
- Drink plenty of fluids while you take levofloxacin tablets.
- Levofloxacin tablets can be taken with or without food.
- If you miss a dose of levofloxacin tablets and it is:
 - **8 hours or more** until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
 - **less than 8 hours** until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.
- Do not skip any doses of levofloxacin tablets 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 tablets?**”.
 - you have a nerve problem. See “**What is the most important information I should know about levofloxacin tablets?**”.
 - you have a central nervous system problem. 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?**”.
 - your healthcare provider tells you to stop taking levofloxacin.

Taking all of your levofloxacin doses will help make sure that all of the bacteria are killed. Taking all of your levofloxacin 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 tablets, 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 and other similar antibiotic medicines may not work for you in the future.

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

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 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 you take levofloxacin tablets, call your healthcare provider right away. You should use 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 may cause serious side effects, including:

- See “**What is the most important information I should know about levofloxacin tablets?**”
- **Serious allergic reactions.** Allergic reactions can happen in people taking fluoroquinolones, including levofloxacin tablets, even after only 1 dose. Stop taking levofloxacin tablets 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 tablets, even after only 1 dose. Stop taking levofloxacin tablets, 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 tablets.

- **Liver damage (hepatotoxicity):** 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
 - pain or tenderness in the upper right side of your stomach-area
 - 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 tablets 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 tablets (a liver problem).

- **Aortic aneurysm and dissection:** Tell your healthcare provider if you have ever been told that you have an aortic aneurysm, a swelling of the large artery that carries blood from the heart to the body. Get emergency medical help right away if you have sudden chest, stomach, or back pain.
- **Intestine infection (*Clostridium difficile*-associated diarrhea).** *Clostridium difficile*-associated diarrhea (CDAD) can happen with many antibiotics, including levofloxacin. 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. CDAD can happen 2 or more months after you have finished your antibiotic.
- **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)
- **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 tablets.
 - **Changes in blood sugar.** People who take levofloxacin 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?" The most common side effects of levofloxacin tablets include:
 - nausea
 - headache
 - diarrhea
 - insomnia
 - constipation
 - dizziness

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

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.

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 levofloxacin tablets at room temperature between 20°C to 25° C (68°F to 77°F).
- Keep levofloxacin tablets in a tightly closed container.
- Levofloxacin Tablets come in child-resistant bottles of 20's, 30's, 50's and 100's.

General information about the safe and effective use of 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 that is written for health professionals.

Please address medical inquiries to drugsafety@vionausa.com or Tel.: 1-888-304-5011.

What are the ingredients in levofloxacin tablets?

Active ingredients: levofloxacin, USP

Inactive ingredients: crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 6000, talc and titanium dioxide.

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