

## **17.5 FDA-Approved Medication Guide**

**MEDICATION GUIDE**  
**LEVAQUIN<sup>®</sup> [Leave ah kwin]**  
**(levofloxacin)**  
**250 mg Tablets, 500 mg Tablets, and 750 mg Tablets**  
**And**  
**LEVAQUIN<sup>®</sup> (levofloxacin) Oral Solution, 25 mg/mL**  
**And**  
**LEVAQUIN<sup>®</sup> (levofloxacin) Injection, for Intravenous Use**  
**And**  
**LEVAQUIN<sup>®</sup> (levofloxacin in 5% dextrose) Injection, for Intravenous Use**

Read the Medication Guide that comes with LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>?**

LEVAQUIN<sup>®</sup> belongs to a class of antibiotics called fluoroquinolones. LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>.

- **Tendon rupture or swelling of the tendon (tendinitis).**
  - Tendons are the tough cords of tissue that connect muscles to bones.
  - Pain, swelling, tears, and inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites can happen in people of all ages who take fluoroquinolone antibiotics, including LEVAQUIN<sup>®</sup>. The risk of getting tendon problems is higher if you:
    - are over 60 years of age
    - are taking steroids (corticosteroids)
    - have had a kidney, heart or lung transplant.
  - Swelling of the tendon (tendinitis) and tendon rupture (breakage) have also happened in patients who take fluoroquinolones who do not have the above risk factors.
  - Other reasons for tendon ruptures 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 LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>. 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 LEVAQUIN<sup>®</sup>. 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

See the section **“What are the possible side effects of LEVAQUIN<sup>®</sup>?”** for more information about side effects.

### **What is LEVAQUIN<sup>®</sup>?**

LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>.

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

- LEVAQUIN<sup>®</sup> is used to prevent anthrax disease (inhalation anthrax).
- It is not known if it is safe to use LEVAQUIN<sup>®</sup> in children for more than 14 days.

It is not known if LEVAQUIN<sup>®</sup> is 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 LEVAQUIN<sup>®</sup>, do not kill viruses.

Call your healthcare provider if you think your condition is not getting better while you are taking LEVAQUIN<sup>®</sup>.

### **Who should not take LEVAQUIN<sup>®</sup>?**

Do not take LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>. Ask your healthcare provider if you are not sure. See the list of the ingredients in LEVAQUIN<sup>®</sup> at end of this Medication Guide.

### **What should I tell my healthcare provider before taking LEVAQUIN<sup>®</sup>?**

See **“What is the most important information I should know about LEVAQUIN<sup>®</sup>?”**

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

- have tendon problems
- 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 LEVAQUIN<sup>®</sup> if your 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 LEVAQUIN<sup>®</sup> will harm your unborn child.
- are breast-feeding or planning to breast-feed. LEVAQUIN<sup>®</sup> is thought to pass into breast milk. You and your healthcare provider should decide whether you will take LEVAQUIN<sup>®</sup> or breast-feed.

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, herbal and dietary supplements. LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup> or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See **“What are the possible side effects of LEVAQUIN<sup>®</sup>?”**
- 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 LEVAQUIN<sup>®</sup>”**.
- 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 LEVAQUIN<sup>®</sup>?”**.
- theophylline (Theo-24<sup>®</sup>, Elixophyllin<sup>®</sup>, Theochron<sup>®</sup>, Uniphyll<sup>®</sup>, Theolair<sup>®</sup>)
- Certain medicines may keep LEVAQUIN<sup>®</sup> from working correctly. Take LEVAQUIN<sup>®</sup> Tablets or Oral Solution 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<sup>®</sup>)
  - didanosine (Videx<sup>®</sup>, Videx<sup>®</sup> 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 LEVAQUIN<sup>®</sup>?**

- Take LEVAQUIN<sup>®</sup> exactly as prescribed by your healthcare provider.
- Take LEVAQUIN<sup>®</sup> at about the same time each day.
- Drink plenty of fluids while taking LEVAQUIN<sup>®</sup>.
- LEVAQUIN<sup>®</sup> Tablets can be taken with or without food.
- Take LEVAQUIN<sup>®</sup> Oral Solution 1 hour before or 2 hours after eating.
- If you miss a dose of LEVAQUIN<sup>®</sup>, take it as soon as you remember. Do not take more than one dose in one day.
- LEVAQUIN<sup>®</sup> for Injection is given to you by intravenous (I.V.) infusion into your vein, slowly, over 60 or 90 minutes, as prescribed by your healthcare provider. See “What are the possible side effects of LEVAQUIN<sup>®</sup>?”
- Do not skip any doses, or stop taking LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>?”),
  - you have a serious allergic reaction (see “What are the possible side effects of LEVAQUIN<sup>®</sup>?”), 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 LEVAQUIN<sup>®</sup>. If this happens, LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup> after being exposed to anthrax:**

- LEVAQUIN<sup>®</sup> has 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 LEVAQUIN<sup>®</sup> exactly as prescribed by your healthcare provider. Do not stop taking LEVAQUIN<sup>®</sup> without talking with your healthcare provider. If you stop taking LEVAQUIN<sup>®</sup> too soon, it may not prevent you from getting the anthrax disease.
- Side effects may happen while you are taking LEVAQUIN<sup>®</sup>. When taking LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>. It is not known if it is safe to use LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>, you and your healthcare provider should decide whether the benefits of taking LEVAQUIN<sup>®</sup> for anthrax are more important than the risks.

**What should I avoid while taking LEVAQUIN<sup>®</sup>?**

- LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup> affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>, 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 LEVAQUIN<sup>®</sup>?**

LEVAQUIN<sup>®</sup> can cause side effects that may be serious or even cause death. See “**What is the most important information I should know about LEVAQUIN<sup>®</sup>?**”

Other serious side effects of LEVAQUIN<sup>®</sup> include:

- **Liver damage (hepatotoxicity):** Liver damage (hepatotoxicity) can happen in people who take LEVAQUIN<sup>®</sup>. 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 LEVAQUIN<sup>®</sup>. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>. 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
- **Serious allergic reactions.**

Allergic reactions can happen in people taking fluoroquinolones, including LEVAQUIN<sup>®</sup>, even after only one dose. Stop taking LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup> (a liver problem).

- **Skin rash**

Skin rash may happen in people taking LEVAQUIN<sup>®</sup>, even after only one dose. Stop taking LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>.

- **Intestine infection (Pseudomembranous colitis)**

Pseudomembranous colitis can happen with most antibiotics, including LEVAQUIN<sup>®</sup>. 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 LEVAQUIN<sup>®</sup>. 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

LEVAQUIN<sup>®</sup> 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. LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>, stop taking LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>?”

- **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 LEVAQUIN<sup>®</sup>.

The most common side effects of LEVAQUIN<sup>®</sup> include:

- dizziness
- headache
- constipation
- nausea
- diarrhea

In children 6 months and older who take LEVAQUIN<sup>®</sup> to prevent anthrax disease, vomiting is also common.

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

LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>. 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 LEVAQUIN<sup>®</sup>?**

Store LEVAQUIN<sup>®</sup> Film-Coated Tablets at 59° to 86° F (15°C to 30°C). Keep the container closed tightly.

Store LEVAQUIN<sup>®</sup> Oral Solution at 59° to 86° F (15°C to 30°C).

**Keep LEVAQUIN<sup>®</sup> and all medicines out of the reach of children.**

**General Information about LEVAQUIN<sup>®</sup>**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LEVAQUIN<sup>®</sup> for a condition for which it is not prescribed. Do not give LEVAQUIN<sup>®</sup> 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 LEVAQUIN<sup>®</sup>. If you would like more information about LEVAQUIN<sup>®</sup>, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about LEVAQUIN<sup>®</sup> that is written for healthcare professionals. For more information go to [www.levaquin.com](http://www.levaquin.com) or call 1-800-526-7736.

**What are the ingredients in LEVAQUIN<sup>®</sup>?**

- 250 mg LEVAQUIN<sup>®</sup> Film-Coated Tablets:
  - Active ingredient: levofloxacin.
  - Inactive ingredients: hypromellose, crospovidone, microcrystalline cellulose, magnesium stearate, polyethylene glycol, titanium dioxide, polysorbate 80 and synthetic red iron oxide.
- 500 mg LEVAQUIN<sup>®</sup> Film-Coated Tablets:
  - Active ingredient: levofloxacin.
  - Inactive ingredients: hypromellose, crospovidone, microcrystalline cellulose, magnesium stearate, polyethylene glycol, titanium dioxide, polysorbate 80 and synthetic red and yellow iron oxides.
- 750 mg LEVAQUIN<sup>®</sup> Film-Coated Tablets:
  - Active ingredient: levofloxacin.
  - Inactive ingredients: hypromellose, crospovidone, microcrystalline cellulose, magnesium stearate, polyethylene glycol, titanium dioxide, polysorbate 80.
- LEVAQUIN<sup>®</sup> Oral Solution (25 mg/mL):
  - Active ingredient: levofloxacin.
  - Inactive ingredients: sucrose, glycerin, sucralose, hydrochloric acid, purified water, propylene glycol, artificial and natural flavors, benzyl alcohol, ascorbic acid, and caramel color. It may also contain a solution of sodium hydroxide for pH adjustment.
    - LEVAQUIN<sup>®</sup> Oral Solution may look clear yellow to clear greenish-yellow in color.
- LEVAQUIN<sup>®</sup> Injection in Single-Use Vials:
  - Active ingredient: levofloxacin.
  - Inactive ingredients: water for injection. LEVAQUIN<sup>®</sup> for Injection Single Use Vials do not contain any preservatives.
- LEVAQUIN<sup>®</sup> Injection Premix in Single-Use Flexible Containers:
  - Active ingredient: levofloxacin.
  - Inactive ingredients: Dextrose (D<sub>5</sub>W). Solutions of hydrochloric acid and sodium hydroxide may have been added to adjust the pH.

NDA 20-634/S-053

NDA 20-635/S-058

NDA 21-721/S-021

Page 15

Manufactured by:

Janssen Ortho LLC, Gurabo, Puerto Rico 00778 (Tablets).

Janssen Pharmaceutica N.V., Beerse, Belgium (Oral Solution, Injection Single-Use Vials).

Hospira, Inc., Lake Forest, IL 60045 (Injection Premix).

Manufactured for:

PriCara, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. Raritan, NJ 08869 (Tablets, Oral Solution)

Ortho-McNeil, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. Raritan, NJ 08869 (Injection Single-Use Vials, Injection Premix)

©Ortho-McNeil-Janssen Pharmaceuticals, Inc.

U.S. Patent No. 5,053,407

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