17.5 FDA-Approved Patient Labeling

Patient Information About:

LEVAQUIN® (levofloxacin) Tablets

250 mg Tablets, 500 mg Tablets, and 750 mg Tablets

And

LEVAQUIN® (levofloxacin) Oral Solution, 25 mg/mL

This leaflet contains important information about LEVAQUIN®, and should be read completely before you begin treatment. This leaflet does not take the place of discussions with your doctor or healthcare professional about your medical condition or your treatment. This leaflet does not list all benefits and risks of LEVAQUIN®. The medicine described here can be prescribed only by a licensed healthcare professional. If you have any questions about LEVAQUIN® talk to your healthcare professional. Only your healthcare professional can determine if LEVAQUIN® is right for you.

What is LEVAQUIN®?

LEVAQUIN® is a quinolone antibiotic used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria. LEVAQUIN® kills many of the types of bacteria that can infect the lungs, sinuses, skin, and urinary tract and has been shown in a large number of clinical trials to be safe and effective for the treatment of bacterial infections.

Sometimes viruses rather than bacteria may infect the lungs and sinuses (for example, the common cold). LEVAQUIN®, like other antibiotics, does not kill viruses.

You should contact your healthcare professional if you think that your condition is not improving while taking LEVAQUIN®. LEVAQUIN® Tablets are terra cotta pink for the 250 mg tablet, peach colored for the 500 mg tablet, or white for the 750 mg tablet. The appearance of LEVAQUIN® Oral Solution may range from clear yellow to clear greenish-yellow.

How and when should I take LEVAQUIN®?

LEVAQUIN® should be taken once a day for 3, 5, 7, 10, 14 or 28 days depending on your prescription. LEVAQUIN® Tablets should be swallowed and may be taken with or without food. LEVAQUIN® Oral Solution should be taken 1 hour before or 2 hours after eating. Try to take the tablet and oral solution at the same time each day and drink fluids liberally.

You may begin to feel better quickly; however, in order to make sure that all bacteria are killed, you should complete the full course of medication. Do not take more than the prescribed dose of LEVAQUIN® even if you missed a dose by mistake. You should not take a double dose.

Who should not take LEVAQUIN®?

You should not take LEVAQUIN® if you have ever had a severe allergic reaction to any of the group of antibiotics known as "quinolones" such as ciprofloxacin. Serious and occasionally fatal allergic reactions have been reported in patients receiving therapy with quinolones, including LEVAQUIN®.

If you are pregnant or are planning to become pregnant while taking LEVAQUIN®, talk to your healthcare professional before taking this medication. LEVAQUIN® is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.

LEVAQUIN® is not recommended for children.

What are possible side effects of LEVAQUIN®?

LEVAQUIN® is generally well tolerated. The most common adverse drug reactions (≥3%) are nausea, headache, diarrhea, insomnia, constipation, and dizziness.

You should be careful about driving or operating machinery until you are sure LEVAQUIN® is not causing dizziness.

Allergic reactions have been reported in patients receiving quinolones including LEVAQUIN®, even after just one dose. If you develop hives, skin rash or other symptoms of an allergic reaction, you should stop taking this medication and call your healthcare professional.

Hepatotoxicity (liver damage) has been reported in patients receiving LEVAQUIN®. Call your doctor right away if you have unexplained symptoms such as: nausea or vomiting, stomach pain, fever, weakness, abdominal pain or tenderness, itching, unusual or unexplained tiredness, loss of appetite, light colored bowel movements, dark colored urine or yellowing of your skin or the whites of your eyes.

Pain, swelling, and tears of Achilles, shoulder, or hand tendons have been reported in patients receiving fluoroquinolones, including LEVAQUIN®. The risk for tendon effects is higher if you are over 65 years old, and especially if you are taking corticosteroids. If you

develop pain, swelling, or rupture of a tendon, you should stop taking LEVAQUIN®, avoid exercise and strenuous use of the affected area, and contact your healthcare professional.

Sun sensitivity (photosensitivity), which can appear as skin eruption or severe sunburn, can occur in some patients taking quinolone antibiotics after exposure to sunlight or artificial ultraviolet (UV) light (e.g., tanning beds). LEVAQUIN® has been infrequently associated with photosensitivity. Avoid excessive exposure to sunlight or artificial UV light while taking LEVAQUIN®. Use a sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your physician.

If you have diabetes and you develop a hypoglycemic reaction while on LEVAQUIN®, you should stop taking LEVAQUIN® and call your healthcare professional.

Convulsions have been reported in patients receiving quinolone antibiotics including LEVAQUIN®. If you have experienced convulsions in the past, be sure to let your physician know that you have a history of convulsions.

Quinolones, including LEVAQUIN®, may also cause central nervous system stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and rarely, suicidal thoughts or acts.

Diarrhea that usually ends after treatment is a common problem caused by antibiotics. A more serious form of diarrhea can occur during or up to 2 months after the use of antibiotics. This has been reported with all antibiotics including with LEVAQUIN®. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your physician as soon as possible.

In a few people, LEVAQUIN®, like some other antibiotics, may produce a small effect on the heart that is seen on an electrocardiogram test. The rare heart problem is called QT prolongation and can cause an abnormal heartbeat and can be very dangerous. The chances of this event are increased in those with a family history of prolonged QT interval, low potassium (hypokalemia), and who are taking drugs to control heart rhythm, called class IA (quinidine, procainamide) or class III (amiodarone, sotalol) antiarrhythmic agents. You should call your healthcare professional right away if you have any prolonged heart palpitations (a change in the way your heart beats) or a loss of consciousness (fainting spells).

If you notice any side effects not mentioned in this leaflet or you have concerns about the side effects you are experiencing, please inform your healthcare professional.

For more complete information regarding LEVAQUIN®, please refer to the full prescribing information, which may be obtained from your healthcare professional, pharmacist, or the Physicians Desk Reference (PDR).

What about other medicines I am taking?

Taking warfarin and LEVAQUIN® together can further predispose you to the development of bleeding problems. If you take warfarin, be sure to tell your healthcare professional.

Many antacids and multivitamins may interfere with the absorption of LEVAQUIN® and may prevent it from working properly. You should take LEVAQUIN® either 2 hours before or 2 hours after taking these products.

It is important to let your healthcare professional know all of the medicines you are using.

Other information

Take your dose of LEVAQUIN® once a day.

Complete the course of medication even if you are feeling better.

Keep this medication out of the reach of children.

Some quinolones, including LEVAQUIN®, may produce false-positive urine screening results for opiates using commercially available immunoassay kits. Confirmation of positive opiate screens by more specific methods may be necessary.

This information does not take the place of discussions with your doctor or healthcare professional about your medical condition or your treatment.

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