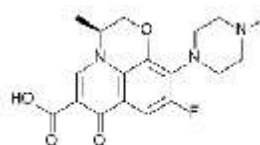


Rx LEVOFLOXACIN

(Levofloxacin is an antibiotic for treating bacterial infections)



GENERIC NAME: levofloxacin

DRUG CLASS AND MECHANISM

Levofloxacin is an antibiotic for treating bacterial infections. Many common infections in humans are caused by bacteria. Bacteria can grow and multiply, infecting different parts of the body. Drugs that control and eradicate these bacteria are called antibiotics. Levofloxacin is an antibiotic that stops multiplication of bacteria by preventing the reproduction and repair of their genetic material, DNA. It is in a class of antibiotics called fluoroquinolones, a class that includes ciprofloxacin (Cipro), norfloxacin (Noroxin), ofloxacin (Floxin), trovafloxacin (Trovan), and lomefloxacin (Maxaquin). The FDA approved levofloxacin in December 1996.

GENERIC AVAILABLE: No

PRESCRIPTION: Yes

PREPARATIONS: Tablets: 250, 500, and 750 mg; Oral solution: 25 mg/mL; Injection: 5 mg/ml and 25 mg/ml

PRESCRIBED FOR

Levofloxacin is used to treat infections of the sinuses, skin, lungs, ears, airways, bones, and joints caused by susceptible bacteria. Levofloxacin also is frequently used to treat urinary infections, including those resistant to other antibiotics, as well as prostatitis (infection of the prostate). Levofloxacin is effective in treating infectious diarrhea caused by *E. coli*, *Campylobacter jejuni*, and *Shigella* bacteria. Levofloxacin also can be used to treat various obstetric infections, including mastitis (infection of the breast).

DOSING

The usual dose is 250-750 mg given once daily for 5-60 days depending on the type of infection. It is important to take oral formulations at least 2 hours before or 2 hours after any antacid or mineral supplement containing iron, calcium, zinc, or magnesium since these bind levofloxacin and prevent its absorption into the body.

DRUG INTERACTIONS

Iron, calcium, zinc, or magnesium can attach to levofloxacin and other fluoroquinolones and prevent their absorption from the intestine into the blood. Therefore, products (for example, antacids) that contain iron, calcium, zinc or magnesium should be taken at least 2 hours before or 2 hours after levofloxacin. Other drugs that contain these minerals and can similarly interact with levofloxacin include sucralfate (Carafate) and didanosine (Videx, Videx EC).

Taking nonsteroidal antiinflammatory drugs (NSAIDs) with levofloxacin may increase the risk of CNS stimulation, resulting in over-excitation. There have been reports of changes in blood sugar (increases and decreases) in patients treated with fluoroquinolones and antidiabetic agents. Fluoroquinolones may increase blood levels of theophylline (Theodur), cyclosporine (Sandimmune, Neoral), and the effect of warfarin (Coumadin).

USES

This medication is used to treat a variety of bacterial infections. Levofloxacin belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria. This antibiotic only treats bacterial infections. It will not work for viral infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

HOW TO USE

Take this medication by mouth, usually once daily with or without food, or as directed by your doctor. Drink plenty of fluids while taking this medication unless otherwise directed by your doctor. Take this medication at least 2 hours before or 2 hours after taking any medications containing magnesium or aluminum. Some examples include quinapril, certain forms of didanosine (chewable/dispersible buffered tablets or pediatric oral solution), vitamins/minerals, and antacids. Sucralfate, bismuth subsalicylate, iron, and zinc are also included. These medications bind with levofloxacin preventing its full absorption. Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals. Continue to take this medication until the full-prescribed amount is finished even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a relapse of the infection. Inform your doctor if your condition does not improve. Read the Patient Information Leaflet available from your pharmacist. If you have any questions, consult your doctor or pharmacist.

SIDE EFFECTS

Nausea, stomach upset, loss of appetite, diarrhea, drowsiness, dizziness, headache, or trouble sleeping may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: joint/muscle/tendon pain or swelling (tendonitis, tendon rupture), sunburn (sun sensitivity). Tell your doctor immediately if any of these highly unlikely

but very serious side effects occur: chest pain, change in the amount of urine, dark urine, easy bruising/bleeding, fainting, fast/irregular heartbeat, mental/mood changes (e.g., suicidal thought or severe depression), persistent nausea/vomiting, persistent sore throat or fever, seizures, unusual fatigue, yellowing eyes and skin. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection (oral or vaginal fungal infection). Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge or other new symptoms. This medication may rarely cause a severe intestinal condition (pseudomembranous colitis) due to a resistant bacteria. This condition may occur while receiving therapy or even weeks after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have the following symptoms because these products may make them worse. Seek immediate medical attention if you develop: abdominal or stomach pain/cramping, blood/mucus in your stool, persistent diarrhea. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, hives, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking levofloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolones such as ciprofloxacin, gatifloxacin, gemifloxacin, or moxifloxacin; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain or nervous system disorders (e.g., cerebral arteriosclerosis, tumors, increased intracranial pressure), heart problems (e.g., cardiomyopathy, slow heart rate, torsades de pointes, QTc prolongation), history of seizures, kidney disease, muscle/joint/tendon problems, untreated mineral imbalance (e.g., low potassium). This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths or sunlamps. Use a sunscreen and wear protective clothing when outdoors. If you have diabetes and are taking insulin or oral anti-diabetic drugs (e.g., glyburide), you may experience changes in blood glucose levels due to infection or use of levofloxacin. Monitor your blood glucose frequently while using this medication and notify your doctor if you experience symptoms of high or low blood sugar. Symptoms of high blood sugar include increased thirst and urination. Symptoms of low blood sugar include dizziness, hunger, sweating and fast pulse. Caution is advised when using this drug in the elderly because they may be more sensitive to its side effects (e.g., tendon problems, especially if they are also taking corticosteroids drugs such as prednisone). Caution is advised when using this drug in children. Contact your doctor for more information. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. Based on information for similar drugs, levofloxacin may pass into breast milk. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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