Levaquin (levofloxacin) - Drug Summary

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Levaquin (levofloxacin)

BOXED WARNING

Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture in all ages. Risk is further increased in patients >60 yrs of age, patients taking corticosteroids, and with kidney, heart, or lung transplants. May exacerbate muscle weakness with myasthenia gravis; avoid in patients with known history of myasthenia gravis.

THERAPEUTIC CLASS

Fluoroquinolone

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Pneumonia

Oral/IV:
Nosocomial Pneumonia: 750mg q24h for 7-14 days
Community-Acquired Pneumonia: 750mg q24h for 5 days or 500mg q24h for 7-14 days

Acute Bacterial Sinusitis

750mg q24h for 5 days or 500mg q24h for 10-14 days

Acute Bacterial Exacerbation of Chronic Bronchitis

500mg q24h for 7 days

Skin and Skin Structure Infections

Complicated: 750mg q24h for 7-14 days
Uncomplicated: 500mg q24h for 7-10 days

Chronic Bacterial Prostatitis

500mg q24h for 28 days

Urinary Tract Infections

Complicated/Acute Pyelonephritis: 750mg q24h for 5 days or 250mg q24h for 10 days
Uncomplicated: 250mg q24h for 3 days

Inhalational Anthrax (Postexposure)

>50kg: 500mg q24h for 60 days

Plague

Pneumonic/Septicemic Plague and Prophylaxis:
500mg q24h for 10-14 days

PEDIATRIC DOSAGE & INDICATIONS

Inhalational Anthrax (Postexposure)

≥6 Months of Age:

<50kg: 8mg/kg q12h for 60 days
Max: 250mg/dose
>50kg: 500mg q24h for 60 days

Plague

Pneumonic/Septicemic Plague and Prophylaxis:
≥6 Months of Age:
<50kg: 8mg/kg q12h for 10-14 days
Max: 250mg/dose
>50kg: 500mg q24h for 10-14 days

DOSING CONSIDERATIONS

Renal Impairment
750mg q24h:
CrCl 20-49mL/min: 750mg q48h
CrCl 10-19mL/min or Hemodialysis/Chronic Ambulatory Peritoneal Dialysis: 750mg initial dose, then 500mg q48h

500mg q24h:
CrCl 20-49mL/min: 500mg initial dose, then 250mg q24h
CrCl 10-19mL/min or Hemodialysis/Chronic Ambulatory Peritoneal Dialysis: 500mg initial dose, then 250mg q48h

250mg q24h:
CrCl 20-49mL/min: No dose adjustment
CrCl 10-19mL/min: 250mg q48h; if treating uncomplicated UTI, no dose adjustment required
Hemodialysis/Chronic Ambulatory Peritoneal Dialysis: No information on dose adjustment available

ADMINISTRATION

IV/Oral route

Drink fluids liberally

Oral
Take antacids, metal cations, and multivitamins at least 2 hrs before or 2 hrs after oral administration
Take at the same time each day
Tab: Take w/ or w/o food
Sol: Take 1 hr before or 2 hrs after eating

IV
Not for rapid or bolus IV infusion
Do not coadminister w/ any sol containing multivalent cations through the same IV line
Infuse over 60 min (250-500mg) or over 90 min (750mg)
Refer to PI for administration, preparation, stability, compatibility, and thawing instructions

HOW SUPPLIED

Inj: 5mg/mL in D5W [50mL, 100mL, 150mL]; Sol: 25mg/mL [480mL]; Tab: 250mg, 500mg, 750mg

WARNINGS/PRECAUTIONS

D/C if patient experiences pain, swelling, inflammation, or rupture of a tendon. Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions reported; d/c immediately at the 1st appearance of a skin rash, jaundice, or any other sign of hypersensitivity, and institute supportive measures. Severe hepatotoxicity, including acute hepatitis and fatal events, reported; d/c immediately if signs and symptoms of hepatitis occur. Convulsions, toxic psychoses, and increased intracranial pressure (including pseudotumor cerebri) reported. CNS stimulation may occur; d/c and institute appropriate measures if CNS events occur. Caution with CNS disorders (eg, severe cerebral arteriosclerosis, epilepsy) or risk factors that may predispose to seizures or lower seizure threshold. *Clostridium difficile*-associated diarrhea (CDAD) reported; may need to d/c if CDAD is suspected or confirmed. Cases of sensory or sensorimotor axonal polyneuropathy resulting in paresthesias, hypoesthesias, dysesthesias, and weakness reported; d/c immediately if symptoms of neuropathy occur. May prolong QT interval; avoid with known QT interval prolongation or uncorrected hypokalemia. Increased incidence of musculoskeletal disorders in pediatric patients. Blood glucose disturbances reported in diabetics; d/c and initiate appropriate therapy if hypoglycemic reaction occurs. May cause photosensitivity/phototoxicity reactions; avoid excessive exposure to sun/UV light and d/c if occurs. May increase risk of bacterial resistance if used in the absence of a proven/suspected bacterial infection or a prophylactic indication. Crystalluria and cylindruria reported; maintain adequate hydration. May produce false-positive urine screening results for opiates. Caution in elderly and with renal impairment.

ADVERSE REACTIONS

Tendinitis, tendon rupture, nausea, diarrhea, constipation, headache, insomnia, dizziness.

DRUG INTERACTIONS

See Boxed Warning. Caution with drugs that may lower the seizure threshold. Avoid with Class IA (eg, quinidine, procainamide) and Class III (eg, amiodarone, sotalol) antiarrhythmics. May enhance effects of warfarin; monitor PT and INR. Disturbances of blood glucose in diabetic patients receiving a concomitant antidiabetic agent reported; monitor glucose levels. NSAIDs may increase risk of CNS stimulation and convulsive seizures. May prolong theophylline $T_{1/2}$ and increase theophylline levels/risk of theophylline-related adverse reactions; monitor theophylline levels closely. Probenecid or cimetidine may increase exposure and reduce renal clearance. (PO) Antacids containing Mg^{2+}, aluminum, as well as sucralfate, metal cations such as iron, and multivitamin preparations with zinc or didanosine chewable/buffered tab or pediatric powder for oral sol may substantially interfere with the GI absorption and lower systemic concentrations; take at least 2 hrs before or 2 hrs after oral levofloxacin.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Fluoroquinolone; inhibits bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerases), enzymes required for DNA replication, transcription, repair, and recombination.

PHARMACOKINETICS

Absorption: Administration of variable doses resulted in different parameters. (PO) Rapid and complete. (Tab: 500mg, 750mg) Absolute bioavailability (99%). **Distribution:** V_d=74-112L (500mg, 750mg); plasma protein binding (24-38%); found in breast milk. **Metabolism:** Limited. **Elimination:** (PO) Urine (87% unchanged, <5% desmethyl and N-oxide metabolites), feces (<4%). Refer to PI for additional pharmacokinetic information.

ASSESSMENT

Assess for risk factors for developing tendinitis and tendon rupture, history of myasthenia gravis, drug hypersensitivity, CNS disorders or risk factors that may predispose to seizures or lower seizure threshold, QT interval prolongation, uncorrected hypokalemia, renal/hepatic impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for tendon rupture, tendinitis, exacerbation of myasthenia gravis, hypersensitivity reactions, hepatotoxicity, CNS effects, CDAD, peripheral neuropathy, ECG changes, arrhythmias, musculoskeletal disorders (pediatric patients), photosensitivity/phototoxicity reactions, and other adverse reactions. Monitor hydration status, blood glucose levels, and renal function. Monitor for evidence of bleeding, PT, and INR with warfarin.

PATIENT COUNSELING

Inform that drug only treats bacterial, not viral, infections. Advise to take as prescribed; inform that skipping doses or not completing full course of therapy may decrease effectiveness and increase likelihood of drug resistance. Advise to contact physician if pain, swelling, or inflammation of a tendon, or weakness or inability to move joints develops; instruct to d/c therapy and rest/refrain from exercise. Advise to d/c use and notify physician if allergic reaction, skin rash, or signs/symptoms of liver injury occur. Instruct to inform physician if experiencing any symptoms of muscle weakness, including respiratory difficulties. Advise to notify physician of any history of convulsions, QT prolongation, or myasthenia gravis. Inform that peripheral neuropathy has been associated with therapy, and that symptoms may occur soon after initiation of therapy and may be irreversible; instruct to d/c treatment immediately and contact physician if symptoms of peripheral neuropathy develop. Instruct to use caution with activities requiring mental alertness and coordination; advise to notify physician if persistent headache with or without blurred vision occurs. Instruct to contact physician immediately if watery and bloody diarrhea (with or without stomach cramps and fever) develop, even as late as ≥2 months after last dose. Advise to inform physician if child has tendon or joint-related problems prior to, during, or after therapy. Advise to minimize or avoid exposure to natural or artificial sunlight. Instruct diabetic patients being treated with antidiabetic agents to d/c therapy and notify physician if hypoglycemia occurs. Advise to inform physician if taking warfarin.

STORAGE

(Tab) 15-30°C (59-86°F). (Sol) 25°C (77°F); excursions permitted to 15-30°C (59-86°F). (Inj) Single-use Vials: Controlled room temperature. Protect from light. Premixed Sol: ≤25°C (77°F); brief exposure ≤40°C (104°F) does not adversely affect product. Avoid excessive heat and protect from freezing and light. Diluted Sol (5mg/mL): Stable at ≤25°C (77°F) for 72 hrs; 5°C (41°F) for 14 days; -20°C (-4°F) for 6 months.

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