Avelox (moxifloxacin hydrochloride) - Drug Summary

Schering Plough Corporation

Related Drug Information

Avelox
(moxifloxacin hydrochloride)

BOXED WARNING

Fluoroquinolones are associated w/ 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 w/ kidney, heart, or lung transplants. May exacerbate muscle weakness w/ myasthenia gravis; avoid in patients w/ known history of myasthenia gravis.

View FDA-Approved Full Prescribing Information for Avelox

THERAPEUTIC CLASS

Fluoroquinolone

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Skin and Skin Structure Infections

Uncomplicated: 400mg PO/IV q24h for 7 days

Complicated: 400mg PO/IV q24h for 7-21 days

Intra-Abdominal Infections

Complicated: 400mg PO/IV q24h for 5-14 days

Acute Bacterial Sinusitis

400mg PO/IV q24h for 10 days

Acute Bacterial Exacerbation of Chronic Bronchitis

400mg PO/IV q24h for 5 days

Community-Acquired Pneumonia

400mg PO/IV q24h for 7-14 days

Plague

400mg PO/IV q24h for 10-14 days

Conversions

Patients started w/ IV therapy may be switched to tabs when clinically indicated

ADMINISTRATION

Oral/IV route

Tab
W/ Multivalent Cations:

Administer at least 4 hrs before or 8 hrs after products containing Mg^{2+}, aluminum, iron or zinc, including antacids, sucralfate, multivitamins, and didanosine buffered tabs for oral sus or the pediatric powder for oral sol

W/ Food:
Take w/ or w/o food
Drink fluids liberally

IV
Administer by IV infusion only; avoid rapid or bolus IV infusion
Infuse IV over 60 min by direct infusion or through a Y-type IV infusion set

Drug and Diluent Compatibilities:
Do not add other IV substances, additives, or other medications to inj or infuse simultaneously through same IV line
Flush the line before and after infusion w/ an infusion sol compatible w/ the inj as well as w/ other drug(s) administered via this common line if the same IV line or a Y-type line is used for sequential infusion of other drugs, or if the "piggyback" method of administration is used

Compatible IV Sol:
0.9% NaCl inj
1M NaCl inj
D5 inj
Sterile Water for inj
D10 for inj
Lactated Ringer's for inj

HOW SUPPLIED

Inj: 400mg/250mL; Tab: 400mg

WARNINGS/PRECAUTIONS

D/C if pain, swelling, inflammation, or rupture of a tendon occurs. May prolong QT interval; avoid w/ known QT interval prolongation, ventricular arrhythmias including torsades de pointes, ongoing proarrhythmic conditions (eg, clinically significant bradycardia, acute myocardial ischemia), or uncorrected hypokalemia or hypomagnesemia. Elderly using IV formulation may be more susceptible to drug-associated QT prolongation. May lead to QT prolongation in patients w/ mild, moderate, or severe liver cirrhosis, or in patients w/ metabolic disturbances associated w/ hepatic insufficiency; monitor ECG in patients w/ liver cirrhosis. Serious anaphylactic reactions and other serious and sometimes fatal events reported; d/c immediately and institute supportive measures if skin rash, jaundice, or any other signs of hypersensitivity occur. Convulsions, increased intracranial pressure (eg, pseudotumor cerebri), and other CNS reactions reported; d/c and institute appropriate measures if CNS reactions (eg, dizziness, confusion, tremors) occur. Use therapy when the benefits of treatment exceed the risks w/ CNS disorders (eg, severe cerebral arteriosclerosis, epilepsy) or in the presence of other 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 peripheral neuropathy occur. Blood glucose disturbances (eg, hypo/hyperglycemia) in diabetics reported; d/c therapy and immediately initiate appropriate therapy if hypoglycemic reaction occurs. May cause photosensitivity/phototoxicity reactions; d/c if phototoxicity occurs. Avoid excessive exposure to sun/UV light. May result in bacterial resistance if used in the absence of a proven/strongly suspected bacterial infection or a prophylactic indication.

ADVERSE REACTIONS

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

DRUG INTERACTIONS

See Boxed Warning. Avoid w/ Class IA (eg, quinidine, procainamide), Class III (eg, amiodarone, sotalol) antiarrhythmics, or other drugs that prolong the QT interval (eg, cisapride, erythromycin, antipsychotics, TCAs). NSAIDs may increase risk of CNS stimulation and convulsions. May enhance anticoagulant effects of warfarin or its derivatives; monitor PT and INR. Disturbances of blood glucose in diabetic patients receiving a concomitant antidiabetic agent reported; monitor glucose levels. (Tab) Antacids containing Mg^{2+} or aluminum, sucralfate, metal cations (eg, iron), multivitamins containing iron or zinc, or formulations containing divalent and trivalent cations such as didanosine buffered tabs for oral sus or the pediatric powder for oral sol, may substantially interfere w/ absorption and lower systemic concentrations.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Fluoroquinolone; bactericidal action results from inhibiting topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair, and recombination.

PHARMACOKINETICS

Absorption: (PO) Well-absorbed; absolute bioavailability (approx 90%). **Distribution:** V_d=1.7-2.7L/kg; plasma protein binding (approx 30-50%). **Metabolism:** Glucuronide and sulfate conjugation. **Elimination:** approx 45% unchanged; urine (20%), feces (25%). Single dose: $T_{1/2}$=11.5-15.6 hrs (PO), 8.2-15.4 hrs (IV). Refer to PI for additional pharamcokinetic parameters.

ASSESSMENT

Assess for risk factors for developing tendinitis and tendon rupture, history of myasthenia gravis, drug hypersensitivity, known QT interval prolongation, ventricular arrhythmias including torsades de pointes, uncorrected hypokalemia or hypomagnesemia, ongoing proarrhythmic conditions, liver cirrhosis, CNS disorders or risk factors that may predispose to seizures or lower seizure threshold, diabetes, hepatic impairment, pregnancy/nursing status, and possible drug interactions. Obtain baseline culture and susceptibility tests.

MONITORING

Monitor for ECG changes (eg, QT interval prolongation), signs/symptoms of anaphylactic reactions, CNS reactions, drug resistance, CDAD, peripheral neuropathy, tendon rupture, tendinitis, photosensitivity/phototoxicity reactions, and other adverse reactions. Monitor for muscle weakness in patients w/ myasthenia gravis. Monitor blood glucose levels in diabetic patients. Monitor PT and INR if administered w/ warfarin or its derivatives.

PATIENT COUNSELING

Inform that drug treats only bacterial, not viral infections. Instruct to take exactly ud; skipping doses or not completing full course may decrease effectiveness and increase bacterial resistance. Instruct to notify physician if pain, swelling, or inflammation of a tendon, or weakness or inability to move joints occurs; advise to rest and refrain from exercise and to d/c therapy. Instruct to notify physician if experiencing worsening muscle weakness or breathing problems, palpitations or fainting spells, sunburn-like reaction or skin eruption, or if watery and bloody stools (even ≥2 months after last dose) develop. Advise to notify physician of all medications and supplements currently being used. Instruct to inform physician of any personal or family history of QT prolongation, proarrhythmic conditions, convulsions, or psychiatric illness. Instruct diabetic patients being treated w/ antidiabetic agents to d/c therapy and notify physician if hypoglycemia occurs. Instruct to d/c and notify physician if an allergic reaction, skin rash, or symptoms of peripheral neuropathy develop. Inform that drug may cause dizziness, lightheadedness, and vision disorders; instruct to use caution w/ activities requiring mental alertness or coordination. Advise to minimize or avoid exposure to natural or artificial light (eg, tanning beds or UVA/B treatment). Inform that efficacy studies of therapy could not be conducted in humans w/ plague for feasibility reasons and that approval for plague was based on efficacy studies conducted in animals.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). (Tab) Avoid high humidity. (Inj) Do not refrigerate.

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