Taj Pharmaceuticals Ltd.

Moxifloxacin HCl

CAS No. : 186826-86-8

Systematic (IUPAC) name

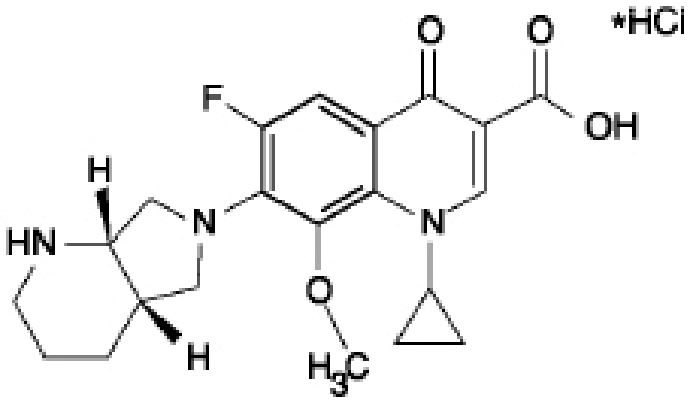
1-cyclopropyl-7-[(1S,6S)-2,8-diazabicyclo
[4.3.0]non-8-yl]-6-fluoro-8-methoxy-4-oxo- quinoline-3-carboxylic acid

Identifiers

ATC code J01MA14
PubChem 152946
DrugBank APRD00281
ChemSpider 134802

Chemical data

Formula C21H24FN3O4
Mol. mass 401.431 g/mol
SMILES eMolecules & PubChem



Pharmacokinetic data

Bioavailability 86 to 92%
Protein binding 30 to 50%
Metabolism Glucuronide and sulfate conjugation
Cytochrome P450 system not involved
Half life 12 hours
Excretion hepatic
Therapeutic considerations
Pregnancy cat.

WARNING

This medication may rarely cause tendon damage (e.g., tendinitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have had a kidney, heart or lung transplant. Stop exercising, rest, and seek immediate medical attention if you develop joint/muscle/tendon pain or swelling.

USES

Moxifloxacin is used to treat a variety of bacterial infections. This medication belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria.
This antibiotic treats only bacterial infections. It will not work for virus 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 with or without food, usually once daily or as directed by your doctor. The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this drug unless your doctor tells you otherwise.

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Take this medication at least 4 hours before or 8 hours after taking any drugs that contain magnesium or aluminum. Some examples include quinapril, certain forms of didanosine (chewable/dispersible buffered tablets or pediatric oral solution), vitamins/minerals, and antacids. Follow the same instructions if you take bismuth subsalicylate, sucralfate, iron, and zinc. These medications bind with moxifloxacin and prevent its full absorption.
Antibiotics work best when the amount of medicine in your body is kept at a constant level. It is important not to miss a dose. To help you remember, take this medication at the same time every day.

SIDE EFFECTS

Nausea, diarrhea, dizziness, lightheadedness, headache, weakness, or trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., anxiety, confusion, hallucinations, depression, rare thoughts of suicide), shaking (tremors). Moxifloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Seek immediate medical attention if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration. This medication may rarely cause a severe intestinal condition (pseudomembranous colitis) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have any of the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling, severe dizziness, trouble breathing.

PRECAUTIONS

Before taking moxifloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolone antibiotics (e.g., ciprofloxacin, levofloxacin); or if you have any other allergies.
This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: history of a certain heart problem (QT prolongation in the EKG), untreated low levels of potassium or magnesium in the blood.
Before using this medication, tell your doctor or pharmacist your medical history, especially of: diabetes, family history of a certain heart problem (QT prolongation in the EKG), heart problems (e.g., slow/fast/irregular heartbeat, heart failure, recent heart attack), joint/tendon problems (e.g., tendonitis, bursitis), liver disease, nervous system disorder (e.g., peripheral neuropathy), seizure disorder, conditions that increase your risk of seizures (e.g., brain/head injury, brain tumors, cerebral atherosclerosis).
This his drug may make you dizzy or lightheaded. Use caution while driving, using machinery, or taking part in any activity that requires alertness. Limit alcoholic beverages.

MISSED DOSE

If you miss a dose, take 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 at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

The recommended adult dose of moxifloxacin is 400 mg once daily, with or without food. The medication may be taken for 5 to 10 days, depending on the particular infection being treated. Some people may require up to 14 days of treatment with moxifloxacin. Moxifloxacin tablets should be swallowed whole with plenty of fluids. Moxifloxacin should be taken at least 4 hours before or 8 hours after multivitamins that contain iron or zinc, or antacids that contain magnesium, aluminum, or calcium. Ask your pharmacist if you are not sure if your mulitvitamins or antacids contain these ingredients. It is important that this medication be taken exactly as prescribed by your doctor. If you miss a dose, take it as soon as possible and continue with your regular schedule. If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to make up for a missed one.

DRUG DESCRIPTION

Moxifloxacin Hydrochlorideis a synthetic broad spectrum antibacterial agent and is available as Tablets for oral administration and as I.V. for intravenous administration. Moxifloxacin, a fluoroquinolone, is available as the monohydrochloride salt of 1-cyclopropyl-7-[(S,S)-2,8-diazabicyclo[4.3.0]non-8-yl]-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3 quinoline carboxylic acid. It is a slightly yellow to yellow crystalline substance with a molecular weight of 437.9. The inactive ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol and ferric oxide.

Moxifloxacin Hydrochlorideis I.V. is available in ready-to-use 250 mL latex-free flexibags as a sterile, preservative free, 0.8% sodium chloride aqueous solution of moxifloxacin hydrochloride (containing 400 mg moxifloxacin) with pH ranging from 4.1 to 4.6. The appearance of the intravenous solution is yellow. The color does not affect, nor is it indicative of, product stability. The inactive ingredients are sodium chloride, USP, Water for Injection, USP, and may include hydrochloric acid and/or sodium hydroxide for pH adjustment. I.V. contains approximately 34.2 mEq (787 mg) of sodium in 250 mL.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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