

Stajer

(Moxifloxacin HCl U.S.P.)

اسٹاجر

موسکی فلکسائن ہائیڈروکلورائیڈ ٹیبلٹ (یو.ایس.پی.)

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS

- Fluoroquinolones, including moxifloxacin, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:
 - Tendinitis and tendon rupture
 - Peripheral neuropathy
 - Central nervous system effects
- Discontinue moxifloxacin immediately and avoid the use of fluoroquinolones, including moxifloxacin, in patients who experience any of these serious adverse reactions.
- Fluoroquinolones, including moxifloxacin, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid moxifloxacin in patients with known history of myasthenia gravis.
- Because fluoroquinolones, including moxifloxacin, have been associated with serious adverse reactions, reserve moxifloxacin for use in patients who have no alternative treatment options for the following indications:
 - Acute bacterial sinusitis
 - Acute bacterial exacerbation of chronic bronchitis

COMPOSITION

Each film coated tablet contains: Moxifloxacin as Hydrochloride 400mg.
"Product contains Lactose"

DESCRIPTION

Stajer is a synthetic broad spectrum antibacterial agent.

CLINICAL PHARMACOLOGY

Mechanism of Action: Moxifloxacin has in vitro activity against a wide range of Gram-positive and Gram negative microorganisms. The bactericidal action of moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV required for bacterial DNA replication, transcription, repair, and recombination.

PHARMACOKINETICS

Absorption: Moxifloxacin, given as an oral tablet, is well absorbed from the gastrointestinal tract. The absolute bioavailability of moxifloxacin is approximately 90 percent.

Distribution: Moxifloxacin is approximately 50% bound to serum proteins, independent of drug concentration. Moxifloxacin is widely distributed throughout the body, with tissue concentrations often exceeding plasma concentrations. The rates of elimination of moxifloxacin from tissues generally parallel the elimination from plasma.

Metabolism: Moxifloxacin is metabolized via glucuronide and sulfate conjugation. The cytochrome P450 system is not involved in moxifloxacin metabolism, and is not affected by moxifloxacin. The sulfate conjugate (M1) accounts for approximately 38% of the dose, and is eliminated primarily in the feces. Approximately 14% of an oral dose is converted to a glucuronide conjugate (M2), which is excreted exclusively in the urine.

Elimination: Approximately 45% of an oral dose of moxifloxacin is excreted as unchanged drug (~20% in urine and ~25% in feces). A total of 96% ± 4% of an oral dose is excreted as either unchanged drug or known metabolites.

INDICATIONS, DOSAGE AND ADMINISTRATION

Stajer tablets can be taken with or without food, drink fluids liberally. Stajer 400 mg film-coated tablets are indicated for the treatment of the following bacterial infections in patients of 18 years and older caused by bacteria susceptible to moxifloxacin. Dose is 400 mg (orally) once every 24 hours. The duration of therapy depends on the type of infection.

Infection	Daily Dose	Duration
Acute bacterial sinusitis	400 mg	10 days
Acute bacterial exacerbation of chronic bronchitis	400 mg	5 days
Plague	400 mg	10 - 14 days
Community acquired pneumonia	400 mg	7 - 14 days
Uncomplicated skin and skin structure infections	400 mg	7 days
Complicated skin and skin structure infections	400 mg	7 - 21 days
Complicated intra-abdominal infections	400 mg	5 - 14 days

Moxifloxacin should be administered at least 4 hours before or 8 hours after products containing magnesium, aluminum, iron or zinc, including antacids, sucralfate, multivitamins and didanosine chewable/buffered tablets.

SIDE EFFECTS

The most common adverse reactions (>0.3%) leading to discontinuation with the 400 mg oral doses were nausea, diarrhea, dizziness, and vomiting.

Body as a whole: Headache, abdominal pain, asthenia, moniliasis, pain, malaise, lab test abnormal (not specified), allergic reaction, leg pain, back pain, chills, infection, chest pain, hand pain.

Cardiovascular: Palpitation, tachycardia, hypertension, peripheral edema, QT interval prolonged.

Central nervous system: Insomnia, nervousness, anxiety, confusion, somnolence, tremor, vertigo, paresthesia.

Digestive: Vomiting, abnormal liver function test, dyspepsia, dry mouth, constipation, oral moniliasis, anorexia, stomatitis, glossitis, flatulence, gastrointestinal disorder, cholestatic jaundice, GGTP increased.

Hemic and lymphatic: Prothrombin decrease, thrombocythemia, thrombocytopenia, eosinophilia, leukopenia.

Metabolic and nutritional: Amylase increased, lactic dehydrogenase increased.

Musculoskeletal: Arthralgia, myalgia.

Respiratory: Dyspnea, cough increased, pneumonia, pharyngitis, rhinitis, sinusitis.

Skin/appendages: Rash (maculopapular, purpuric, pustular), pruritus, sweating, dry skin.

Special senses: Taste perversion.

Urogenital: Vaginal moniliasis, vaginitis, cystitis.

WARNINGS AND PRECAUTIONS

Tendinitis and Tendon Rupture: This adverse reaction most frequently involves the Achilles tendon, and has also been reported with the rotator cuff (the shoulder), the hand, the biceps, the thumb, and other tendons. Discontinue moxifloxacin immediately if the patient experiences pain, swelling, inflammation or rupture of a tendon.

Peripheral neuropathy: Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones including moxifloxacin. Discontinue moxifloxacin immediately if the patient experiences symptoms of peripheral neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.

Central Nervous System Effects: Fluoroquinolones, including moxifloxacin, have been associated with an increased risk of central nervous system (CNS) reactions, including: convulsions and increased intracranial pressure (including pseudotumor cerebri) and toxic psychosis. Fluoroquinolones may also cause CNS reactions of nervousness, agitation, insomnia, anxiety, nightmares, paranoia, dizziness, confusion, tremors, hallucinations, depression, and, suicidal thoughts or acts. Discontinue moxifloxacin immediately.

Exacerbation of Myasthenia Gravis: Fluoroquinolones, including moxifloxacin, have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis. Avoid moxifloxacin in patients with known history of myasthenia gravis.

QT Prolongation: Prolongation of the QT interval and isolated cases of torsade de pointes has been reported. Avoid use in patients with known prolongation, proarrhythmic conditions such as clinically significant bradycardia or acute myocardial ischemia, hypokalemia, hypomagnesemia, and with drugs that prolong the QT interval.

Hypersensitivity and other serious reactions: Serious and sometimes fatal reactions, including anaphylactic reactions, may occur after first or subsequent doses of moxifloxacin. Discontinue moxifloxacin at first sign of skin rash, jaundice or any other sign of hypersensitivity.

Clostridium difficile-Associated Diarrhea: Evaluate if diarrhea occurs.

Blood Glucose Disturbances: As with all fluoroquinolones, disturbances in blood glucose, including both hypoglycemia and hyperglycemia have been reported with moxifloxacin.

Photosensitivity/Phototoxicity: Moderate to severe photosensitivity/phototoxicity reactions can be associated with the use of fluoroquinolones, including moxifloxacin, after sun or UV light exposure. Therefore, excessive exposure to these sources of light should be avoided. Moxifloxacin should be discontinued if phototoxicity occurs.

Development of Drug Resistant Bacteria: Prescribing moxifloxacin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

DRUG INTERACTIONS

Warfarin: Prothrombin time or other suitable coagulation test should be closely monitored if a quinolone antimicrobial is administered concomitantly with warfarin or its derivatives.

Antidiabetic Agents: Disturbances of blood glucose, including hyperglycemia and hypoglycemia, have been reported. Therefore, careful monitoring of blood glucose is recommended when these agents are co-administered.

Nonsteroidal anti-inflammatory drugs (NSAIDs): Although not observed with moxifloxacin in preclinical and clinical trials, the concomitant administration of a nonsteroidal anti-inflammatory drug with a quinolone may increase the risks of CNS stimulation and convulsions.

Drugs that Prolong QT: Moxifloxacin should be avoided with Class IA and Class III antiarrhythmics.

USE IN SPECIAL POPULATIONS

Pregnancy Category C: Because no adequate or well-controlled studies have been conducted in pregnant women, moxifloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Geriatric: Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture. This risk is further increased in patients receiving concomitant corticosteroid therapy. Caution should be used when prescribing moxifloxacin to elderly patients. No dosage adjustment is necessary based on age.

Pediatric: Safety and effectiveness in pediatric patients and adolescents less than 18 years of age have not been established.

Gender: Dosage adjustments based on gender are not necessary.

Renal Insufficiency: No dosage adjustment is necessary in patients with renal impairment.

Hepatic Insufficiency: No dosage adjustment is recommended for mild, moderate, or severe hepatic insufficiency. However, due to metabolic disturbances associated with hepatic insufficiency, which may lead to QT prolongation, moxifloxacin should be used with caution in these patients.

CONTRAINDICATIONS

Stajer is contraindicated in persons with a history of hypersensitivity to moxifloxacin or any member of the quinolone class of antibacterial.

OVERDOSAGE

Single oral overdoses up to 2.8 g were not associated with any serious adverse events. In the event of acute overdose, Empty the stomach and maintain adequate hydration. Monitor ECG due to the possibility of QT interval prolongation. Carefully observe the patient and give supportive treatment. The administration of activated charcoal as soon as possible after oral overdose may prevent excessive increase of systemic moxifloxacin exposure. About 3% and 9% of the dose of moxifloxacin, as well as about 2% and 4.5% of its glucuronide metabolite are removed by continuous ambulatory peritoneal dialysis and hemodialysis, respectively.

PRESENTATION

Stajer 400mg tablet: 1x5's/pack

DOSAGE

As directed by the physician

INSTRUCTION

Store below 30°C.

Protect from sunlight and moisture
Keep out of reach of children

Detailed prescribing information is available on request.

Manufactured by:
AsianContinental (Pvt.) Ltd.
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Karachi-Pakistan.



An ISO Certified Company

LFT/056/00

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
دوا کو 30°C سے کم درجہ حرارت پر رکھیں۔

دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔