Name of the product: Moxara tablets

Size of the Insert : (11.5x5.5)inches

Moxara
Tablets

موکزرہ ٹیبلٹس

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRIAL 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 withknown 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

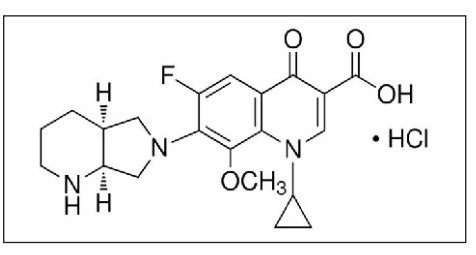
COMPOSITION:

Each Film Coated Tablet Contains

Moxifloxacin as HCl BP/USP: 400 mg

DESCRIPTION:

Moxara (moxifloxacin) hydrochloride is a synthetic antibacterial agent for oral 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. Its empirical formula is $C_{21}H_{24}FN_3O_4$*HCl and its chemical structure is as follows:



PHARMACOLOGY:

Pharmacodynamics:

Mechanism of Action: Moxara (moxifloxacin) is a member of the fluoroquinolone class of antibacterial agents. The bactericidal action of moxifloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division.

Pharmacokinetics:

Absorption: Moxifloxacin, given as an oral tablet, is well absorbed from the gastrointestinal tract. The absolute bioavailability of moxifloxacin is approximately 90 percent. Co-administration with a high fat meal (that is, 500 calories from fat) does not affect the absorption of moxifloxacin.

Distribution: Moxifloxacin is approximately 30–50% bound to serum proteins, independent of drug concentration. The volume of distribution of moxifloxacin ranges from 1.7 to 2.7 L/kg. Moxifloxacin is widely distributed throughout the body, with tissue concentrations often exceeding plasma concentrations. Moxifloxacin has been detected in the saliva, nasal and bronchial secretions, mucosa of the sinuses, skin blister fluid, subcutaneous tissue, skeletal muscle, and abdominal tissues and fluids following oral or intravenous administration of 400 mg.

Metabolism: Approximately 52% of an oral or intravenous dose of 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 or intravenous dose is converted to a glucuronide conjugate (M2), which is excreted exclusively in the urine. Peak plasma concentrations of M2 are approximately 40% those of the parent drug, while plasma concentrations of M1 are generally less than 10% those of moxifloxacin. In vitro studies with cytochrome (CYP) P450 enzymes indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2.

Excretion: Approximately 45% of an oral or intravenous 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. The mean (± SD) apparent total body clearance and renal clearance are 12 ± 2 L/hr and 2.6 ± 0.5 L/hr, respectively.

INDICATIONS:

Moxara (Moxifloxacin) is a fluoroquinolone antibacterial indicated for treating infections in adults 18 years of age and older caused by designated susceptible bacteria, in the conditions listed below:

- Community Acquired Pneumonia
- Skin and Skin Structure Infections: Uncomplicated and Complicated
- Complicated Intra Abdominal Infections
- Plague
- Acute Bacterial Sinusitis
- Acute Bacterial Exacerbation of Chronic Bronchitis

To reduce the development of drug resistant bacteria and maintain the effectiveness of Moxara (Moxifloxacin) and other antibacterial drugs. Moxara (Moxifloxacin) should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

DRUG INTERACTIONS:

Interacting Drug	Interaction
Multivalent cation containing products including antacids, sucralfate, multivitamins	Decreased Moxara (Moxifloxacin) absorption. Take Moxara (Moxifloxacin) Tablet at least 4 hours before or 8 hours after these products.
Warfarin	Anticoagulant effect enhanced. Monitor prothrombin time/INR, and bleeding.
Class IA and Class III antiarrhythmics	Proarrhythmic effect may be enhanced. Avoid concomitant use.
Antidiabetic agents	Carefully monitor blood glucose.

CONTRAINDICATIONS:

Moxara (Moxifloxacin) is contraindicated in persons with a history of hypersensitivity to moxifloxacin or any member of the quinolone class of antibacterials.

WARNINGS AND PRECAUTIONS:

- Prolongation of the QT interval and isolated cases of torsade de pointes have been reported. Avoid use in patients with known prolongation, proarrhythmic conditions such as clinically significant bradycardia or acutemyocardial ischemia, Hypokalemia, hypomagnesemia, and with drug 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 Moxara (Moxifloxacin). Discontinue Moxara (Moxifloxacin) at first sign of skin rash, jaundice or any other sign of hypersensitivity.
- ***Clostridium difficile-Associated Diarrhea:*** Evaluate if diarrhea occurs.

ADVERSE REACTIONS:

Most common reactions (3% or greater) were nausea, diarrhea, headache, and dizziness.

USE IN SPECIFIC POPULATIONS:

Pregnancy: Based on animal data may cause fetal harm.

Geriatrics: Increased risk for severe tendon disorders further increased by concomitant corticosteroid therapy and increased risk of prolongation of the QT interval.

DOSAGE AND ADMINISTRATION:

Type of Infection	Dose Every 24 hours	Duration (days)
Community Acquired Pneumonia	400 mg	7–14
Uncomplicated Skin and Skin Structure Infections (SSSI)	400 mg	7
Complicated SSSI	400 mg	7–21
Complicated Intra-Abdominal Infections	400 mg	5–14
Plague	400 mg	10–14
Acute Bacterial Sinusitis	400 mg	10
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg	5

No dosage adjustment in patients with renal or hepatic impairment.

STORAGE & PRECAUTIONS:

Avoid direct sunlight and protect from moisture and heat. Store below 25°C. Keep all medicines out of the reach of children. To be sold and used on the prescription of Registered Medical Practitioners only.

PRESENTATION:

Moxara Tablets 400mg are available in packing containing 5 film coated tablets.

عمومی خوراک: ڈاکٹر کی ہدایت کے مطابق۔

احتیاط: دھوپ، نمی اور گرمی سے بچائیں۔ 25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔ مستند ڈاکٹر کے نسخہ پر فروخت اور استعمال کریں۔

Complete Medical Information only for doctors on request.

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