Visomox®

Moxifloxacin Hydrochloride USP Film Coated Tablet

DESCRIPTION

Visomox® is a preparation of Moxifloxacin. Moxifloxacin hydrochloride (equivalent to 400 mg Moxifloxacin) is a member of the fluoroquinolone class of antibacterial agents. 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.

INDICATIONS AND USAGE

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:

- Acute Bacterial Sinusitis caused by *Streptococcus pneumoniae, Haemophilus influenzae,* or *Moraxella catarrhalis*.
- Acute Bacterial Exacerbation of Chronic Bronchitis caused by *Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae,* methicillin-susceptible *Staphylococcus aureus,* or *Moraxella catarrhalis*.
- Community Acquired Pneumonia caused by *Streptococcus pneumoniae* (including multi-drug resistant *Streptococcus pneumoniae* [MDRSP]), *Haemophilus influenzae, Moraxella catarrhalis,* methicillin-susceptible *Staphylococcus aureus, Klebsiella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*.
- Skin and Skin Structure Infections: Uncomplicated and Complicated Skin and Skin Structure Infection caused by methicillin-susceptible *Staphylococcus aureus* or *Streptococcus pyogenes* and methicillin-susceptible *Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae,* or *Enterobacter cloacae respectively*.
- Complicated Intra-Abdominal Infections caused by *Escherichia coli, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, Enterococcus faecalis, Proteus mirabilis, Clostridium perfringens, Bacteroides thetaiotaomicron,* or *Peptostreptococcus species*.
- Plague caused by *Yersinia pestis*.

DOSAGE AND ADMINISTRATION

The dose of **Visomox®** is 400 mg (orally) once every 24 hours. The duration of therapy depends on the type of infection as described in Table.

Type of Infection	Dose Every 24 hours	Duration (days)
Acute Bacterial Sinusitis	400 mg	10
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg	5
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

* With multivalent cations : Administer **Visomox®** tablets at least 4 hours before or 8 hours after products containing magnesium, aluminum, iron or zinc, including antacids, sucralfate, multivitamins and didanosine buffered tablets for oral suspension or the pediatric powder for oral solution.

* No dosage adjustment in patients with renal or hepatic impairment.
* **Visomox®** Tablets can be taken with or without food, drink fluids liberally.

CONTRAINDICATIONS

Known hypersensitivity to Moxifloxacin or other quinolones.

SIDE EFFECTS

- Nausea
- Diarrhea
- Headache and dizziness

PRECAUTION AND WARNING

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. Clostridium difficile-associated diarrhea: Evaluate if diarrhea occurs.

USE IN SPECIFIC POPULATIONS

1. Pregnancy: 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.

2. Nursing Mothers: Moxifloxacin is excreted in the breast milk of rats. Moxifloxacin may also be excreted in human milk. Because of the potential for serious adverse reactions in infants who are nursing from mothers taking Moxifloxacin, 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.

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

4. Geriatric Use: Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as Moxifloxacin. The clinical trial data demonstrate that there is no difference in the safety and efficacy of oral Moxifloxacin in patients aged 65 or older compared to younger adults.

5. Renal Impairment: The pharmacokinetic parameters of Moxifloxacin are not significantly altered in mild, moderate, severe, or end-stage renal disease. No dosage adjustment is necessary in patients with renal impairment, including those patients requiring hemodialysis (HD) or continuous ambulatory peritoneal dialysis (CAPD).

6. Hepatic Impairment: 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.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Visomox® Tablet: Box containing 1 strip of 10 tablets. Each film coated tablet contains Moxifloxacin Hydrochloride USP eq. to Moxifloxacin 400 mg.

SK+F
Manufactured by
ESKAYEF BANGLADESH LIMITED
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