

Composition : Floxalone-400 : Each Film Coated Tablet Contains Moxifloxacin 400mg as Moxifloxacin Hydrochloride USP.

Pharmacology : Moxifloxacin is a member of the fluoroquinolone class of antibacterial agents. It is well absorbed from the gastrointestinal tract. The absolute bioavailability of moxifloxacin is approximately 90 percent. Moxifloxacin is approximately 30-50% bound to serum proteins, independent of drug concentration. Approximately 52% of an oral dose of moxifloxacin is metabolized via glucuronide and sulfate conjugation. Approximately 45% of an oral dose of moxifloxacin is excreted as unchanged drug (~20% in urine and ~25% in feces).

Indications : It is indicated for treating the following infections : Acute Bacterial Sinusitis, Acute Bacterial Exacerbation of Chronic Bronchitis, Community Acquired Pneumonia, Uncomplicated Skin and Skin Structure Infections, Complicated Skin and Skin Structure Infections, Complicated Intra-Abdominal Infections.

Dosage and administration : Dosage for Adult Patients : The dose of Moxifloxacin is 400mg orally once every 24 hours. The duration of therapy depends on the type of infection as described in table.

Indications	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	400 mg	7
Complicated Skin and Skin Structure Infections	400 mg	7-21
Complicated Intra-Abdominal Infections	400 mg	5-14

Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with a known hypersensitivity to Moxifloxacin or other quinolones.

Precautions : Moxifloxacin has been shown to prolong the QT interval in some patients. The drug should be avoided in patients with known prolongation of the QT interval. It is also associated with an increased risk of tendinitis and tendon

Floxalone-400

Tablet



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rupture in all ages. It should be discontinued if the patient experiences pain, swelling, inflammation of rupture of a tendon.

Side effects : The most common adverse reactions are dizziness, headache, diarrhoea, constipation, nausea, vomiting and insomnia.

Use in pregnancy and lactation : Pregnancy Category C. There is 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. Moxifloxacin may 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.

Use in Child : There is no data available.

Drug Interactions : Antacids, sucralfate, multivitamins and other products containing multivalent cations may reduce the absorption of Moxifloxacin. Therefore, Moxifloxacin should be taken at least 4 hours before or 8 hours after these agents. It may enhance the anticoagulant effects of warfarin or its derivatives in the patient population. So concomitant use of Moxifloxacin with them should be avoided.

Overdose : The administration of activated charcoal as soon as possible after oral overdose may prevent excessive increase of systemic Moxifloxacin exposure. The patient should be carefully observed and given supportive treatment.

Storage : Store below 30°C in a dry place.

Packing : Floxalone-400 : Each box contains 1 X 7's tablets in blister pack.