FLOROMOX

MOXIFLOXACIN BP

Compositions:
Each film coated tablet contains Moxifloxacin Hydrochloride BP 436.340 mg equivalent to Moxifloxacin 400 mg .

Pharmacology:
Moxifloxacin is a synthetic broad spectrum, flouroquinolone derivative antibacterial agent. 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.

Dosage And Administration:
Adults : The dose of Moxifloxacin is 400 mg once daily. The duration of therapy depends on the type of infection as described in the following: In Acute Bacterial Sinusitis: 400 mg once daily for 10 days. In Acute Bacterial Exacerbation of Chronic Bronchitis: 400 mg once daily for 5 days. In Community Acquired Pneumonia: 400 mg once daily for 7-14 days. In Uncomplicated Skin & Skin Structure infections: 400 mg once daily for 7 days. In Complicated Skin & Skin Structure infections: 400 mg once daily for 7-21 days. In Complicated Intra-Abdominal infections: 400 mg once daily for 5-14 days. Pelvic inflammatory diseases: 400 mg once daily for 14 days

Contraindications:
Moxifloxacin is contraindicated in persons with a history of hypersensitivity to Moxifloxacin or any member of the quinolone class of antimicrobial agents and any component of this formulation.

Warning And Precaution:
Moxifloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity. Moxifloxacin should be discontinued if the patient experiences pain, swelling, inflammation or rupture of a tendon.

Side Effects:
The following one or more side effects may be observed: tendinopathy and tendon rupture, QT prolongation, hypersensitivity reactions, clostridium difficile-associated diarrhea, peripheral neuropathy, photosensitivity, phototoxicity etc.

Use in Pregnancy and Lactation:
Pregnancy Category C. Moxifloxacin is not recommended during pregnancy & lactation.

Drug Interaction:
Antacids, Sucralfate, Multivitamins and other products containing Multivalent Cations: Antacids, sucralfate, multivitamins and other products containing multivalent cations reduces the absorption of Moxifloxacin. Moxifloxacin should be administered 4 hours before or 8 hours after antacids, sucralfate, multivitamins and other products with multivalent cations. Warfarin: Moxifloxacin, have been reported to enhance the anticoagulant effects of warfarin or its derivatives in the patient population. NSAIDs: NSAIDs may increase the risk of CNS stimulation.

Overdosage:
Single oral overdoses up to 2.8 gm were not associated with any serious adverse events. In

the event of acute overdose, the stomach should be emptied and adequate hydration maintained. The patient should be given 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.

Storage:
Keep out of reach of children. Store at room temperature away from light and moisture.

Packing:
Floromox Tablet: Each box contains 2x10 tablets in Alu-alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.