Revalon»

Moxifloxacin 400 mg Tablet

COMPOSITION

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

PHARMACOLOGY

Revalon» (Moxifloxacin) is a 4th generation synthetic broad spectrum, fluoroquinolone class of antibacterial drug. It has activity against a wide range of gram-positive, gram-negative, anaerobic and atypical bacteria including *Mycoplasma pneumoniae*. It acts by inhibiting topoisomerase II (DNA gyrase) and topoisomerase IV which are necessary for bacterial DNA replication, transcription & repair.

INDICATION

Revalon» (Moxifloxacin) is indicated for the treatment of acute bacterial sinusitis, acute exacerbation of chronic bronchitis, community acquired pneumonia, uncomplicated & complicated skin and skin structure infections, complicated intra-abdominal infections, pelvic inflammatory disease and Plague.

DOSAGE AND ADMINISTRATION

Type of Infection	Dose	Duration
Acute Bacterial Sinusitis	400 mg once daily	7-10 days
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg once daily	5-10 days
Community-Acquired Pneumonia	400 mg once daily	7-14 days
Uncomplicated Skin and Skin Structure Infections	400 mg once daily	7 days
Complicated Skin and Skin Structure Infections	400 mg once daily	7-21 days
Complicated Intra-Abdominal Infections	400 mg once daily	5-14 days
Pelvic Inflammatory Disease	400 mg once daily	14 days
Plague	400 mg once daily	10 days

No dose adjustment is necessary in patients with renal or hepatic impairment.

CONTRAINDICATIONS

It is contraindicated in the patients with a history of hypersensitivity to Moxifloxacin or other quinolones.

SIDE EFFECTS

Common side effects of Moxifloxacin include nausea, vomiting, diarrhea, headache, dizziness, risk of retinal detachment and increased the risk of tendinitis & tendon rupture.

WARNING & PRECAUTIONS

Moxifloxacin may cause tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches and confusion). These reactions can occur within hours to weeks after starting Moxifloxacin. Patients of any age or without pre-existing risk factors have experienced these adverse reactions. Discontinue Moxifloxacin immediately at the first signs or symptoms of any serious adverse reaction.

USE IN PREGNANCY & LACTATION

Pregnancy Category C. There is, however, 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. It is excreted in human milk.

USE IN CHILDREN & ADOLESCENT

Safety and effectiveness of Moxifloxacin in pediatric patients and adolescent less than 18 years of age have not been established.

DRUG INTERACTION

Moxifloxacin absorption is decreased when administered with Antacid, Sucralfate, Multivitamins and Multivalent Cations (e.g. Iron or Zinc). Moxifloxacin may enhance the risk of convulsions with NSAIDs, bleeding with warfarin & QT prolongation with Class IA & Class IIIA antiarrhythmic drug. So concomitant use of Moxifloxacin with them should be avoided.

OVERDOSE

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.

STORAGE CONDITION

Keep below 30^{0}C temperature, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 10 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.