MOXIF

For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

Abbreviated Prescribing information for MOXIF (Moxifloxacin Hydrochloride 400mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Moxifloxacin a, fluoroquinolone, bactericidal activity results from the inhibition of both type II topoisomerases (DNA gyrase and topoisomerase IV) required for bacterial DNA replication, transcription and repair.

INDICATION: Moxifloxacin tablets are indicated for the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, community acquired pneumonia, skin and soft tissue infections, uncomplicated urinary tract infection and pelvic inflammatory disease, in adults 18 years and above.

DOSAGE AND ADMINISTRATION: Adult: Dose is 400mg once every 24 hours and therapy duration depends on type of infection from 5 days to 10 days. No dose adjustment needed if switching to oral from Intravenous infusion formulation. Should be administered 4 hours before or 8 hours after antacids (magnesium or aluminum, as well as sucralfate, metal cations such as iron, and multivitamin preparations with zinc, or didanosine chewable/buffered tablets or the pediatric powder for oral solution).

CONTRAINDICATION: Hypersensitivity to fluoroquinolones, or to ingredients; tendon disease/disorder related to quinolones; congenital/acquired QT prolongation; electrolyte disturbances; bradycardia; heart failure with reduced left ventricular ejection fraction; Symptomatic arrhythmia history; patients less than 18 years age; pregnancy/lactation; drugs causing QTc prolongation; Impaired liver function (Child Pugh C); and patients with transaminases increase >5 fold ULN.

WARNINGS & PRECAUTIONS: Tendinopathy and Tendon Rupture; Exacerbation of Myasthenia Gravis; QT Prolongation; Hypersensitivity Reactions; Fatal serious skin reaction (TEN, SJS); *C. Difficile*-Associated Diarrhea; Peripheral Neuropathy; Arthropathic effect (produce erosions of cartilage of weight-bearing joints); Blood Glucose Disturbances; Photosensitivity/Phototoxicity; Chances of development of drug resistant bacteria if not used as per proven indication (prophylactic indication); patients having suspected/known CNS disorder (nervousness, agitation, insomnia, anxiety, nightmares or paranoia,).

DRUG INTERACTIONS: Interact with Antacids, Sucralfate, Multivitamins and other products containing Multivalent Cations, warfarin, NSAIDs, medications affecting prolongation of QTc.

ADVERSE REACTIONS: Nausea, Diarrhea, Vomiting, Constipation, Abdominal pain, Abdominal pain upper, Dyspepsia, anemia, Pyrexia, ALT increase, Hypokalemia, Headache, Dizziness, Insomnia, Thrombocythemia, Eosinophilia, Neutropenia, Thrombocytopenia, Leukopenia, Leukocytosis, Atrial fibrillation, Palpitations, Tachycardia, Cardiac failure congestive, Angina pectoris, Cardiac failure, Cardiac arrest, Bradycardia, Vertigo, Tinnitus, Dry mouth, Abdominal discomfort, Flatulence, Abdominal distention, Gastritis, GERD, Fatigue, Chest pain, Asthenia, Edema peripheral, Pain, Malaise Infusion site extravasation, Edema, Chills, Chest discomfort, Facial pain, Allergic reaction, serious fatal skin reaction, injection site reaction, tendon disorders, Photosensitivity/toxicity reaction.

MARKETED BY:

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