MOXIF IV INJECTION

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

Abbreviated Prescribing information for MOXIF IV INJECTION (Moxifloxacin Intravenous Infusion) [Please refer the complete prescribing information available at www.torrentpharma.com]

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

DOSAGE AND ADMINISTRATION: Adult: Dose is 400mg once every 24 hours and therapy duration depends on type of infection. No dose adjustment needed if switching to oral. Inspect visually for particulate matter/discoloration of solution prior to administration. MOXIF IV should be administered by intravenous infusion only with aseptic measures; no other routes should be used. Protect from light.

CONTRAINDICATION: Hypersensitivity to moxifloxacin and other quinolones, or to ingredients of the solution; 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 patient's transaminases increase >5 fold ULN.

WARNINGS & PRECAUTIONS: Caution required for 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.

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, 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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(Additional information is available on request)