MOXIF 400

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

Abbreviated Prescribing information for **MOXIF 400** (Moxifloxacin Tablets I.P.)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Moxifloxacin has in vitro activity against a wide range of Gram-positive and Gram-negative pathogens. The bactericidal action of moxifloxacin results from the inhibition of both type II topoisomerases (DNA gyrase and topoisomerase IV) required for bacterial DNA replication, transcription and repair. It appears that the C8-methoxy moiety contributes to enhanced activity and lower selection of resistant mutants of Gram-positive bacteria compared to the C8-H moiety. The presence of the bulky bicycloamine substituent at the C-7 position prevents active efflux, associated with the norA or pmrA genes seen in certain Gram-positive bacteria. Pharmacodynamic investigations have demonstrated that moxifloxacin exhibits a concentration dependent killing rate. Minimum bactericidal concentrations (MBC) were found to be in the range of the minimum inhibitory concentrations (MIC).

INDICATIONS: 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: For adults: The recommended dose is one 400 mg film-coated tablet once daily.

CONTRAINDICATION: Hypersensitivity to moxifloxacin, other quinolones or to any of the excipients. Pregnancy and lactation., Patients below 18 years of age, Patients with a history of tendon disease/disorder related to quinolone treatment., Both in preclinical investigations and in humans, changes in cardiac electrophysiology have been observed following exposure to moxifloxacin, in the form of QT prolongation. For reasons of drug safety, moxifloxacin is therefore contraindicated in patients with:,Congenital or documented acquired QT prolongation ,Electrolyte disturbances, particularly in uncorrected hypokalaemia ,Clinically relevant bradycardia ,Clinically relevant heart failure with reduced left-ventricular ejection fraction ,Previous history of symptomatic arrhythmias ,Moxifloxacin should not be used concurrently with other drugs that prolong the QT interval Due to limited clinical data, moxifloxacin is also contraindicated in patients with impaired liver function (Child Pugh C) and in patients with transaminases increase > 5fold 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:

TORRENT PHARMACEUTICALS LTD.

IN/MOXIF 400mg/Dec-24/05/ABPI
(Additional information is available on request)