

TOPCEF-O 200

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

Abbreviated Prescribing information for TOPCEF-O 200 (Cefixime 200 mg and Ofloxacin 200 mg)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Cefixime is a semisynthetic, cephalosporin antibiotic for oral administration. Ofloxacin is bactericidal and acts by inhibiting DNA gyrase and topoisomerase IV.

INDICATION: For the treatment in adults with: Urinary Tract infections, Typhoid fever

DOSAGE AND ADMINISTRATION: 1 or 2 tablets given twice daily or as directed by physician.

CONTRAINDICATION: **Ofloxacin:** in patients with known hypersensitivity to 4-quinolone antibacterials or any of the tablet excipients. Ofloxacin should not be used in patients with a past history of tendonitis. Ofloxacin is contra-indicated in patients with a history of epilepsy or with a lowered seizure threshold, in children or growing adolescents, and in pregnant or breast-feeding women. Patients with latent or actual defects in glucose-6-phosphate dehydrogenase activity may be prone to haemolytic reactions when treated with quinolone antibacterial agents. **Cefixime:** Patients with known hypersensitivity to cephalosporin or Penicillin antibiotics.

WARNINGS & PRECAUTIONS: **Ofloxacin:** Hypersensitivity and allergic reactions have been reported. Anaphylactic and anaphylactoid reactions can progress to life-threatening shock. Clostridium difficile-associated disease: If pseudo-membranous colitis is suspected, ofloxacin must be stopped immediately. Patients predisposed to seizures: ofloxacin should be discontinued. Cardiac Disorders: Very rare cases of QT interval prolongation have been reported. Patients with history of psychotic disorder: Psychotic reactions have been reported. Patients with impaired liver function: Ofloxacin should be used with caution in patients with impaired liver function, as liver damage may occur. Cases of fulminant hepatitis potentially leading to liver failure (including fatal cases) have been reported. Myasthenia gravis: Ofloxacin should be used with caution in patients with a history of myasthenia gravis. Peripheral neuropathy: Sensory or sensorimotor peripheral neuropathy has been reported in patients receiving fluoroquinolones. Hypoglycaemia has been reported. Patients with latent or diagnosed glucose-6-phosphate-dehydrogenase deficiency may be predisposed to haemolytic reactions if they are treated with quinolones. Patients with rare hereditary disorders: Patients with rare galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Cefixime:** Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs. Cephalosporins should be given with caution to penicillin-sensitive patients, If an allergic effect occurs with cefixime, the drug should be discontinued. Cefixime should be administered with caution in patients with markedly impaired renal function. Pseudomembranous colitis is associated with the use of broad-spectrum antibiotics.

DRUG INTERACTION: **Cefixime** A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, A false positive direct Coombs test has been reported. Increases in prothrombin times have been noted in a few patients. Care should therefore be taken in patients receiving anticoagulation therapy. **Ofloxacin:** Drugs known to prolong QT interval: Ofloxacin, like other fluoroquinolones, should be used with caution. Antacids, Sucralfate, Metal Cations: can reduce absorption. With high doses of quinolones, impairment of excretion and an increase in serum levels may occur when co-administered with other drugs that undergo renal tubular secretion. **Interaction with laboratory tests:** Determination of opiates or porphyrins in urine may give false-positive results during treatment with ofloxacin. It may be necessary to confirm positive opiate or porphyrin screens by more specific methods. Vitamin K antagonists: Coagulation tests should be monitored in patients treated with vitamin K antagonists because of a possible increase in the effect of coumarin derivatives.

ADVERSE REACTIONS: Ofloxacin: Fungal infection, pathogen resistance, Anaemia, Haemolytic Anaemia, Leukopenia, Eosinophilia, Thrombocytopenia, Anaphylactic shock, Peripheral sensory neuropathy, Convulsion, Extra-pyramidal symptoms, other disorders of muscular coordination, Tinnitus, Hearing loss, jaundice cholestatic, Erythema multiforme, Toxic epidermal necrolysis, Photo-sensitivity reaction, Drug eruption, Vascular purpura, Vasculitis, Rhabdomyolysis, Myopathy, Muscular weakness, acute renal failure. **Cefixime:** diarrhea, stool changes, nausea, abdominal pain, dyspepsia, vomiting and flatulence, Headache, dizziness, Allergies in the form of rash, pruritus, drug fever and arthralgia. Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis Thrombocytosis, hypereosinophilia, neutropenia, agranulocytosis. Transient rises in liver transaminases, alkaline phosphatase, genital pruritus and vaginitis.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent house, Off Ashram road,
Ahmedabad - 380009, INDIA

IN/ TOPCEF-O 200 /FEB 2015/01/AbPI
(Additional information is available on request)