

## TOPCEF CLAV 200

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

Abbreviated Prescribing information for TOPCEF CLAV 200 tablets [FDC of Cefixime 200 mg and Potassium Clavulanate tablets 125 mg] [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com) ]

**PHARMACOLOGICAL PROPERTIES:** Cefixime is an orally active third generation bactericidal cephalosporin (beta lactam antibiotic) with broad spectrum of coverage. Clavulanic acid is an irreversible 'suicide' inhibitor of intracellular and extracellular  $\beta$ -lactamases.

**INDICATIONS:** For the treatment of adult patients with, infections caused by susceptible microorganisms, viz. urinary tract infection, upper and lower respiratory tract infections, and gonococcal urethritis. It is also useful in the treatment of the uncomplicated urinary tract infections, otitis media, acute bronchitis and acute exacerbations of chronic bronchitis and uncomplicated gonorrhoea when caused by susceptible strains of the microorganisms.

**DOSAGE AND ADMINISTRATION:** Adults and Children over 12 Years: One tablet twice daily. The usual course of treatment is 7 days. This may be continued for up to 14 days if required.

**CONTRAINDICATION:** Patients with known hypersensitivity to cephalosporin antibiotics.

**WARNINGS & PRECAUTIONS:** Exercise caution when use in patients who have shown hypersensitivity to other drugs and penicillins. Risk of Clostridium difficile induced antibiotic-associated diarrhea and Pseudomembranous colitis.

**LABORATORY TEST INTERACTIONS:** A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions. A false positive direct Coombs test and increases in prothrombin times has been reported.

**ADVERSE REACTIONS:** Diarrhoea, stool changes, nausea, abdominal pain, dyspepsia, vomiting, flatulence, pseudo – membranous colitis, headache, dizziness, hypersensitivity reactions (in the form of rash, pruritus, drug fever, arthralgia, urticaria and angioedema), erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia, agranulocytosis, changes in liver and renal function tests, transient rises in liver transaminases, alkaline phosphatase, jaundice, genital pruritus and vaginitis.

### MARKETED BY:



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**IN/ TOPCEF CLAV 200 /200mg,125mg/Mar-2015/01/AbPI**

(Additional information is available on request)