For the Use of a Registered Medical Practitioner Only

1. GENERIC NAME & BRAND NAME

Cefixime Tablets I.P. 200 mg

CEFI™-200

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Cefixime I.P. (as Trihydrate)

equivalent to Anhydrous Cefixime 200mg

Excipients q.s.

Colour: Lake Brilliant Blue and Titanium Dioxide I.P.

3. DOSAGE FORM AND STRENGTH

Kindly refer to section 1& 2

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

For the treatment of enteric (typhoid) fever, urinary tract infections, respiratory tract infections and biliary tract infections

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

The usual course of treatment is 7 days. This may be continued for up to 14 days if required.

Adults, Elders and children over 10 years:

The recommended adult dosage is 200-400 mg daily according to the severity of infection, given either as a single dose or in two divided doses.

Renal function should be assessed, and dosage should be adjusted in severe renal impairment.

Children:

The recommended dosage for children is 8 mg/kg/day administered as a single dose or in two divided doses. As a general guide for prescribing in children the following daily doses in terms of volume of Paediatric Oral Suspension are suggested:

6 months up to 1 year:	7.5 ml daily
Children 1-4 years:	10 ml daily
Children 5-10 years:	20 ml daily

Children weighing more than 50 kg or older than 10 years should be treated with the recommended adult dose (200 - 400 mg daily depending on the severity of infection).

The safety and efficacy of cefixime has not been established in children less than 6 months.

Renal Impairment: No adjustment is needed in patients with creatinine clearances of 20 ml/min or greater. In patients with creatinine clearance of less than 20 ml/min, it is recommended that a dose of 200 mg once daily should not be exceeded.

Patients on CAPD or haemodialysis:

Follow the same recommendation as that for patients with creatinine clearances of less than 20 ml/min.

4.3 CONTRAINDICATIONS

It is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics or any of the other components of the product or penicillin antibiotics

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Severe cutaneous adverse reactions:

Adverse reactions such as toxic epidermal necrolysis, Stevens Johnson syndrome and drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in some patients on cefixime. When severe cutaneous adverse reactions occur, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Cefixime should administer with caution to patients who have shown hypersensitivity to other drugs.

Hypersensitivity to penicillins:

Cefixime should be given with caution same as with other cephalosporins to patients with a history of hypersensitivity to penicillin, as there is some evidence of partial cross allergenicity between the penicillins and cephalosporins. Patients have had severe reactions (including anaphylaxis) to both classes of drugs. If an allergic effect occurs with Cefixime, the drug should be discontinued, and the patient treated with appropriate agents if necessary.

Haemolytic anaemia:

Drug induced haemolytic anaemia, including severe cases with a fatal outcome, has been described for cephalosporins (as a class). The recurrence of haemolytic anaemia after re-administration of cephalosporins in a patient with a history of cephalosporin (including cefixime) –associated haemolytic anaemia has also been reported.

Renal failure acute:

Cefixime may cause acute renal failure including tubulointerstitial nephritis as an underlying pathological condition. In case of an acute renal failure, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Renal impairment:

Cefixime should be administered with caution in patients with markedly impaired renal function.

Paediatric use:

Safety of cefixime in premature or new-born infant has not been established.

Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies show that a toxin produced by Clostridium difficile is a primary cause of antibiotic associated diarrhoea.

Pseudomembranous colitis is associated with the use of broad spectrum antibiotics (including macrolides, semisynthetic penicillins, lincosamides and cephalosporins) ;it is therefore important to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment. Management of pseudomembranous colitis should include sigmoidoscopy, appropriate bacteriologic studies, fluids, electrolytes and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, oral

vancomycin is the drug of choice for antibiotic associated pseudomembranous colitis produced by C. difficile. Other causes of colitis should be excluded.

4.5 DRUGS INTERACTIONS

The important drug interactions are listed below

No	Drug	Drug interaction	Remark
1	Carbamazepine	Elevate the plasma level	Monitor plasma level
2	Anticoagulants	Increased prothrombin time	Monitor prothrombin time
3	Drug/laboratory test interaction	False positive reaction for ketones in urine may occur with tests using nitroprusside but not with those using nitroferricyanide.	

4.6 USE IN SPECIAL POPULATIONS

Pregnancy and lactation: Pregnancy Category B. It should be used during pregnancy only if clearly needed. It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

4.7 UNDERISABLE EFFECTS

Blood and lymphatic system disorders: Thrombocytopenia, Thrombocytosis, Eosinophilia, Leucopenia, Hypereosinophilia, Neutropenia, Agranulocytosis, Haemolytic anaemia, Granulocytopenia.

Gastrointestinal: Nausea, Vomiting, Dyspepsia, Diarrhoea, loose or frequent stools, abdominal pain, flatulence, mouth ulceration

Hepatobiliary disorders: Jaundice

Infections and infestations: Pseudomembranous colitis.

Investigations: Blood urea increased, Blood creatinine increased, Aspartate aminotransferase increased, Alanine aminotransferase increased, Blood bilirubin increased.

Nervous system disorders: Dizziness, Headache, seizures

Respiratory, thoracic and mediastinal disorders: Dyspnoea

Renal and urinary disorders: Renal failure acute including tubulointerstitial nephritis as an underlying pathological condition

Immune System disorders, administrative site conditions, skin and subcutaneous tissue disorders: Anaphylactic reaction, Drug rash with eaosinophilia and systemic symptoms (DRESS), Serum sickness-like reaction, Pruritus, Rash, Arthralgia, Drug Fever, Erythema multiforme, Stevens Johnson syndrome, Angiooedema, Toxic epidermal necrolysis, Urticaria, Pyrexia, Face oedema, Vaginitis, Genital pruritus.

Drug-induced skin reaction: Acute Generalized Exanthematous Pustulosis (AGEP)

4.8 OVERDOSAGE

Adverse reactions seen at dose levels up to 2 g cefixime in normal subjects did not differ from the profile seen in patients treated at the recommended doses. Cefixime is not removed from the circulation in significant quantities by dialysis. Gastric lavage may be indicated. No specific antidote exists. General supportive measures are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 MECHANISM OF ACTION

Bactericidal action of cefixime results from inhibition of cell-wall synthesis.

5.2 PHARMACODYNAMIC PROPERTIES

Cefixime is an oral third generation cephalosporin which has marked in vitro bactericidal activity against a wide variety of Gram positive and Gram negative organisms.

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Escherichia coli, Proteus mirabilis, Klebsiella species, Haemophilus influenzae* (beta lactamase positive and negative), *Branhamella catarrhalis* (beta lactamase positive and negative) and *Enterobacter* species. It is highly stable in the presence of beta lactamase enzymes.

Most strains of enterococci (*Streptococcus faecalis*, group D Streptococci) and *Staphylococci* (including coagulase positive and negative strains and meticillin resistant strains) are resistant

to cefixime. In addition, most strains of *Pseudomonas*, *Bacteroides fragilis*, *Listeria monocytogenes* and *Clostridia* are resistant to cefixime.

5.3 PHARMACOKINETIC PROPERTIES

Absorption	The absolute oral bioavailability of cefixime is in the range of 22-54%. Absorption is not significantly modified by the presence of food. Cmax is about 1.5 and 3 mcg/ml.
Distribution	Protein binding is approximately about 30%
Metabolism	No metabolites found.
Elimination	Cefixime is predominantly eliminated as unchanged drug in the urine

6.0 NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. Cefixime did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage in vitro and did not exhibit clastogenic potential in vivo in the mouse micronucleus test. In rats, fertility and reproductive performance were not affected by cefixime at doses up to 25 times the adult therapeutic dose.

7.0 DESCRIPTION

CEFI 200 is supplied for oral administration, as a film coated tablet of Cefixime. Each film coated tablet of CEFI 200 contains Cefixime (as Trihydrate) equivalent to Anhydrous Cefixime 200mg.

8.0 PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES:

Not applicable

8.2 SHELF-LIFE

Refer Pack

8.3 PACKAGING INFORMATION:

Refer Pack

8.4 STORAGE CONDITION AND HANDING INSTRUCTIONS

Refer Pack

9. PATIENT COUNSELLING INFORMATION

Advise a patient to contact a doctor if any of the following side effects are noted:

- Allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Skin rash, blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever.
- Advise patient to stop taking this medicine if patient develop severe watery diarrhoea.

10. DETAILS OF MANUFACTURER

Refer Pack for manufacturer details.

Marketed by:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 6 &
11 to 16 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER

Refer Pack for Permission/License details.

12. DATE OF REVISION

Version 4.0, Dated 6th September 2023

For Product Complaints/Adverse events or Queries please write to

webmasterindia@abbott.com