EXTACEF - 200 DT

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

EXTACEF - 200 DT

Cefixime Dispersible Tablets 200 mg

Strength: Cefixime 200 mg per Tablet

Pharmaceutical form: Oral Solid (Tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration:

Each dispersible tablet contains:

Cefixime USP as Trihydrate

equivalent to Anhydrous

Cefixime 200

mg

Excipients ..... q.s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Off-white, circular, flat, beveled uncoated tablets with break line on one side and circle engraved on other side and having strawberry flavor.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications:

Extacef is an orally active cephalosporin antibiotic which has marked in vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms.

It is indicated for the treatment of the following acute infections when caused by susceptible micro-organisms:

Upper Respiratory Tract Infections (URTI): e.g. otitis media; and other URTI where the causative organism is known or suspected to be resistant to other commonly used antibiotics, or where treatment failure may carry

significant risk.

Lower Respiratory Tract Infection: e.g. bronchitis.

Urinary Tract Infections: e.g. cystitis, cystourethritis, uncomplicated pyelonephritis. Clinical efficacy has been demonstrated in infections caused by commonly occuring pathogens including Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia

coli, Proteus mirabilis, Kliebsiella species, Haemophilus influenzae (beta-lactamase positive and negative), Branhamella catarrhalis (beta-lactamase positive and negative) and Enterobacter species.

Extacef 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 meticillinresistant strains) are resistant to Extacef. In addition, most strains of Pseudomonas, Bacteriodes fragalis, Listeria monocytogenes and Clostridia are resistant to Extacef.

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. For oral administration.

Adults and Children over 10 Years:

Usual Recommended Dose: Cefixime 200 to 400 mg daily according to the severity of infection and given either as a single dose or in two divided doses. Or, as prescribed by the physician.

Children weighing more than 50 kg or older than 10 years should be treated with the recommended adult dose. The safety and efficacy of Cefixime have not been established in children for less than 6 months.

Method of Administration: For oral Administration. Absorption of Cefixime is not significantly modified by the presence of food. Thus, EXTACEF 200 DT may be taken regardless of food.

Directions for Reconstitution of the Dispersible Tablets

Dispersible Tablets should be reconstituted by the addition of an adequate amount of clean potable water (5 to 10 ml) immediately before use. Stir well until the tablet gets properly dispersed in the water and then swallow.

Special populations

Elderly population: Elderly patients may be given the same dose as recommended for adults. Renal function should be assessed, and dosage should be adjusted in severe renal impairment.

Renal Impairment: EXTACEF may be administered in the presence of impaired renal function. Normal dose and schedule may be given in patients with creatinine clearances

of 20 ml/min or greater. In patients whose creatinine clearance is less than 20 ml/min or patients on peritoneal dialysis or hemodialysis, it is recommended that a dose of 200 mg once daily should not be exceeded.

Pediatric population: Safety of Cefixime in premature or newborn infants has not been established. Use of Cefixime under 6 months of age is not recommended. For dosage, please refer 'Posology and Method of Administration' section.

4.3 Contraindications:

EXTACEF 200 DT is contraindicated in patients with known hypersensitivity to Cefixime or to cephalosporin/beta-lactam antibiotics or to any component of the formulation.

4.4 Special warnings and precautions for use:

Hypersensitivity to penicillins: As with other cephalosporins, cefixime should be given with caution 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 EXTACEF, the drug should be discontinued and the patient treated with appropriate agents if necessary.

Severe cutaneous adverse reactions: Severe cutaneous 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. EXTACEF should be given with caution to patients who have shown hypersensitivity to other drugs.

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

Acute renal failure: As with other cephalosporins, cefixime may cause acute renal failure including tubulointerstitial nephritis as an underlying pathological condition. When acute renal failure occurs, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Antibiotic-associated diarrhoea: Treatment with broad spectrum antibiotics

alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate 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, semi-synthetic 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 Interaction with other medicinal products and other forms of interaction: Anticoagulants: As with other cephalosporins, increase in prothrombin time has been noted in a few patients. Care should therefore be taken in patients receiving anticoagulation therapy. Cefixime should be administered with caution to patients receiving coumarin-type anticoagulants, e.g., warfarin potassium. Since cefixime may enhance effects of the anticoagulants, prolonged prothrombin time with or without bleeding may occur.

Other forms of interaction: 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 has been reported during treatment with cephalosporin antibiotics, therefore it should be recognized that a

positive Coombs test may be due to the drug.

4.6 Pregnancy and lactation: <u>Pregnancy</u>

Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 400 times the human dose and has revealed no evidence of impaired fertility or harm to the fetus due to Cefixime. In rabbits, at doses up to 4 times the

human dose, there was no evidence of a teratogenic effect. There are no adequate and well-controlled studies in pregnant women. Thus, EXTACEF 200 DT can be administered to pregnant women only if clearly needed and under medical supervision. **Breast-feeding**

It is not known whether Cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with Cefixime.

Fertility

There was no evidence of impaired fertility found in animal studies.

4.7 Effects on ability to drive and use machines:

In the case of side effects such as encephalopathy (which may include convulsion, confusion, impairment of consciousness, movement disorders), the patient should not operate machines or drive a vehicle.

4.8 Undesirable effects:

Extacef is generally well tolerated. The majority of adverse reactions observed in clinical trials & or marketing use were mild and self-limiting in nature.

System Organ Class	Preferred Term	Frequency
Infections and infestations:	Pseudomembranous colitis Vaginitis	not known
Blood and lymphatic system class:	Eosinophilia, Agranulocytosis, Leucopenia, Neutropenia,Granulocytopenia, Haemolytic anaemia Thrombocytopenia, Thrombocytosis, Prolonged PT/Coagulation	not known
Immune System Disorders:	Anaphlactic reaction, Angio-oedema, Serum sickness-like reaction	not known

Nervous System Disorders:	Dizziness, Headache Cases of convulsions have been reported with cephalosporins including cefixime. Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.	not known

Respiratory, thoracic and mediastinal disorders:	Dyspnoea	not known
Gastrointestinal disorders:	Abdominal pain, Diarrhoea, Dyspepsia, Nausea, Vomiting, Anorexia, Flatulence	not known
Hepatobiliary disorders:	Jaundice, Hepatitis	not known
Skin and subcutaneous tissue disorders:	Drug Rash with eosinophilia and systemic symptom not known (DRESS), Erythema multiforme, Pruritus Rash, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Urticaria, Genital pruritus, Acute generalized exanthematous pustulosis (AGEP)	not known
Renal and urinary disorders	Acute renal failure with tubulointerstitial nephritis a not known an underlying pathological condition	not known
General disorders and administration site conditions:	Pyrexia, Face oedema	not known

Investigations:	Aspartate aminotransferase increased Alanine aminotransferase increased Blood alkaline phosphate increased Blood bilirubin increased Blood urea increased Blood creatinine increased	not known

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.'

4.9 Overdose:

Symptoms: There is no experience regarding overdose with cefixime. 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.

Treatment: Cefixime is not removed from the circulation in significant quantities by dialysis. No specific antidote exists. General supportive measures are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 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.

5.2 Pharmacokinetic Properties:

Absorption and Distribution: The absolute oral bioavailability of cefixime is in the range of 22 to 54%. Absorption is not significantly modified by the presence of food. Cefixime may therefore be given without regard to meals. Typically, the peak serum levels following the recommended adult or pediatric doses are between 1.5 and 3 mcg/ml. little or no accumulation of cefixime occurs following multiple dosing. Serum protein binding is concentration-independent with a bound fraction of approximately 65%. Cefixime is almost exclusively bound to the albumin fraction. Protein binding of cefixime is only concentration-dependent in human serum at very high concentrations which are not

seen following clinical dosing.

Metabolism and Excretion: There is no evidence of metabolism of cefixime *in vivo*. Approximately 50% of the absorbed dose is excreted unchanged in the urine in 24 hours. In animal studies, it was noted that cefixime is also excreted in the bile in excess of 10% of the administered dose. The serum half-life of cefixime in healthy subjects is

independent of dosage form and averages 3 to 4 hours, but may range up to 9 hours in some volunteers.

5.3 Preclinical Safety Data:

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:

Microcrystalline Cellulose, Saccharin Sodium, Flavour Capsaroma Strawberry, Levomenthol, Magnesium Stearate, Purified Talc.

6.2 Incompatibilities:

Not Known

6.3 Shelf life

30 Months

6.4 Special precautions for storage

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container:

Strip	Strip of 10 Tablets
Mono Carton	1 Strip along with Leaflet
Duplex Box	10 Mono carton
Shipper Packing	10 Duplex Box of 10 Mono Carton . Packed with BOPP tape having Blue Cross Logo, with “H” type packing on bottom and topside.
Pack Size	10x10x1x10’s

6.6 Special precautions for disposal

No special requirements

7. Marketing authorisation holder and manufacturing site addresses

Blue Cross Laboratories Pvt Ltd.

A-12, MIDC, Ambad, Nashik – 422010, Maharashtra, India.

8 Marketing Authorization Number

18586

9. Date of First Registration / Renewal of the Registration

Date of last renewal of authorization – 01/01/2026

10. Date of Revision of the Text

March 2026