1. NAME OF THE MEDICINAL PRODUCT

Product name: **STARBACT TABLET**, Cefixime Tablet USP 200 mg
Strength: 200 mg
Pharmaceutical form: Oral Film Coated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Cefixime Trihydrate USP
Eq. to Anhydrous Cefixime 200 mg
Colour: Titanium Dioxide BP
Excipients q.s.

For complete list of excipients refer Section 6.1

3. PHARMACEUTICAL FORM

Off white, round, biconvex, film coated tablet with plain surface on both side.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Acute exacerbations of chronic bronchitis
- Community-acquired Pneumonia
- Lower urinary tract infections
- Pyelonephritis
- Sinusitis
- Pharyngitis

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults: The recommended dose of Cefixime is 400 mg daily. This may be given as 400 mg once daily or as 200 mg every 12 hours.
Children: The recommended dose is 8 mg/kg/day. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.

PEDIATRIC DOSAGE CHART		
Patient Weight (kg)	Dose/Day (mg)	Dose/Day (Tablets)
6.25	50	½
12.5	100	1
18.75	150	1½
25	200	2
31.25	250	2½
37.5	300	3

Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose.

4.3 CONTRAINDICATIONS

Hypersensitivity to cefixime, other cephalosporin antibiotics or to any of the excipients. Previous, immediate and/or severe hypersensitivity reaction to penicillin or any beta-lactam antibiotic.

4.4 SPECIAL WARNING AND PRECAUTION FOR USE

Superinfection/Clostridium difficile-associated Diarrhea and Colitis: Possible

emergence and overgrowth of non-susceptible bacteria or fungi, especially Enterobacter, Pseudomonas, enterococci, staphylococci, or Candida. Careful observation of the patient is essential.

History of GI Disease: Use cefixime with caution in patients with a history of GI disease, particularly colitis.

Hypersensitivity Reactions: Hypersensitivity reactions such as anaphylaxis (including shock and fatalities), angioedema, serum sickness-like reactions, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. The use of cefixime should be discontinued immediately and appropriate emergency measures should be initiated.

Decreased Prothrombin Activity: Prolonged PTand prolonged partial thromboplastin time reported.

Pregnancy: Cefixime should not be used in pregnant mothers unless considered essential by the physician.

Lactation: It is unknown whether cefixime is excreted in human breast milk. Cefixime should not be prescribed to breast-feeding mothers.

Renal insufficiency: Cefixime should be administered with caution in adult patients with creatinine clearance < 20 ml / min.

Pediatric Use: Safety and efficacy not established in children <6 months of age.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND 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

Carbamazepine

Nifedipine, Probenecid

Anticoagulants, oral (warfarin).

4.6 FERTILITY, PREGNANCY AND LACTATION

Pregnancy: Cefixime should not be used in pregnant mothers unless considered essential by the physician.

Lactation: It is unknown whether cefixime is excreted in human breast milk. Cefixime should not be prescribed to breast-feeding mothers.

4.7 EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES

Not known

4.8 UNDESIRABLE EFFECTS

Gastrointestinal Disturbances: The most frequent side effects seen with Cefixime are diarrhea and stool changes. Moderate to severe diarrhoea has been reported. Other gastrointestinal side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting and flatulence. Pseudomembranous colitis has been reported.

Central Nervous System: Headache and dizziness.

Hypersensitivity Reactions: Allergies in the form of rash, pruritus urticaria, drug fever and arthralgia have been observed. These reactions usually subsided upon discontinuation of therapy.

Haematological and Clinical Chemistry: Thrombocytopenia, leukopenia and eosinophilia have been reported.

Miscellaneous: Other possible reactions include genital pruritus and vaginitis.

4.9 OVERDOSE

There is no experience with overdoses with cefixime.

Gastric lavage may be indicated in overdosage. No specific antidote exists. Cefixime is not removed from the circulation in significant quantities by dialysis.

5. PHARMACOLOGICAL PARTICULARS

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Third-generation cephalosporin antibacterial

ATC code: J01DD08

Cefixime is an antibacterial agent of the cephalosporin class. Like other cephalosporins, Cefixime inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins (PBPs); which in turn inhibit the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

5.2 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. Cefixime may therefore be given without regard to meals.

Distribution:

The mean volume of distribution of cefixime is 0.1 L/kg. Penetration into tissue fluid is slow (mean tmax=6.7h) but peak concentration similar to those of plasma has been achieved. Lower levels are found in palatine tonsil, maxillary sinus mucosa, sputum and middle ear discharge. Very high concentrations occur in bile. After single oral doses of 100 mg, mean biliary concentrations is 135 mg/ml. Cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30%. Protein binding of cefixime is only concentration dependent in human serum at very high concentrations which are not seen following clinical dosing.

Elimination:

Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine.

Half life:

Half life of Cefixime in adults with normal renal function is 2.4–4 hours. In patients with renal impairment, half-life averages 6–11.5 hours.

5.3 PRE-CLINICAL SAFETY

Preclinical effects were observed in dosages far above the maximal human dosage which are therefore hardly relevant for the clinical use of Cefixime Trihydrate.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Starch BP
Microcrystalline Cellulose BP
Sodium Starch Glycolate BP
Purified Talc BP
Colloidal Anhydrous Silica BP
Croscarmellose Sodium BP

Magnesium Stearate BP
Colour White Coating In-House
Isopropyl Alcohol BP
Methylene Chloride BP

6.2 INCOMPATIBILITIES
None

6.3 SHELF LIFE
24 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store in a Below 30 °C. Protect from light & moisture.

6.5 NATURE AND CONTENTS OF CONTAINER
10 tablets are in Alu-Alu blister pack. Such 1 Alu-Alu blister are packed in a printed cartons with package insert.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
Not applicable.

7. MARKETING AUTHORIZATION HOLDER
SAKAR HEALTHCARE LIMITED
Block No. 10-13, Sarkhej-Bavla Highway,
Changodar, Ahmedabad - 382213, Gujarat, India
Phone :+91-02717 250477
Fax :+91-02717 251621
E.mail : info@sakarhealthcare.com

8.
MARKETING AUTHORISATION NUMBER(S)
Not Applicable

9.
DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
Not Applicable

10.
DATE OF REVISION OF THE TEXT
Not Applicable