Summary of Product Characteristics for Pharmaceutical Products

1. **Name of the medicinal product:**

   Cachmax -DS (Cefixime for oral suspension USP 100mg/5ml)

2. **Qualitative and quantitative composition:**

   Each 5 ml reconstituted suspension contains:

   Cefixime USP (As Trihydrate)

   Equivalent to anhydrous Cefixime 100 mg

   For the full list of excipients, see section 6.1.

3. **Pharmaceutical form:** Powder for Oral Suspension

4. **Clinical particulars:**

4.1 Therapeutic indications:

Indicated in the treatment of following infections:

- Uncomplicated urinary tract infections
- Otitis media
- Pharyngitis and tonsillitis
- Acute bronchitis and acute exacerbations of chronic bronchitis
- Uncomplicated gonorrhea.

4.2 Posology and method of administration:

Route/ Way of administration: Oral.

Children: The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses. As a general guide for prescribing in children the following daily doses are suggested.

6 months upto 1 year: 3.75 mL daily.

Children 1-4 years: 5 mL daily.

Children 5- 10 years: 10 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.

Reconstitution direction for oral suspension: To reconstitute suspend with water (Previously boiled and cooled).

Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half amount of water for reconstitution and shake well. Add remainder of water and make up the volume upto the mark of the bottle.

4.3 Contraindications

Cefixime for oral suspension is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

4.4 Special warnings and precautions for use

Before therapy with cefixime oral suspension is instituted careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporin's, penicillin's or other drugs. If this product is to be given to penicillin sensitive patients, caution should be exercised because cross hypersensitivity among beta lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If allergy reactions to cefixime oral suspension occur discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines and airway management as clinically indicated.

Precautions:

General

The possibility of the emergence of resistant organisms which might result in overgrowth should be kept in mind, particularly during prolonged treatment. In such use, careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

The dose of Cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and

hemodialysis(HD). Patients on dialysis should be monitored carefully. Cefixime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Cephalosporin's may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

4.5 Interaction with other medicinal products and other forms of interaction Carbamazepine: Elevated carbamazepine levels have been reported in post marketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Warfarin and Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women. Cefixime should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

The following adverse reactions may occur: *Gastrointestinal*: Diarrhea, loose stools, abdominal pain, dyspepsia, nausea, and vomiting.

Hypersensitivity Reactions: Anaphylactic/ anaphylactoid reactions, skin rashes, urticaria, pruritus, angioedema. *Hepatic:* Transient elevations in SGPT, SGOT, alkaline phosphatase.

Renal: Transient elevations in BUN or creatinine.
Central Nervous System: Headaches, dizziness.

Hemic and Lymphatic Systems: Transient thrombocytopenia, leukopenia, eosinophilia. Prolongation in prothrombin time was seen rarely.

Abnormal Laboratory Tests: Hyperbilirubinemia.

Other: Genital pruritus, vaginitis, candidiasis.

Reporting of suspected adverse reactions

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of cefixime did not differ from the profile seen in patients treated at the recommended doses.

5.Pharmacological properties

5.1 Pharmacodynamic properties

Cefixime is a semi synthetic, broad spectrum, third generation cephalosporin which has marked in vitro bactericidal activity against a wide variety of gram positive and gram negative organisms.

As with other cephalosporin, bactericidal action of Cefixime results from inhibition of cell wall synthesis. Cefixime is stable in presence of beta lactamase enzymes.

Cefixime has been shown to be active against following gram positive and gram negative organisms.

Gram Positive

a) *Streptococcus pneumonia.*
b) *Streptococcus pyogenes.*

Gram Negative

a) *Haemophilus influenza (beta lactamase positive and negative).*
b) *Proteus mirabilis.*

c) *Branhamella catarrhalis (beta Lactamase positive and negative).*
d) *Escherichia Coli M*ost 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

Only 40 to 50% of an oral dose of cefixime is absorbed from the gastrointestinal tract, whether taken before or after meals, although the rate of absorption may be decreased in the presence of food. Cefixime is better absorbed from oral suspension than from tablets. Absorption is fairly slow, peak plasma concentrations of 2 to 3 micrograms/mL and 3.7 to
4.6 micrograms/mL have been reported between 2 and 6 hours after single doses of 200 and 400 mg, respectively. The plasma half life is usually about 3 to 4 hrs and may be prolonged when there is renal impairment. About 65% of cefixime is bound to plasma proteins.

Information on the distribution of cefixime in body tissues and fluids is limited. It crosses the placenta. Relatively high concentrations may be achieved in bile and urine. About 20% of an oral dose (or 50% of an absorbed dose) is excreted unchanged in the urine within 24 hrs. Up to 60% may be eliminated by non renal mechanisms; there is no evidence of metabolism but some is probably excreted into the faeces from bile. It is not substantially removed by dialysis.

5.3 Preclinical safety data

There are no pre-clinical data of relevance

6.Pharmaceutical particulars

6.1 List of excipients:

S. No.	Name of Material	Specification
1.	Xanthan Gum	USP
2.	Sodium Benzoate	USP
3.	Sucrose	USP

4.	Trusil Pineapple flavor	IH
5.	Colloidal Silicon dioxide	USP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

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

Keep away from the reach of Children.

6.5 Nature and contents of container

Packed in 60 ml/100 ml HDPE bottle.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing authorization holder

Cachet Pharmaceuticals Pvt. Ltd

415, Shah Nahar, Worli, Mumbai 400 018. India.

8. Marketing authorisation number(s)

H2022/CTD9204/19798

9. Date of first authorisation/renewal of the authorisation

2023 May 03

10. Date of revision of the text

2023 May 03