SUMMARY OF PRODUCT CHARACTERISTICS

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

   (Cefuroxime Axetil for Oral Suspension USP)

2. **Qualitative and quantitative composition:**

   Each 5 ml of reconstituted suspension contains:

   Cefuroxime Axetil USP (Amorphous)

   Equivalent to Cefuroxime 125 mg

   Excipients with known effect:- Sucrose,Aspartame.

   For the full list of excipients, see section 6.1

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

4. **Clinical particulars:**

4.1 Therapeutic indications:

FUROXIMED for Oral Suspension is Indicated for the treatment of pediatric patients 3 months to 12 years of age with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

Pharyngitis/Tonsillitis caused by Streptococcus pyrogenes

The usual drug of choice In the treatment and prevention of streptoccccal Infections, Including theprophylaxis of rheumatic fever, is panicillin given by the intramuscular route. FUROXIMED for Oral Suspension is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefuroxime in tha subsequent prevention of rheumatic fevernot available.

Ac:uts Bacterial Otitis Media caused by Streptococcus pneumoniae, Haemophilus influenzae (including beta-lactamase-produclng strains), Moraxella catalrrhalis (Including beta-lactamese·produclng strains), or streptococcus pyogenes.

Impetigo caused by staphylococcus aureus {including beta-lactamase·producing strains} or streptococcus pyrogenes. To reduce the development of drug-resistant bacteria and maintain the effectiveness of FUROXIMED and otherantibacterial drugs, FUROXIMED should be used only to treat or prevent Infections that are proven or strongly suspected to be caused by susceptible bacteria.

4.2 Posology and method of administration:

Route/ Way of administration: Oral.

Population/Infection	**Dosage**	**Daily Maximum Dose**	**Duration (days)**
Pediatric Patients (3 months to 12 years)			
Pharyngitis/tonsillitis	20 mg/kg/day divided b.i.d.	500 mg	10
Acute otitis media	30 mg/kg/day divided b.i.d.	1,000 mg	10
Acute bacterial maxillary sinusitis	30 mg/kg/day divided b.i.d.	1,000 mg	10
Impetigo	30 mg/kg/day divided b.i.d.	1,000 mg	10

Reconstitution direction for oral suspension:

Shake the bottle well to loosen the powder.Fill the boiled and cooled water up to the mark on bottle.Shake the bottle well to mix the contents .The medicine should be taken after food for optimum absorption.

Reconstituted suspension should be stored in refrigerator and used within 10 days.

4.3 Contraindications

Hypersensitivity to cephalosporin antibiotics or to any components of the formulation. Hypersensitivity to penicillin and other beta-lactam antibiotics

4.4 Special warnings and precautions for use

Precaution:

As with other broad-spectrum antibiotics, prolonged administration of cefuroxime axetil may result in overgrowth of nonsusceptible microorganisms. If superinfection occurs

during therapy, appropriate measures should be taken Cephalosporins, including cefuroxime axetil, should be given with caution to patients receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function. Cefuroxime axetil, as with other broad-spectrum antibiotics, should be prescribed with caution in individuals with a history of colitis. The safety and effectiveness of cefuroxime axetil have not been established in patients with gastrointestinal malabsorption. Patients with gastrointestinalmalabsorption were excluded from participating in clinical trials of cefuroxime axetil. Cephalosporins 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 exogenousVitamin K administered as indicated.

Warning:

Before therapy with FUROXIMED products is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to FUROXIMED products, other cephalosporins, penicillins, 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 a clinically significant allergic reaction to FUROXIMED products occurs, discontinue the drug and institute appropriate therapy. 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. *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including FUROXIMED, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. *difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require

colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since DAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of probenecid increases the area under the mean serum concentration time-curve by 50%.Drugs that reduce gastric acidity may result in a lower bioavailability of FUROXIMED compared with that of fasting state and tend to cancel the effect of postprandial absorption. In common with other antibiotics, cefuroxime axetil may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data from the use of cefuroxime in pregnant women. Studies in animals have shown no harmful effects on pregnancy, embryonal or fetal development, parturition or postnatal development.

Fertility

There are no data on the effects of cefuroxime axetil on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, as this medicine may cause dizziness, patients should be warned to be cautious when driving or operating machinery.

4.8 Undesirable effects

The most common adverse reactions are Candida overgrowth, eosinophilia, headache, dizziness, gastrointestinal disturbances and transient rise in liver enzymes.

The frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data (for example from placebo-controlled studies) for calculating incidence were not available. In addition the incidence of adverse reactions associated with cefuroxime axetil may vary according to the indication.

Data from large clinical studies were used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e. those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than true frequency. Placebo-controlled trial data were not available. Where incidences have been calculated from clinical trial data, these were based on drug-related (investigator assessed) data. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: bactericidal second-generation cephalosporin antibiotic,

ATC code: J01DC02.

Mechanism of action

Cefuroxime is a bactericidal second-generation cephalosporin. The antibacterial action of cefuroxime results from inhibition of bacterial cell wall synthesis by binding to essential target proteins in bacterial cytoplasmic membranes. Cefuroxime has bactericidal activity against a wide range of bacterial organisms, including beta-lactamase producing strains.

5.2 Pharmacokinetic properties

Peak levels of cefuroxime are achieved within 30 to 45 minutes after intramuscular administration. The serum half-life after either intramuscular or intravenous injection is approximately 70 minutes. In the first weeks of life the serum half-life of cefuroxime can be 3 - 5 times that in the adult. Concurrent administration of probenecid prolongs the excretion of the antibiotic and produces an elevated peak serum level. Protein binding has been variously stated as 33 - 50% depending on the methodology used. There is an almost complete recovery (85-90 %) of unchanged cefuroxime in urine within 24 hours of administration. The major part is excreted in the first six hours. Cefuroxime is not metabolized and is excreted by glomerular filtration and tubular secretion. Serum levels of cefuroxime are reduced by dialysis.

Concentrations of cefuroxime in excess of the minimum inhibitory levels for common pathogens can be achieved in bone, synovial fluid and aqueous humour. Cefuroxime passes the blood-brain barrier when the meninges are inflamed.

5.3 Preclinical safety data

There are no pre-clinical data of relevance

6. Pharmaceutical particulars

6.1 List of excipients:

Kyron T-114C

Sucrose

Colloidal Silicon Dioxide

Citric acid Anhydrous
Sodium Citrate
Aspartame

Saccharin Sodium

Sodium benzoate

Flavour peppermint
Flavour Vanilla

Colour sunset yellow FCF

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.

Phone No. Office +91-22-40829991

Email:-regulatory@cachetpharma.com

8. Marketing authorization number(s)

06576/08556/NMR/2020

9. Date of first authorization/renewal of the authorization

Date of first authorization: 14/10/2021

10. Date of revision of the text

02/01/2023