

CEFAIM Capsule Dry Suspension

Cefixime (as trihydrate) USP

1. Cefaim 400mg capsules.
2. Cefaim 100mg/5ml Dry Suspension (30ml).
2. Cefaim 200mg/5ml Dry Suspension (30ml).

INDICATIONS:

Cefaim is indicated in the treatment of the following infections caused by the following micro-organisms susceptible to Cefaim.

MICROORGANISMS:

• *Streptococcus sp.* • *Streptococcus pneumoniae* • *Neisseria gonorrhoeae* • *Neisseria meningitidis* • *Moraxella (Branhamella) catarrhalis* • *Escherichia coli* • *Klebsiella sp.* • *Serratia sp.* • *Proteus sp.* • *Providencia sp.* • *Morganella morganii* • *Heat nobilis influenzae* • *Haemophilus parainfluezae* • *Salmonella sp.* • *Shigella sp.* • *Aeromonas hydrophila* • *Pasteurella multocida* • *Citrobacter freundii* • *Citrobacter amalonaticus* • *Citrobacter diversus* • *Enterobacter sp.* • *Acinetobacter Iwoff* • *Yeremia enterocolitica* • *Campylobacter jejuni*

INFECTIONS:

RESPIRATORY TRACT INFECTIONS

- Infections of the upper and lower airways
- Pulmonary infections of bacterial etiology
- Bronchitis (acute, chronic)
- Pneumonia
- Bronchiectasis with infection
- Secondary infections in chronic respiratory diseases

EAR, NOSE AND THROAT INFECTIONS

- Otitis media
- Sinusitis
- Tonsillitis
- Pharyngitis
- Laryngitis

GASTROINTESTINAL INFECTIONS

- Typhoid

URINARY TRACT INFECTIONS

- Infections of the kidneys and efferent urinary tract
- Uncomplicated urinary tract infections.
- Complicated and uncomplicated urinary tract infections except for Prostatitis
- Pyelonephritis
- Cystitis
- Gonococcal urethritis
- Uncomplicated gonorrhoea (cervical/urethral)

BILIARY TRACT INFECTIONS

- Infections of the biliary tract
- Cholecystitis
- Cholangitis

SCARLET FEVER

DOSAGE & ADMINISTRATION:

Absorption of Cefaim is not significantly modified by the presence of food. The usual course of treatment is 5-14 days.

Adults & Children over 12 years:

The recommended adult dosage is 400mg daily administered as single dose.

Children (Use Dry Oral Suspension):

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

Dry Oral Suspension	
Children 1-4 years	: 2.5 ml daily
Children 5-9 years	: 5 ml daily
Children 10-12years	: 7.5 ml daily
Adult & Children over 12 years	: 10 ml daily

The dosage in children aged 6 months to one year should be calculated on mg/kg basis Children weighing more than 30 kg or older than 12 year's should be treated with the recommended adult dose. The safety and efficacy of cefixime has not been established in children aged less than 6 months.

THE ELDERLY:

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.

DOSAGE IN RENAL IMPAIRMENT:

Cefaim may be administered in the presence of impaired renal function. Normal dose and frequency may be given in patients with creatinine clearance of 20ml/min or greater. In patients whose creatinine clearance is less than 20ml/min, it is recommended that a dose of 200mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or haemodialysis should follow the same recommendation as for the patients with creatinine clearance of less than 20ml/min.

and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or haemodialysis should follow the same recommendation as for the patients with creatinine clearance of less than 20ml/min.

CONTRAINDICATIONS:

Patients with known allergy to the Cephalosporin group of antibiotics.

PRECAUTIONS AND WARNINGS:

• As a general rule, the duration of treatment with this drug should be limited to a minimum period required for the treatment of the patient's condition, after susceptibility of the micro-organism to the drug has been confirmed, in order to prevent the emergence of drug-resistant micro-organisms.

• Careful inquiry should be made to determine whether the patient has had previous hypersensitivity to cephalosporins, penicillins or other drugs.

• Particular care should be exercised in patients with a personal or familial predisposition to allergic reaction such as bronchial asthma, rash or urticaria.

• Particular care should be exercised in patients with severe gastrointestinal disturbances involving vomiting and diarrhoea.

• Particular care should be exercised in patients with severely impaired renal function, patients with poor oral nutrition, patients receiving parenteral nutrition elderly patients or patients in a debilitated state.

• Renal function should be monitored with particular care when combining cefixime with an aminoglycoside antibiotic, Polymyxin B, Polymyxin E (Colistin) or high-dosed loop diuretics (e.g. furosemide). This is applied especially to patients with pre existing renal impairment.

• Adverse reactions to drugs are liable to occur more frequently in the elderly patients since they usually have physiological hypofunction.

• Bleeding tendency due to Vitamin K deficiency may occur in the elderly.

USE IN PREGNANCY AND BREAST FEEDING:

Like Other cephalosporins, Cefam is included in therapeutic category B of PDA for use in Pregnancy. Reproduction studies have been performed in mice and rats at doses up to 400 times the human dose and have revealed no evidence of harm to the fetus due to cefixime.

Because animal reproduction studies are not always predictive of human response, this drug 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.

DRUG INTERACTIONS:

A prolonged prothrombin time has been reported in patients who had been administered cefixime and anticoagulants of the coumarin-type.

OVERDOSE:

There have been limited clinical experiences with overdose of cefixime to date.

ADVERSE REACTIONS::

Anaphylactic reaction including shock internal swelling of the larynx with airways constriction

Fever, Stevens-Johnson syndrome Rash, Erythema (Erythema multiforme), Pruritus, Leukopenia, Eosinophilia, Thrombocytopenia

Increases in GOT, GPT and alkaline phosphatases

Serious colitis (such as pseudo membranous colitis), Diarrhoea, Abdominal pain, Vomiting, Nausea

Transient elevation in BUN or creatinine

Headache, Dizziness

DIRECTIONS FOR RECONSTITUTION:

Please see carton for reconstitution of Dry Suspension.

Dose:

Use as prescribed by the physician.

PRECAUTIONS:

- Keep away from children.

- Store at room temperature.

- Suspension can be used for upto one week after preparation.

- Protect from direct sunlight, heat and moisture.

خوراک: دواؤڈاکٹرکی ہدایت کے مطابق استعمال کریں

ہدایات: دوا کو بچوں کی پہنچ سے دور رکھیں۔

دوا کو کمرے کی درجہ حرارت پر رکھیں۔

روشنی، دھوپ اور نمی سے بچائیں۔

سپینشن بنانے کے بعد ایک ہفتہ تک استعمال کیا جاسکتا ہے۔



Manufactured by:

Aims Pharmaceuticals

Plot # 291, Industrial Triangle

Kahuta Road, Islamabad - Pakistan.

www.aimspharmaceuticals.com