

Cef-3[®]

Cefixime USP

Cef-3[®] (Cefixime) is a broad spectrum cephalosporin antibiotic of third generation for oral administration. It is a bactericidal antibiotic and is stable to hydrolysis by many beta-lactamases. **Cef-3[®]** kills bacteria by interfering in the synthesis of the bacterial cell wall. **Cef-3[®]** is highly active against *Neisseria gonorrhoeae*, *Haemophilus influenzae*, *Moraxella catarrhalis* including beta-lactamase producers, most of the Enterobacteriaceae, beta-haemolytic *Streptococcus* (group A & B) and *Streptococcus pneumoniae*. **Cef-3[®]** is more active than other oral cephalosporins against *Escherichia coli*, *Klebsiella* spp, *Proteus mirabilis* and *Serratia marcescens*. **Cef-3[®]** is also active against *Streptococcus pyogenes*. 40-50% of an oral dose is absorbed from gastro-intestinal tract, whether taken with meals or not. The plasma half life is usually about 3 to 4 hours and may be prolonged when there is renal impairment. About 65% of **Cef-3[®]** in the circulation is bound to plasma protein. **Cef-3[®]** is mainly excreted unchanged in bile and urine.

COMPOSITION

Cef-3[®] Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

Cef-3[®] DS Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg.

Cef-3[®] Tablet: Each film coated tablet contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

Cef-3[®] DS Tablet: Each film coated tablet contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg.

Cef-3[®] Powder for Suspension: Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

Cef-3[®] Forte Powder for Suspension: Each 5 ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

INDICATION

Upper and lower respiratory tract infections, Urinary tract infections, Gonococcal urethritis, Acute otitis media.

DOSAGE AND ADMINISTRATION

Cef-3[®] Capsule/Tablet: 200 mg - 400 mg, as a single dose or in 2 divided doses daily for 7-14 days, according to the severity of infection.

Cef-3[®] Powder for Suspension:

Child dose: 8 mg/kg daily as a single dose or in two divided doses for 7-14 days according to the severity of infection or for children of age $\frac{1}{2}$ -1 year: 3.75 ml or 75 mg; 1-4 years: 5 ml or 100 mg; 5-10 years: 10 ml or 200 mg; 11-12 years: 15 ml or 300 mg; above 12 years: adult dose.

Cef-3[®] Forte Powder for Suspension:

Child dose: 8 mg/kg daily as a single dose or in two divided doses for 7-14 days according to the severity of infection or for children of age $\frac{1}{2}$ -1 year: 1.88 ml or 75 mg; 1-4 years: 2.5 ml or 100 mg; 5-10 years: 5 ml or 200 mg; 11-12 years: 7.5 ml or 300 mg; above 12 years: adult dose.

SIDE EFFECTS

Cef-3[®] is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature. Gastro-intestinal disturbances : Diarrhoea (if severe diarrhoea occurs, Cef-3[®] should be discontinued), changes in the colour of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported. Central nervous system disturbances: Headache, dizziness. Others: Hypersensitivity reactions which usually subside upon discontinuation of therapy; infrequent and reversible haematological changes; elevation of serum amylase.

CONTRA-INDICATION

Patients with known hypersensitivity to cephalosporin group of drugs.

PRECAUTION

Cef-3[®] should be prescribed with caution in individuals with a history of gastrointestinal diseases, particularly colitis. Dosage adjustment is only necessary in severe renal failure (creatinine clearance < 20 ml. min⁻¹)

USE IN PREGNANCY AND LACTATION

No data are available, so it is probably best to avoid using the drug during pregnancy and by the nursing mothers.

USE IN ELDERLY

No special precautions are necessary. Old age is not an indication for dose adjustment.

USE IN CHILDREN

For children younger than 12 years or weighing less than 50 kg, the usual dose is 8 mg/kg/day.

DRUG INTERACTION

No data are available.

STORAGE CONDITION

Capsule/Tablet: Store below 30°C, protect from light and moisture.

Powder for Suspension: Store below 25°C, protect from light and moisture. After reconstitution the suspension should be used within 7 days if kept at room temperature and within 14 days if kept in refrigerator (2°C- 8°C).

DIRECTIONS FOR RECONSTITUTION OF SUSPENSION

Cef-3[®] Powder for Suspension: To prepare 30 ml suspension, 20 ml boiled and cooled water is required. To prepare 40 ml suspension, 25 ml boiled and cooled water is required. To prepare 50 ml suspension, 35 ml boiled and cooled water is required.

Cef-3[®] Forte Powder for Suspension: To prepare 30 ml suspension, 20 ml boiled and cooled water is required. To prepare 40 ml suspension, 25 ml boiled and cooled water is required. To prepare 50 ml suspension, 35 ml boiled and cooled water is required. Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half of the total amount of water and shake well. Add remainder of water, then shake again.

INFORMATION FOR THE PATIENT

- 1) Shake well before using the suspension.
- 2) Do not discontinue the therapy suddenly, without consulting your doctor.
- 3) Discard unused portion of reconstituted suspension after the above mentioned time.
- 4) Keep away from the reach of the children.

HOW SUPPLIED

Cef-3[®] Capsule: Box containing 3's/5's/6's/10's/12's/18's/20's/30's/100's Capsules in Blister/Strip Pack.

Cef-3[®] DS Capsule: Box containing 3's/5's/6's/10's/12's/14's/18's/20's/30's/100's Capsules in Blister/Strip Pack.

Cef-3[®] Tablet: Box containing 3's/6's/10's/12's/18's/20's Tablets in Blister Pack.

Cef-3[®] DS Tablet: Box containing 3's/6's/10's/12's/15's/18's/20's Tablets in Blister Pack.

Cef-3[®] Powder for Suspension: 30 ml / 40 ml / 50 ml / 100 ml glass bottle containing powder for suspension with a measuring cup / plastic dropper.

Cef-3[®] Forte Powder for Suspension: 30 ml / 37.5 ml / 40 ml / 50 ml in glass bottle containing powder for suspension with a measuring cup / plastic dropper.

SQUARE