

Cef-3[®]

Cefixime

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.

Cef-3[®] Paediatric Drops: Each ml reconstituted suspension contains Cefixime Trihydrate USP equivalent to Cefixime 25 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/Paediatric Drops:

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 1/2-1 year: 75 mg; 1-4 years: 100 mg; 5-10 years: 200 mg; 11-12 years: 300 mg; above 12 years: adult dose.

SIDE EFFECTS

Cefixime 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, Cefixime 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.

CONTRAINDICATION

Patients with known hypersensitivity to cephalosporin group of drugs.

PRECAUTION

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

Powder for Suspension/Paediatric Drops: Store below 25° C, protected from light and moisture.

After reconstitution the suspension/drops can be used within 7 days if be kept at room temperature and within 14 days if be kept in refrigerator (2°-8° C). Always keep the bottle tightly closed.

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[®]** Paediatric Drops: To prepare 21 ml suspension, 14 ml boiled and cooled water is required.

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

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 12 Capsules in Blister Pack.

Cef-3[®] DS Capsule: Box containing 6 Capsules in Blister Pack.

Cef-3[®] Tablet: Box containing 10 Tablets in Blister Pack.

Cef-3[®] DS Tablet: Box containing 6 Tablets in Blister Pack.

Cef-3[®] Powder for Suspension (30 ml): Bottle containing dry powder for 30 ml suspension.

Cef-3[®] Powder for Suspension (40 ml): Bottle containing dry powder for 40 ml suspension.

Cef-3[®] Powder for Suspension (50 ml): Bottle containing dry powder for 50 ml suspension.

Cef-3[®] Forte Powder for Suspension (50 ml): Bottle containing dry powder for 50 ml suspension.

Cef-3[®] Paediatric Drops (21 ml): Bottle containing dry powder for 21 ml Paediatric Drops.