Emixef®

Cefixime Capsule & Dry Suspension

Presentation

Emixef® 200 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.
Emixef® 400 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg.
Emixef® Powder for Suspension: After reconstitution according to direction, each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.
Emixef® DS Powder for Suspension: After reconstitution according to direction, each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

Description

Cefixime is a semi-synthetic, broad spectrum cephalosporin antibiotic of third generation for oral administration. It is a bactericidal antibiotic, kills bacteria by interfering in the synthesis of the bacterial cell wall. Cefixime is highly stable in the presence of beta-lactamase enzymes. Cefixime has marked *in-vitro* bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms including beta lactamase producers.
Clinical efficacy of Cefixime has been demonstrated in infections caused by commonly occurring pathogens including Gram-positive organism *Streptococcus pneumoniae, Streptococcus pyogenes,* Gram-negative organism *Escherichia coli, Proteus mirabilis, Klebsiella spp., Haemophilus influenzae* (beta-lactamase positive and negative), *Moraxella catarrhalis* (beta-lactamase positive and negative), *Salmonella typhi* and *Enterobacter species.*

Indications and Uses

Emixef is indicated in the following infectious diseases -

- **Respiratory Tract Infections:**
  - Pneumonia
  - Sinusitis
  - Pharyngitis and Tonsillitis
  - Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis (AECB)
- Otitis Media
- Typhoid Fever
- Urinary Tract Infections
- Uncomplicated gonorrhea (cervical/urethral)

Dosage and Administration

The usual treatment of Emixef is 7 days. This may be continued for up to 14 days according to the severity of infection.

Emixef Capsule

Adult and child over 12 years: 200 or 400 mg daily as a single dose or in two divided doses.

Emixef Suspension

Child over 6 months: 8 mg/kg daily as a single dose or in 2 divided doses

Patient Weight (Kg)	Dose (mg/day)	Dose (ml/day)	
		Emixef	Emixef DS
6.25	50	2.5	1.25
12.5	100	5	2.5
18.75	150	7.5	3.75
25	200	10	5
31.25	250	12.5	6.25
37.5	300	15	7.5

Side-effects

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials are mild and self limiting in nature.
Gastro-intestinal disturbance: Diarrhea (if severe diarrhea occurs, Cefixime should be discontinued), changes in the color of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported.
CNS disturbances: Headache, dizziness.
Others: Hypersensitivity reactions which usually subsided upon discontinuation of therapy; infrequent and reversible hematological changes; elevation of serum amylase.

Precautions

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)

Use in Pregnancy and Lactation

Pregnancy: Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Lactation: It is not known whether Cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Use in Elderly

No special precautions are necessary. No dosage adjustment is required for elderly.

Contraindication

Patients with known hypersensitivity to Cefixime or cephalosporin group of drugs.

Drug Interactions

Carbamazepine: Elevated carbamazepine levels have been reported in postmarketing 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.

Direction for Reconstitution of Suspension

- To prepare 50 ml suspension, 25 ml boiled and cooled water is required.
- To prepare 40 ml suspension, 20 ml boiled and cooled water is required.
- To prepare 30 ml suspension, 15 ml boiled and cooled water is required.
- To prepare 50 ml DS suspension, 25 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, and then shake again.
Note: Shake the suspension well before each use. Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool and dry place, preferably in refrigerator and unused portion should be discarded after 14 days.

Overdosage

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.

Commercial Pack

Emixef® 200 Capsule: Box containing 2 Alu-Alu blister strips of 6 capsules.
Emixef® 400 Capsule: Box containing 2 Alu-Alu blister strip of 4 capsules.
Emixef® Suspension: Bottle containing powder for the preparation of 50 ml, 40 ml or 30 ml suspension.
Emixef® DS Suspension: Bottle containing powder for the preparation of 50 ml suspension.

Manufactured by
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