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CEFIXIME TRIHYDRATE

ACECEF

100 mg / 5 mL Powder for Oral Suspension

ANTIBACTERIAL

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FORMULATION:
Each 5 mL (1 teaspoonful) of the reconstituted suspension contains:
Cefixime (as Trihydrate) USP ..... 100 mg

PRODUCT DESCRIPTION:
White to light yellow/orange coloured, orange flavored, free flowing powder when reconstituted it gives yellow to orange coloured suspension.

PHARMACODYNAMICS:
Cefixime is a third generation cephalosporin with antibacterial activity similar to penicillins, carbacephems and cephamycins. Cefixime exerts its bactericidal activity by interfering with the synthesis of the bacterial cell wall. It binds to specific penicillin-binding proteins responsible for the synthesis of peptidoglycan, a heteropolymeric structure that gives the cell wall its mechanical stability. The final stage of peptidoglycan synthesis involves completion of the cross-linking of the terminal glycine residue of the pentaglycine bridge to the fourth residue of the pentapeptide. The transpeptidase that catalyzes this step is inhibited by cephalosporins. Thus, inhibition of the transpeptidase interrupts peptidoglycan synthesis, causing formation of defective cell walls and osmotically unstable spheroplasts and lysis of the bacteria.

PHARMACOKINETICS:
Only 40 to 50% of an oral dose of Cefixime is absorbed from the gastrointestinal tract, whether taken before or after meals, although the rate of absorption may be decreased in the presence of food. Cefixime is better absorbed from oral suspension than from tablets. Absorption is fairly slow; peak plasma concentrations of 2 to 3 micrograms/mL and 3.7 to 4.6 micrograms/mL have been reported between 2 and 6 hours after single doses of 200 and 400 mg, respectively. The plasma half-life is usually about 3 to 4 hours and may be prolonged when there is renal impairment. About 65% of Cefixime is bound to plasma proteins. Information on the distribution of Cefixime in body tissues and fluids is limited. It crosses the placenta. Relatively high concentrations may be achieved in bile and urine. About 20% of an oral dose (or 50% of an absorbed dose) is excreted unchanged in the urine within 24 hours. Up to 60% may be eliminated by non renal mechanism; there is no evidence of metabolism but some is probably excreted in the feces from bile. It is not substantially removed by dialysis.

ANTIMICROBIAL ACTION:
Cefixime is bactericidal and is stable to hydrolysis by many beta-lactamase. It has a mode of action and spectrum of activity similar to that of the third generation cephalosporin cefotaxime, but some enterobacteriaceae are less susceptible to Cefixime. Haemophilus influenzae, Moraxella catarrhalis (Branhamella catarrhalis) and Neisseria gonorrhoeae are sensitive, including penicillinase-producing strains of the Gram-positive bacteria. Streptococci are sensitive to Cefixime but most strains of Staphylococci, Enterococci and Listeria spp. are not. Enterobacter spp., Pseudomonas aeruginosa, and Bacteroides spp. are resistant to Cefixime.

INDICATIONS:
For the treatment of infections due to sensitive Gram-positive and Gram-negative bacteria.

DOSAGE AND ADMINISTRATION:
Children over 6 months: 8 mg/kg daily in 1 to 2 divided doses; or
6 months up to 1 year: 7.5 mL daily.
Children 1 to 4 years: 10 mL daily.
Children 5 to10 years: 20 mL daily.
The usual course of treatment is 7 days. This may be continued for up to 14 days if required.
Or as prescribed by the physician.

DIRECTION FOR RECONSTITUTION:
Shake bottle to loosen the powder. Slowly add boiled and then cooled water up to the mark on the bottle. Shake vigorously. The reconstituted suspension should be stored at temperatures between 2°C to 8°C and should be used within 7 days.

Shake well before use.

CONTRAINDICATION:
Cefixime for oral suspension is contraindicated in patients with known allergy to Cefixime or other cephalosporins.

WARNINGS AND PRECAUTIONS:
Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. Antibiotics, including cefixime, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.
Treatment with broad spectrum antibiotics, including Cefixime, alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of severe antibiotic-associated diarrhea including pseudomembranous colitis. Pseudomembranous colitis has been reported with the use of Cefixime and other broadspectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider this diagnosis in patients who develop diarrhea in association with the use of antibiotics.
The dose of Cefixime Suspension should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully. Cefixime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. 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 exogenous vitamin K administered as indicated.

PREGNANCY AND LACTATION:

Pregnancy: Pregnancy Category B. 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. 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.
Labor and Delivery Cefixime has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.
Lactation: It is not known whether Cefixime is excreted in human milk. Consideration should be given to discontinuing breast feeding temporarily during treatment with Cefixime.

DRUG INTERACTIONS:
Care should be exercised in patients receiving anticoagulants and Cefixime due to the possibility that Cefixime may increase prothrombin times.
Carbamazepine: Elevated carbamazepine levels have been reported when administered concomitantly with Cefixime. Drug monitoring when these drugs are given together is advised.
Warfarin and Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.
Cefixime causes false positive reactions with:
- Nitroprusside test
- Coombs' test
- Clinitest®, Benedict's solution, Fehling's solution.

ADVERSE DRUG REACTIONS:
The most frequently reported adverse effects of Cefixime are gastrointestinal disturbances, especially diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension was comparable to the incidence seen in adult patients receiving tablets.
Several patients developed severe diarrhea and/or documented pseudomembranous colitis, and a few required hospitalization.
Gastrointestinal (GI): Diarrhea, loose stools, abdominal pain, dyspepsia, nausea, and vomiting. Several cases of documented pseudomembranous colitis were identified during the studies. The onset of pseudomembranous colitis symptoms may occur during or after therapy.
Hypersensitivity Reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities), skin rashes, urticaria, drug fever, pruritus, angioedema, and facial edema. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported.
Hepatic: Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, jaundice.
Renal: Transient elevations in BUN or creatinine, acute renal failure.
Central Nervous System: Headaches, dizziness, seizures.
Hemic and Lymphatic Systems: Transient thrombocytopenia, leukopenia, neutropenia, and eosinophilia. Prolongation in prothrombin time was seen rarely.
Abnormal Laboratory Tests: Hyperbilirubinemia.
Other: Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.
Adverse reactions: Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, and colitis. Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced.

OVERDOSE AND TREATMENT:
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.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.
Keep all medicines out of children's reach.
Do not freeze.

AVAILABILITY:
HDPE Bottle x 30 mL (Box of 1's).
HDPE Bottle x 60 mL (Box of 1's).

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Manufacturer:
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