X-ime-200/X-ime-OD/X-ime
Cefixime (Tablet USP / for Oral Suspension USP)

Prescription Only Medicine

Composition

Each film-coated tablet contains:
Cefixime USP as Trihydrate
equivalent to Anhydrous Cefixime 200 mg
Colour : Titanium Dioxide BP.

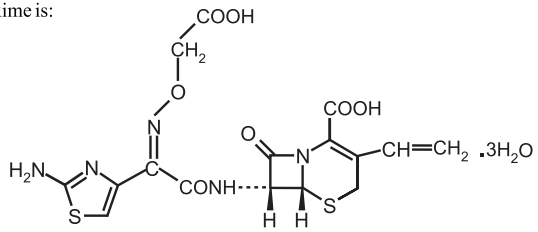
Each film-coated tablet contains:
Cefixime USP as Trihydrate
equivalent to Anhydrous Cefixime 400 mg
Colour : Tartrazine.

Each 5ml (after re-constitution) contains:
Cefixime USP as Trihydrate
equivalent to Anhydrous Cefixime 50 mg
Colour : Tartrazine

Drug Description

X-ime (cefixime) for Oral Suspension is a semisynthetic, cephalosporin antibiotic for oral administration. Chemically, it is (*6R,7R*)-7-[2-(2-Amino-4-thia-zolyl)glyoxylamido]-8-oxo-3-vinyl-5- thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid, 7-(Z)-[O-(carboxymethyl) oxime] trihydrate. Molecular weight = 507.50 as the trihydrate. Chemical Formula is $C_{16}H_{15}N_5O_7S_2 3H_2O$

The structural formula for cefixime is:



Pharmacodynamics

Cefixime an antibiotic, is a third generation cephalosporin. Cefixime is highly Beta Lactam stable in the presence of beta-lactamase enzymes. As a result, many organisms resistant to Penicillins and some Cephalosporins due to the presesnce of beta-lactamases, may be susceptible to Cefixime. Cefixime inhibits bacterial cell wall synthesis by binding to one or more of the penicillin binding proteins (PBPs); which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

Phamacokinetics

Absorption: 40% to 50% is absorbed following oral administration. The suspension form provides a higher serum level than the tablet form. Absorption is delayed by food, but the total amount absorbed is not affected.
Distribution: Cefixime is Widely distributed throughout the body and reaches therapeutic concentration in most tissues and body fluids, including synovial, pericardial, pleural, peritoneal, bile, sputum, and urine; bone, myocardium, gallbladder, and skin and soft tissue. About 65% is bound to plasma protein.
Peak serum concentrations occur between 2 and 6 hours following oral administration. However, time to maximal absorption is delayed approximately 0.8 hours when administered with food.
Excretion: Cefixime is excreted primarily in Urine. The Half-life elimination in patients with Normal renal function is 3-4 hours; With Renal failure: Up to 11.5 hours.

Indications

X-ime is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:
Uncomplicated Urinary Tract Infections caused by *Escherichia coli* and *Proteus mirabilis.*
Otitis Media caused by *Haemophilus influenzae* (beta-lactamase positive and negative strains), *Moraxella (Branhamella) catarrhalis,* (most of which are beta-lactamase positive) and *S. pyogenes*.
Pharyngitis and Tonsillitis, caused by *S. pyogenes.*
Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis, caused by *Streptococcus pneumoniae* and *Haemophilus influenzae* (beta-lactamase positive and negative strains).
Uncomplicated gonorrhea (cervical/urethral), caused by *Neisseria gonorrhoeae* (penicillinase-and non-penicillinase- producing strains).
Typhoid fever caused by Salmonella typhi.
Appropriate cultures and susceptibility studies should be performed to determine the causative organism and its susceptibility to cefixime; however, therapy may be started while awaiting the results of these studies. Therapy should be adjusted, if necessary, once these results are known.

Dosage And Administration

Adults: The recommended dose Xime is 400 mg daily. This may be given as a 400mg. in single dose daily or as 200mg. tablet every 12 hour. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended.
Children: The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.
In Typhoid fever**:** 20 mg/kg/day for 10-14 days; maximum 400 mg. Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose.
S. pyogenes infections should be treated for 10 days.

Renal Impairment

X-ime may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearances of 60 mL/min or greater. Patients whose clearance is between 21 and 60 mL/min or patients who are on renal hemodialysis may be given 75% of the standard dosage at the standard dosing interval (i.e., 300 mg daily). Patients whose clearance is < 20 mL/min, or patients who are on continuous ambulatory peritoneal dialysis may be given half the standard dosage at the standard dosing interval (i.e., 200 mg daily). Neither hemodialysis nor peritoneal dialysis remove significant amounts of drug from the body.

Side Effects
Cefixime is generally well tolerated and side effects are usually transient.
Reported side effects include:
Diarrhea, loose stools, abdominal pain, dyspepsia, nausea, vomiting, skin rashes, urticaria, drug fever, pruritus, Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, jaundice, Headaches, dizziness, seizures, Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.

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.

Warning:
BEFORE THERAPY WITH XIME IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS.

Pseudomembranous colitis has been reported with the use of Xime and other broad- spectrum 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

Symptoms of Pseudomembranous colitis may occur during or after antibiotic treatment and may range in severity from mild to life-threatening. Mild cases of Pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, management should include fluids, electrolytes, and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, suitable antibiotic should be started.

Precaution:
Prescribing X-ime (cefixime) for Oral Suspension in the absence of a proven or strongly suspected bacterial infection of a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

The possibility of the emergence of resistant organisms which might result in overgrowth should be kept in mind, particularly during prolonged treatment. In such use, careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

The dose of X-ime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD).

Usage in 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. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Overdose
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.

Contraindications:
X-ime is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Storage
Store below 30^0 C. Protect from light. Keep all medicine out of reach of children.

Presentation:
X-ime-200 Tablets available in a pack of 2 strips of 10s.
X-ime-OD Tablets available in a packing 1 strip of 10s.
Suspension available in 100 ml & 60 ml bottle.

Marketed and Distributed in Kenya by:
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Manufactured in India by:
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