Cefimax 400

Cefixime Tablets USP 400 mg

COMPOSITION:
Each film-coated tablet contains:
Cefixime trihydrate USP
equivalent to Anhydrous Cefixime 400 mg
Excipients q.s.
Approved color used

PHARMACOTHERAPEUTIC CLASS:
Cefixime is a beta-lactam antibiotic belonging to the third-generation cephalosporin group that can be administered orally.

PHARMACOLOGICAL PROPERTIES:
Pharmacokinetics: Pharmacokinetic studies have demonstrated the bioequivalence of the tablet and granule formulations.

Absorption:
- Following oral administration of a single 200 mg dose, peak serum concentrations (Cmax) average 3 micrograms/mL and are reached (Tmax) in approximately 3 to 4 hours.
- Following administration of a 400 mg dose, peak serum concentrations are higher (3.4 to 5 micrograms/mL), but not in proportion to the increase in dose.
- The bioavailability of cefixime is approximately 50% at the 200 mg dose. It is not altered by food intake. However, the time to reach peak serum concentrations is delayed by approximately one hour.

Distribution:
- The apparent volume of distribution is approximately 15 liters. In animals, cefixime diffuses into the vast majority of tissues studied, with the exception of the brain. In humans, following 200 mg doses at 12-hour intervals, pulmonary concentrations—measured 4 and 8 hours after the last dose—are in the order of 1 microgram/g of tissue; these concentrations exceed the MIC90 values for susceptible pathogens responsible for pulmonary infections.
- Serum protein binding is approximately 70% and occurs primarily with albumin, independent of concentration (at therapeutic doses).

Elimination:
- Cefixime elimination is characterized by a half-life (T½) of between 3 and 4 hours (mean: 3.3 hours). The product is eliminated by the kidneys in unchanged form (16 to 20% of the ingested dose); extra-renal elimination is primarily biliary (25%).
- No metabolites have been detected in the serum or urine of either animals or humans. The pharmacokinetic characteristics of cefixime are slightly modified in the elderly. The slight increase in peak serum concentrations and bioavailability, and the slight decrease in the amount excreted (15 to 25%), do not require any dose reduction in this population.

Pharmacodynamics:
Like other cephalosporins, the mechanism of action of cefixime is based on the inhibition of bacterial cell wall synthesis. Cefixime exhibits *in vitro* bactericidal activity against many Gram-positive and Gram-negative organisms.

Antibacterial activity spectrum:

Susceptible species:
- Gram-positive aerobes: *Streptococcus*, *Streptococcus pneumoniae* (30–70%).
- Gram-negative aerobes: *Branhamella catarrhalis*, *Citrobacter koseri*, *Escherichia coli* (5–15%), *Haemophilus influenzae*, *Klebsiella* (0–20%), *Neisseria gonorrhoeae*, *Pasteurella*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia*.
- Anaerobes: *Fusobacterium* (10–20%), *Prevotella* (30–70%).

Resistant species:
- Gram-positive aerobes: *Corynebacterium diphtheriae*, enterococci, *Listeria*, *Staphylococcus*.
- Gram-negative aerobes: *Acinetobacter*, *Citrobacter freundii*, *Pseudomonas*, *Serratia*.
- Anaerobes: all except *Prevotella* and *Fusobacterium*.

INDICATIONS:
- Acute pharyngitis/tonsillitis,
- Bacterial superinfection of acute bronchitis and exacerbation of chronic bronchitis,
- Pulmonary infections of bacterial origin,
- Sinusitis and acute otitis,
- Acute pyelonephritis without uropathy,
- Obstetric infections caused by susceptible organisms, in possible combination with doxycycline and/or
- Metronidazole;
- Lower urinary tract infections, complicated or uncomplicated, excluding prostatitis; male gonococcal urethritis;

DOSAGE:
In pediatrics, the dosage is generally 8 mg/kg of body weight, divided into two doses with a 12-hour interval.
In adults and children over 12 years of age:
- The dosage is 400 mg/day in two doses, with a 12-hour interval. In the case of gonococcal urethritis, efficacy is achieved with a single daily dose of 400 mg of cefixime.

CONTRAINDICATIONS: Known allergy to cephalosporin antibiotics.

SIDE EFFECTS: These are primarily digestive disorders: diarrhea, nausea, vomiting, dyspepsia, and abdominal pain. Some rare cases of headache and dizziness have been reported.

DRUG INTERACTIONS: No clinically significant interactions were reported during clinical trials. Regarding pharmacokinetics, it was demonstrated that the combination of 1 g of probenecid with cefixime led to a 25% reduction in the product's total clearance.

PRECAUTIONS FOR USE: In patients allergic to other beta-lactams, the possibility of cross-allergy must be considered. In cases of severe renal impairment, it may be necessary to adjust the daily dose based on creatinine clearance (creatinine clearance < 20 ml/min leads to an increase in plasma elimination half-life and peak serum concentrations; reducing the daily dose from 400 mg to 200 mg is mandatory).

STORAGE:
Store in a cool, dry, and dark place at a temperature not exceeding 30°C; protect from light and moisture.
Keep the medication out of the reach of children.

Manufacturing license no.: MH/104288A

US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in