

COMPOSITION:

Cemaxi 200 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg

PHARMACOLOGY:

Cemaxi 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.

INDICATIONS:

Cemaxi (cefixime) is a cephalosporin antibiotic indicated for

- -Uncomplicated Urinary Tract Infections
- -Otitis Media
- -Pharyngitis and Tonsillitis
- -Acute Exacerbations of Chronic Bronchitis
- -Uncomplicated Gonorrhea (cervical/urethral)

DOSAGE AND ADMINISTRATION:

The recommended dose of Cemaxi is 200 or 400 mg daily as a single dose or in two divided doses. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended. The capsule may be administered without regard to food. In the treatment of infections due to Streptococcus pyogenes, a therapeutic dosage of cefixime should be administered for at least 10 days.

CONTRAINDICATIONS:

Contraindicated in patients with known allergy to cefixime or other cephalosporins.

WARNINGS AND PRECAUTIONS:

Hypersensitivity reactions including shock and fatalities have been reported with cefixime. Discontinue use if a reaction occurs. Clostridium difficile associated diarrhea: Evaluate if diarrhea occurs.

ADVERSE REACTIONS:

Most common adverse reactions are gastrointestinal such as diarrhea (16%), nausea (7%), loose stools (6%), abdominal pain (3%), dyspepsia (3%), and vomiting, (6)

DRUG INTERACTIONS:

Elevated carbamazepine levels have been reported in postmarketing experience when Cemaxi is administered concomitantly. Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly with warfarin and anticoagulants.

USE IN SPECIFIC POPULATIONS:

Pregnancy: Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 40 times the human dose and have revealed no evidence of harm to the fetus due to Cemaxi. 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.

Nursing Mothers It is not known whether Cemaxi is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Renal Impairment: Cemaxi may be administered in the presence of impaired renal function. Dose adjustment is required in patients whose creatinine clearance is less than 60 mL/min.

OVERDOSAGE EFFECTS:

Gastric lavage may be indicated; otherwise, no specific antidote exists. Cemaxi 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 dose up to 2 g of Cemaxi did not differ from the profile seen in patients treated at the recommended doses.

STORAGE CONDITIONS:

Store below 30°C temperature, dry place and away from light. Keep all medicine out of the reach of children.

COMMERCIAL PACKING:

Cemaxi Capsule: Each Box containing 3X4's Capsules in Alu-Alu blister packs.

