TEXIT
Cefixime

400 mg Capsule
200 mg Capsule
100 mg/5 ml PFS

DESCRIPTION

TEXIT (Cefixime) is a broad spectrum antibiotic of 3rd generation Cephalosporin group. Cefixime has a longer duration of action than the other Cephalosporins that are active by mouth. It is a bactericidal antibiotic and is stable to many beta-lactamases. Cefixime kills bacteria by interfering in the synthesis of the bacterial cell wall. Peak plasma concentration attained within 2-6 hrs, plasma half-life usually 3-4 hrs, and about 65% is bound to plasma protein. Oral suspension produces 25%-50% higher peak plasma concentration than tablet.

COMPOSITION

TEXIT- 400 Capsule : Each capsule contains Cefixime Trihydrate USP equivalent to 400 mg Cefixime.
TEXIT-200 Capsule : Each capsule contains Cefixime Trihydrate USP equivalent to 200 mg Cefixime .
TEXIT PFS : When reconstituted each 5ml suspension contains Cefixime Trihydrate USP equivalent to 100 mg Cefixime.

INDICATION

TEXIT (Cefixime) is indicated for the treatment of following infections:

- **Upper and lower respiratory tract infections :** acute bronchitis and acute exacerbation of chronic bronchitis, acute sinusitis, pneumonia caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*
- **Otitis media** caused by *Haemophilus influenzae, Moraxella catarrhalis* & *S. pyogenes*
- **Pharyngitis & Tonsillitis** caused by *S. pyogenes*
- **Uncomplicated urinary tract infections** caused by *Escherichia coli* & *Proteus mirabilis*
- **Uncomplicated cervical and rectal infections**
- **Uncomplicated gonorrhea (Cervical & Urethral)** caused by *Neisseria gonorrhea*
- **Multi-Drug Resistant (MDR) enteric fever**

DOSAGE AND ADMINISTRATION

Adults : 200 mg- 400 mg daily in 1-2 divided doses.
Gonorrhoea : 400 mg as a single dose.
Children : ***Over 6 months :*** 8 mg/kg daily in 1-2 divided doses.
6 months - 1 year : 75 mg **(3.75 ml TEXIT PFS)** daily in 1-2 divided doses.
1 year - 4 years : 100 mg **(5 ml TEXIT PFS)** daily in 1-2 divided doses.
5 years - 10 years : 200 mg **(10 ml TEXIT PFS)** daily in 1-2 divided doses.
> 50 kg or > 10 years : should be treated with the recommended adult dose.

Otitis media should be treated with the suspension because suspension results in higher peak blood levels than the tablet. In the treatment of infections due to S. pyogenes, a therapeutic dosage of Cefixime should be administered for at least 10 days.

In renal impairment : Dose should be adjusted according to Creatinine Clearance (CC). CC 20-60 ml/min : 75 % of standard dose and CC < 20 ml/min : 50 % of standard dose.

CONTRAINDICATION

TEXIT (Cefixime) is contraindicated in known hypersensitivity to Cefixime or other antibiotics of Cephalosporin group.

PRECAUTION

TEXIT (Cefixime) should be administered with caution in renal impairment, a history of colitis, and on anticoagulant therapy. Like other antibiotics, pseudomembranous colitis has been reported with Cefixime.

PREGNANCY AND LACTATION

Pregnancy : Pregnancy category B. Although the use of Cefixime in pregnancy not known to be harmful, this drug should be used during pregnancy only if clearly needed. ***Lactation :*** Since Cefixime is excreted in breast milk in low concentration, caution should be exercised when Cefixime is administered to a nursing woman.

SIDE EFFECTS

Gastrointestinal : Diarrhea, abdominal pain, dyspepsia, nausea and vomiting. *Hypersensitivity Reactions :* skin rashes, urticaria, pruritus, angioedema and facial edema. *Hepatic :* Hepatitis, jaundice. *Renal :* Transient elevations in BUN or creatinine, renal failure. *Central Nervous System :* Headache, dizziness & seizures. *Hemic and Lymphatic Systems :* Thrombocytopenia, leukopenia, neutropenia and eosinophilia. Prolongation in prothrombin time was seen rarely. *Other :* Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.

DRUG INTERACTION

Carbamazepine : Elevates Carbamazepine blood level. *Warfarin :* Increased prothrombin-time.

DIRECTION FOR RECONSTITUTION OF TEXIT SUSPENSION

Shake the bottle until all powder flows freely. Then add boiled & cool water, 30 ml (6 teaspoonfull) for **TEXIT PFS** and shake well to mix powder. For better mixing add total water in two portion and shake well each time.

Note : *After reconstitution keep the bottle tightly closed and shake the bottle well before each use. Reconstituted suspension must be used within 7 days if kept at room temperature or within 10 days when stored in a refrigerator.*

STORAGE

Store in cool, dry place and away from light. Keep out of the reach of children.

HOW SUPPLIED

TEXIT- 400 Capsule : Box containing 1 x 4's capsule in Alu-Alu strip.
TEXIT-200 Capsule : Box containing 2 x 4's capsule in Alu-Alu strips.
TEXIT PFS : Bottle containing dry powder to make 50 ml suspension.

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Manufactured by
Apex Pharma Ltd.
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