

CEFAXE

Cefixime Dispersible Tablets 100 mg
Cefixime Dispersible Tablets 200 mg.
Cefixime Dispersible Tablets 400 mg
Cefixime for Oral Suspension USP 100mg

Each uncoated dispersible tablet contains:

Cefixime (As Trihydrate) USP
eq. to Anhydrous Cefixime 100 mg.
Excipients q.s.

Each uncoated dispersible tablet contains:

Cefixime (As Trihydrate) USP
eq. to Anhydrous Cefixime 200 mg.
Excipients q.s.

Each uncoated dispersible tablet contains:

Cefixime (As Trihydrate) USP
eq. to Anhydrous Cefixime 400 mg.
Excipients q.s.

Each 5 ml. of the reconstituted suspension contains:

Cefixime (As Trihydrate) USP
eq. to Anhydrous Cefixime 100 mg.
Excipients q.s.

In a flavoured syrupy base

Approved colour added

PHARMACOLOGY:

Cefixime, like other cephalosporin's and penicillin's kills bacteria by interfering in the synthesis of bacterial cell wall. Cefixime is an orally active third-generation cephalosporin with a broad spectrum of activity against in a variety of both gram-positive and gram-negative bacteria including many beta-lactamase producing strains of streptococci, Haemophilus influenzae, Neisseria Gonorrhoeae and majority of the enterobacteriaceae. Activity of cefixime against staphylococcus aureus, enterococci, Listeria monocytogenes, and pseudomonas species is poor. The relatively long elimination half-life of cefixime (approximately 3.0 hours) has made possible once to twice daily administration with the potential added benefit of improved patient compliance.

PHARMACOKINETICS:

Cefixime is absorbed slowly after oral administration, the time taken to reach maximum plasma concentration (Tmax) increases with increasing dose.

Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mcg/ml. The absolute oral bioavailability of Cefixime is in the range of 22.54%. Little or no accumulation of Cefixime occurs following multiple dosing.

The mean volume of distribution of Cefixime is 0.11/kg. Penetration into tissue fluid is slow but peak concentrations similar to those of plasma have been achieved. Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of Cefixime have not been isolated from human serum or urine.

INDICATIONS:

CEFAXE is indicated in the treatment of the following infections caused by susceptible organisms.

1. Urinary tract infections
2. Upper and Lower respiratory tract infections
3. Acute otitis media.
4. Gonococcal urethritis
5. Typhoid.

DOSAGE AND DIRECTIONS FOR USE:

CEFAXE by oral administration. It can be given to the adults in the following dosages.

The usual adult dose of Cefixime (anhydrous) is 200 – 400 mg per day administered orally, either as a single dose or in two divided doses, although lower doses may prove sufficient to treat uncomplicated urinary tract infections.

For Children: 8 mg/kg daily, as either a single dose or in two divided doses, is recommended. In uncomplicated gonococcal urethritis, a single oral dose of 400 mg has been found to be effective. OR As directed by the physician.

CONTRAINDICATION:

Hypersensitivity to cephalosporin antibiotics.

SIDE EFFECTS AND ADVERSE REACTIONS:

Cefixime is generally well tolerated. Majority of adverse reactions in clinical trials were mild and self-limiting in nature.

The most frequent side effects seen with Cefixime are diarrhoea and stool changes; diarrhoea has been more commonly associated with higher doses. Some cases of moderate to severe diarrhoea have been reported; this has occasionally warranted cessation of therapy.

Other side effects include headache and dizziness. Mild transient changes in liver and renal function tests have been observed. Allergies in the form of rash, pruritus, urticaria, drug fever and arthralgia have been observed.

DRUG INTERACTIONS:

In common with other cephalosporins, increase in prothrombin times has been noted in a few patients. Care should therefore be taken in patients receiving anticoagulation therapy.

PRECAUTIONS:

The possibility of the emergence of resistant organisms which might result in overgrowth should be kept in mind, particularly during prolonged treatment.

CEFAXE should be used with caution in patients with marked renal impairment.

PREGNANCY AND LACTATION:

CEFAXE should not be used in pregnancy or in nursing mothers unless considered essential by the physician.

STORAGE INSTRUCTIONS:

Store below 25°C protected from light and moisture.

Keep the medicine out of reach of children.

PRESENTATION:

1 X 10 Alu/Alu blister in a unit carton with package insert.

60ml Glass bottle in a unit carton with package insert.

Mfg. Lic. No. : MB/06/308

Mfg. In India by :

M/s ASSOCIATED BIOTECH

Vill krishanpura, PO Gurumajra Baddi Distt Solan.