Fixhac[™]

Cefixime Trihydrate USP

Composition:

Fixbac[™] 200 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

Fixbac™ 400 Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to Cefixime 400 mg.

Fixbac™ PFS: After reconstitution, each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 100 mg.

Fixbac™ DS PFS: After reconstitution, each 5 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 200 mg.

Fixbac™ PD PFS: After reconstitution, each 1 ml suspension contains Cefixime Trihydrate USP equivalent to Cefixime 25 mg.

Description:

Fixbac™ (Cefixime) is a broad-spectrum, cephalosporin antibiotic for oral administration. Fixbac™, like other cephalosporins and penicillins kills bacteria by interfering in the synthesis of the bacterial cell wall. The cell walls of bacteria are essential for their normal growth and development. Fixbac™ binds with high affinity to penicillin-binding proteins in the bacterial cell wall thus interfering with peptidoglycan synthesis. Peptidoglycan is a heteropolymeric structure that provides the cell wall with mechanical stability.

Indications:

Urinary tract infections

Upper and lower respiratory tract infections

Typhoid fever

Acute otitis media

Gonococcal infections and other infections due to sensitive Gram-positive and Gram-negative bacteria.

Dosage and administration:

Adult and child over 10 years: 200-400 mg daily in 1-2 divided doses.

Child over 6 months: 8 mg/kg daily in 1-2 divided doses or 6 months-1 year: 75 mg daily

1-4 years: 100 mg daily

5-10 years: 200 mg daily

Uncomplicated gonorrhoea 400 mg as a single dose.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindications:

Cephalosporin hypersensitivity.

Waring & precautions:

Sensitivity to beta-lactam antibacterials, renal impairment, false positive urinary glucose and false positive Coomb's test. **Pregnancy:** Not known to be harmful.

Lactation: Caution should be exercised when administered to a nursing woman.

Neonate: No data available.

Side effects:

Diarrhoea and rarely antibiotic-associated colitis, nausea, vomiting, abdominal discomfort, headache, allergic reactions including rashes, pruritus, urticaria, serum sickness-like reactions with rashes, fever & arthralgia, and anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrolysis reported, disturbances in liver enzymes, transient hepatitis and cholestatic jaundice, other side-effects reported include eosinophilia and blood disorders (including thrombocytopenia, leucopenia, agranulocytosis, aplastic anaemia and haemolytic anaemia, reversible interstitial nephritis, hyperactivity, nervousness, sleep disturbances, hallucinations, confusion, hypertonia and dizziness.

Storage:

Store in a cool & dry place below 25°C, protect from light. Keep out of the reach of children.

The reconstituted suspension should be used within 7 days of preparation if kept in room temperature or within 14 days of preparation if kept under refrigeration.

Packing:

Fixbac™ 200 Capsule: Each box contains 12 capsules in blister packs.

Fixbac[™] 400 Capsule: Each box contains 6 capsules in blister packs.

Fixbac™ PFS: Each bottle contains powder for the reconstitution of 30 ml & 50 ml suspension.

Fixbac™ DS PFS: Each bottle contains powder for the reconstitution of 50 ml suspension.

Fixbac™ PD PFS: Each bottle contains powder for the reconstitution of 21 ml suspension.

Manufactured by:

Jenphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.

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