MEROCEF

CEFUROXIME USP

Compositions:
Merocef 250 Tablet: Each flim-coated tablet contains Cefuroxime Axetil USP equivalent to 250 mg Cefuroxime. Merocef 500 Tablet: Each flim-coated tablet contains Cefuroxime Axetil USP equivalent to 500 mg Cefuroxime. Merocef suspension: After reconstitution, each 5 ml suspension contains contains Cefuroxime Axetil USP equivalent to 125 mg Cefuroxime. Merocef 750 IV/IM injection: Each vial contains Cefuroxime 750 mg as Sterile Cefuroxime Sodium USP.

Pharmacology:
Merocef (Cefuroxime) is a 2nd generation cephalosporin antibacterial agent, which has broad-spectrum bactericidal activity against a wide range of common pathogens, including b-lactamase producing strains. Cefuroxime has good stability to bacterial b-lactamase and consequently, is active against many Ampicillin-resistant and Amoxycillin-resistant strains.

Dosage And Administration:
Infection Dosage Duration Oral: Tablet (May be administered without regard to meals.) Adolescents & Adults (13 years and older): Pharyngitis or Tonsillitis 250 mg bid 5-10 days Acute bacterial maxillary sinusitis 250 mg bid 10 days Acute bacterial exacerbation of chronic bronchitis 250-500 mg bid 10 days Secondary bacterial infection of acute bronchitis 250-500 mg bid 5-10 days Uncomplicated skin and skin-structure infection 250-500 mg bid 10 days Uncomplicated urinary tract infection 125-250 mg bid 7-10 days Uncomplicated gonorrhea 1000 mg single dose Early lyme disesse 500 mg bid 20 days Pediatric patients (Up to 12 years who can swallow tablets whole) Acute otitis media 250 mg bid 10 days Acute bacterial maxillary sinusitis 250 mg bid 10 days Pharyngitis or Tonsillitis 125 mg bid 5-10 days Suspension (Must be administered with food, shake the bottle well before each use) Pediatric patients (3 months to 12 years) Pharyngitis or Tonsillitis 20 mg/kg bid 5-10 days Acute otitis media 30 mg/kg bid 10 days Acute bacterial maxillary sinusitis 30 mg/kg bid 10 days Parenteral dosage: Adults: 750 mg to 1.5 g IM/IV every 8 hourly, uasally 5 to 10 days. Infants and children (>3 months): 50 to 100 mg/kg /day in equally divided doses every 6 to 8 hours. Use 100 mg/kg/day (not to exceed the maximum adults dose) for more severe or serious infections. Bone & joint infections: 150 mg/kg/day (not to exceed the maximum adult dose) in equally divided doses every 8 hours. Bacterial Meningitis: Initially 200 to 240 mg/kg/day IV in divided doses every 6 to 8 hours. Preparative prophylaxis: for surgical procedures, administer 1.5 g IV prior to surgery (1/2 to 1 hour before). Thereafter, give 750 mg IV or IM every 8 hours when the procedure in prolonger. In Impaired renal fuction: Dose should be in impaired renal function. Dosage in adults should he determined by the degree of renal impairment and the susceptibility of the causative organism according to the table below- Creatinine clearance (ml/min) Dose Frequency >20 750 mg- 1.5 gm 8 hourly 10-20 750 mg 12 hourly

Contraindications:
Contraindicated in patients with known hypersensitivity to Cephalosporin’s group of antibiotic.

Warning And Precaution:
As with other antibiotics, prolonged use of Cefuroxime may result in the over growth of non-susceptible organisms (e.g. Candida, Enterococci, Clostridium difficile), which may require interruption of treatment.

Side Effects:
Generally Cefuroxime is well tolerated. However few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur. Besides these rarely (0.2%) renal dysfunction, anaphylaxis, angioedema, pruritus, rash, serum sickness and urticaria have been reported.

Use in Pregnancy and Lactation:
While all antibiotics should be avoided in the first trimester if possible, Cefuroxime has been safely used in later pregnancy to treat urinary and other infections. Cefuroxime is excreted in human milk, and consequently caution should be exercised when Cefuroxime is administered to a nursing mother.

Drug Interaction:
Concomitant administration of probenecid with Cefuroxime axetil increases the area under the serum concentration versus time curve by 50%. Drugs that reduce gastric acidity may result in a lower bioavailability of Cefuroxime axetil compared with that of fasting state and tend cancel the effect of postprandial absorption.

Overdosage:
Overdose of Cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of Cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

Storage:
Store in a cool and dry place, protected from light. Suspension: Store below 30° C protected from light and moisture. Injection: Store below 25° C protected from light. The reconstituted solution for IV or IM administration maintains potency for 24 hours at room temperature and for 48 hours when refrigerated at 5° C.

Packing:
Merocef 250 Tablet: Each box contains 2x10 tablets in alu-alu blister pack. Merocef 500 Tablet: Each box contains 2x10 tablets in alu-alu blister pack. Merocef Suspension: Each bottle contains dry powder for 70 ml suspension with a measuring spoon. Merocef 750 IM/IV injection: Pack of 1 vial containing cefuroxime 750 mg as Cefuroxime sodium USP accompanied by a solvent of 10 ml water for injection & a 10 ml disposable syringe.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.