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. Merocef 1.5 gm IV Injection: Each vial contains Cefuroxime 1.5 gm, as sterile Cefuroxime Sodium USP.

Pharmacology:
Cefuroxime is a 2nd generation Cephalosporin antibiotic active against a wide range of Gram positive and Gram negative organisms including many beta-lactamase producing strains. It is indicated for the treatment of infections caused by sensitive bacteria.

Dosage And Administration:
Oral: Tablet (May be administered without regard to meals.) Adolescents & adults (13 years & above): Pharyngitis or Tonsillitis: 250 mg bid, 5-10 days. Acute bacterial maxillary SinusitisP: 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 infections: 250-500 mg bid, 10 days. Uncomplicated urinary tract infections: 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 / 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 gm IM or IV every 8 hourly, usually 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 adult 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. Preperative prophylaxis: For surgical procedures, administer 1.5 gm IV prior to surgery (1/2 to 1 hour before). Thereafter, give 750 mg IV or IM every 8 hours when the procedure is prolonged. In impaired renal function: Dose should be reduced 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 <10 750 mg 24 hourly* * Since Cefuroxime dialyzable, patients on haemodialysis should be given a further dose at the end of the dialysis. In paediatric patients with renal insuffciency, the frequency of dosing should be modified consistent with the recommendations for adults.

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

Warning And Precaution:
Prolonged administration of Cefuroxime may result in overgrowth of nonsusceptible

microorganisms. If superinfection occurs during therapy, appropriate measures should he taken. Cefurxime should be given with caution to patients receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function.

Side Effects:
Generally Cefuroxime is well tolerated. However few side effects like nausea, vomiting, diarrhoea, 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:
Though all antibiotics should be avoided in the first trimester of pregnancy, Cefuroxime may be given only if clearly needed in later pregnancy to treat urinary & other infections. Since Cefuroxime is excreted into the breast milk in small quantities, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime.

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 to cancel the effect of postprandial absorption.

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

Storage:
Tablet: 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 Suspenssion: Each bottle contains dry powder for 70 ml suspension with a measuring spoon. Merocef 750 mg IM/IV Injection: Pack of 1 vial containing Cefuroxime 750 mg as Cefuroxime Sodium USP accompanied by a solvent ampoule of 10 ml water for injection & a 10 ml disposable syringe. Merocef 1.5 gm IV Injection: Pack of 1 vial containing Cefuroxime 1.5 gm as Cefuroxime Sodium USP accompanied by two solvent ampoule of 10 ml water for injection & a 20 ml disposable syringe.

Manufactured By:
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