

UNIPIM

Cefepime USP 500mg & 1gm Injection

Composition : Unipim-500 : Each vial contains Cefepime 500mg as Cefepime Hydrochloride USP sterile powder.

Unipim-1gm : Each vial contains Cefepime 1gm as Cefepime Hydrochloride USP sterile powder.

Description : Cefepime is a fourth generation Cephalosporin antibiotic and is active against a wide range of Gram positive and Gram negative aerobic organisms. Cefepime inhibits bacterial cell wall synthesis by binding to one or more of the penicillin binding proteins (PBPs).

Indications : It is indicated for moderate to severe Pneumonia caused by *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Streptococcus pneumoniae*, and other Gram negative organisms; Empiric therapy for Febrile Neutropenia; Treatment of Uncomplicated and Complicated Urinary Tract Infections, including pyelonephritis caused by typical urinary tract pathogens; Uncomplicated Skin and Skin structure infections caused by *Staphylococcus aureus* or *Streptococcus pyogenes*; It is also used for Complicated Intra-abdominal infections used in combination with metronidazole.

Dosage and administration : Adult : Recommended Dosage Schedule

❖ Moderate to severe Pneumonia : 1-2gm IV every 12hr for 10 days.

❖ Empiric therapy for febrile Neutropenia : 2gm IV every 8hr for 7 days.

❖ Mild to moderate Complicated or Uncomplicated Urinary Tract Infection, including pyelonephritis : 500mg-1gm IV every 12hr for 7-10 days.

❖ Severe Complicated or Uncomplicated Urinary Tract Infection, including pyelonephritis : 2gm IV every 12hr for 10 days.

❖ Moderate to severe Uncomplicated skin and skin structure infections : 2gm IV every 12hr for 10 days.

❖ Complicated Intra-abdominal Infections used in combination with Metronidazole : 2gm IV every 12hr for 7-10 days.

Dosing adjustment in renal impairment : Adults : Recommended maintenance schedule based on creatinine clearance (ml/minute)

Child : Children aged over 2 months and weighing upto 40 kg may be given 50mg/kg twice daily. This dose may be given 3 times daily for febrile neutropenia. Or, as directed by the registered physician.

Method of Administration :

Reconstitution

Single dose vials	Amount of diluent to be added (ml)
500mg IV	5.0
500mg IM	1.3
1gm IV	10.0
1gm IM	2.4
2gm IV	10.0

Use in pregnancy and lactation : Pregnancy category B. There are no adequate well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Since Cefepime is excreted in human milk in very low concentration, caution should be exercised when Cefepime is administered to a nursing mother.

Contraindication : Patients with hypersensitivity to Cefepime or to Cephalosporin group of antibiotics, penicillins and other beta-lactam antibiotic.

Precautions : Prolonged use of Cefepime may result in overgrowth of non-susceptible microorganisms. Repeated evaluation of the patient's condition is essential. Precautions should be taken to adjust the dose in renal impaired patient.

Side effects : Common side effects included fever, headache, rash, pruritus, diarrhea, nausea and vomiting. After administration of the injection, localized reaction could be occur at the site of injection.

Drug interactions : Aminoglycosides increase nephrotoxic potential when taken with Cefepime. Nephrotoxicity has been reported following concomitant administration of other Cephalosporins with potent diuretics such as frusemide.

Packing :

Unipim-500 IV/IM injection : 1 Combipack which contains a vial of 500mg Cefepime (as Cefepime Hydrochloride USP sterile powder) and an ampoule of 5ml water for injection USP.

Unipim-1gm IV/IM injection : 1 Combipack which contains a vial of 1gm Cefepime (as Cefepime Hydrochloride USP sterile powder) and an ampoule of 10ml water for injection USP.

Manufactured by



DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh