Superpime

Injection IM/IV

Cefepime Hydrochloride USP

L= 240 mm
H= 200 mm

Composition
Superpime 500 mg IM/ IV: Each vial contains sterile Cefepime Hydrochloride & Arginine USP powder equivalent to Cefepime 500 mg.
Superpime 1 g IM/ IV: Each vial contains sterile Cefepime Hydrochloride & Arginine USP powder equivalent to Cefepime 1 g.

Pharmacology
Cefepime Hydrochloride is a broad spectrum semisynthetic 4th generation Cephalosporin Antibiotic, which is administered parenterally. Cefepime Hydrochloride is a white to pale yellow powder which is highly soluble to water. Cefepime inhibits bacterial cell wall synthesis. It binds to one or more of the penicillin binding proteins (PBPs); which is turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell wall and inhibiting cell wall biosynthesis. Bacteria eventually die due to ongoing activity of cell wall autolytic enzymes while cell wall assembly is arrested. Intramuscularly absorption of Cefepime is rapid and the serum protein binding is approximately 20%, elimination half-life is 2 hours and the time of peak plasma concentration 0.5-1/5 hours. Cefepime is excreted from the body via urine as 85% unchanged drug.

Indications
Moderate to severe Pneumonia caused by *Pseudomonas aeruginosa, Klebsiella pneumoniae, Streptococcus pneumoniae* and other gram negative organisms.
Empiric monotherapy for **Febrile Neutropenia;**
Uncomplicated and complicated urinary tract infections, including pyelonephritis caused by typical urinary tract pathogens (*E. coli, Klebsiella pneumoniae, Proteus mirabilis).*
Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* or *Streptococcus pyogenes*. It is also used for Intra-abdominal infections with metronidzole and also active against methicillin-susceptible staphylococci and many other gram-negative bacilli.

Dosage and Administration
Children :
Febrile Neutropenia : 50 mg/kg every 8 hours for 7-10 days.
Uncomplicated skin/soft tissue infections, pneumonia and complicated/uncomplicated UTI: 50 mg/kg twice daily.
Adults :
Most infection : 1-2 g every 12 hours for 5-10 days; higher doses or more frequent administration may be required in Pseudomonas infections.
Dosing adjustment in renal impairment : Recommended maintenance schedule based on creatinine clearance (ml/minute), compared to normal dosing schedule.
Hemodialysis : Removed by dialysis; administer supplemental dose of 250 mg after each dialysis session.
Peritoneal dialysis : Removed to a lesser extent than Hemodialysis; administer 250 mg every 48 hours.
Continuous arteriovenous or renovenous hemofiltration : Dose as normal creatinine clearance (eg, >30mL/minute)

Recommended Dosage Schedule for Superpime

Site and Type of Infection	Dose	Frequency	Duration (Days)
Moderate to Severe Pneumonia	1-2 g IV	q12h	10
Febrile Neutropenia	2 g IV	q8h	7
Mild to Moderate Uncomplicated or Complicated UTI, including pyelonephritis	500 mg - 1g IM/IV	q12h	7-10
Severe Uncomplicated or Complicated UTI, including pyelonephritis	2 g IV	q12h	10
Moderate to Severe Uncomplicated Skin & Skin Structure infections	2 g IV	q12h	10
Complicated Intra-abdominal Infections (used in combination with Metronidazole)	2 g IV	q12h	7-10

Reconstitution:

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

Superpime is compatible at concentrations between 1 and 40 mg/ml with the following IV infusion fluids :
1) 0.9% Sodium Chloride
2) 5% and 10% Dextrose
Or as directed by the physician.

Contraindication
Cefepime is contraindicated in patients with a history of hypersensitivity to cefepime, cephalosporin or any other components of the product.

Warning & Precaution
As like other antimicrobials, prolonged use of Cefepime may result in overgrowth of nonsusceptible microorganisms. Repeated evaluation of the patient's condition is essential.

Side Effects
Less then 10% patient have positive Coombs' test without hemolysis and 1% to 10% patients have fever, headache, rash, pruritus, diarrhea, nausea and vomiting. After administered the injection, localized pain, erythema could be occur at injection site.

Use in Pregnancy and Lactation
There are no adequate and well-controlled studies of Cefepime use in pregnant women. This drug should be used during pregnancy only if clearly needed. Cefepime is excreted in human milk in very low concentrations. Caution should be exercised when Cefepime is administered to a nursing mother.

Use in Children & Adolescents
The safety and effectiveness of cefepime have been established in the age groups 2 months up to 16 years.

Drug Interaction
Cefepime interact with probenecid, aminoglycosides and other cephalosporins.

Storage
Store below 30^{0}C temperature in dry place, protected from light.
Keep all medicines out of reach of children.

Packing
Superpime 500 mg IM/IV : Each box contains a blister strip of one vial of Cefepime 500 mg Injection with 1 ampoule of 5 ml water for injection and a 5 ml disposable syringe, a baby needle and an alcohol pad.
Superpime 1 g IM/IV: Each box contains a blister strip of one vial of Cefepime 1 g Injection with 1 ampoule of 10 ml water for injection and a 10 ml disposable syringe, an alcohol pad and a butterfly needle.

* Further information is available on request.

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Manufactured by:
The ACME Laboratories Ltd.
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