Ceftipime®

Cefepime Hydrochloride USP

(For Intravenous & Intramuscular Use)

Presentation: Each vial contains 500 mg, 1 g & 2 g Cefepime as Cefepime Hydrochloride (with L-Arginine). Cefepime hydrochloride is a semi-synthetic, broad-spectrum cephalosporin (4th generation) antibiotic for parenteral administration. Cefepime Hydrochloride is a white to pale yellow powder, which is freely soluble in water.

Indications & Usage:
Moderate to severe Pneumonia caused by *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Streptococcus pneumoniae* and other gram negative organisms.
Empiric monotherapy for *Febrile Neutropenia*; Treatment of uncomplicated and complicated *Urinary tract infections*, including *pyelonephritis* caused by typical urinary tract pathogens (*Escherichia coli,Klebsieila 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 metronidazole and also active against methicillin susceptible staphylococci and many other gram-negative bacilli.

Pharmacology: Cefepime inhibits bacterial cell wall synthesis by binding 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 lyse due to ongoing activity of cell wall autolytic enzymes while cell wall assembly is arrested. Intramuscularly absorption of cefepime is rapid and complete 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 excreted from' the body via urine as 85% unchanged drug.

Dosage & administration: The drug will be either injected into a large muscle (such as buttock or hip) or added to an intravenous fluid that will drip through a needle or catheter placed in the vein for 30 minutes.
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 infections: 1-2 gm every 12 hours for 5-10 days; higher doses or more frequent administration may be required in Pseudomonal infections.
Dosing adjustment in renal impairment: Adults: 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 venovenous hemofiltration: Dose as normal Clcr (eg, >30 mL/minute).

Recommended Dosage Schedule for CEFTIPIME®

Site and type of infection	Dose	Frequency	Duration (Days)
Moderate to Severe Pneumonia Due to *S. pneumoniae*, *P. aeruginosa*, *K pneumoniae, or Enterobacter* species	1-2gm IV	q^{12h}	10
Empiric therapy for febrile neutropenic Patients	2 gm IV	q^{8h}	7
Mild to Moderate Uncomplicated or complicated UTI, including pyelonephritis, due to *E. coli, K pneumoniae, or P. mirabilis*	500mg-1gm	q^{12h}	7-10
Severe Uncomplicated or Complicated UTI, including pyelonephritis, due to *E coli K pneumoniae.*	2 gm IV	q^{12h}	10
Moderate to Severe Uncomplicated Skin and Skin Structure infections due to *S. aureus or S. pyogenes*	2 gm IV	q^{12h}	10
Complicated Intra-abdominal infections (used in combination with metronidazole) caused by *E. coli*, virindabs group streptococci, *P. aeruginosa*, *K. pneumoniae* Enterobacter species	2gm IV	q12h	7-10

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

Ceftipime® 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

Pregnancy and lactation: There are no adequate and well controlled studies of cefepime use in pregnant women. Because animal reproduction studies are not always predictive of human response, 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.

Side effects: Less than 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.

Overdose: Patients who receive an overdose should be carefully observed and given supportive treatment. In the presence of renal insufficiency, hemodialysis, not peritoneal dialysis, is recommended to aid in the removal of cefepime from the body. Accidental overdosing might occur if large doses are given to patients with reduced renal function. In clinical trials, Ceftipime® overdosage occurred in a patient with renal failure (creatinine clearance <11 mL/min) who received 2g for q24h for 7 days. The patient exhibited seizures, encephalopathy and neuromuscular excitability.

Drug Interactions: High dose probenecid decreases clearance and increases effect of cefepime. Aminoglycosides increases nephrotoxic potential when taken with cefepime. Nephrotoxicity has been reported following concomitant administration of other cephalosporins with potent diuretics such as furosemide.

Precautions: As like other antimicrobials, prolonged use of cefepime may result in overgrowth of non susceptible microorganisms. Repeated evaluation of the patient's condition is essential.

Storage: Store in a cool (below 30°), dry place and away from light and children.

Supply: 500mg IV/IM, 1gm IV/IM & 2gm IV. All strength supplied with WFI & a complementary pouch.

Manufactured by
RENATA LIMITED
Rajendrapur, Gazipur, Bangladesh.
April, 2016

C-Code : 105212501V01