Only for the use of Medical Professionals

Pime-4®

Cefepime

Description

Pime-4® is a preparation of Cefepime Hydrochloride. It is a semi-synthetic, fourth generation broad spectrum cephalosporin with a wide range of activity against gram-positive and gram-negative bacteria. Cefepime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. It is highly resistant to hydrolysis by most beta-lactamases and exhibits rapid penetration into gram negative bacterial cells.

Indications

Pime-4® is indicated in the treatment of the following infections:

i. Moderate to Severe Pneumonia due to *S. pneumoniae, P. aeruginosa, K. pneumoniae*, or Enterobacter species

ii. Empiric therapy for Febrile Neutropenic patients

iii. Mild to Moderate Uncomplicated or Complicated Urinary Tract Infections, including pyelonephritis, due to *E. coli*, *K. pneumoniae*, or *P. mirabilis*

iv. Severe Uncomplicated or Complicated Urinary Tract Infections, including pyelonephritis, due to *E. coli* or *K. pneumoniae*

v. Moderate to Severe Uncomplicated Skin and Skin Structure Infections due to *S. aureus* or *S. pyogenes*

vi. Complicated Intra-abdominal Infections (used in combination with metronidazole) caused by *E. coli*, viridans group streptococci, *P. aeruginosa, K. pneumoniae*, Enterobacter species, or *B. fragilis*.

Dosage and administration

Pime-4® can be administered either IV or IM. The dose and route of administration should be determined according to the susceptibility of the causative organism, the severity of the infection and the condition and renal function of the patient; higher doses or more frequent administration may be required in pseudomonal infections. Pime-4® should be administered intravenously over approximately 30 minutes.

Recommended adult dosage and routes of administration schedule for Pime-4®

Site & type of infection	Dose	Frequency	Duration
Moderate to severe Pneumonia	1-2 gm IV	12 hourly	10 days
Empiric therapy for Febrile neutropenic patients	2 gm IV	8 hourly	7 days
Mild to moderate uncomplicated or complicated urinary tract infections (including pyelonephritis)	500 mg-1 gm IV/IM*	12 hourly	7-10 days
Severe uncomplicated or complicated UTI, including Pyelonephritis	2 gm IV	12 hourly	10 days

Moderate to severe uncomplicated skin and skin structure infections	2 gm IV	12 hourly	10 days
Complicated Intra-abdominal infections (Used in combination with metronidazole)	2 gm IV	12 hourly	7-10 days
* IM route of administration is indicated only for mild to moderate, uncomplicated or complicated UTIs due to E. coli when the IM route is considered to be a more appropriate route of drug administration.			

Impaired hepatic function: No dosage adjustment is necessary for patients with impaired hepatic function.

Impaired renal function: In patients with impaired renal function (creatinine clearance 60 mL/min), the dose of Cefepime (cefepime Hydrochloride) should be adjusted. The recommended initial dose of Cefepime should be the same as in patients with normal renal function.

In patients undergoing continuous ambulatory peritoneal dialysis: Cefepime may be administered at normally recommended doses at a dosage interval of every 48 hours.

In patients undergoing hemodialysis: Approximately 68% of the total amount of cefepime present in the body at the start of dialysis will be removed during a 3-hour dialysis period. The dosage of Cefepime for hemodialysis patients is 1 g on Day 1 followed by 500 mg every 24 hours for the treatment of all infections except febrile neutropenia, which is 1 g every 24 hours. Cefepime should be administered at the same time each day following the completion of hemodialysis on hemodialysis days.

Paediatric Patients (2 months up to 12 years): The maximum dose for Paediatric patients should not exceed the recommended adult dose.

The recommended dosages schedule for Paediatric patients:

Paediatric patients upto 40 kg in weight	Dose	Frequency	Duration
Uncomplicated and complicated urinary tract infections, including pyelonephritis	50 mg/kg	12 hourly	7-10 days
Uncomplicated skin and skin structure infections	50 mg/kg	12 hourly	10 days
Pneumonia	50 mg/kg	12 hourly	10 days
Febrile Neutropenic patients	50 mg/kg	8 hourly	7 days

Preparation of solutions of Pime-4® (IV/IM) injections
Single-dose vial administration amount of diluents to be added: 500 mg IV with 5 ml water for injection, 500 mg IM with 1.3 ml water for injection, 1 gm IV with 10 ml water for injection, 1 gm IM with 2.4 ml water for injection, 2gm IV with 10 ml water for injection. These solutions may be stored up to 24 hours at room temperature or 7 days in a refrigerator.

Preparation of Pime-4® Intravenous Infusion: Pime-4® injection is compatible at concentrations between 1 and 40 mg/ml with the following IV infusion fluids: 0.9% Sodium chloride, 5% & 10% Dextrose.

Use in pregnancy and Lactation
There are no adequate and well-controlled studies of cefepime use in pregnant women. Reproduction studies performed in mice, rabbits and rats showed no evidence of fetal damage (at a maximum human daily dose). Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus. Cefepime is excreted in human breast milk in very low concentrations (0.5µg/mL). Caution should be exercised when cefepime is administered to a nursing woman.

Side-effects
Cefepime is generally well tolerated. However, few side-effects including rash, pruritus, urticaria, fever, headache, nausea, vomiting, diarrhoea, dizziness, oral moniliasis may occur.

Contraindications
Cefepime is contraindicated in patients who have shown immediate hypersensitivity reactions to cefepime or the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics.

Precautions
As with other antibiotics, prolonged use of cefepime may result in overgrowth of non-susceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken. The dose of Cefepime should be adjusted in patients with impaired renal function (Creatinine clearance 60 ml/min). Cefepime should be prescribed with caution in individuals with a history of gastrointestinal diseases, particularly colitis.

Drug Interactions
Renal function should be monitored carefully if high doses of aminoglycosides are to be administered with Cefepime because of the increased potential of nephrotoxicity and ototoxicity of aminoglycoside antibiotics. Nephrotoxicity has been reported following concomitant administration of other cephalosporins with potent diuretics such as furosemide.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.

Presentation
Pime-4® 500 mg Injection: A white to pale yellow, sterile dry powder for reconstitution. Each vial contains Cefepime 500 mg as Hydrochloride USP mixed with L-Arginine USP.
Pime-4® 1 gm Injection: A white to pale yellow, sterile dry powder for reconstitution. Each vial contains Cefepime 1gm as Hydrochloride USP mixed with L-Arginine USP.
Pime-4® 2 gm Injection: A white to pale yellow, sterile dry powder for reconstitution. Each vial contains Cefepime 2gm as Hydrochloride USP mixed with L-Arginine USP.

Package quantities
Pime-4® 500 mg Injection: Box containing 1 vial of dry powder equivalent to 500 mg Cefepime as Hydrochloride USP mixed with L-Arginine USP, 1 ampoule of 5 ml of Water for Injection BP and a 5 ml disposable syringe.
Pime-4® 1gm Injection: Box containing 1 vial of dry powder equivalent to 1g Cefepime as Hydrochloride USP mixed with L-Arginine USP, 1 ampoule of 10 ml of Water for Injection BP and a 10 ml disposable syringe. Pime-4® 2gm Injection: Box containing 1 vial of dry powder equivalent to 2g Cefepime as Hydrochloride USP mixed with L-Arginine USP, 1 ampoule of 10 ml of Water for Injection BP and a 10 ml disposable syringe.

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