Maxpime®

Cefepime

Maxpime® is a preparation of Cefepime hydrochloride. It is a semi-synthetic, broad spectrum and a fourth generation cephalosporin antibiotic for parenteral administration. It is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis.

COMPOSITION

Maxpime® 1 gm IM/IV injection: Each vial contains Cefepime 1 gm as Cefepime hydrochloride USP buffered with L-Arginine sterile powder and each ampoule contains 10 ml water for injection BP.

INDICATION, DOSAGE & ADMINISTRATION

The recommended adult and pediatric dosages and routes of administration are outlined in the following table. **Maxpime®** (Cefepime) should be administered intravenously over approximately 30 minutes. Before administration ensure that the powder has been fully dissolved in the solution.

Adults

Site and Type of Infection	Dose	Frequency	Duration (Days)
Moderate to severe Pneumonia due to *S. pneumoniae*, P. aeruginosa, K. pneumoniae,* or *Enterobacter* species	1-2 g IV	Every 12 hours	10
Empiric therapy for febrile neutropenic patients	2 g IV	Every 8 hours	7**
Mild to moderate Uncomplicated or Complicated Urinary Tract Infections, including pyelonephritis, due to *E. coli, K. pneumoniae,* or *P. mirabilis**	0.5-1 g IV/IM***	Every 12 hours	7-10
Severe Uncomplicated or Complicated Urinary Tract infections, including pyelonephritis, due to *E- coli* or *K. pneumoniae**	2 g IV	Every 12 hours	10
Moderate to Severe Uncomplicated Skin and skin structure infections due to *S. aureus* or *S. pyogenes*	2 g IV	Every 12 hours	10
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*	2 g IV	Every 12 hours	7-10

* including cases associated with concurrent bacteremia.

** or until resolution of neutropenia. In patients whose fever resolves but who remain neutropenic for more than 7 days, the need for continued antimicrobial therapy should be re-evaluated frequently.

*** 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.

Pediatric patients (2 months up to 16 years)

The maximum dose for pediatric patients should not exceed the recommended adult dose. The usual recommended dosage in pediatric patients up to 40 kg in weight for uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, and pneumonia is 50 mg/kg/dose, administered every 12 hours (50 mg/kg/dose, every 8 hours for febrile neutropenic patients), for durations as given above.

Maxpime® 1 gm Injection:

Intramuscular (IM) administration: Add 3 ml sterile water for Injection to 1 gm vial, shake & wait until the solution becomes clear.

Intravenous (IV) administration: Add 10 ml of sterile water for Injection to 1 gm vial and shake. The solution should be administered over approximately 30 minutes.

CONTRAINDICATION

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.

SIDE EFFECT

As with some other drugs in this class, encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor and coma), myoclonus and seizures have been reported. Although most cases occurred in patients with renal impairment who received doses of Cefepime that exceeded recommended dosage schedules, some cases of encephalopathy occurred in patients receiving a dosage adjustment for their renal function. If seizures associated with drug therapy occur, the drug should be discontinued. Antoconvulsant therapy can be given if clinically indicated. Precautions should be taken to adjust daily dosage in patients with renal insufficiency or other conditions that may compromise renal function to reduce antibiotic concentrations that can lead or contribute to these and other serious adverse events, including anaphylactic shock, transient leucopenia, agranulocytosis and thrombocytopenia have been reported.

DRUG INTERACTION

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.

USE IN PREGNANCY & LACTATION

Pregnancy (Category B).

Nursing Mothers

Cefepime is excreted in human breast milk in very low concentrations (0.5 ug/mL). Caution should be exercised when Cefepime is administered to a nursing woman.

STORAGE CONDITION

Store below 25^0 C. protected from light and moisture. Use reconstituted solution immedietly. Reconstituted solutions are stable for 6 hours at room temperature and for 24 hours at 2^0-8^0 C.

HOW SUPPLIED

Maxpime® 1 gm IM/IV injection: Pack of 1 vial contains 1 gm Cefepime as Cefepime hydrochloride USP accompanied by a solvent ampoule (contains 10 ml water for injection BP). It also contains a complementary pouch comprised of disposable syringe (10 ml), butterfly needle, alcohol pad and first aid bandage.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Bangladesh