

These solutions may be stored up to 24 hours at room temperature or 7 days in a refrigerator.

Ximepime Injection is compatible at concentrations between 1 and 40 mg/ml with the following IV infusion fluids: (1) 0.9% Sodium Chloride (2) 5% & 10% Dextrose

#### Contraindication

Cefepime injection is contraindicated in patients who have shown immediate hypersensitivity reactions to the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics & any component of the formulation.

#### 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.

#### Precaution

In patients with impaired renal function (Creatinine clearance  $\leq 60$  ml/min), the dose of Cefepime should be adjusted. As with other antimicrobials, prolonged use of Cefepime may result in overgrowth of nonsusceptible microorganisms. Cefepime should be prescribed with caution in individuals with a history of gastrointestinal diseases, particularly colitis.

#### Side-Effect

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

#### Use In pregnancy and lactation

**Pregnancy:** 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.  
**Lactation:** Cefepime is excreted in human milk in very low concentrations. Caution should be exercised when cefepime is administered to a nursing mother.

#### 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. Symptoms of overdose include encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor and coma), seizures and neuromuscular excitability.

#### Storage

Ximepime injection should be stored in a cool and dry place and protected from light.

#### Commercial Pack

**Ximepime 500 IM/IV injection:** Pack of 1 vial containing 500 mg Cefepime as Cefepime Hydrochloride USP with L-Arginine sterile powder accompanied by 1 ampoule of 5 ml water for injection BP and a 5 ml disposable syringe.

**Ximepime 1 gm IM/IV injection:** Pack of one vial containing 1 gm Cefepime as Cefepime Hydrochloride USP with L-Arginine sterile powder accompanied by 1 ampoule of 10 ml water for injection BP and a 10 ml disposable syringe.

#### Manufactured by

Globe Pharmaceuticals Ltd.  
Bangladesh



# Ximepime Injection

(Cefepime USP)

#### Presentation

**Ximepime 500 mg IM/IV injection:** Each vial contains Cefepime 500 mg as Cefepime Hydrochloride USP with L-Arginine sterile powder.

**Ximepime 1 gm IM/IV injection:** Each vial contains Cefepime 1 gm as Cefepime Hydrochloride USP with L-Arginine sterile powder.

#### Description

Ximepime Injection is a fourth generation broad spectrum cephalosporin antibiotic which inhibits bacterial cell wall synthesis by binding to one or more of the penicillin binding proteins (PBPs). It is highly resistant to hydrolysis by most beta-lactamases and exhibits rapid penetration into gram-negative bacterial cells. Its broad spectrum of activity encompasses a wide range of bacteria, including gram-negative microorganisms, such as *Enterobacter*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis* and *Pseudomonas aeruginosa*, and gram-positive microorganisms, such as methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, and Viridans group streptococci.

#### Indication

Ximepime Injection is indicated in the treatment of the following infections:

- ◆ Pneumonia (moderate to severe)
- ◆ Uncomplicated and Complicated Urinary Tract Infections (Including pyelonephritis)
- ◆ Uncomplicated Skin and Skin Structure Infections
- ◆ Complicated Intra-abdominal Infections
- ◆ Empiric Therapy for Febrile Neutropenic Patients

#### Dose and Administration

##### Recommended Dosage Schedule for Ximepime (Adults)

Site and Type of Infection	Dose	Frequency	Duration (days)
<b>Moderate to Severe Pneumonia</b> due to <i>S.pneumoniae</i> , <i>P.aeruginosa</i> , <i>K.pneumoniae</i> or <i>Enterobacter</i> species	1-2 gm IV	q12h	10
<b>Empiric Therapy for Febrile Neutropenic patients</b>	2 gm IV	q8h	7
<b>Mild to Moderate Uncomplicated or Complicated Urinary Tract Infections</b> (including pyelonephritis) due to <i>E.coli</i> or <i>K.pneumoniae</i> or <i>P.mirabilis</i>	500 mg-1 gm IM/IV	q12h	7-10
<b>Severe Uncomplicated or Complicated Urinary Tract Infections</b> (including pyelonephritis) due to <i>E.coli</i> or <i>K.pneumoniae</i>	2 gm IV	q12h	10
<b>Moderate to Severe Uncomplicated Skin and Skin Structure Infections</b> due to <i>S.aureus</i> or <i>S.pyogenes</i>	2 gm IV	q12h	10
<b>Complicated Intra-abdominal Infections</b> (used in combination with metronidazole) caused by <i>E.Coli</i> , viridans group streptococci, <i>P.aeruginosa</i> , <i>K.pneumoniae</i> , <i>Enterobacter</i> species or <i>B.fragilis</i> .	2 gm IV	q12h	7-10
<b>Pediatric Patients (2 months to 16 years)</b>			
<b>Febrile Neutropenic Patients:</b> 50 mg/kg given IV every 8 hours for 7-10 days			
<b>Uncomplicated Urinary Tract Infections (including pyelonephritis), Uncomplicated Skin and Skin Structure Infections and Pneumonia</b> (up to 40kg in Weight): 50 mg/kg given IV every 12 hours			
<b>Bacterial Meningitis</b> (2 months to 15 years): 50 mg/kg given IV every 8 hours			

The maximum dose for pediatric patients should not exceed the recommended adult dose.

**Impaired Hepatic Function:** No adjustment is necessary for patients with impaired hepatic function.

**Impaired Renal Function:** In patients with impaired renal function (Creatinine clearance  $\leq 60$ ml/min), the dose of Cefepime should be adjusted to compensate for the slower rate of renal elimination. The recommended initial dose of Cefepime should be the same as in patients with normal renal function except in patients undergoing hemodialysis.

#### Preparation of Solutions of Ximepime Injection

Single Dose Vials	Amounts of Diluents to be added (ml)
500 mg IM	1.3
500 mg IV	5.0
1 gm IM	2.4
1 gm IV	10.0

