Constitute the 1 gram or 2 grams vial of cefepime for injection with the one of the following diluents:

Patients: In order to keep the injection sterile, the vial and its contents should be protected from exposure to light after reconstitution. Cefepime for injection is stable for 24 hours at room temperature and for 24 hours at room temperature and for 7 days under refrigeration (2-8°C). The diluted solution may be frozen temporarily without loss of activity. However, the diluted solution should not be left at room temperature and should be protected from light before and after reconstitution. Once reconstituted, the solution may be administered immediately or refrigerated (2-8°C) for up to 24 hours before administration. The injection should be given by injection into the venous system. The concentration of cefepime should be at least 1 mg/mL before manual injection. If the concentration is below 1 mg/mL, the cefepime for injection should be further reconstituted to at least 1 mg/mL before injection.

Intravenous (IV) Infusion

Cefepime for Injection is to be administered for the full course of therapy. Cefepime solution should be reconstituted by adding 2 mL of sterile water to each 1 g vial or 4 mL to each 2 g vial of cefepime for injection. The concentration of the reconstituted solution should be at least 1 mg/mL. Do not use the needle to draw the drug solution into the syringe. The needle should be inserted into the vial so that it fills with the solution. The solution should be drawn directly from the vial into the syringe. The solution should be given intravenously slowly over 30 to 60 minutes. Cefepime for Injection should not be mixed with other drugs except as noted in Table 1. Cefepime for Injection may also be reconstituted with 0.9% Sodium Chloride Injection. Do not mix with diluents other than those found in Table 1. Cefepime for Injection may be administered intravenously (into the venous system) as follows:

- **For Patients**
  - **IV** For patients with normal renal function, the usual adult dose of cefepime for injection is 1 gram (2 grams) given intravenously every 8 hours. If patients are allergic to penicillins or cephalosporins and the infection is not life-threatening, cefepime for injection 2 grams (2 g) may be given intravenously every 12 hours. For patients with normal renal function, the usual adult dose of cefepime for injection is 1 gram (2 grams) given intravenously every 8 hours. If patients are allergic to penicillin or cephalosporins and the infection is not life-threatening, cefepime for injection 2 grams (2 g) may be given intravenously every 12 hours.
- **IM** The recommended doses of cefepime for injection in patients with renal impairment are presented in Table 2 below. Cefepime for injection may be administered intramuscularly (into the muscle) as follows:

**Site and Type of Infection**

**Dose**

- **Mild to Moderate Uncomplicated or Complicated Urinary Tract Infections**
  - Cefepime for Injection: 1 gram (2 grams) given intravenously every 8 hours, or 2 grams (2 grams) given intravenously every 12 hours.
- **Severe Uncomplicated or Severe Complicated Lower Urinary Tract Infections**
  - Cefepime for Injection: 2 grams (2 grams) given intravenously every 8 hours, or 4 grams (2 grams) given intravenously every 12 hours.
- **Complicated Skin and Soft Tissue Infections**
  - Cefepime for Injection: 1 gram (2 grams) given intravenously every 8 hours, or 2 grams (2 grams) given intravenously every 12 hours.
- **Complicated Intra-Abdominal Infections (used in combination with metronidazole)**
  - Cefepime for Injection: 1.5 grams (2 grams) given intravenously every 8 hours, or 3 grams (2 grams) given intravenously every 12 hours.
- **Pneumonia**
  - Cefepime for Injection: 1 to 2 g IV Every 8 to 12 hours for 5 to 10 days, or 2 to 4 g IV Every 12 hours for 5 to 10 days.
- **Surgical Prophylaxis**
  - Cefepime for Injection: 1 gram (2 grams) given intravenously before surgery and then every 8 hours for 48 hours after surgery.

**Pharmacy Admixture Incompatibility**

The recommended adult dosages and routes of administration are outlined in Table 1 below for patients with creatinine clearance greater than 60 mL/min except in patients undergoing hemodialysis. The recommended doses of cefepime for injection in patients with renal impairment are presented in Table 2 below. Cefepime for injection may be administered intramuscularly (into the muscle) as follows:

- **Mild to Moderate Uncomplicated or Complicated Urinary Tract Infections**
  - Cefepime for Injection: 1 gram (2 grams) given intravenously every 8 hours, or 2 grams (2 grams) given intravenously every 12 hours.
- **Severe Uncomplicated or Severe Complicated Lower Urinary Tract Infections**
  - Cefepime for Injection: 2 grams (2 grams) given intravenously every 8 hours, or 4 grams (2 grams) given intravenously every 12 hours.
- **Complicated Skin and Soft Tissue Infections**
  - Cefepime for Injection: 1 gram (2 grams) given intravenously every 8 hours, or 2 grams (2 grams) given intravenously every 12 hours.
- **Complicated Intra-Abdominal Infections (used in combination with metronidazole)**
  - Cefepime for Injection: 1.5 grams (2 grams) given intravenously every 8 hours, or 3 grams (2 grams) given intravenously every 12 hours.
- **Pneumonia**
  - Cefepime for Injection: 1 to 2 g IV Every 8 to 12 hours for 5 to 10 days, or 2 to 4 g IV Every 12 hours for 5 to 10 days.
- **Surgical Prophylaxis**
  - Cefepime for Injection: 1 gram (2 grams) given intravenously before surgery and then every 8 hours for 48 hours after surgery.
Streptococcus pneumoniae

(PBP).

a wide range of Gram-positive and Gram-negative bacteria. Within bacterial cells, the molecular targets of cefepime are the penicillin binding proteins

minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for cefepime against isolates of similar genus or organism

hours (n=29) and every 12 hours (n=13) schedules. Following a single intravenous dose, total body clearance and the steady-state volume of distribution

Pediatric patients

[see Dosage and Administration (2.3)].

clearance decreased proportionally with creatinine clearance in patients with abnormal renal function, which serves as the basis for dosage adjustment

requiring hemodialysis was 13.5 (±2.7) hours and in patients requiring continuous peritoneal dialysis was 19 (±2) hours. Cefepime total body

[see Dosage and Administration (2.3)].

911 mcg of cefepime (C19H24N6O5S2) per mg, calculated on an anhydrous basis. It is highly soluble in water.

Cefepime for Injection, USP is a semi-synthetic, cephalosporin antibacterial for parenteral administration. The chemical name is 1-[(6R,7R)-7-

epilepticus

of consciousness including confusion, hallucinations, stupor, and coma), myoclonus, seizures, neuromuscular excitability, and nonconvulsive status

occurrences of the following: encephalopathy, myoclonus, and seizures

When geriatric patients received the usual recommended adult dose, clinical efficacy and safety were comparable to clinical efficacy and safety in

Of the more than 6400 adults treated with cefepime for injection in clinical studies, 35% were 65 years or older while 16% were 75 years or older.

8.5          Geriatric Use

is

(12.3)

H. influenzae
type b. In those patients in whom meningeal seeding is from a distant infection site or in whom meningitis is suspected or documented,

Table 10: Susceptibility Test Interpretive Criteria for Cefepime¥

Table 11: Acceptable Quality Control Ranges for Cefepime

Table 12: Demographics of Evaluable Patients (First Episodes Only)

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