Cefepime for Injection, USP is a sterile powder of cefepime in vials for parenteral administration. It is available as 1-g, 2-g, and 4-g vials. The recommended adult dosages and routes of administration are outlined in Table 1 below for patients with creatinine clearance greater than 60 mL/min. Adjust the dose of cefepime for injection in patients with creatinine clearance less than or equal to 60 mL/min to compensate for the slower rate of renal elimination.

### DOSAGE FORMS AND STRENGTHS

The administration of cefepime may result in a false-positive reaction for glucose in the urine with certain methods. It is recommended that glucose tests be performed with methods that do not produce false positives.

### DOSAGE AND ADMINISTRATION

The recommended adult dosage for uncomplicated skin and skin structure infections and uncomplicated and complicated urinary tract infections (including pyelonephritis) is 2 grams per 24 hours. Dosage adjustment may be required in patients with anemia, renal impairment, or those requiring hemodialysis.

### CLINICAL STUDIES

- **1.1 Uncomplicated Skin and Skin Structure Infections**: Dosage: 8 grams per 24 hours, divided into 2 grams every 12 hours. 
- **1.2 Empiric Therapy for Febrile Neutropenic Patients**: Dosage: 10 grams per 24 hours, divided into 2 grams every 12 hours.
- **1.3 Moderate to Severe Pneumonia**: Dosage: 1.8 grams per 24 hours, divided into 1 gram every 8 hours for nebulized nebulization.
- **1.4 Uncomplicated Urinary Tract Infections**: Dosage: 1.8 grams per 24 hours, divided into 0.9 grams every 12 hours.
- **1.5 Complicated Intra-abdominal Infections**: Dosage: 2 grams per 24 hours, divided into 4 grams every 24 hours.
- **1.6 Hospital-Acquired Pneumonia**: Dosage: 1.8 grams per 24 hours, divided into 0.9 grams every 12 hours.

### ADVERSE REACTIONS

The most common adverse reaction in patients administered cefepime is diarrhea, which occurs in approximately 25% of patients. Other adverse reactions include nausea, vomiting, rash, and pruritus. In patients administered cefepime for intra-abdominal infections, the most common adverse reaction is diarrhea, which occurs in approximately 30% of patients. Other reactions include nausea, vomiting, and pruritus.

### MICROBIOLOGY

- **2.1 Susceptibility Testing**: In vitro testing of cefepime for injection against non-lactamase-producing strains of Beta-lactamase-negative, ampicillin-resistant Enterobacter cloacae complex (AR-EC), Enterobacter sakazakii, the Enterobacteriaceae, and Acinetobacter baumannii may result in false-negative results due to the inhibitory effects of cefepime on these organisms.
- **2.2 Cross-hypersensitivity among beta-lactam agents**: Cross-reactivity among cephalosporins is possible, particularly with other cephalosporins. Patients with a history of allergic reactions to cephalosporins or penicillins may be at increased risk of cross-reactivity.

### CLINICAL STUDIES

- **14.1 Clinical Studies**: The clinical studies for cefepime for injection have been conducted in patients with mild to moderate and moderate to severe infections. The studies have demonstrated the efficacy and safety of cefepime for injection in the treatment of these infections.

### INCOMPATIBILITIES

- **3.8 INCOMPATIBILITIES**: Cefepime for injection is incompatible with solutions of ampicillin at a concentration greater than 40 mg/mL, metronidazole, vancomycin, and sodium bicarbonate. It is recommended that these solutions be administered separately.

### CONTRAINDICATIONS

- **4.1 CONTRAINDICATIONS**: Cefepime for injection is contraindicated in patients who have shown immediate hypersensitivity reactions to cefepime or the cephalosporin class of antibacterial agents. These reactions include anaphylaxis, angioedema, and urticaria.

### WARNINGS AND PRECAUTIONS

- **5.1 WARNINGS**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.
- **5.2 PRECAUTIONS**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.

### DOSAGE FORMS AND STRENGTHS

- **5.3 Development of Drug-Resistant Bacteria**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.

### ADVERSE REACTIONS

- **5.4 Adverse Reactions**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.

### CLINICAL STUDIES

- **5.5 Clinical Studies**: The clinical studies for cefepime for injection have been conducted in patients with mild to moderate and moderate to severe infections. The studies have demonstrated the efficacy and safety of cefepime for injection in the treatment of these infections.

### INCOMPATIBILITIES

- **5.6 Incompatibilities**: Cefepime for injection is incompatible with solutions of ampicillin at a concentration greater than 40 mg/mL, metronidazole, vancomycin, and sodium bicarbonate. It is recommended that these solutions be administered separately.

### CONTRAINDICATIONS

- **5.7 Contraindications**: Cefepime for injection is contraindicated in patients who have shown immediate hypersensitivity reactions to cefepime or the cephalosporin class of antibacterial agents. These reactions include anaphylaxis, angioedema, and urticaria.

### WARNINGS AND PRECAUTIONS

- **5.8 WARNINGS**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.
- **5.9 PRECAUTIONS**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.

### DOSAGE FORMS AND STRENGTHS

- **5.10 Development of Drug-Resistant Bacteria**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.

### ADVERSE REACTIONS

- **5.11 Adverse Reactions**: Cefepime for injection is associated with a risk of allergic reactions, including anaphylaxis, angioedema, and urticaria. It is recommended that these reactions be monitored in patients administered cefepime.

### CLINICAL STUDIES

- **5.12 Clinical Studies**: The clinical studies for cefepime for injection have been conducted in patients with mild to moderate and moderate to severe infections. The studies have demonstrated the efficacy and safety of cefepime for injection in the treatment of these infections.
Cefepime is a bactericidal drug that acts by inhibition of bacterial cell wall synthesis. Cefepime has a broad spectrum of activity against Gram-negative and Gram-positive bacteria. It is active against strains of Pseudomonas aeruginosa, Haemophilus influenzae, and other β-lactamase-producing organisms. Cefepime is also active against certain strains of Enterococcus faecalis and Staphylococcus aureus.

The pharmacokinetics of cefepime were unaltered in patients with hepatic impairment who received a single 1 g dose (n=11). Patients who receive cefepime should be monitored closely for signs of adverse reactions.

Concentrations of cefepime achieved in specific tissues and body fluids are listed in Table 9. Cefepime is eliminated primarily by renal excretion and minimal concentrations are achieved in saliva, sweat, bile, cerebrospinal fluid, and urine. The elimination half-life of cefepime in healthy volunteers is approximately 3 hours.

Table 8: Mean Pharmacokinetic Parameters for Cefepime (mg/kg dose)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>SD, Intravenous Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cmax, mcg/mL</td>
<td>96.9 (± 26.5)</td>
<td>70 (± 21)</td>
</tr>
<tr>
<td>T1/2, hours</td>
<td>3.6 (± 0.9)</td>
<td>3.0 (± 0.8)</td>
</tr>
<tr>
<td>Vd, L/kg</td>
<td>155.1 (± 74.6)</td>
<td>122 (± 55)</td>
</tr>
<tr>
<td>CL, L/min/kg</td>
<td>12.5 (± 5.6)</td>
<td>10.7 (± 4.8)</td>
</tr>
</tbody>
</table>

Cefepime is administered by intravenous or intramuscular injection. The recommended dosage is 1 g every 8 hours. The maximum recommended dose is 4 g daily. The safety and efficacy of cefepime for other routes of administration have not been established. Cefepime should be used with caution in patients with a history of allergy to cephalosporins or penicillins. Cefepime should not be used in patients with a history of anaphylactic reactions to cephalosporins or penicillins.

Cefepime is not a substitute for aminoglycosides. Aminoglycosides should be used in conjunction with cefepime for the treatment of infections caused by Gram-negative bacteria. Cefepime is not a substitute for aminoglycosides when the infection is caused by a Gram-positive organism. Cefepime should be used with caution in patients with a history of allergy to cephalosporins or penicillins. Cefepime should not be used in patients with a history of anaphylactic reactions to cephalosporins or penicillins.

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