In patients undergoing peritoneal dialysis (2 L/hr.), Cefazolin for Injection achieves peak urine concentrations of approximately 2,400 mcg/mL and 4,000 mcg/mL respectively following 500 mg for Injection. Studies of cord blood show prompt transfer of Cefazolin for Injection across the placenta. In synovial fluid, the level of Cefazolin for Injection becomes approximated to 185 mcg/mL and was approximately 4 mcg/mL at 8 hours following a 1 gram dose. Concentrations peaked at approximately 185 mcg/mL and were approximately 4 mcg/mL at 8 hours following a 500 mg dose, and 3 mcg/mL at 8 hours following a 1 gram dose.

The pH of the reconstituted solution is between 4 and 6. Cefazolin for Injection, USP is available in a single dose of 500 mg in 1 mL of a 4.9% sodium chloride injection or 1 gram of cefazolin in 1 mL of 2.9% sodium chloride injection. The reconstituted solution is for parenteral administration. It is the sodium salt of 3-\{(5-methyl-1H-1,2,4-thiazol-3-yl)methyl\}amino\{3-\[(2\text{-}R\text{-}amino\text{-}3\text{-}hydr
droxypropyl\text{-}2\text{-}y
diethylamino\text{-}5\text{-}oxo\text{-}1\text{-}pyrroli
dine\text{-}1\text{-}carboxylate\}}dehy
droxypropyl\text{-}2\text{-}y
diethylamino\text{-}5\text{-}oxo\text{-}1\text{-}pyrroli
dine\text{-}1\text{-}carboxylate\}. For the sodium content of the reconstituted solution and the parenteral solution, see Table 1.

1. DESCRIPTION:

Cefazolin for Injection, USP is effective in the eradication of susceptible bacteria in the following infections when due to susceptible organisms.

1.1. Respiratory Tract Infections:

Due to S. aureus, S. pneumoniae, and a variety of anaerobic species, and some strains of enterococci. Infections of the respiratory tract including those due to methicillin-susceptible and -resistant S. aureus (MRSA) and S. pneumoniae are susceptible to Cefazolin for Injection.

1.2. Skin and Skin Structure Infections:

Due to S. aureus, S. pneumoniae, S. pyogenes (Group A beta-hemolytic streptococci), and many of the viridans group streptococci. Clindamycin may be used in combination with Cefazolin for Injection in patients with mild to moderate infections caused by clindamycin susceptible strains of beta-hemolytic streptococci.

1.3. Urinary Tract Infections:

Due to E. coli, P. mirabilis, Klebsiella species, and some strains of enterococci and enterococci. Cefazolin for Injection is not recommended for the treatment of urinary tract infections (UTIs), particularly those caused by Escherichia coli.

1.4. Bone and Joint Infections:

Due to S. aureus and methicillin-sensitive S. epidermidis.

1.5. General Infections:

E. coli, P. mirabilis, Klebsiella species, and some strains of enterococci.

Cefazolin is approved for the treatment of skin and skin structure infections caused by methicillin-sensitive and -resistant strains of S. aureus, and other strains of streptococci.

2. SUSCEPTIBILITY TESTING

2.1. In Vitro Testing

Cefazolin is a cephalosporin and is usually effective against the majority of Gram-positive and Gram-negative bacteria that are susceptible to the drug. Cefazolin is active against many species of Staphylococcus, Streptococcus, and Enterobacteriaceae. However, some strains of Enterobacter cloacae, Proteus mirabilis, and E. coli are resistant to cefazolin. Cefazolin is also active against some strains of Pseudomonas aeruginosa and Klebsiella species. It is less active against some strains of Enterococcus faecalis and Enterococcus faecium.

Cefazolin is not effective against Mycobacterium tuberculosis or Nocardia species. It is not effective against the majority of aerobic and anaerobic fungi, including Candida species. Cefazolin is not effective against peptococci, peptostreptococci, and Clostridium species. Cefazolin is not effective against most species of Bacteroides, but it may be effective against some strains of Bacteroides fragilis and Bacteroides thetaiotaomicron.

3. THERAPEUTIC USES

Cefazolin is indicated for the treatment of the following infections when due to susceptible organisms:

3.1. Respiratory Tract Infections

Due to S. aureus, S. pneumoniae, and a variety of anaerobic species, and some strains of enterococci. Cefazolin for Injection is not recommended for the treatment of urinary tract infections (UTIs), particularly those caused by Escherichia coli.

3.2. Skin and Skin Structure Infections

Due to S. aureus, S. pneumoniae, S. pyogenes (Group A beta-hemolytic streptococci), and many of the viridans group streptococci. Clindamycin may be used in combination with Cefazolin for Injection in patients with mild to moderate infections caused by clindamycin susceptible strains of beta-hemolytic streptococci.

3.3. Urinary Tract Infections

Due to E. coli, P. mirabilis, Klebsiella species, and some strains of enterococci and enterococci. Cefazolin for Injection is not recommended for the treatment of urinary tract infections (UTIs), particularly those caused by Escherichia coli.

3.4. Bone and Joint Infections

Due to S. aureus and methicillin-sensitive S. epidermidis.

3.5. General Infections

E. coli, P. mirabilis, Klebsiella species, and some strains of enterococci.

Cefazolin is approved for the treatment of skin and skin structure infections caused by methicillin-sensitive and -resistant strains of S. aureus, and other strains of streptococci.
Pediatric Dosage

Pediatric patients, a total daily dosage of 25 to 50 mg per kg (approaching 10 to 20 mg per kg body weight divided into 3 or 4 equal doses), is effective for most mild to moderately severe infections. A daily dose of 25 mg per kg body weight is recommended.

Pediatric Dosage Guide

<table>
<thead>
<tr>
<th>Weight</th>
<th>Dosage</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mg/kg/day</td>
<td>500 mg q 8 h</td>
<td>2 times/day</td>
</tr>
<tr>
<td>25 mg/kg/day</td>
<td>250 mg q 6 h</td>
<td>3 times/day</td>
</tr>
</tbody>
</table>

In pediatric patients with moderate to mild renal impairment (creatinine clearance of 25 to 55 mL/min.), the dosage may be increased to 100 mg per kg body weight daily in divided doses.

In pediatric patients with severe, life-threatening infections (e.g., endocarditis, meningitis), the dosage may be increased to 1.5 grams every 6 hours.

Dosage Adjustment for Patients with Reduced Renal Function

In patients with renal impairment, the dosage should be adjusted as follows:

<table>
<thead>
<tr>
<th>Type of Infection</th>
<th>Dose Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal pneumonia</td>
<td>500 mg q 8 h</td>
</tr>
<tr>
<td>Severe, life-threatening infections (e.g., endocarditis, meningitis)</td>
<td>1.5 grams q 6 h</td>
</tr>
</tbody>
</table>

Pediatric patients with moderate renal impairment (creatinine clearance of 25 to 55 mL/min.) may be given the adult dose of 100 mg per kg body weight daily in divided doses.

Pediatric patients with severe, life-threatening infections (e.g., endocarditis) may be given the adult dose of 1.5 grams every 6 hours.

ADVERSE REACTIONS:

Nausea and vomiting have been reported rarely.

Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see WARNINGS). Nausea and vomiting may occur after antibiotic treatment.

Other Gastrointestinal: Diarrhea, vomiting, abdominal pain, and diarrhea have been reported rarely.

Hematological: Neutropenia, leucopenia, thrombocytopenia, and anemia have been rarely reported.

Other: Dyspnea, flushing, hypotension, urticaria, rash, angioedema, and swelling have been reported rarely.

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Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see WARNINGS). Nausea and vomiting have been reported rarely.

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