Cefazolin for Injection, USP

**INDICATIONS AND USAGE**

Cefazolin for Injection, USP is a broad-spectrum, cephalosporin antibiotic indicated for the treatment of infections caused by susceptible bacteria. It is indicated for the treatment of infections caused by susceptible bacteria, including skin and skin structure infections such as cellulitis, abscess, and furunculosis.

**CONTRAINDICATIONS**

Cefazolin for Injection should be administered with caution to patients with a history of allergy to penicillins or cephalosporins. Patients with a history of anaphylaxis to penicillins or cephalosporins should not be given cefazolin.

**PRECAUTIONS**

Cefazolin for Injection is not indicated for the treatment of infections caused by enterococci, anaerobic bacteria, or mycobacteria. Treatment of infections due to mycobacteria should be directed by therapy appropriate for the specific infection.

**ADVERSE REACTIONS**

Cefazolin for Injection may cause adverse reactions such as rash, pruritus, urticaria, nausea, and vomiting. Anaphylaxis, eosinophilia, itching, drug fever, skin rash, and Stevens-Johnson syndrome have been reported rarely.

**USAGE IN SPECIFIC POPULATIONS**

Cefazolin for Injection may be considered for use in children over 1 year of age. Pediatric dosing guidelines are available.

**DOSAGE AND ADMINISTRATION**

Cefazolin for Injection is administered intravenously or intramuscularly. The usual recommended dose is 1 gram of cefazolin every 8 hours. For infections caused by susceptible bacteria, a single 1-gram dose of cefazolin may be sufficient. For infections caused by penicillin-resistant Staphylococcus aureus, a dose of 2 grams every 8 hours may be necessary.

**NURSING MOTHERS**

Cefazolin for Injection is not known to be excreted in breast milk. The decision to give breast milk to infants of mothers who are receiving cefazolin should be made with consideration of the benefit of the drug to the mother.

**TERATOGENIC EFFECTS**

There are no adequately controlled studies in pregnant women. Cefazolin for Injection should be administered with caution during pregnancy.

**CLASSIFICATON**

Cefazolin for Injection is classified by the U.S. Food and Drug Administration as Pregnancy Category B.

**HYPERSENSITIVITY TESTING**

Testing for sensitivity to cefazolin should be performed in patients with a history of sensitivity to cephalosporins or penicillins. Testing should be performed before the administration of cefazolin.

**HOW SUPPLIED**

Cefazolin for Injection is supplied as 500 mg and 1 gram for injection in vials of 25, 50, or 100 mg per milliliter. The vials are sterile and contain an aqueous suspension of cefazolin sodium.

**PEDIATRIC DOSAGE**

The pediatric dosage of cefazolin is based on body weight. The usual recommended dose is 1 gram every 8 hours, divided into 4 doses.

**PHARMACOLOGICAL ACTIONS**

Cefazolin for Injection is a broad-spectrum cephalosporin antibiotic that is active against a wide range of aerobic and anaerobic bacteria. It is active against beta-lactamase-positive and beta-lactamase-negative strains of bacteria. Cefazolin is active against Gram-positive, Gram-negative, and anaerobic bacteria.

**CLINICAL PHARMACOLOGY**

Cefazolin for Injection is rapidly absorbed following intravenous or intramuscular administration. It is widely distributed, including to the brain and urine. Cefazolin is eliminated primarily by renal excretion.

**CLINICAL STUDIES**

In clinical trials, cefazolin was effective in the treatment of infections caused by susceptible bacteria. Mean peak serum levels were 29 mcg/mL (range 13 to 44 mcg/mL) with 50 mg/L of cefazolin per kg (approximately 10 to 20 mg per pound) of body weight, divided into 3 or 4 doses.

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<thead>
<tr>
<th>Dosage (mg/kg/day)</th>
<th>Approximate mg/q 8 h</th>
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<tbody>
<tr>
<td>50</td>
<td>13.6</td>
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<td>100</td>
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**SIDE EFFECTS**

Cefazolin for Injection may cause side effects such as nausea, vomiting, diarrhea, and constipation. It may also cause allergic reactions such as rash, pruritus, urticaria, and anaphylaxis.

**DILUTION**

Cefazolin for Injection is stable in 5% Dextrose Injection, USP, 5% Sodium Chloride Injection, USP, or Sodium Chloride and Dextrose Injection, USP for up to 24 hours at room temperature. It is not recommended to dilute Cefazolin for Injection in 5% Dextrose and 0.2% Sodium Chloride Injection, USP, 5% or 10% Dextrose Injection, USP, or 5% Sodium Bicarbonate Injection, USP. Cefazolin for Injection is stable in Sterile Water for Injection, USP, or Sodium Chloride Injection, USP for up to 24 hours at room temperature.

**RECONSTITUTION**

Cefazolin for Injection should be reconstituted with Sterile Water for Injection, USP, or Sodium Chloride Injection according to the table below.

**PACKAGING**

Vial Size | Amount of Diluent | Approximate Vol. (mL) |
----------|------------------|---------------------|
250 mg    | 250 mg dilution   | 0.25 mL             |
500 mg    | 500 mg dilution   | 0.5 mL              |
1 gram    | 1 gram dilution   | 1 mL                |

**COMPATIBILITY**

Cefazolin for Injection is compatible with 5% Dextrose and 0.2% Sodium Chloride Injection, USP, 5% Dextrose and 0.45% Sodium Chloride Injection, USP, 5% or 10% Dextrose Injection, USP, and 5% Sodium Bicarbonate Injection, USP. It is not recommended to dilute Cefazolin for Injection in 5% Dextrose and 0.2% Sodium Chloride Injection, USP, 5% or 10% Dextrose Injection, USP, or 5% Sodium Bicarbonate Injection, USP.

**REPOSITORY INFORMATION**

Cefazolin for Injection should be stored at room temperature and protected from light. It is stable for 1 year at room temperature and protected from light.