Zolibac™ IM/IV Injection

Cefazolin USP

PRESENTATION

Zolibac™ 500 mg IM/IV Injection: Each vial contains Cefazolin 500 mg (as sterile Cefazolin Sodium USP) and each ampoule contains 5 ml Water for Injection BP.

Zolibac™ 1 gm IM/IV Injection: Each vial contains Cefazolin 1 gm (as sterile Cefazolin Sodium USP) and each ampoule contains 5 ml Water for Injection BP.

PHARMACOLOGY

Cefazolin is a 1st generation broad spectrum parenteral Cephalosporin antibiotic. It interferes with the synthesis of bacterial cell wall by inhibiting transpeptidase enzyme. As a result the bacterial cell wall is weakened, the cell swells and then ruptures.

INDICATION

Zolibac™ is indicated in the treatment of the following serious infections due to susceptible organisms: Respiratory Tract Infections, Urinary Tract Infections, Skin and Skin Structure Infections, Biliary Tract Infections, Bone and Joint Infections, Genital Infections, Septicemia, Endocarditis and Perioperative Prophylaxis.

DOSAGE AND ADMINISTRATION

Adult Dose

Type of Infection	Dose	Frequency
Moderate to severe infections	500 mg to 1 gm	Every 6 to 8 hours
Mild infections caused by susceptible Gram-positive cocci	250 mg to 500 mg	Every 8 hours
Acute uncomplicated urinary tract infections	1 gm	Every 12 hours
Pneumococcal pneumonia	500 mg	Every 12 hours
Severe life-threatening infections (e.g. Endocarditis, Septicemia etc.)*	1 gm to 1.5 gm	Every 6 hours

* In rare instances, doses up to 12 gm per day can be used.

Perioperative Prophylactic Use

To prevent postoperative infection in contaminated or potentially contaminated surgery, recommended doses are:

a. 1 gm IM or IV administered ½ hour to 1 hour prior to the start of surgery.

b. For lengthy operative procedures (e.g. 2 hours or more), 500 mg to 1 gm IM or IV during surgery.

c. 500 mg to 1 gm IM or IV every 6 to 8 hours for 24 hours postoperatively.

In surgery where the occurrence of infection may be particularly devastating (e.g. open-heart surgery and prosthetic arthroplasty), the prophylactic administration may be continued for 3 to 5 days following the completion of surgery.

Patients with Impaired Renal Function

Creatinine clearance (ml/min)	Dose (based on unit doses of 500 mg & 1 gm)	Frequency
35 to 54	1 unit dose	Every 8 hours
11 to 34	½ unit dose	Every 12 hours
10	½ unit dose	Every 18 to 24 hours

All reduced dosage recommendations should be applied after an initial loading dose appropriate to the severity of the infection.

Patients with Hepatic Insufficiency

No dosage adjustment is necessary in patients with hepatic insufficiency.

Pediatric Dose

In pediatric patients, a total daily dosage of 25 to 50 mg per kg of body weight, divided into 3 or 4 equal doses, is effective for most mild to moderate infections. Total daily dosage may be increased to 100 mg per kg of body weight for severe infections. Safety for use in premature infants and in neonates has not been established.

CONTRAINDICATION

Cefazolin is contraindicated in patients with known allergy to the Cephalosporin group of Antibiotics.

ADVERSE EFFECT

Common side effects include: Injection site reactions (pain, swelling, skin rash, or a hard lump), diarrhea, stomach pain, stomach cramps, nausea, vomiting, loss of appetite, skin rash or itching, hives, white patches or sores inside the mouth or on the lips, vaginal itching or discharge, heartburn, gas, rectal itching, confusion, weakness, hypotension, drowsiness, headache and allergic reactions.

PRECAUTION

As with all Cephalosporins, Cefazolin should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly Colitis.

As with other β-lactam antibiotics, seizures may occur if inappropriately high doses are administered to patients with impaired renal function.

DRUG INTERACTION

Probenecid may decrease renal tubular secretion of Cephalosporins when used concurrently, resulting in increased and more prolonged Cephalosporin blood levels.

PREGNANCY AND LACTATION

Pregnancy Category B.

Cefazolin is present in very low concentrations in the milk of nursing mothers. Caution should be exercised when Cefazolin is administered to a nursing woman.

RECONSTITUTION PROCEDURE

The content of one vial is to be dissolved in 2 ml (for 500 mg IM/IV Injection) & 2.5 ml (for 1 gm IM/IV Injection) Water for Injection.

STORAGE

After reconstitution, **Zolibac**™ is stable for 24 hours at room temperature or for 10 days if stored under refrigeration (5°C or 41°F). Reconstituted solution may range in color from pale yellow to yellow without a change in potency.

HOW SUPPLIED

Zolibac™ 500 mg IM/IV Injection: Pack of 1 vial containing 500 mg Cefazolin (as sterile Cefazolin Sodium USP) accompanied by 1 ampoule of 5 ml Water for Injection for IM/IV Injection. It also contains a complementary pouch comprised of disposable syringe (5 ml), baby needle, alcohol pad and first aid bandage.

Zolibac™ 1 gm IM/IV Injection: Pack of 1 vial containing 1 gm Cefazolin (as sterile Cefazolin Sodium USP) accompanied by 1 ampoule of 5 ml Water for Injection for IM/IV Injection. It also contains a complementary pouch comprised of disposable syringe (5 ml), alcohol pad and first aid bandage.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Bangladesh