Cefalin-1gm
Injection

DRUG INTERNATIONAL LTD.

Composition : Each vial contains Cefazolin 1gm sterile powder (As Cefazolin Sodium USP).

Pharmacology : Cefazolin is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. The serum half-life for cefazolin is approximately 1.8 hours following IV administration and approximately 2 hours following IM administration. Cefazolin is excreted unchanged in the urine.

Indications : Cefazolin is indicated for the treatment of the following infections caused by 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 : Cefazolin should be administered intravenously or intramuscularly.

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)*	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 gram IV or IM administered 1/2 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 gram IV or IM during surgery.

c. 500mg to 1 gm IV or IM 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	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.

Pediatric Dose : In pediatric patients a total daily dosage of 25 to 50mg 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 100mg per kg of body weight for severe infections. Safety for use in premature infants and in neonates has not been established. Or, as directed by the registered physician.

Reconstitution : The content of one vial is to be dissolved in 2.5ml (for 1gm IV/IM Injection) Water for Injection.

Contraindication : It is contraindicated in patients with known hypersensitivity to Cefazolin or Cephalosporin class of antibacterial drugs, Penicillins, other Beta-lactams or any other components of this product.

Precautions : As with all Cephalosporin, 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.

Side effects : Side Effects are: Gastrointestinal: Diarrhea, oral candidiasis (oral thrush), vomiting, nausea, stomach cramps, anorexia, and pseudomembranous colitis. Allergic: Anaphylaxis, eosinophilia, itching, drug fever, skin rash, Stevens-Johnson syndrome. Hematologic: Neutropenia, leukopenia, thrombocytopenia, thrombocythemia. Hepatic: Transient rise in SGOT, SGPT, and alkaline phosphatase levels has been observed. As with other cephalosporins, reports of hepatitis have been received. Renal:As with other cephalosporins, reports of increased BUN and creatinine levels, as well as renal failure, have been received.

Use in pregnancy & lactation : Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. 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.

Use in Child : See Dosage & Administration.

Drug interactions : Probenecid may decrease renal tubular secretion of cephalosporins when used concurrently, resulting in increased and more prolonged cephalosporin blood levels.

Overdose : There is no data available.

Storage : Store below 30°C in a dry place.

Packing : Each combipack contains 1 vial of Cefazolin 1gm sterile powder (As Cefazolin Sodium USP) with 1 ampoule of 5ml water for injection BP.