Cefaking
Injection

DRUG INTERNATIONAL LTD.

Composition : **Cefaking-500 Injection:** Each vial contains Cefoperazone 500mg as Cefoperazone Sodium USP.
Cefaking-1gm Injection: Each vial contains Cefoperazone 1000mg as Cefoperazone Sodium USP.
Cefaking-2gm Injection: Each vial contains Cefoperazone 2000mg as Cefoperazone Sodium USP.

Pharmacology : The mean serum half-life of cefoperazone is approximately 2.0 hours, independent of the route of administration. Cefoperazone is excreted mainly in the bile. Maximum bile concentrations are generally obtained between one and three hours following drug administration.

Indications : It is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory Tract Infections, Peritonitis & Other Intra-abdominal Infections, Bacterial, Septicemia, Skin and Skin Structures Infections, Pelvic Inflammatory Disease, Endometritis & Other Infections of the Female Genital Tract, Urinary Tract Infections, Enterococcal Infections etc.

Dosage and administration : The usual adult daily dose of sterile Cefoperazone is 2 to 4 gm per day administered in equally divided doses every 12 hours. In severe infections or infections caused by less sensitive organisms, the total daily and/or frequency may be increased. Patients have been successfully treated with a total daily dosage of 6 to 12 gm divided into 2, 3 or 4 administrations ranging from 1.5 to 4 gm per dose. When treating infections caused by *Streptococcus pyogenes*, therapy should be continued for at least 10 days. Or, as directed by the registered physician.

Administration : Cefaking for intravenous or intramuscular use may be initially reconstituted with compatible solution. Solutions should be allowed to stand after reconstitution to allow any foaming to dissipate to permit visual inspection for complete solubilization. Vigorous and prolonged agitation may be necessary to solubilize cefaking in higher concentrations (above 333mg Cefoperazone/ml). The maximum solubility of cefaking is approximately 475mg cefoperazone/ml of compatible diluent.

Contraindication : Cefoperazone is contraindicated in patients with hypersensitivity to Cefoperazone or any other components of this product.

Precautions : Cefoperazone is extensively excreted in bile. The serum half-life of Cefoperazone is increased 2 to 4 fold in patients with hepatic disease and/or biliary obstruction. In general, total daily dosage above 4 gm should not be necessary in such patients. If higher dosages are used, serum concentrations should be monitored.

Side effects : Hypersensitivity: As with all Cephalosporins, hypersensitivity manifested by skin reactions (1 patient in 45), drug fever (1 in 260), or a change in Coombs Test (1 in 60) has been reported. These reactions are more likely to occur in patients with a history of allergies, particularly to Penicillin.

Use in pregnancy and lactation : Pregnancy Category B. There are no adequate and well-controlled clinical studies in pregnant or breastfeeding women. It should only be used in pregnant women if the potential benefit justifies the potential risk to the foetus. Since it is not known if Cefoperazone is distributed into milk, the drug should be used with caution in nursing women.

Use in Child : Safety and effectiveness in children have not been established.

Drug Interactions : A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution.

Overdose : Symptoms of overdose include blood in the urine, diarrhea, nausea, upper abdominal pain, and vomiting.

Storage : Store below 30^{o}C in a dry place.

Packing : **Cefaking-500 Injection :** Blister pack of 1 vial containing 500mg Cefoperazone (As sterile Cefoperazone Sodium USP) accompanied by one ampoule of 5ml water for injection BP for IM/IV injection.
Cefaking-1gm Injection : Blister pack of 1 vial containing 1000mg Cefoperazone (As sterile Cefoperazone Sodium USP) accompanied by one ampoule of 10ml water for injection BP for IM/IV injection.
Cefaking-2gm Injection : Blister pack of 1 vial containing 2000mg Cefoperazone (As sterile Cefoperazone Sodium USP) accompanied by one ampoule of 10ml water for injection BP for IM/IV injection.