Cefopen™

Cefoperazone

Cefopen™ (Cefoperazone) is a bactericidal Cephalosporin antibiotic which is resistant to most beta-lactamases and active against a wide range of aerobic & anaerobic, Gram positive & Gram negative bacteria. The bactericidal action of Cefoperazone results from the inhibition of bacterial cell wall synthesis. Cefoperazone has a high degree of stability in the presence of beta-lactamases produced by most Gram negative pathogens. Cefoperazone is usually active against organisms which are resistant to other beta-lactam antibiotics because of beta-lactamase production.

COMPOSITION

Cefopen™ **1 gm** IM/IV Injection : Each vial contains sterile Cefoperazone Sodium USP equivalent to Cefoperazone 1 gm. Each ampoule contains 10 ml water for injection BP.

Cefopen™ **2 gm** IM/IV Injection : Each vial contains sterile Cefoperazone Sodium USP equivalent to Cefoperazone 2 gm. Each ampoule contains 10 ml water for injection BP.

INDICATION

Cefopen™ 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

Sterile Cefoperazone Sodium can be administered by IM or IV injection (following dilution).

Adult: 2 to 4 grams per day administered in equally divided doses every 12 hours. In severe infections or infections caused by less sensitive organisms, the total daily dose and/or frequency may be increased. Patients have been successfully treated with a total daily dosage of 6-12 grams divided into 2, 3, or 4 administrations ranging from 1.5 to 4 grams per dose. When treating infections caused by *Streptococcus pyogenes*, therapy should be continued for at least 10 days.

RECONSTITUTION

Cefopen™ 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 **Cefopen**™ in higher concentrations (above 333 mg Cefoperazone/ml). The maximum solubility of **Cefopen**™ is approximately 475 mg Cefoperazone/ml of compatible diluent.

PEDIATRIC USE

Safety and effectiveness in children have not been established.

GERIATRIC USE

Reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

CONTRAINDICATION

Cefoperazone is contraindicated in patients with known allergy to the Cephalosporin-class of antibiotics.

SIDE EFFECT

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.

PREGNANCY & LACTATION

Pregnancy Category B. This drug should be used during pregnancy only if clearly needed. Only low concentrations of Cefoperazone is excreted in human milk. Although Cefoperazone passes poorly into breast milk of nursing mothers, caution should be exercised when Cefoperazone is administered to a nursing woman.

PRECAUTION

Cefoperazone is extensively excreted in bile. The serum half-life of Cefoperazone is increased 2-4 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.

STORAGE CONDITION

Cefopen™ is to be stored in a dry place, below 25°C and protected from light prior to reconstitution. The reconstituted solution may be stored for 24 hours if kept in room temperature (below 25°C).

HOW SUPPLIED

Cefopen™ 1 gm IM/IV Injection: Each box contains one vial of Cefoperazone 1 gm powder for injection accompanied by one ampoule of 10 ml water for injection BP. It also contains a complementary pouch comprised of disposable syringe (10 ml), butterfly needle, alcohol pad and first aid band.

Cefopen™ 2 gm IM/IV Injection: Each box contains one vial of Cefoperazone 2 gm powder for injection accompanied by one ampoule of 10 ml water for injection BP. It also contains a complementary pouch comprised of disposable syringe (10 ml), butterfly needle, alcohol pad and first aid band.

Manufactured by

SQUARE
SQUARE PHARMACEUTICALS LTD.
Bangladesh

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