Hepatic Impairment

potential benefits and possible risks involved should be considered before instituting therapy.

vi. Pelvic inflammatory disease, endometritis, gonorrhoea, and other infections of the genital tract

CONTRAINDICATIONS

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam or sulbactam. Patients with a history of allergy to sulbactam and cefoperazone or any of the cephalosporins should be cautioned concerning ingestion of alcoholic beverages in conjunction with administration of Sulbactam/Cefoperazone. It is contraindicated in patients with a known allergy to penicillins, sulbactam, cefoperazone, or any of the cephalosporins.

Sulbactam does not possess any useful antibacterial activity, except against Neisseriaceae and Acinetobacter. As sulbactam also binds with some penicillin-binding proteins, sensitive strains are also often rendered more susceptible to Sulbactam/cefoperazone than to cefoperazone alone.

The combination of Sulbactam and Cefoperazone is active against all organisms sensitive to cefoperazone. In addition, it demonstrates synergistic activity (up to 4-fold reduction in the minimum inhibitory concentrations for the combination versus those for each component) in a variety of organisms.

Sulbactam Sodium and Cefoperazone Sodium combination consists of a beta-lactamase inhibitor plus a beta lactam antibiotic. This sulbactam/cefoperazone combination is available as a dry powder.

PHARMACOLOGY

The antibacterial component of Sulbactam/Cefoperazone is cefoperazone, a third generation cephalosporin, which acts against sensitive organisms during the stage of active multiplication by inhibiting the biosynthesis of cell wall mucopeptide. Cefoperazone alone.

DOSAGE AND ADMINISTRATION

The usual adult dose of the combination is 2 to 4 g/day (i.e., 1 to 2 g/day each of Cefoperazone and Sulbactam) given IV or IM in equally divided doses every 12 hours. In severe or refractory infections, the daily dosage may be increased to 8 g (i.e., 4 g each of Cefoperazone and Sulbactam) given IV in equally divided doses every 12 hours. The recommended maximum daily dosage of Sulbactam is 4 g (8 g of the combination).

Children

The usual dosage in children is 40-80 mg/kg/day (20 to 40 mg/kg/day each of Cefoperazone and Sulbactam) every 6 to 12 hours. In serious or refractory infections, these dosages may be increased up to 240 mg/kg/day (160 mg/kg/day cefoperazone activity).

Use in Neonates

For neonates in the first week of life, the drug should be given every 12 hours. The maximum daily dosage of sulbactam in paediatrics should not exceed 80 mg/kg/day.

Renal Impairment

Dosage regimens of sulbactam/cefoperazone should be adjusted in patients with a marked decrease in renal function (creatinine clearance of less than 33 mL/min) to compensate for the reduced clearance of sulbactam. Patients with creatinine clearances between 15 and 30 mL/min should receive a maximum of 1 g of sulbactam every 12 hours (maximum daily dosage of 2 g sulbactam), while patients with creatinine clearances of less than 15 mL/min should receive a maximum of 500 mg of sulbactam every 12 hours (maximum daily dosage of 1 g sulbactam). The pharmacokinetic profile of sulbactam is significantly altered by haemodialysis. Thus, dosing should be scheduled to follow a dialysis period.

Hepatic Impairment

Cefoperazone is extensively excreted through the bile. Dose modification may be necessary in cases of severe biliary obstruction, severe hepatic dysfunction or in cases of renal dysfunction consistent with either of those conditions. In such cases, dosage should not exceed 2 g/day of cefoperazone without close monitoring of serum concentrations.

Intravenous Administration

Reconstitution

For intravenous infusion, each vial of Cefoperazone and Sulbactam should be reconstituted with the appropriate amount of 5% Dextrose and 0.9% Sodium Chloride Injection or Sterile Water for Injections IP, then further diluted to 20 mL with the same solution, and followed by administration over 15 to 60 minutes. Lactated Ringer’s solution is a suitable vehicle for intravenous infusion, however it is not for initial reconstitution.

For intravenous injection, each vial should be reconstituted as above and administered over a minimum of 3 minutes.

Intramuscular Administration

After initial reconstitution Lidocaine HCL 2 % can be added for Intramuscular administration.

INCOMPATIBILITY

Aminoglycosides

Solutions of sulbactam/cefoperazone and aminoglycosides should not be directly mixed, since there is a physical incompatibility between them.

Lactated Ringer’s Solution

Initial reconstitution with Lactated Ringer’s Solution should be avoided since this mixture has been shown to be incompatible. However, a two-step dilution process involving initial reconstitution in Sterile Water for Injections IP will result in a compatible mixture when further diluted with Lactated Ringer’s Solution.

Shelf life: Please refer to carton/label.

STORAGE AND HANDLING INSTRUCTIONS

Store below 25°C. Protect from light. Keep out of reach of children.

Reconstituted Solution

Reconstituted solution is stable for 7 days at 2°C - 8°C and for 24 Hours at 8°C - 25°C.

How supplied

Glass vial in a carton.

Marketed by:
Biocon Biologics India Limited
Biocon House, Sesimic Park, Electronics City, Phase –II, Bengaluru - 560 100, India.

Registered trademark

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To report adverse events and/or product complaints visit our website www.biocon.com or call toll free No: 1800 102 9465 or e mail us at drugsafety@biocon.com.