Dosage/Direction for Use : Reconstitution

For IV infusion, each vial should be reconstituted with suitable amount of sterile water for injection, normal saline, 5% dextrose in water, and then diluted to 20 ml using the same diluent followed by admin over 15-60 minutes. For IV injection, each vial should be reconstituted as above and given over at least 3 minutes.

Adults: Daily dosage recommendations for sulbactam/cefoperazone in adults are as follows (See Table 1)

Table 1.

Ratio	SBT/CPZ (g)	SBT Activity (g)	CPZ Activity (g)
1:1	2-4	1-2	1-2
1:2	1.5-3	0.5-1	1-2
SBT = Sulbactam; CPZ = Cefoperazone			

Doses should be administered every 12 hrs in equally divided doses. In severe or refractory infections the daily dosage of sulbactam/cefoperazone may be increased up to 8 g of the 1:1 ratio (ie, cefoperazone 4 g activity) or 12 g of the 1:2 ratio (ie, cefoperazone 8 g activity). Patients receiving the 1:1 ratio may require additional cefoperazone administered separately. Doses should be administered every 12 hrs in equally divided doses. The recommended maximum daily dose of sulbactam is 4 g.

Renal Dysfunction: Dosage regimens of sulbactam/cefoperazone should be adjusted in patients with marked decrease in renal function (creatinine clearance <30 mL/min) to compensate for the reduced renal clearance of sulbactam. Patients with creatinine clearance 15-30 mL/min should receive a maximum of sulbactam 1 g administered every 12 hrs (maximum daily dose: sulbactam 2 g), while patients with creatinine clearance <15 mL/min should receive a maximum of sulbactam 500 mg every 12 hrs (maximum daily dose: sulbactam 1g). In severe infections it may be necessary to administer additional cefoperazone.The pharmacokinetic profile of sulbactam is significantly altered by hemodialysis. The serum half-life of cefoperazone is reduced slightly during hemodialysis. Thus, dosing should be scheduled to follow a dialysis period.

Children: Daily dosage recommendations

sulbactam/cefoperazone in children are as follows (See Table 2)

Table 2.

Ratio	SBT/CPZ (mg/kg/day)	SBT Activity (mg/kg/day)	CPZ Activity (mg/kg/day)
1:1	40-80	20-40	20-40
1:2	30-60	10-20	20-40
SBT = Sulbactam; CPZ = Cefoperazone			

Doses should be administered every 6-12 hrs in equally divided doses. In serious or refractory infections, these dosages may be increased up to 160 mg/kg/day of the 1:1 ratio or 240 mg/kg/day of the 1:2 ratio (160 mg/kg/day cefoperazone activity). Doses should be administered in 2 or 4 equally divided doses

Neonates: For neonates in the 1st week of life, the drug should be given every 12 hrs. The maximum daily dosage of sulbactam in pediatrics should not exceed 80 mg/kg/day. For doses of sulbactam/cefoperazone requiring >80 mg/kg/day cefoperazone activity, the 1:2 ratio product must be

Intravenous Administration: For intermittent infusion, each vial of sulbactam/cefoperazone should be reconstituted with the appropriate amount (see Cautions for Usage) of 5% dextrose in water, 0.9% sodium chloride injection or sterile water for injection and then diluted to 20 mL with the same solution followed by administration over 15-60 minutes. reconstitution

Lactated Ringer's solution is a suitable vehicle for intravenous infusion, however, not for initial reconstitution For intravenous injection, each vial should be reconstituted as mentioned previously and administered over a minimum of 3 minutes.

Intramuscular Administration: Lidocaine HCl 2% is a suitable vehicle for intramuscular administration, however, not for initial reconstitution

Storage : Store at a temperature below 25° C. protected from light. Do not freeze.
Improper storage may deteriorate the product.

Presentation : A white dry powder of Cefoperazone & Sulbactam filled in clear glass vial .

Manufactured by:
AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA
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Scan for Batch Certificate

For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

Rx Cefoperazone & Sulbactam For Injection

AMERICAN
CEFORZONE SB 1.5

For IM/IV Use Only

Composition:

Each vial contains:

Cefoperazone Sodium (Sterile) I.P
Eq. to anhydrous Cefoperazone 1000 mg
Sulbactam Sodium (Sterile) I.P
Eq. to anhydrous Sulbactam 500 mg

Description : White or almost white powder or crystalline powder, very hygroscopic.

Pharmacokinetics

Cefoperazone, a bactericidal antibiotic, inhibits bacterial cell wall synthesis of actively dividing cells by binding to one or more penicillin binding proteins (PBPs). Sulbactam is a β-lactamase inhibitor and acts primarily by irreversible inactivation of β-lactamases.

·Inhibiting bacterial cell wall synthesis.
·Preventing destruction antibiotics, from chemicals released from bacteria.

Side-effects

Cefoperazone & Sulbactam Injection. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

·Allergic reactions
·Neutropenia
· Diarrhea
·Nausea
·Vomiting
·Pain at site of injection
·Rash, skin reactions, fever, eosinophilia, urticaria, and pruritus. Haematological - Slight decreases in Hb conc and haematocrit value. GI effects, diarrhoea or loose stools, nausea, and vomiting. Mild, transient elevations of serum SGOT, SGPT, and alkaline phosphatase concentrations. Renal effects - Transient elevations in BUN and serum creatinine concentrations.

Precautions & How to Use

Before using Cefoperazone & Sulbactam Injection, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

·Avoid alcohol while taking this medication
·History of gastrointestinal disease
·If you develop bloody or watery diarrhea contact your doctor immedately
·Inform your doctor if you have had allergic reactions to penicillins or other cephalosporins in the past
·It is important that you finish the entire course as prescribed
·Kidney problems

Drug Interactions

Cefoperazone & Sulbactam Injection may interact with the following drugs and products:

·Alcohol
·Allopurinol
·Amikacin
·Aminoglycoside antibiotics
·Gentamicin
·Probenecid

Contraindications

Hypersensitivity to Cefoperazone & Sulbactam Injection is a contraindication. In addition, Cefoperazone & Sulbactam Injection should not be used if you have the following conditions:

·Asthma
·Clostridium difficile infection
·Diabetes
·Hypersensitivity
·Hypersensitivity to cephalosporins
·Kidney or gastrointestinal disease

Sulbactam is able to inhibit the most common forms of beta-lactamase but is not able to interact with the ampC cephalosporinase. Thus, it confers little protection against bacteria such as Pseudomonas aeruginosa, Citrobacter, Enterobacter, and Serratia, which often express this gene.

In the United States, sulbactam is combined to form cefoperazone/sulbactam and ampicillin/sulbactam. It does possess some antibacterial activity when administered alone, but it is too weak to have any clinical importance. Its use in the UK is restricted to hospitals.