1.17 Summary of Product Characteristics (SPC)

1. Name of the medicinal product

1.1 (Invented) Name of the medicinal product

CEFOPERAZONE & SULBACTAM FOR INJECTION (1.5 GM)

1.2 Strength

Each combipack contains:

a) Sterile Cefoperazone Sodium BP
Eq. to Cefoperazone 1000 mg
Sterile Sulbactam Sodium USP
Eq. to Sulbactam 500 mg

b) Sterilised Water for Injections BP

1.3 Pharmaceutical Form

Dry Powder for injection

2. Qualitative and Quantitative Formula

CEFOPERAZONE & SULBACTAM FOR INJECTION

Batch Size: 18,000 Vials (30.00 Kg)

Sr. No.	Ingredient	Spec.	Overages (%)	Label Claim (mg)	Qty/Batch (Kg)
1.	Cefoperazone Sodium BP Eq. to Cefoperazone	BP	----	1000 mg	11.258 Kg
2.	Sulbactam sodium USP eq. to Sulbactam	USP	----	500 mg	5.862 Kg
Average weight of filled powder					**17.120 Kg**

STERILISED WATER FOR INJECTIONS BP

Batch Size: 10,000 Ampoules

Sr. No.	Ingredient	Qty/ Ampoule	Specification	Qty/Batch	Functions
1.	Sterilised water for injections BP	10.000 ml	BP	100 Lit	Solvent for Parenteral formulation
Average weight		10 ml			

Std average weight of the Ampoule: 10 ml

3. Pharmaceutical form

A white to off white crystalline powder.

4. Clinical particulars

4.1 Therapeutic Indication:

The combination of Cefoperazone sodium and Sulbactam sodium is indicated for the treatment of the following infections caused by susceptible organisms.

Respiratory tract infections (Upper and Lower), Urinary Tract Infections, Peritonitis, Cholecystitis, Cholangitis and other intra-abdominal infections, Bacterial sinusitis, Meningitis, Skin and soft tissue infections, Bone and Joint infections, Pelvic Inflammatory disease - endometritis, gonorrhea and other infections of the genital tract.

4.2 Contraindications

It is contraindicated in patients with a known allergy to penicillins, sulbactam, cefoperazone, or any of the cephalosporins.

4.3 Special warnings and precautions for use:

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam or cephalosporin therapy. These reactions are more apt to occur in individuals with a history of hypersensitivity reactions to multiple

allergens. If an allergic reaction occurs, the drug should be discontinued and the appropriate therapy instituted. As with other antibiotics, overgrowth of non-susceptible organisms may occur during the prolonged use of Sulbactum/Cefoperazone. It has not been extensively studied in premature infants or neonates. Therefore, in treating premature infants and neonates, the potential benefits and possible risks involved should be considered before instituting therapy.

4.4 Interaction with other medicinal products and other forms of interaction

A reaction characterized by flushing, sweating, headache and tachycardia has been reported when alcohol was ingested during and as late as the fifth day after Cefoperazone administration. A similar reaction has been reported with certain other cephalosporins and patients should be cautioned concerning ingestion of alcoholic beverages in conjunction with administration of Sulbactum/ Cefoperazone. For patients requiring artificial feeding orally or parenterally, solutions containing ethanol should be avoided.

4.5 Adverse Drug Reactions

Sulbactam/cefoperazone is generally well-tolerated. The majority of adverse events are of mild or moderate severity and are tolerated with continued treatment. The most frequent side effects observed with Sulbactum/Cefoperazone have been gastrointestinal. Others include dermatologic reactions, headache, injection pain, chills, and anaphylactoid reactions.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The antibacterial component of Sulbactum/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. 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 Sulbactum/Cefoperazone than to

Cefoperazone alone. The combination of Sulbactum 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.

5.2 Pharmacokinetic properties

Absorption: The mean serum concentration obtained at 30 min after 1 g I.V. Cefoperazone is 114 mcg/ml. The mean serum concentration obtained at 15 min. after 500 mg and 1000 mg IV Sulbactam are 21- 40 mcg/ml and 48-88 mcg/ml respectively. The average peak plasma concentration at 5 minutes after intravenous dose of 1g is 81mg/litre. Distribution: The protein binding of Cefoperazone is 82-93% and that of Sulbactam is 38%. Metabolism and Excretion: No significant quantity of metabolites of Cefoperazone has been found in the urine. Cefoperazone is excreted mainly in the bile. About 75-85% of Sulbactam is excreted in the urine during the first eight hours of administration.

5.3 Preclinical safety data

Clinical studies of the combination of sulbactam plus beta-lactam antibiotics or penicillins have revealed no major hematologic, renal, hepatic, or central nervous system reactions. Diarrhea has not been a major problem after intravenous use. Incidence of side-effects due to Cefoperazone is as follows: G.I. effects- 2-3%, cutaneous reactions 1-3%, haemotological 1-2%, miscellaneous 1.5-3%

6. Pharmaceutical particulars

6.1 List of Excipients

6.2 Incompatibilities

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 Injection will result in a compatible mixture when further diluted with Lactated Ringer's Solution.

6.3 Shelf life

Unopened: 24 months

6.4 Special precautions for storage

Unopened: Do not store above 25°C. Keep the vials in the outer carton.

6.5 Nature and contents of container

CEFOPERAZONE & SULBACTAM FOR INJECTION is packed in 20 ml Clear glass Vial USP Type III & one ampoule of 10 ml of sterilized water for injection packed in monocarton along with package insert.

6.6 Special precautions for disposal

Reconstitution table Sterilised Water for Injection (Intravenous Injection):

Vial size	Volume of Diluent to be added	Approx available volume	Approx displacement volume
1g	10ml	10.5ml	0.5ml

The reconstituted solution should be clear. Do not use if particles are present.

For single use only. Discard any unused contents.

7. REGISTRANT

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9. DATE OF REVISION OF THE TEXT:

Not Applicable

10. NAME AND ADDRESS OF MANUFACTURER

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