

Summary of product characteristic (SMPC)

1. Name of Medicinal Product

Ceftriaxone and Sulbactam for Injection 1.5 g (SYCEPH-SB 1.5 G Injection)

2. Composition

Each combipack contains:

Each vial contains:

1) Ceftriaxone Sodium USP

equivalent to Ceftriaxone..... 1g

Sulbactam Sodium USP

equivalent to Sulbactam..... 0.5g

2) Sterilized Water for Injection BP 10ml

3. Pharmaceutical form

Powder for injection

4. Clinical particulars

4.1 Therapeutic indications

Treatment of skin and soft tissue infections, cholecystitis, osteomyelitis, chronic suppurative bacterial otitis media, gonorrhoea, chancroid, syphilis, UTI infections, meningitis, nosocomial infection caused by susceptible bacteria.

4.2 Dosage and Administration:

To be administered by slow intravenous (I.V.) injection, or as a slow I.V. infusion, after reconstitution with sterile water for injection (SWFI).

Adults

The usual adult daily dose is 1.5-3 grams given once a day (or in equally divided doses twice a day) depending on the type and severity of the infection. The total daily dose should not exceed 6 grams.

Paediatric patients

For treatment of Skin and Soft tissue infections the recommended total daily dose is 75-100mg/kg given once a day or (in equally divided doses twice a day). The total daily dose should not exceed 1.5 grams.

For treatment of acute bacterial otitis media: A single intramuscular dose of 75 mg/kg (not to exceed 1.5 gram) is recommended.

In treatment of Meningitis: The initial therapeutic dose should be 125 mg/kg (not to exceed 6 grams) Daily dose may be administered once a day or in equally divided doses 12 hourly. The usual duration of therapy is 7-14 days.

For treatment of serious infections other than meningitis: Recommended total daily dose is 75-100 mg/kg given in divided doses every 12 hours. The total daily dose should not exceed 3 grams.

DIRECTIONS FOR USE:

Each vial should be reconstituted with sterile water for injection BP. Shake well until powder gets dissolved.

Intravenous injection:

1.5 g Syceph-SB should be dissolved in 9.6 ml water for injection BP. The injection should be administered over at least 2-4 minutes directly into the vein or via the tubing of intravenous infusion.

For I.V. infusion use, reconstituted solution may be further diluted with a compatible diluent (e.g., sterile water for injection, 0.9% sodium chloride injection, 5% or 10% dextrose solution). I.V. infusion may be administered over a period of at least 30 minutes. The reconstituted solution should be used immediately after preparation. Do not freeze. Unused portion of solution should be discarded immediately.

If any particles are visible in the vial after dissolving the content, please do not use the solution.

4.3 Contraindications

Hypersensitivity.

4.4 Special warnings and precautions for use

Serious or occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam therapy. These reactions are more likely to occur in individuals with a history of hypersensitivity reactions to multiple allergens. If an allergic reaction develops, the drug should be discontinued and appropriate therapy instituted. Pseudomembranous colitis has been reported with the use of cephalosporins [and other broad spectrum antibiotics]; therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use. Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by clostridium difficile is the primary cause of antibiotic-associated colitis. Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte, and protein supplement as indicated.

General:

Although transient elevations of BUN and serum creatinine have been observed at the recommended dosage, the nephrotoxic potential of ceftriaxone is similar to that of other cephalosporins. Ceftriaxone is excreted via both biliary and renal excretion. Therefore, patients with renal failure normally require no adjustment in dosage when usual doses of ceftriaxone are administered but concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be decreased accordingly.

Dosage adjustments should not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, dosage should not exceed 2 gm daily without close monitoring of serum concentrations.

Alterations in prothrombin times have occurred rarely in patients treated with ceftriaxone. Patients with impaired vitamin K synthesis or low vitamin k stores (e.g. chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during CEFTRIXONE AND SULBACTAM FOR INJECTION treatment. Vitamin k administration (10 mg weekly) may be

necessary if the prothrombin time is prolonged before or during therapy. Prolonged use of ceftriaxone may result in overgrowth of non-susceptible organisms. Careful observation of the patient is essential. CEFTRIXONE AND SULBACTAM FOR INJECTION should be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Considering the maximum duration of treatment and the class of the compound, carcinogenic studies with ceftriaxone in animals have not been performed. The maximum duration of animal toxicity studies was 6 months.

Mutagenesis: Genetic toxicology tests included the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured in vitro with ceftriaxone. Ceftriaxone showed no potential for mutagenic activity in these studies.

Impairment of Fertility: Ceftriaxone produced no impairment of fertility when given intravenously to rats at daily doses of upto 586 mg/kg/day, approximately 20 times the recommended clinical dose of 2 g/day.

4.5 Interaction with other medicinal products and other forms of interaction

There is no specific drug interaction evidence available

4.6 Pregnancy and lactation

Pregnancy category B: The drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Low concentrations of ceftriaxone are excreted in human milk. No risk to nursing infants has been reported but caution should be exercised when ceftriaxone is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of ceftriaxone in neonates, infants and children have been established, sulbactam is also found to be safe in children and infants.

4.7 Effects on ability to drive and use machines:

None known.

4.8 Undesirable effects:

G.I. effects, cutaneous reactions.

4.9 Overdose

Limited information is available on the acute toxicity of ceftriaxone and sulbactam for injection. There is no specific antidote. If acute overdosage of ceftriaxone and sulbactam occurs, supportive and symptomatic treatment should be initiated. Haemodialysis or Peritoneal dialyses are ineffective in reducing ceftriaxone concentration following overdosage.

5. Pharmacological properties

Syceph-SB is an anti-infective combination of Ceftriaxone + Sulbactam. Ceftriaxone is a broad-spectrum semi-synthetic third generation cephalosporin with a potent bactericidal activity against a wide range of gram-positive and gram-negative bacteria. Sulbactam is a beta-lactamase inhibitor.

5.1 Pharmacodynamic properties

Syceph-SB is an anti-infective combination of Ceftriaxone + Sulbactam. Ceftriaxone is a broad-spectrum semi-synthetic third generation cephalosporin with a potent bactericidal activity against a wide range of gram-positive and gram-negative bacteria. Sulbactam is a beta-lactamase inhibitor.

5.2 Pharmacokinetics:

Ceftriaxone:

Following intramuscular injection, mean peak plasma ceftriaxone levels are approximately half those observed after intravenous administration of an equivalent dose. The maximum plasma concentration after a single intramuscular dose of 1 gram is about 81 mg/l and is reached in 2 to 3 hours after administration. The area under the plasma concentration-time curve after intramuscular administration is equivalent to that after intravenous administration of an equivalent dose. After intravenous bolus administration of ceftriaxone 500 mg and 1 g, mean peak plasma ceftriaxone (C_{max}) levels are approximately 120 and 200 mg/l respectively. After intravenous infusion of ceftriaxone 500 mg, 1 g and 2 g, the plasma ceftriaxone levels are approximately 80, 150 and 250 mg/l respectively. An 8 to 15 % increase in C_{max} is seen on repeated administration; steady state is reached in most cases within 48 to 72 hours depending on the route of administration.

Distribution: The volume of distribution of ceftriaxone is 7 to 12 litre. Ceftriaxone is reversibly bound to albumin. Plasma protein binding is about 95 % at plasma concentrations below 100 mg/l. Binding is saturable and the bound portion decreases with rising concentration (up to 85 % at a plasma concentration of 300 mg/l).

Metabolism: Ceftriaxone is not metabolized systemically; but is converted to inactive metabolites by the gut flora.

Elimination: Plasma clearance of total ceftriaxone (bound and unbound) is 10 to 22 ml/min. Renal clearance is 5 to 12 ml/min. 50 to 60 % of ceftriaxone is excreted unchanged in the urine, primarily by glomerular filtration, while 40 to 50 % is excreted unchanged in the bile. The elimination half-life of total ceftriaxone in adults is about 8 hours.

Sulbactam

After a 30-minute injection of 1g of sulbactam, a peak concentration of approximately 43 mcg/ml is obtained. Plasma protein binding is approximately 38%. The mean serum half-life of sulbactam is approximately 1 hour in healthy volunteers. Approximately 75 to 85% of sulbactam is excreted unchanged in the urine during the first 8 hours after administration to individuals with normal renal function

5.3 Preclinical safety data

None

6. Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

None

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Store at temperature not exceeding 30°C in a cool dry place.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

Combi pack of 1 vial + Solvent.

6. Pharmaceutical particulars**6.1 List of excipients**

Not applicable

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 year

6.4 Special precautions for storage

Store at temperature not exceeding 30°C in a cool and dry place.

Keep out of reach of children.

6.5 Nature and contents of container

Combipack of 1 Vial +Solvent.

6.6 Special precautions for disposal and other handling

NA

Manufactured by

Makcur Laboratories Ltd.

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Marketed by

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Ceftriaxone and Sulbactam
For Injection 1.5g

Syceph-SB[®]
1.5 g

Syceph-SB[®] Injection
1.5 g

COMPOSITION:

Each combi-pack contains:

(1.) Each vial contains:
Ceftriaxone Sodium USP
eq. to Ceftriaxone Anhydrous 1g
Sulbactam Sodium USP
eq. to Sulbactam 0.5 g

(2.) Each ampoule contains:
Sterilised water for Injections BP
10 ml

Direction for reconstitution
Dissolve the content of vial in 10ml
sterilised water for injection

Use immediately after reconstitution,
do not freeze.

Dosage: As directed by the physician.

Storage: Store at temperature not
exceeding 30°C in a cool dry place.

KEEP OUT OF REACH OF CHILDREN

WARNING: If any particles are
visible in the vial after dissolving
the contents please do not use
the solution

This pack contains:
1. Vial of Sterile Ceftriaxone Sodium USP
and Sulbactam Sodium USP
2. 10 ml Sterile water for injection

Syceph-SB[®]
Injection 1.5 g

Ceftriaxone and Sulbactam
For Injection 1.5g
Composite Pack
Vial with Solvent
For I.V use



Syceph-SB[®] Injection
1.5 g

NAFDAC REG. NO.:

Mfg. Lic. No.: G/1097

Batch No.: Mc23046

Mfg. Date: 04/2023

Exp. Date: 03/2026

Refer the WFI ampoule for batch details.

Marketed by:

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Gujarat (India).



Syceph-SB[®]
Injection 1.5 g

Ceftriaxone and Sulbactam
For Injection 1.5g
Composite Pack
Vial with Solvent
For I.V use