

Information For the User
Ceftriaxone (1000mg) + Sulbactam (500mg)

Fritcet S 1.5g Injection

Ceftriaxone (1000 mg) + Sulbactam (500 mg) Injection

Description:

Ceftriaxone is a third-generation cephalosporin antibiotic, while Sulbactam is a beta-lactamase inhibitor that extends the activity of beta-lactam antibiotics like Ceftriaxone against beta-lactamase-producing bacteria. This combination offers broad-spectrum antibacterial activity against a wide range of both gram-positive and gram-negative bacteria, making it suitable for the treatment of serious infections. The combination is particularly effective against bacteria that may be resistant to Ceftriaxone alone.

Composition:

Each vial contains:

- Ceftriaxone Sodium: 1000 mg (equivalent to 1 g of Ceftriaxone)
- Sulbactam Sodium: 500 mg

Reconstitution solvent: (Sterile water for injection or saline as directed by the manufacturer)

Indications:

Ceftriaxone + Sulbactam injection is indicated for the treatment of infections caused by susceptible organisms, including:

- Lower respiratory tract infections (e.g., pneumonia, bronchitis)
- Urinary tract infections (UTIs)
- Skin and soft tissue infections
- Intra-abdominal infections
- Bone and joint infections
- Bacterial septicemia

- Meningitis
- Gonorrhea
- Typhoid fever
- Surgical prophylaxis

Dosage and Administration:

Adults and Children (over 12 years or ≥ 50 kg):

- Usual dose: 1–2 g of Ceftriaxone + 0.5–1 g of Sulbactam, once or twice daily, depending on the severity of the infection.
- For severe infections, the dose may be increased, up to 4 g of Ceftriaxone + 2 g of Sulbactam per day, divided into 1 or 2 doses.

Children (under 12 years or < 50 kg):

- Usual dose: 20–80 mg/kg/day of Ceftriaxone + 10–40 mg/kg/day of Sulbactam, divided into 2 doses, depending on the severity of the infection.

Neonates (≤ 14 days):

- 20–50 mg/kg/day of Ceftriaxone + 10–25 mg/kg/day of Sulbactam as a single dose.

Reconstitution:

1. Reconstitute the powder with sterile water for injection or normal saline, as per the manufacturer's instructions.
2. Shake gently until the powder is fully dissolved.
3. Use the reconstituted solution immediately for best results.

Route of Administration:

- **IM injection:** Inject deep into a large muscle (e.g., gluteus), if reconstituted with lidocaine (if provided).

- **IV injection:** Administer slowly over 2-4 minutes.
 - **IV infusion:** For larger doses, administer the solution over a period of 30 minutes to 1 hour.
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Contraindications:

- **Hypersensitivity to Ceftriaxone, Sulbactam, or any excipient in the formulation.**
 - **Neonates with hyperbilirubinemia or those who require calcium-containing IV solutions.**
 - **Severe liver dysfunction or history of cholestatic jaundice due to Ceftriaxone therapy.**
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Warnings and Precautions:

- **Hypersensitivity reactions:** Cross-sensitivity with penicillins may occur.
 - **Neonates:** Avoid using in neonates with hyperbilirubinemia or those requiring calcium-containing solutions due to the risk of precipitation.
 - **Superinfection:** Prolonged use may lead to secondary infections, including *Clostridioides difficile*-associated diarrhea.
 - **Renal or hepatic impairment:** Adjust doses in patients with impaired renal or liver function.
 - **Blood disorders:** Prolonged use of Ceftriaxone may lead to transient increases in liver enzymes, blood clotting issues, or thrombocytopenia.
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Side Effects:

- **Common:** Pain at the injection site, rash, diarrhea, nausea, or fever.
- **Less common:** Vomiting, dizziness, or headache.
- **Rare:** Severe allergic reactions (e.g., anaphylaxis), thrombocytopenia,

pseudomembranous colitis, or gallbladder sludge.

- **Others:** Elevated liver enzymes, changes in renal function, or blood dyscrasias.
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Storage:

- **Store the unopened vial at room temperature (below 25°C).**
 - **Once reconstituted, use the solution immediately or store as directed by the manufacturer (usually refrigerated at 2–8°C) and discard after 24 hours.**
 - **Keep the vial tightly closed and out of reach of children.**
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Note:

Ceftriaxone + Sulbactam is a prescription-only medication and must be administered by a healthcare professional. Ensure to complete the entire course of therapy as prescribed to avoid the development of antibiotic resistance. If any severe reactions occur, such as difficulty breathing, swelling, or a severe rash, immediate medical attention should be sought.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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