

Information For the User
Ceftriaxone (500mg) + Sulbactam (250mg)

Fritcet S 750 Injection

Ceftriaxone (500 mg) + Sulbactam (250 mg) Injection

Description:

Ceftriaxone is a third-generation cephalosporin antibiotic with broad-spectrum activity against gram-positive and gram-negative bacteria.

Sulbactam is a beta-lactamase inhibitor that extends the activity of Ceftriaxone by inhibiting bacterial beta-lactamases, enzymes that degrade beta-lactam antibiotics. The combination of Ceftriaxone and Sulbactam is effective against infections caused by beta-lactamase-producing organisms, enhancing its therapeutic utility in treating resistant bacterial infections.

Composition:

Each vial contains:

- **Ceftriaxone Sodium:** Equivalent to 500 mg of Ceftriaxone
- **Sulbactam Sodium:** Equivalent to 250 mg of Sulbactam

Reconstitution solvent: (Sterile water for injection or saline, depending on manufacturer recommendations)

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 g of Ceftriaxone + 0.5 g of Sulbactam once or twice daily, depending on infection severity.
- **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 infection severity.

Neonates (≤ 14 days):

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

Reconstitution:

1. Reconstitute with sterile water for injection or normal saline, as per the manufacturer's instructions.
2. Shake gently until the powder is completely dissolved.
3. Use the reconstituted solution immediately to ensure maximum efficacy.

Route of Administration:

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

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

- **Known 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 a history of cholestatic jaundice related to Ceftriaxone therapy.**
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Warnings and Precautions:

- **Hypersensitivity reactions:** Cross-sensitivity with penicillins may occur.
 - **Neonates:** Ceftriaxone should not be used in neonates with hyperbilirubinemia or in patients requiring calcium-containing solutions due to the risk of precipitation.
 - **Superinfection:** Prolonged use may lead to the growth of resistant organisms such as *Clostridioides difficile*, which can result in pseudomembranous colitis.
 - **Renal or hepatic impairment:** Dose adjustments may be required in patients with impaired renal or liver function.
 - **Blood disorders:** Prolonged therapy may lead to thrombocytopenia, increases in liver enzymes, or other hematologic changes.
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Side Effects:

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

pseudomembranous colitis, or gallbladder sludge.

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

- **Store the unopened vial at room temperature, below 25°C.**
 - **After reconstitution, use the solution immediately or store it according to the manufacturer's guidelines, 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 should be administered by healthcare professionals. Ensure to complete the entire prescribed course of therapy to avoid the development of 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:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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