

Information For the User
Ceftriaxone (250mg) + Tazobactam (31.25mg)

Fritcet TZ 281.25 Injection

Ceftriaxone (250 mg) + Tazobactam (31.25 mg) Injection

Description:

Ceftriaxone is a third-generation cephalosporin antibiotic with a broad spectrum of activity against a variety of gram-positive and gram-negative bacteria. Tazobactam is a beta-lactamase inhibitor that works by inhibiting the bacterial enzymes (beta-lactamases) that typically degrade beta-lactam antibiotics like Ceftriaxone. This combination enhances Ceftriaxone's efficacy, especially against bacteria that produce beta-lactamase, thereby providing a wider coverage against resistant organisms.

Composition:

Each vial contains:

- Ceftriaxone Sodium: Equivalent to 250 mg of Ceftriaxone
- Tazobactam Sodium: Equivalent to 31.25 mg of Tazobactam

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

Indications:

Ceftriaxone + Tazobactam 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 + 125 mg of Tazobactam once or twice daily, based on the infection severity.
- For severe infections, the dose may be increased up to 4 g of Ceftriaxone + 500 mg of Tazobactam per day, divided into 1 or 2 doses.

Children (under 12 years or < 50 kg):

- Usual dose: 20–80 mg/kg/day of Ceftriaxone + 2.5–10 mg/kg/day of Tazobactam, divided into 2 doses, depending on infection severity.

Neonates (≤ 14 days):

- 20–50 mg/kg/day of Ceftriaxone + 2.5–6.25 mg/kg/day of Tazobactam, given as a single dose.

Reconstitution:

1. Reconstitute the vial with sterile water for injection or normal saline, as per the manufacturer's guidelines.
2. Shake gently until the powder is fully dissolved.
3. Use the reconstituted solution immediately for optimal 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 larger doses, administer over a period of 30 minutes to 1 hour.

Contraindications:

- Hypersensitivity to Ceftriaxone, Tazobactam, or any excipient in the formulation.
- Neonates with hyperbilirubinemia or those who need calcium-containing IV solutions.
- Severe liver dysfunction or a history of cholestatic jaundice due to Ceftriaxone therapy.

Warnings and Precautions:

- **Hypersensitivity reactions:** Cross-sensitivity with penicillins may occur.
- **Neonates:** Do not administer to neonates with hyperbilirubinemia, and avoid co-administration with calcium-containing solutions due to the risk of precipitation.
- **Superinfection:** Prolonged use may lead to secondary infections like *Clostridioides difficile*-associated diarrhea.
- **Renal or hepatic impairment:** Dose adjustments may be needed for patients with renal or hepatic dysfunction.
- **Blood disorders:** Prolonged therapy may lead to thrombocytopenia, liver enzyme elevation, or other hematologic changes.

Side Effects:

- **Common:** Pain at the injection site, nausea, rash, diarrhea, 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.

Storage:

- Store the unopened vial at room temperature (below 25°C).
- After reconstitution, use the solution immediately or store according to the manufacturer's instructions, typically refrigerated at 2–8°C, and discard after 24 hours.
- Keep the vial tightly closed and out of reach of children.

Note:

Ceftriaxone + Tazobactam is a prescription-only medication and should be administered by healthcare professionals. Complete the prescribed course of therapy to avoid resistance. If any severe reactions occur (e.g., difficulty breathing, swelling, severe rash), seek immediate medical attention.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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