

# Fritcet TZ 1.125 Injection

**Product Information: Ceftriaxone Sodium I.P. 1000 mg + Tazobactam Sodium I.P. 125 mg Injection**

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## Composition

- Ceftriaxone Sodium I.P.: 1000 mg
- Tazobactam Sodium I.P.: 125 mg
- Formulation Type: Sterile powder for reconstitution for intravenous (IV) or intramuscular (IM) use.

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## Pharmacological Class

- Class: Cephalosporin antibiotic (Ceftriaxone) + Beta-lactamase Inhibitor (Tazobactam).
- Mechanism of Action:
  - Ceftriaxone: A third-generation cephalosporin that works by inhibiting bacterial cell wall synthesis, leading to cell lysis and death. It has a broad spectrum of activity against both Gram-positive and Gram-negative bacteria.
  - Tazobactam: A beta-lactamase inhibitor that protects ceftriaxone from bacterial enzymes (beta-lactamases) that would otherwise inactivate it, thus extending the antibiotic's spectrum against beta-lactamase-producing bacteria.

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## Indications

This combination is used for the treatment of a wide variety of severe bacterial infections, including:

1. Lower Respiratory Tract Infections: Pneumonia, including community-acquired and hospital-acquired pneumonia.
2. Urinary Tract Infections (UTIs): Including pyelonephritis and complicated UTIs.
3. Intra-abdominal Infections: Peritonitis, abdominal abscesses, and other abdominal infections.
4. Skin and Soft Tissue Infections: Complicated skin infections, including diabetic foot infections.
5. Bacteremia (Septicemia): Bloodstream infections.
6. Gynecological Infections: Pelvic inflammatory disease, endometritis.
7. Bone and Joint Infections: Including osteomyelitis.
8. Meningitis: Bacterial meningitis caused by susceptible organisms.
9. Febrile Neutropenia: Used as empiric therapy in neutropenic patients at high risk of infection.

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## Dosage and Administration

- Adults:
  - For most infections: 1 g of Ceftriaxone + 125 mg of Tazobactam every 12 hours, administered by IV infusion or IM injection.
  - Severe infections or higher-risk patients: Dosage may be increased to 2 g of Ceftriaxone + 250 mg of Tazobactam every 12 hours.

- **Pediatric Patients ( $\geq 3$  months):**
  - 20-50 mg/kg of Ceftriaxone and 2.5-6.25 mg/kg of Tazobactam every 12 hours (max: 2 g of Ceftriaxone per dose).
  - Neonates: Special dosage adjustments required for premature and full-term infants.
- **Route of Administration:**
  - Intravenous (IV): Reconstitute the powder with sterile water for injection. For IV infusion, dilute further with 0.9% sodium chloride or 5% dextrose. Administer as an IV infusion over 30 minutes.
  - Intramuscular (IM): Reconstitute and inject slowly into a large muscle mass.
  - For both routes, the reconstituted solution must be used immediately or stored as per guidelines (usually within 6 hours at room temperature).

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## Contraindications

- Hypersensitivity to Ceftriaxone, Tazobactam, or any other cephalosporin antibiotics.
- Neonates ( $\leq 28$  days) who require calcium treatment due to the risk of precipitates forming between ceftriaxone and calcium-containing solutions.
- Patients with a history of severe allergic reactions (e.g., anaphylaxis) to penicillins or other beta-lactam antibiotics.

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## Warnings and Precautions

1. **Hypersensitivity Reactions:** Anaphylaxis, rash, and other allergic reactions can occur. Exercise caution in patients with a

- history of penicillin or cephalosporin allergy.
2. **Clostridium difficile-associated Diarrhea:** Monitor for signs of diarrhea or colitis; if symptoms occur, discontinue treatment and consider alternative therapy.
  3. **Renal Impairment:** Dose adjustments are necessary in patients with renal insufficiency.
  4. **Biliary Sludge and Cholelithiasis:** Ceftriaxone can precipitate biliary sludge, especially in high doses or prolonged therapy.
  5. **Superinfection:** Prolonged use may lead to fungal or bacterial superinfections.
  6. **Severe Diarrhea:** May occur as a side effect; discontinue treatment if severe.

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## Adverse Effects

- **Common:**
  - Local reactions (pain, swelling, or irritation at the injection site), fever, rash, diarrhea, nausea, and headache.
- **Serious:**
  - Allergic reactions (including anaphylaxis), hematologic issues (thrombocytopenia, eosinophilia, leukopenia), liver enzyme elevation, and renal dysfunction.
  - Biliary Sludge: Ceftriaxone use in high doses or for prolonged periods can cause biliary sludge, particularly in pediatric patients.

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## Drug Interactions

- **Calcium-containing solutions:** Ceftriaxone should not be mixed or simultaneously infused with calcium-containing IV solutions (e.g., Ringer's,

Hartmann's), especially in neonates, due to risk of precipitation.

- **Probenecid:** Increases Ceftriaxone levels by inhibiting renal excretion, possibly leading to increased side effects.
- **Other Antibiotics:** Use cautiously when combined with other antibiotics, as it may lead to antagonistic or synergistic effects.

- Supplied in single-dose vials containing 1000 mg Ceftriaxone and 125 mg Tazobactam as a sterile powder.
- Available in packs of 1 vial or multiples for hospital use.

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### Storage Instructions

- Store below 25°C (room temperature).
- Protect from moisture and light.
- After reconstitution, the solution should be used immediately or stored under appropriate conditions (usually 6 hours at room temperature).
- Do not freeze the reconstituted solution.

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### Clinical Benefits

- **Broad-spectrum coverage:** Effective against a wide range of bacterial infections, including resistant strains.
- **Enhanced Efficacy:** The addition of Tazobactam expands the efficacy of Ceftriaxone against beta-lactamase-producing bacteria, improving outcomes in complicated infections.
- **Empiric Therapy:** Useful in hospitalized patients, especially those with multiple or severe infections.
- **Well-tolerated:** Most patients tolerate the combination well, with manageable side effects when used appropriately.

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**Ceftriaxone Sodium I.P. 1000 mg + Tazobactam Sodium I.P. 125 mg Injection** is a potent and broad-spectrum antibiotic combination designed to treat a variety of severe bacterial infections. It is particularly effective for managing complicated infections and is used in hospital settings under the supervision of a healthcare professional.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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### Packaging