

Fritcet 500 Injection

Ceftriaxone (500 mg) Injection

Description:

Ceftriaxone is a third-generation cephalosporin antibiotic with a broad spectrum of activity against both gram-positive and gram-negative bacteria. It is commonly used to treat a variety of severe infections, particularly those that require quick therapeutic intervention. Ceftriaxone is effective in treating bacterial infections of the respiratory, urinary, and other systems, and is also used for surgical prophylaxis.

Composition:

Each vial contains:

- Ceftriaxone Sodium: Equivalent to 500 mg of Ceftriaxone

Reconstitution solvent: (Sterile water for injection or lidocaine solution, depending on the method of administration)

Indications:

Ceftriaxone injection is indicated for the treatment of:

- Lower respiratory tract infections (e.g., pneumonia, bronchitis)
 - Urinary tract infections (UTIs)
 - Skin and soft tissue infections
 - Bone and joint infections
 - Intra-abdominal infections
 - Bacterial septicemia
 - Meningitis
 - Gonorrhea
 - Typhoid fever
 - Surgical prophylaxis
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Dosage and Administration:

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

- Usual dose: 1-2 g once daily or as directed by the physician.
- For severe infections: Doses may be increased up to 4 g per day, divided into 1 or 2 doses.

Children (under 12 years or < 50 kg):

- Usual dose: 20–80 mg/kg/day as a single dose or divided into two doses, depending on infection severity.

Neonates (≤ 14 days):

- 20–50 mg/kg/day as a single dose.

Reconstitution:

1. Reconstitute the powder with sterile water for injection or as per the manufacturer's guidelines.
2. Shake the vial gently until the powder is fully dissolved.
3. Use the reconstituted solution promptly for optimal efficacy.

Route of Administration:

- IM injection: Inject deep into a large muscle (e.g., gluteus), if reconstituted with lidocaine.
 - IV injection: Administer the solution slowly over 2-4 minutes.
 - IV infusion: For higher doses, administer over a period of 30 minutes.
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Contraindications:

- **Known hypersensitivity to Ceftriaxone, cephalosporins, or any excipient in the formulation.**
 - **Neonates with hyperbilirubinemia or those receiving calcium-containing IV solutions.**
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Warnings and Precautions:

- **Hypersensitivity reactions: Cross-sensitivity with penicillins may occur.**
 - **Superinfection risk: Extended use may lead to the growth of resistant organisms, such as *Clostridioides difficile*, leading to pseudomembranous colitis.**
 - **Neonates: Avoid the use of Ceftriaxone in neonates with hyperbilirubinemia, and never co-administer with calcium-containing IV fluids due to the risk of precipitation.**
 - **Renal or hepatic impairment: Adjust doses in patients with impaired renal or liver function.**
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Side Effects:

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

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

Note:

Ceftriaxone is a prescription-only medication and should be administered by healthcare professionals. Complete the prescribed course of therapy to ensure effective treatment and prevent 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:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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