

CEFTRADOT-TZ

Ceftriaxone and Tazobactam for Dry Injection (Veterinary Use)

Description

Ceftriaxone and Tazobactam for Injection is a sterile dry powder combination formulated for parenteral use in veterinary species. The product contains Ceftriaxone, a third-generation cephalosporin with broad-spectrum bactericidal activity, and Tazobactam, a β -lactamase inhibitor that protects Ceftriaxone from enzymatic degradation.

The formulation is designed for **once-daily dosing** and provides effective therapy against both Gram-positive and Gram-negative organisms, including β -lactamase producing strains.

After reconstitution with sterile water, the solution is administered via intramuscular or intravenous injection in animals. It is used in livestock and companion animals for a wide range of bacterial infections.

Specifications

- **Dosage Form:** Sterile lyophilized powder for injection
- **Appearance (Dry):** White to off-white crystalline powder
- **Appearance (After Reconstitution):** Clear to slightly opalescent solution
- **pH of Reconstituted Solution:** 6.0 to 8.0 (typically)
- **Sterility:** Must comply with pharmacopeial sterility tests
- **Bacterial Endotoxins:** Within pharmacopeial limits
- **Assay (Active Content):** 90–110% of labelled claim
- **Moisture Content:** Within specified pharmacopeial limits
- **Container Closure System:** Type I glass vial sealed with rubber stopper and aluminium cap
- **Packaging Integrity:** Must maintain sterility and prevent contamination under storage conditions

Composition

Each vial contains:

- **Ceftriaxone Sodium U.S.P.**, equivalent to **Ceftriaxone**: 3.0 gm or 4.0 gm
- **Tazobactam Sodium U.S.P.**, equivalent to **Tazobactam**: 375 mg or 500 mg
- **Excipients**: q.s. (bulking agents, stabilizers, buffers as required)
- **Sterile Water for Injection**: Supplied in a separate ampoule or vial for reconstitution

Pharmacological Category

- **Therapeutic Class**: Antimicrobial agent
- **Drug Class**: β -lactam antibiotic (cephalosporin) + β -lactamase inhibitor
- **Mechanism of Action**:
 - **Ceftriaxone**: Inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins
 - **Tazobactam**: Inhibits β -lactamase enzymes, preventing the inactivation of Ceftriaxone

Indications (Veterinary Use)

Indicated for use in animals (large and small) for the treatment of infections caused by susceptible bacteria, including:

- Respiratory tract infections
- Urinary tract infections
- Skin and soft tissue infections
- Mastitis, metritis, and reproductive tract infections
- Post-operative and post-parturient infections
- Septicaemia
- Gastrointestinal tract infections

Applicable for species such as: cattle, buffalo, sheep, goats, pigs, dogs, and cats.

Dosage and Route of Administration

Route:

- Intramuscular (I.M.)
- Intravenous (I.V.)

Dosage Guidelines:

- **Large Animals (e.g., cattle, buffalo):** 20–30 mg/kg body weight once daily
- **Small Animals (e.g., dogs, cats):** 25–50 mg/kg body weight once daily

Duration of Treatment: 3–5 days or as advised by a registered veterinary practitioner

Reconstitution: Use the entire contents of sterile water ampoule to dissolve the powder immediately before use.

Presentation / Product Form

- **Form:** Sterile dry powder for injection
- **Pack Sizes:**
 - 3.375 gm vial (Ceftriaxone 3 gm + Tazobactam 375 mg)
 - 4.5 gm vial (Ceftriaxone 4 gm + Tazobactam 500 mg)
- **Each pack contains:**
 - 1 vial of sterile powder
 - 1 ampoule/vial of sterile water for reconstitution

Key Advantages

- Broad-spectrum antibacterial activity
- Effective against β -lactamase producing organisms
- Once-daily dosing improves compliance
- Rapid onset with high tissue penetration
- Can be used in both companion and food-producing animals
- Supports faster clinical recovery in severe infections

Adverse Effects

- Local reactions: Pain, redness, swelling at injection site
- Allergic responses: Rash, hypersensitivity, anaphylaxis (rare)
- Gastrointestinal effects: Vomiting, diarrhoea (especially in small animals)
- Prolonged use may affect liver or kidney function (monitor in long-term cases)

Precautions and Contraindications

- Do not use in animals with known allergy to cephalosporins or penicillin's
- Use with caution in animals with impaired kidney or liver function
- Avoid concurrent administration with calcium-containing IV fluids
- Not for prophylactic use unless explicitly indicated by a veterinarian
- Use only under prescription and supervision of a registered veterinarian

Withdrawal Period

- **Meat:** 28 days after last administration
- **Milk:** 7 days after last administration

Ensure full compliance with local withdrawal period regulations for food-producing animals.

Storage and Handling

- Store below 25°C in a dry place, away from light and moisture
- Do not freeze
- Use immediately after reconstitution
- Discard unused reconstituted solution
- Handle using aseptic precautions

Schedule / Regulatory Classification

- **Prescription Drug – Veterinary**
- Schedule H1 / equivalent (varies by country)
- For use only by or on the order of a licensed veterinary practitioner

HS Code / HSN Code

- **HS Code (International):** 3004.20 – Antibiotics for retail
- **HSN Code (India):** 3004.20.90 – Other antibiotic formulations

Special Instructions

- Reconstitute using only the sterile water provided
- Use culture and sensitivity data where possible before initiating therapy
- Complete the full course as prescribed to avoid resistance
- Do not reuse partially used vials
- Follow all local regulations on antibiotic stewardship and veterinary medicine use
- Dispose of used containers and medical waste responsibly

Frequently Asked Questions (FAQs)

Q1: What is U.S.P.?

A: United States Pharmacopeia – an official standard-setting authority for drug quality and purity.

Q2: Why is Tazobactam combined with Ceftriaxone?

A: Tazobactam inhibits β -lactamase enzymes that can degrade Ceftriaxone, enhancing the drug's spectrum and efficacy.

Q3: Can it be used in lactating animals?

A: Yes, but only under veterinary advice. Observe milk withdrawal periods strictly.

Q4: Can this formulation be used in all animals?

A: It is formulated for use in commonly treated veterinary species like cattle, sheep, goats, dogs, and cats. Avoid extra-label use without veterinary prescription.

Q5: What if the animal shows an allergic reaction?

A: Stop treatment immediately and administer appropriate antihistamines or corticosteroids as directed by a veterinarian.

Q6: Can the reconstituted solution be stored?

A: No. It must be used immediately after preparation unless otherwise stated by the manufacturer.

Q7: What is the purpose of the withdrawal period?

A: To ensure that animal-derived food products (milk, meat) are free of drug residues, protecting public health.