

# DOTFAR-TZ

## Ceftiofur Sodium + Tazobactam Sodium Dry Injection For Veterinary Use

### Description

This injectable veterinary formulation combines **Ceftiofur Sodium**, a third-generation cephalosporin antibiotic, with **Tazobactam Sodium**, a potent  $\beta$ -lactamase inhibitor.

Ceftiofur acts by inhibiting bacterial cell wall synthesis, leading to bactericidal activity against a broad spectrum of pathogens. Tazobactam enhances efficacy by inhibiting  $\beta$ -lactamase enzymes produced by resistant bacteria, thus extending the antimicrobial spectrum.

This combination is used to treat serious bacterial infections in animals where  $\beta$ -lactamase producing pathogens are involved.

### Specifications

- **Dosage Form:** Sterile lyophilized powder for injection
- **Appearance (Dry Powder):** White to off-white crystalline powder
- **Appearance (Reconstituted Solution):** Clear to slightly opalescent solution
- **pH (Reconstituted Solution):** 5.5 – 7.0
- **Sterility:** Complies with veterinary pharmacopeial standards
- **Assay:** 90% – 110% of labelled content for both active ingredients
- **Container:** Type I glass vial with rubber stopper and aluminium seal

### Composition

Each vial contains:

- **Ceftiofur Sodium U.S.P.** – 1 gm
- **Tazobactam Sodium U.S.P.** – 125 mg
- **Excipients:** q.s.
- **Sterile Water for Injection:** Supplied separately for reconstitution

## Pharmacological Category

- **Therapeutic Class:** Antibiotic +  $\beta$ -lactamase inhibitor combination
- **Mechanism of Action:**  
Ceftiofur inhibits bacterial cell wall synthesis, while Tazobactam blocks  $\beta$ -lactamase enzymes, protecting Ceftiofur from enzymatic degradation and broadening the antibacterial spectrum.

## Indications (Veterinary Use)

Indicated for the treatment of infections caused by  $\beta$ -lactamase producing and susceptible bacteria in:

- Respiratory tract infections in cattle, swine, and other livestock
- Mastitis and metritis in cattle
- Urinary tract infections
- Skin and soft tissue infections
- Septicaemia and systemic infections

## Dosage and Route of Administration

### **Route:**

- Intramuscular (I.M.) or Subcutaneous (S.C.) injection

### **Dosage:**

- Cattle: 1 mg/kg body weight once daily or as prescribed
- Swine and other animals: Dose adjusted based on veterinary guidance
- Duration: Typically 3–5 days depending on infection severity

### **Reconstitution:**

- Reconstitute with the sterile water supplied immediately prior to use
- Use aseptic technique and administer promptly

## Dosage Form and Presentation

- Sterile dry powder for injection
- Vial size: 1.125 gm (1 gm Ceftiofur + 125 mg Tazobactam)
- Pack includes sterile water ampoule for reconstitution

## **Key Advantages**

- Broad-spectrum cephalosporin with  $\beta$ -lactamase inhibitor protection
- Effective against resistant bacteria producing  $\beta$ -lactamase enzymes
- Rapid bactericidal action
- Suitable for diverse veterinary infections
- Convenient single-dose formulation

## **Adverse Effects**

- Local injection site reactions (swelling, pain)
- Allergic reactions (rare)
- Gastrointestinal upset in sensitive animals (rare)

## **Precautions and Contraindications**

- Contraindicated in animals with known hypersensitivity to cephalosporins or  $\beta$ -lactam antibiotics
- Use cautiously in animals with renal impairment
- Avoid intravenous administration unless specifically directed
- Strictly follow veterinary prescription
- Observe withdrawal periods carefully

## **Withdrawal Period**

- **Meat:** Minimum 7 days
- **Milk:** Minimum 3 days

Withdrawal times may vary by jurisdiction and should comply with local regulatory requirements.

## **Storage and Handling**

- Store below 25°C in a dry, protected place
- Protect from light and moisture
- Do not freeze
- Use immediately after reconstitution
- Dispose of unused product responsibly

## **Schedule / Regulatory Classification**

- Prescription-only veterinary medicine
- Regulated under Schedule H or local equivalents
- Not intended for human use

## **HS Code / HSN Code**

- **HS Code (International):** 3004.90 – Medicaments for veterinary use
- **HSN Code (India):** 3004.90.99 – Veterinary antibiotic combinations

## **Special Instructions**

- Use aseptic technique for preparation and injection
- Complete full course to avoid resistance development
- Do not mix with other drugs unless compatibility is confirmed
- Monitor animals for any adverse reactions

## **Frequently Asked Questions (FAQs)**

### **Q1: What is the role of Tazobactam in this combination?**

A: Tazobactam inhibits  $\beta$ -lactamase enzymes, protecting Ceftiofur from degradation and enhancing antibacterial spectrum.

### **Q2: Can this combination treat resistant bacterial infections?**

A: Yes, it is effective against many  $\beta$ -lactamase producing resistant bacteria.

### **Q3: Is this safe for all animal species?**

A: It is generally safe but must be used under veterinary supervision with species-specific dosing.

### **Q4: How soon after reconstitution should it be used?**

A: Immediately, to maintain sterility and effectiveness.

### **Q5: What is the withdrawal period for milk?**

A: Minimum 3 days, but always check local regulations.