

DOTCEF-S - 4.5

Cefoperazone and Sulbactam for Dry Injection (Veterinary Use)

Description

Cefoperazone and Sulbactam for Injection is a sterile, lyophilized powder for veterinary parenteral use. It combines **Cefoperazone**, a broad-spectrum third-generation cephalosporin antibiotic, with **Sulbactam**, a β -lactamase inhibitor that enhances Cefoperazone's effectiveness against resistant bacterial strains.

This 2:1 ratio (3 gm Cefoperazone + 1.5 gm Sulbactam) offers synergistic action, targeting both β -lactamase-producing and non-producing Gram-positive and Gram-negative pathogens. Ideal for severe systemic infections in food-producing and companion animals.

Specifications

- **Dosage Form:** Sterile lyophilized powder for injection
- **Appearance (Dry Powder):** White to pale yellow crystalline powder
- **Appearance (After Reconstitution):** Clear to slightly yellowish solution
- **pH of Reconstituted Solution:** Approx. 5.0 – 7.0
- **Sterility:** Must comply with USP sterility test
- **Bacterial Endotoxins:** NMT (Not More Than) allowable USP limits
- **Assay (Cefoperazone and Sulbactam):** 90%–110% of label claim
- **Moisture Content:** NMT 6% (USP limits)
- **Reconstitution Time:** < 3 minutes in sterile water
- **Container Closure:** Type I USP vial, rubber stopper, aluminium seal

Composition

Each 4.5 gm vial contains:

- **Cefoperazone Sodium U.S.P.**, equivalent to **Cefoperazone** – 3.0 gm
- **Sulbactam Sodium U.S.P.**, equivalent to **Sulbactam** – 1.5 gm
- **Excipients** – q.s. (to ensure solubility and stability)
- **Sterile Water for Injection** – Included in the pack for reconstitution

Pharmacological Category

- **Antibacterial Agent – Cephalosporin + β -lactamase Inhibitor**
- **Cefoperazone:** Inhibits bacterial cell wall synthesis (bactericidal)
- **Sulbactam:** Inhibits β -lactamase enzymes, preventing drug degradation
- **Activity:** Broad-spectrum (Gram-positive, Gram-negative, anaerobes)

Indications (Veterinary Use)

Used in animals for treatment of bacterial infections including:

- Respiratory infections (pneumonia, bronchitis)
- Urinary tract infections
- Peritonitis and septicaemia
- Post-operative infections
- Mastitis, metritis
- Gastrointestinal infections
- Wound, skin, and soft tissue infections

Recommended for use in:

Cattle, Buffalo, Sheep, Goats, Pigs, Dogs, and Cats

Dosage and Route of Administration

Route:

- Intramuscular (I.M.) or
- Intravenous (I.V.) after reconstitution

Dosage (General Guidance):

- **Large Animals:** 20–30 mg/kg body weight once or twice daily
 - **Small Animals:** 25–50 mg/kg body weight once or twice daily
- Treatment Duration:** Typically 3–7 days depending on infection severity and species
Note: Adjust based on clinical response and veterinary guidance

Dosage Form and Presentation

- **Form:** Sterile Dry Powder for Injection
- **Pack Size:** 4.5 gm vial (3 gm Cefoperazone + 1.5 gm Sulbactam)
- **Contents:**
 - 1 Vial of dry powder
 - 1 Ampoule or Vial of Sterile Water for Injection (free)

Key Advantages

- Effective against β -lactamase producing bacteria
- Rapid clinical recovery in resistant or severe infections
- Excellent tissue and body fluid penetration
- Suitable for once or twice daily dosing
- Can be used in various animal species

Adverse Effects

- Local site irritation or pain
- Allergic reactions: rash, urticaria, anaphylaxis (rare)
- Gastrointestinal effects: vomiting, diarrhoea
- Transient liver enzyme elevation (rare)

Precautions & Contraindications

- Contraindicated in animals allergic to cephalosporins or penicillin's
- Use cautiously in renal or hepatic compromised animals
- Avoid mixing with calcium-containing solutions (I.V. use)
- Not intended for prophylactic use
- For veterinary use only – under prescription

Withdrawal Period

- **Meat:** 28 days
- **Milk:** 7 days

Strictly observe local regulations regarding drug residues in food-producing animals.

Storage and Handling

- Store below 25°C, in a dry, dark place
- Protect from moisture and direct sunlight
- Do not freeze
- Reconstitute just before administration
- Use immediately after mixing
- Discard any unused reconstituted solution safely

Schedule / Regulatory Classification

- **Prescription Only Medicine (Veterinary)**
- Regulated under **Schedule H1** or equivalent (depending on country)
- Must be sold by licensed retailers and used under veterinary supervision

HS Code / HSN Code

- **HS Code:** 3004.20 (Antibiotic preparations for retail sale)
- **HSN Code (India):** 3004.20.90 (Other antibiotics)
Note: Classification may vary depending on country and packaging.

Special Instructions

- Use full prescribed dose and duration to avoid bacterial resistance
- Do not split or reuse vials
- Ensure aseptic preparation and administration
- Store reconstitution water separately if ampoule is opened
- Use only as directed by a qualified veterinary professional

? Frequently Asked Questions (FAQs)

Q1: What is U.S.P.?

A: United States Pharmacopeia – the official quality standard for pharmaceutical substances.

Q2: Why combine Cefoperazone with Sulbactam?

A: Sulbactam inhibits β -lactamase enzymes, which destroy Cefoperazone. The combination improves efficacy against resistant strains.

Q3: Is this safe for pregnant or lactating animals?

A: Use only under strict veterinary guidance. Observe withdrawal periods for milk.

Q4: Can I use the reconstituted solution later?

A: No. Use immediately after reconstitution. Do not store.

Q5: Is this safe for all animal types?

A: Indicated for major livestock and companion animals. Use only in species and dosages recommended by a veterinarian.

Q6: What happens in case of overdose?

A: Discontinue use immediately and seek veterinary care. Overdose may cause gastrointestinal or neurological signs in some species.

