

ACEDOT-SP

ACECLOFENAC I.P. 300 MG + PARACETAMOL I.P. 1500 MG VETERINARY BOLUS

DESCRIPTION

This veterinary bolus combines **Aceclofenac I.P. (300 mg)**, a non-steroidal anti-inflammatory drug (NSAID), with **Paracetamol I.P. (1500 mg)**, an analgesic-antipyretic. The formulation is designed for large animals to provide **dual-action relief** from **pain, inflammation, and fever**, particularly in conditions like musculoskeletal injuries, mastitis, pneumonia, and post-surgical recovery.

SPECIFICATION

Composition per bolus:

- **Aceclofenac I.P.** – 300 mg
- **Paracetamol I.P.** – 1500 mg
- **Excipients** – q.s.

Excipients may include:

Microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium stearate, lactose, and film-coating agents, all I.P.-grade and suitable for veterinary use.

Dosage Form:

Solid Oral Veterinary Bolus

Appearance:

Oblong, white or off-white bolus; smooth surface; may be embossed or coated.

CATEGORY

Pharmacological Class:

- Aceclofenac: Non-Steroidal Anti-Inflammatory Drug (NSAID)
- Paracetamol: Antipyretic and Analgesic

Therapeutic Class:

- Antipyretic
- Analgesic
- Anti-inflammatory

INDICATIONS

Indicated for:

- **Fever (Pyrexia)** of bacterial or viral origin
- **Pain relief** in musculoskeletal disorders (lameness, joint swelling)
- **Inflammatory conditions** such as mastitis, metritis, or pneumonia
- **Post-surgical recovery** (dehorning, castration, etc.)
- Supportive therapy in infectious diseases with inflammation or fever

Suitable for **cattle, buffalo, sheep, goats, and other large ruminants** under veterinary guidance.

PRESENTATION

- **Dosage Form:** Veterinary Oral Bolus
- **Pack Size:** 10 × 4 (40 boluses per box; 4 boluses per strip)
- **Outer Box:** Printed laminated carton with product info and storage conditions
- **Target Species:** Cattle, Buffalo, Large Ruminants

DOSAGE & ROUTE OF ADMINISTRATION

Route: Oral

Recommended Dosage:

- **Large animals (Cattle, Buffalo):** 1 bolus twice daily for 2–3 days, or as directed by the veterinarian
- **Small ruminants (Sheep, Goat):** Dosage adjusted based on body weight
- Administer whole bolus using a bolus applicator or manually

ADVANTAGES

- **Fast-acting pain relief** and **anti-inflammatory action**
- Reduces **fever**, swelling, and general discomfort
- Improves **feed intake**, mobility, and recovery speed
- Combines **two synergistic actives** for broader therapeutic coverage
- Fewer side effects compared to standalone NSAIDs

ADVERSE EFFECTS

Usually well tolerated. Possible rare side effects include:

- Gastrointestinal irritation or ulceration (especially with prolonged use)
- Reduced appetite or lethargy
- Hypersensitivity reactions (rash, swelling)
- Renal stress in dehydrated animals (use with caution)

PRECAUTIONS

- Use with caution in **animals with liver or kidney disorders**
- Avoid concurrent administration with other NSAIDs or corticosteroids
- Ensure animals are **hydrated** before and during treatment
- **Do not exceed the recommended dose**
- Not recommended for **pregnant or lactating animals** without veterinary supervision

WITHDRAWAL PERIOD

- **Meat:** Minimum **7 days** after last dose
- **Milk:** Minimum **3 days**
(Confirm based on local veterinary regulations)

Maintain proper treatment records and observe full withdrawal periods to ensure food safety compliance.

STORAGE CONDITIONS

- Store in a **cool, dry place**, below **30°C**
- Keep away from **direct sunlight, heat, and moisture**
- Keep out of reach of children and non-target species
- Do not use after the expiry date mentioned on the label

HANDLING INSTRUCTIONS

- Use gloves during administration
- Wash hands thoroughly after use
- Do not break or crush the bolus/ Dispose of unused bolus as per local veterinary waste management guidelines

SCHEDULE & REGULATORY CLASSIFICATION

- **Schedule H** equivalent (Prescription-only veterinary product)
- Regulated under the **Drugs and Cosmetics Act, India**, or respective country's veterinary authority
- To be used only under the supervision of a **registered veterinarian**

HS & HSN CODES

- **HS Code (International):** 3004.90 – Medicaments for veterinary use
- **HSN Code (India):** 30049099 – Other veterinary medicaments not elsewhere classified

HUMAN VS. VETERINARY APPLICATION

Veterinary Use Only

- Dosage and excipients tailored for **ruminant physiology**
- **Not intended for human use** under any condition
- Human exposure may lead to incorrect dosing, liver stress, or allergic reactions

SPECIAL INSTRUCTIONS

- Always administer under veterinary direction
- Do not repeat treatment cycles without reassessment
- Ensure animals are eating and hydrated before treatment
- Combine with antibiotics or antiparasitic drugs if indicated for infection

? FREQUENTLY ASKED QUESTIONS (FAQ)

Q: What is the role of Aceclofenac in this bolus?

A: Aceclofenac is an **NSAID** used to relieve **inflammation and pain** in animals, particularly in joint, muscular, or post-surgical conditions.

Q: What does Paracetamol do in veterinary use?

A: Paracetamol is a **fast-acting antipyretic (fever reducer)** and **mild analgesic**, enhancing the comfort and healing process.

Q: Can this bolus be used in pregnant animals?

A: Avoid use in pregnant or lactating animals unless absolutely necessary and prescribed by a veterinarian.

Q: How soon does it act?

A: Onset of action is typically within **1–2 hours**, with peak relief in **4–6 hours** post-administration.

Q: Can this be given along with antibiotics?

A: Yes — it is often prescribed alongside antibiotics to manage **fever and inflammation** during bacterial infections.

Q: Is this bolus safe for long-term use?

A: No — it is intended for **short-term symptomatic relief**. Prolonged use may risk GI irritation or renal stress.

