

DOTMEC-R

Ivermectin IP 0.1% w/v + Rafoxanide IP 3.0% w/v Oral Suspension

For Veterinary Use Only

Description

A broad-spectrum veterinary oral suspension combining **Ivermectin** and **Rafoxanide**, designed for effective control of internal parasites (nematodes, flukes) and certain ectoparasites in livestock.

Ivermectin is a macrocyclic lactone with systemic antiparasitic activity against gastrointestinal and pulmonary nematodes, and some external parasites.

Rafoxanide is a salicylamide anthelmintic especially effective against liver flukes (*Fasciola* spp.), blood-feeding nematodes, and some ectoparasites.

This combination offers synergistic action against **mixed parasitic infections** in animals like cattle, buffaloes, sheep, and goats.

Specification

- **Composition per mL:**
 - Ivermectin IP — 0.1% w/v (1 mg/mL)
 - Rafoxanide IP — 3.0% w/v (30 mg/mL)
 - Excipients — q.s. to 1 mL
- **Appearance:**
Homogenous, milky or slightly coloured suspension. Must be shaken well before administration.
- **Formulation Type:**
Ready-to-use oral suspension
- **pH Range:**
Typically formulated between 4.5 to 6.5 for stability and efficacy
- **Preservatives (if applicable):**
IP-compliant antimicrobial preservatives may be included depending on formulation and shelf life requirement
- **Packaging:**
HDPE bottles with tamper-evident caps; available in 1 Litre and 100 mL sizes
- **Shelf Life:**
24 months from the date of manufacture, under prescribed storage conditions

Pharmacological Category

Anthelmintic / Antiparasitic agent — Combination of macrocyclic lactone (Ivermectin) and salicylamide (Rafoxanide)

Indications

Indicated for the **treatment and control** of mixed parasitic infestations in:

- Cattle
- Buffaloes
- Sheep
- Goats

Effective against:

- Gastrointestinal nematodes (roundworms)
- Liver flukes (immature and mature stages of *Fasciola hepatica* and *Fasciola gigantica*)
- Lungworms (*Dictyocaulus* spp.)
- Blood-feeding parasites
- Limited efficacy against ectoparasites (depending on parasite type and species)

Dosage and Route of Administration

- **Route:** Oral (by mouth)
- **Recommended Dosage:**
 - Cattle & Buffaloes: **1 mL per 6 kg** body weight
 - Sheep & Goats: **1 mL per 4 kg** body weight
 - Or as advised by a registered veterinary practitioner
- **Dosing Frequency:**

Single dose typically effective. Repeat in 4–6 weeks for heavy fluke infestations, under veterinary advice
- **Instructions:**

Shake bottle thoroughly before use to ensure uniform suspension

✔ Advantages

- Broad-spectrum activity against nematodes and flukes
- Convenient oral dosage form; no injection stress
- Reduces overall parasite burden and improves animal productivity
- Single-dose efficacy in most cases
- Economical combination therapy

⚠ Adverse Effects

- Mild, self-limiting gastrointestinal disturbances (e.g. soft phecex)
- Hypersensitivity or allergic reactions (rare)
- Signs of neurotoxicity (e.g. tremors, incoordination) if overdosed
- Do not exceed recommended dose

🛡 Precautions

- Use only as prescribed by a qualified veterinarian
- Do not administer to severely debilitated or unthrifty animals
- Not for human use — veterinary use only
- Not to be used in animals producing milk for human consumption unless permitted under specific withdrawal guidelines
- Do not mix with other veterinary medicinal products unless advised
- Ensure proper body weight estimation before dosing
- Shake well before each use

🕒 Withdrawal Period

- **Meat and Offal:** Minimum **28 days** post last dose (may vary by local regulation)
- **Milk:** Not to be used in lactating animals producing milk for human consumption unless specifically allowed

Storage and Handling

- Store below 30 °C in a cool, dry place
- Protect from light and direct sunlight
- Do not freeze
- Keep container tightly closed after each use
- Keep out of reach of children and unauthorized personnel
- Dispose of empty containers and expired products responsibly

Regulatory Classification / Schedule

- Prescription Veterinary Drug
- **Schedule H (India)** or equivalent regulatory class under local laws
- Not for sale without the prescription of a registered veterinary practitioner
- For veterinary use only — **strictly not for human use**

HS Code & HSN Code

- **HS Code (International): 3004.90** – Medicaments (excluding antibiotics) containing two or more constituents
- **HSN Code (India): 3004.90.99** – Veterinary medicinal products, others

Note: Classification may vary under latest customs/tariff guidelines. Confirm with local authorities for export/import purposes.

Special Instructions

- Weigh animals accurately to avoid under or over-dosing
- Administer orally only — not for injectable use
- Shake well before each use
- Do not mix with other medications without consulting a veterinarian
- Follow local environmental and waste management laws when disposing of unused product or empty containers
- Keep product label and leaflet for reference throughout use

? Frequently Asked Questions (FAQs)

Q: What is Ivermectin and what does it treat?

A: Ivermectin is a macrocyclic lactone that treats internal parasites such as gastrointestinal roundworms and lungworms. It also has limited activity against certain ectoparasites.

Q: What is Rafoxanide used for?

A: Rafoxanide is a salicylamide anthelmintic effective against liver flukes (*Fasciola* spp.) and blood-feeding parasites in ruminants.

Q: Can this product be given to lactating animals?

A: Not unless approved by regulatory authority and the milk is not intended for human consumption during the withdrawal period.

Q: Can the suspension be mixed with feed or water?

A: No. It must be administered directly into the mouth using appropriate dosing equipment.

Q: What if I accidentally overdose the animal?

A: Contact a veterinarian immediately. Overdose can cause neurological symptoms such as tremors, ataxia, and possibly toxicity.

Q: Can I use this in animals other than cattle, sheep, goats, or buffaloes?

A: No. Use only in species listed on the label or as directed by a veterinarian.

Q: How should the product be stored?

A: Store below 30 °C, protect from sunlight, and do not freeze. Shake well before use.

Q: Can I use this product repeatedly?

A: Repeated use without veterinary advice can lead to resistance. Use only when indicated.

