

ATRIZOLE DRENCH

(Albendazole, Ivermectin, Triclabendazole)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ATRIZOLE DRENCH

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:

Albendazole.....10gm

Ivermectin.....0.2gm

Triclabendazole.....12gm

3. PHARMACEUTICAL FORM

Oral Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Calves, sheep and goats.

4.2. Indications for use specifying the target species

Atrizole Drench is indicated for the broad-spectrum treatment and control of internal parasites in livestock, including:

- Gastrointestinal roundworms (Haemonchus spp, Ostertagia spp, Trichostrongylus spp, etc.)
- Lungworms (Dictyocaulus viviparous, Dictyocaulus filaria)
- Liver flukes (Fasciola hepatica, Fasciola gigantica)
- Tapeworms (Moniezia spp.)
- Ectoparasites like mites,lice and **Nasal bots** (all stages): Oestrus ovis (due to Ivermectin)

4.3. Contraindications

Do not use in case of known hypersensitivity to the active substance and/or any of the excipients.

4.4. Special warnings for each target species

Extra-label use in dogs should be avoided as severe adverse reactions may occur. In common with other avermectins, certain breeds of dogs, such as Collies are especially sensitive to ivermectin and particular care should be taken to avoid accidental consumption of the product.

4.5. Special precautions for use

Special precautions for use in animals

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing which may be due to underestimation of bodyweight, misadministration of the product or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Teladorsagia (Ostertagia) circumcincta* in sheep and increasing resistance to triclabendazole has been reported in *Fasciola* species in small ruminants in a number of countries including the EU. Therefore, the use of this product should be based upon local (regional, farm) epidemiological information about susceptibility of the *Teladorsagia (Ostertagia) circumcincta* and trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions to be taken by the person administering the product to animals:

People with known hypersensitivity to the active substances or to the excipients should avoid contact with the product. Direct contact with the skin should be kept to a minimum. Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product. In case of accidental spillage onto skin or into the eyes wash immediately with water. Take off any contaminated clothes. Do not eat, drink or smoke whilst handling the product. Wash hands and exposed skin before meals and after work.

Special precautions for the protection of the environment:

Ivermectin is very toxic to aquatic organisms and dung insects

4.6. Adverse reactions (frequency and seriousness)

Not Known

4.7. Use during pregnancy and lactation or lay

Pregnancy and Lactation:

Atrizole Drench should not be used in the first 45 days of pregnancy in cattle and sheep.
- Safe for use during lactation, but ensure withdrawal periods are observed. Use only according to the risk/benefit assessment by the responsible veterinarian.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

No Data Available.

4.9. Dosage and administration route

For oral use.

-**Cattle:** 1 mL per 10 kg body weight (equivalent to 10 mg Albendazole, 0.2 mg Ivermectin, and 12 mg triclabendazole per kg body weight).

- **Sheep and Goats:** 1 mL per 10 kg body weight.

To ensure a correct dosage, body weight should be determined as accurately as possible. The product is for oral administration using a suitably calibrated dosing gun. The container should be shaken thoroughly before use. Drenching equipment should be cleaned before and after use.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

The timing for treatment should be based on epidemiological factors and should be customized for each individual farm. As with other anthelmintic, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

Dosing Table:

Animal Weight	Dose of the product
20 – 25 kg	2-2.5 ml
26 – 30 kg	3 ml
31 – 35 kg	3.5 ml
36 – 40 kg	4 ml
41 – 50 kg	5 ml
51 – 60 kg	6 ml
61 – 70 kg	7 ml
71 – 80 kg	8 ml
81 – 90 kg	9 ml
91 – 100 kg	10 ml

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

-Overdose may lead to signs of toxicity such as tremors, ataxia, and lethargy.

- In case of overdose, seek veterinary advice immediately. Supportive treatment should be provided.

4.11. Withdrawal period:

Meat and offal: 56 days.

Milk:3 days.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: **QP 54AA51**

5.1. Pharmacodynamics properties

Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes and arthropods, followed by paralysis and death.

Triclabendazole interferes with intracellular transport mechanisms and inhibits protein synthesis and is active against the liver fluke *Fasciola*.

Albendazole exerts its anthelmintic effect by binding to parasitic beta-tubulin, inhibiting microtubule polymerization, which disrupts cell division and glucose uptake in susceptible helminths. This leads to parasite immobilization and death.

5.2. Pharmacokinetic information

Ivermectin is readily absorbed and reaches peak plasma concentrations within 19.7 hours, post administration. Afterwards plasma concentrations decrease with a half-life of 51.4 hours.

Triclabendazole is readily absorbed, oxidized to Triclabendazole sulfoxide and to triclabendazole sulfone. Peak plasma concentrations of triclabendazole sulfoxide and triclabendazole sulfone are reached at 20.6 and 36.3 hours, post administration. Afterwards, plasma concentrations decrease with half-lives of triclabendazole sulfoxide and triclabendazole sulfone of 25.5 and 34.8 hours, respectively. Both metabolites bind strongly to plasma proteins, particularly albumin. More than 90% of the dose is excreted in the faeces, about 2% in the urine and less than 1% in the milk within 10 days.

The inter-individual variability of the kinetics of Ivermectin and metabolites of triclabendazole in ovine species is high.

Albendazole is poorly absorbed orally in animals (<5%), but absorption is enhanced with a fatty meal.

It undergoes rapid hepatic metabolism, primarily to albendazole sulfoxide (the main active metabolite), and is excreted mainly in feces.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

6.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the container: use immediately in 28 days, do not store.

6.3 Special precautions for storage

Store below 25°C

Protect from light and moisture

Protect from frost

Shake well before use

Keep out of the reach of children

To be used as directed by the registered veterinary practitioner only

6.4 Nature and composition of primary conditioning

The product is available in the following pack sizes:

50ml, 100ml, 200ml, 250ml, 500ml & 1000ml

Container and Closure: White high-density polyethylene (HDPE) containers with a polypropylene cap and an aluminium foil seal.

- 7. MARKETING AUTHORISATION HOLDER**
Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.
- 8. MARKETING AUTHORISATION NUMBER**
Reg. No.: 118563
- 9. DATE OF FIRST AUTHORISATION**
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17-02-2025

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