

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tramazole 100 mg/ml oral suspension.

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains 100 mg of albendazole

**3. PACKAGE SIZE**

1.0 L  
2.5 L  
5.0 L  
10.0 L

**4. TARGET SPECIES**

Cattle and sheep

**5. INDICATIONS**

The veterinary medicinal product is a broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The veterinary medicinal product is also ovicidal against fluke and roundworm eggs, thus reducing pasture contamination

In cattle the veterinary medicinal product is active against the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Oesophagostomum*, *Bunostomum*, *Cooperia* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia*,

Lungworms: *Dictyocaulus viviparus*,

Tapeworms: *Moniezia* spp.,

Adult liver fluke: *Fasciola hepatica*

In sheep, the veterinary medicinal product is active against benzimidazole-susceptible strains of the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, (including *N. battus*), *Chabertia* and *Oesophagostomum*.

It is usually effective against inhibited larvae of *Ostertagia*.

Lungworms: *Dictyocaulus filaria*,

Tapeworms: *Moniezia* spp.,

Adult liver fluke: *Fasciola hepatic*

## 6. ROUTES OF ADMINISTRATION

For oral administration only

One ml contains 100mg albendazole. Shake the container well before use.

### **Cattle:**

Worm dose: 7.5 mg albendazole per kg bodyweight. (3.75 ml per 50 kg bodyweight)

Fluke and Worm Dose: 10 mg albendazole per kg bodyweight (5 ml per 50 kg bodyweight)

### **Sheep:**

Worm Dose: 5 mg albendazole per kg bodyweight. (1 ml per 20 kg bodyweight)

Fluke and Worm Dose: 7.5 mg albendazole per kg bodyweight.  
(1.5 ml per 20 kg bodyweight)

## 7. WITHDRAWAL PERIODS

Cattle:

Meat and offal: 14 days.

Milk: 60 hours.

Sheep:

Meat and offal: 4 days.

Do not use in sheep producing milk for human consumption.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

## 9. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.  
Protect from light.

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Tulivin Laboratories Ltd

**14. MARKETING AUTHORISATION NUMBERS**

Vm 11810/4011

**15. BATCH NUMBER**

Lot {number}

**A. PACKAGE LEAFLET**

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Tramazole 100 mg/ml oral suspension for cattle and sheep

**2. Composition**

<b>Active Substance:</b>	<b>mg/ml</b>
Albendazole	100

**Excipients:**

Methyl parahydroxybenzoate	2 mg/ml
Propyl parahydroxybenzoate	0.2 mg/ml
Green S (142)	0.018 mg/ml

A pale blue aqueous suspension.

**3. Target species**

Cattle and sheep.

**4. Indications for use**

The veterinary medicinal product is a broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworm eggs, thus reducing pasture contamination.

In cattle the veterinary medicinal product is active against the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Oesophagostomum*, *Bunostomum*, *Cooperia* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia*,

Lungworms: *Dictyocaulus viviparus*,

Tapeworms: *Moniezia* spp.,

Adult liver fluke: *Fasciola hepatica*

In sheep, the veterinary medicinal product is active against benzimidazole-susceptible strains of the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, (including *N. battus*), *Chabertia* and *Oesophagostomum*.

It is usually effective against inhibited larvae of *Ostertagia*.

Lungworms: *Dictyocaulus filaria*,

Tapeworms: *Moniezia* spp.,

Adult liver fluke: *Fasciola hepatic*

## 5. Contraindications

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

## 6. Special warnings

Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after infection.

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 belonging to another pharmacological class and having a different mode of action should be used.

Resistance to benzimidazoles (which includes albendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including the EU. Resistance to albendazole has been reported in *Cooperia* and *Teladorsagia* species in cattle in developed countries such as New Zealand. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

### Special precautions for safe use in the target species:

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep. Not to be diluted or mixed with other products. Avoid the introduction of contamination during use. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk dosing programmes should be discussed with your veterinary surgeon.

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

- This veterinary medicinal product can cause skin and eye irritation.
- Personal protective equipment consisting of suitable protective clothing, including impermeable rubber gloves, should be worn when handling the veterinary medicinal product.

- In case of accidental spillage onto skin, wash the affected area with soap and water. If irritation persists seek medical advice immediately and show the package leaflet or the label to the physician.
- In case of accidental eye exposure, flush eye thoroughly with running water. If irritation persists seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

#### Pregnancy:

Do not dose ewes at the “fluke and worm” dose rate, (7.5 mg/kg) during tupping or for 1 month after removing the rams.

#### Lactation:

Can be safely used during lactation.

#### Fertility:

The use in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance

### **7. Adverse events**

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

### **8. Dosage for each species, routes and method of administration**

For oral administration only, using properly calibrated dosing equipment.  
One ml contains 100mg albendazole.

#### **Cattle:**

Worm dose: 7.5 mg albendazole per kg bodyweight. (7.5 ml per 100 kg bodyweight)

Fluke and Worm Dose: 10 mg albendazole per kg bodyweight (10 ml per 100 kg bodyweight)

**Sheep:**

Worm Dose: 5 mg albendazole per kg bodyweight. (1 ml per 20 kg bodyweight)

Fluke and Worm Dose: 7.5 mg albendazole per kg bodyweight.  
(1.5 ml per 20 kg bodyweight)

**9. Advice on correct administration**

Shake container well before use.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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 over-dosing.

**10. Withdrawal period**

**Cattle:**

Meat and offal: 14 days.

Milk: 60 hours.

**Sheep:**

Meat and offal: 4 days.

Do not use in sheep producing milk for human consumption.

**11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

**12. Special precautions for the disposal**

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as albendazole may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or used containers.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

### **14. Marketing authorisation numbers and pack sizes**

Vm 11810/4011

Pack sizes: 1, 2.5, 5 and 10L

Not all pack sizes may be marketed.

### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Tulivin Laboratories Ltd  
35 Abbeydale Park  
Newtonards  
Co. Down  
BT23 8RE  
Northern Ireland

Manufacturer responsible for batch release:

Univet Ltd.  
Tullyvin  
Cootehill  
Co. Cavan  
Ireland

### **17. other information**

POM-VPS

Approved 04 December 2025  
*Gavin Hall*