

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Tramazole 100 mg/ml oral suspension for cattle and sheep.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

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

#### **Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
Methyl parahydroxybenzoate	2 mg/ml
Propyl parahydroxybenzoate	0.2 mg/ml
Green S (142)	0.018 mg/ml
Citric acid monohydrate	
Sodium citrate	
Xanthan gum	
Povidone 90	
Polysorbate 20	
Propylene glycol	
Simethicone emulsion	
Purified water	

A pale blue aqueous suspension.

### **3. CLINICAL INFORMATION**

#### **3.1 Target Species**

Cattle and sheep.

#### **3.2 Indications for use for each target species**

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 hepatica*

### 3.3 Contraindications

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

### 3.4 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.

### **3.5 Special precautions for use**

#### 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.

#### Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system.

See the package leaflet for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

#### Pregnancy:

Do not dose ewes at the “fluke and worm” dose rate, (7.5 mg/kg) during tuppung 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

### **3.8 Interaction with other medicinal products and other forms of interaction**

None known.

### **3.9 Administration routes and dosage**

For oral administration only using properly calibrated dosing equipment. To ensure administration of a correct dose, bodyweight should be determined as accurately as

possible; accuracy of the dosing device should be checked. 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.

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

**Cattle:**

Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs,

Dosage: 7.5 mg albendazole per kg bodyweight.

(7.5 ml per 100 kg bodyweight)

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.

Dosage: 10 mg albendazole per kg bodyweight.

(10 ml per 100 kg bodyweight)

**Sheep:**

Worm Dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs,

Dosage: 5 mg albendazole per kg bodyweight.

(1 ml per 20 kg bodyweight)

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.

Dosage: 7.5 mg albendazole per kg bodyweight.

(1.5 ml per 20 kg bodyweight)

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

Do not exceed the stated dose.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 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.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATC vet code: QP52AC11**

### **4.2 Pharmacodynamics**

Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in the absence of microtubules in the intestinal cells of the nematode, with the result that these cells cannot absorb nutrients, thus causing a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, resulting in the

preferential toxicity of albendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

### **4.3 Pharmacokinetics**

Albendazole has poor water solubility and limited absorption from the gastrointestinal tract (about 50% of the oral dose is absorbed in cattle). Following absorption, there is rapid first pass metabolism in the liver and the sulphide moiety of albendazole is oxidised to the pharmacologically active sulphoxide, then to the sulphone, followed by deacetylation of the carbamate group to form the 2-aminosulphone.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

## **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

## **5.3 Special precautions for storage**

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

## **5.4 Nature and composition of immediate packaging**

1 litre, 2.5 litre or 5 litre white high density polyethylene rigid containers closed with a polypropylene screw cap lined with a wood pulp liner coated with a polyvinylidene chloride film.

or

10 litre white high density polyethylene rigid containers closed with a polyethylene screw cap

Not all pack sizes may be marketed.

## **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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 national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Tulivin Laboratories Ltd

## **7. MARKETING AUTHORISATION NUMBER**

Vm 11810/4011

## **8. DATE OF FIRST AUTHORISATION**

18 February 2016

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

September 2025

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT**

Veterinary medicinal product subject to prescription.

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

Approved 04 December 2025

*Gavin Hall*