

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

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

Tramazole 2.5% w/v SC oral suspension for cattle and sheep

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

|                          |              |
|--------------------------|--------------|
| <b>Active Substance:</b> | <b>% w/v</b> |
| Albendazole              | 2.5          |

#### **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> |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Green S (E142)                                                      | 0.018 % w/v                                                                                                                    |
| Methyl parahydroxybenzoate                                          | 0.2 % w/v                                                                                                                      |
| Propyl parahydroxybenzoate                                          | 0.02 % w/v                                                                                                                     |
| Sodium Selenite<br>(equivalent to Selenium                          | 0.09<br>0.027)                                                                                                                 |
| Cobalt Sulfate<br>(equivalent to Cobalt                             | 0.301<br>0.063)                                                                                                                |
| Citric Acid                                                         |                                                                                                                                |
| Sodium Citrate                                                      |                                                                                                                                |
| Xanthan Gum                                                         |                                                                                                                                |
| Povidone K90                                                        |                                                                                                                                |
| Polysorbate 20                                                      |                                                                                                                                |
| Propylene Glycol                                                    |                                                                                                                                |
| Simethicone Emulsion                                                |                                                                                                                                |
| Water Purified                                                      |                                                                                                                                |

Oral suspension.  
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 product is also ovicidal against fluke and roundworm eggs.

In cattle the 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*

The veterinary medicinal product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

#### 3.3 Contraindications

Do not use in cases 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.

Selenium bioavailability is enhanced in lambs receiving ionophores, so concurrent treatment will increase the risk of toxicity.

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. The product should only be used in areas where Cobalt and Selenium deficiencies are known to occur. If in doubt, consult a veterinary surgeon.

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

Avoid direct contact with the veterinary medicinal product.  
Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product.  
In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical advice and show the package leaflet or the label to the physician.

In the event of accidental skin exposure, wash the affected area with soap and water. If irritation persists, seek medical advice 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 and lactation:

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.  
Can be safely used during lactation. 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**

Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon.

### **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. One ml contains 25mg 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.

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

*Dosage:* 10 mg albendazole per kg bodyweight.

**Sheep:**

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

*Dosage:* 5 mg albendazole per 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.

| <b>Sheep</b> |                     |                            | <b>Cattle</b> |                       |                           |
|--------------|---------------------|----------------------------|---------------|-----------------------|---------------------------|
| Bodyweight   | Worm Dose (5 mg/kg) | Fluke and worm (7.5 mg/kg) | Bodyweight    | Worm Dose (7.5 mg/kg) | Fluke and worm (10 mg/kg) |
| Up to 10 kg  | 2 ml                | 3 ml                       | 50 kg         | 15 ml                 | 20 ml                     |
| 11 – 20 kg   | 4 ml                | 6 ml                       | 100 kg        | 30 ml                 | 40 ml                     |
| 21 – 30 kg   | 6 ml                | 9 ml                       | 150 kg        | 45 ml                 | 60 ml                     |
| 31 – 40 kg   | 8 ml                | 12 ml                      | 200 kg        | 60 ml                 | 80 ml                     |
| 41 – 50 kg   | 10 ml               | 15 ml                      | 250 kg        | 75 ml                 | 100 ml                    |
| 51 – 60 kg   | 12 ml               | 18 ml                      | 300 kg        | 90 ml                 | 120 ml                    |

*Cattle over 300 kg: administer a further 15 or 20 ml for each additional 50 kg bodyweight.*

*Sheep over 60 kg: administer a further 2 or 3 ml for each additional 10 kg bodyweight.*

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

No effects at recommended usage. Treatment is symptomatic.

**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**

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.

#### **5. PHARMACEUTICAL PARTICULARS**

##### **5.1 Major incompatibilities**

None known.

##### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

##### **5.3 Special precautions for storage**

No special precautions for storage.

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

1, 2.5, 5 and 10 litre high density polyethylene jerricans with polypropylene closure (screw-fit) with polyethylene faced steran wads.

1, 2.5, 5 and 10 litre high density polyethylene flexi containers with high density polyethylene closures (screw-fit) with expanded polyethylene liners.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 11810/4007

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

23 August 1996

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

July 2026

### **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).

*Gavin Hall*

Approved: 13 August 2026