1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramazole 25 mg/ml oral suspension for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Albendazole 25 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorophyll WS 1 (E141)	3.0 mg
Methyl parahydroxybenzoate (E218)	2.0 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Citric Acid Monohydrate	
Sodium Citrate	
Xanthan Gum	
Povidone 90	
Polysorbate 20	
Propylene Glycol	
Simethicone Emulsion	
Purified Water	

A pale green-coloured 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 worm eggs.

In cattle it 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 it 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 *Ostergia.*
Lungworms: *Dictyocaulus filaria,*
Tapeworms: *Moniezia* spp.,
Adult Liver Fluke: *Fasciola hepatica.*

The veterinary medicinal product is ovicidal and will kill fluke and worm 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.
Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not to be diluted or mixed with other products. Avoid the introduction of contamination during use.
Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep.

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

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. 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 fertility:

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.
The use of the veterinary medicinal product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

Lactation:
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
The use of suitably calibrated measuring equipment is recommended.
Shake the container before use. To ensure a correct dosage, body weight should be determined as accurately as possible.

Cattle:
Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and worm eggs.
Dosage: Approximately 7.5 mg albendazole per kg bodyweight (15 ml per 50 kg bodyweight).

Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle. Dosage: Approximately 10 mg albendazole per kg bodyweight (20 ml per 50 kg bodyweight).

Sheep:
Worm dose: For the control of roundworms, lungworms, tapeworms, fluke and worm eggs. Dosage: Approximately 5 mg albendazole per kg bodyweight (2 ml per 10 kg bodyweight).

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep. Dosage: Approximately 7.5 mg albendazole per kg bodyweight (3 ml per 10 kg bodyweight).

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

Not applicable.

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.
Not authorised for use in sheep producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC11

4.2 Pharmacodynamics

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

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

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

5.4 Nature and composition of immediate packaging

1 Litre, 2.5 Litre and 5 Litre white, high density polyethylene containers with screw caps.
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 or household waste.

Do not contaminate ponds, waterways or ditches with the product or used containers. Dispose of used containers safely.

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

Univet Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/038/001

8. DATE OF FIRST AUTHORISATION

09/01/2004

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

18/05/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).