

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramazole 10% Oral Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Albendazole 10% w/v

Excipients

Green S E142 0.0018% w/v

Propyl Parahydroxybenzoate E216 0.02 % w/v

Methyl Parahydroxybenzoate E218 0.2 % w/v

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

Tramazole 10% 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 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 Ostertagia.

Lungworms: Dictyocaulus filaria,

Tapeworms: Moniezia spp.

Adult Liver Fluke: Fasciola hepatica.

Tramazole 10% is ovicidal and will kill fluke and worm eggs, thus reducing pasture contamination.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Not for use in sheep producing milk for human consumption.

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.

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep.

4.5 Special precautions for use

Special precautions for use in animals

Not to be diluted or mixed with other products. Avoid the introduction of contamination during use.

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not dose ewes at the 'fluke and worm' dose rate, (7.5 mg/kg), during tugging or for 1 month after removing the rams. Tramazole 10% can be safely used during lactation.

The use of Tramazole 10% in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration using properly calibrated dosing equipment. Shake the container before use. Estimate bodyweight accurately.

Cattle:

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

Dosage: Approximately 7.5 mg albendazole per kg bodyweight.
(7.5 ml Tramazole 10% per 100 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.
(10 ml Tramazole 10% per 100 kg bodyweight)

Sheep:

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

Dosage: Approximately 5 mg albendazole per kg bodyweight.
(1 ml Tramazole 10% per 20 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.
(1.5 ml Tramazole 10% per 20 kg bodyweight)

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

Not applicable.

4.11 Withdrawal Period(s)

Animals intended for human consumption should not be slaughtered during treatment.

Cattle must not be slaughtered for human consumption until 14 days after the last treatment.

Sheep must not be slaughtered for human consumption until 4 days after the last treatment.

Milk intended for human consumption may be taken from cows only from 60 hours after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, albendazole.

ATCvet code: QP52AC11

5.1 Pharmacodynamic properties

Tramazole 10% 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 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 fumurate reductase system of helminths and impair energy production.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate

Propyl Parahydroxybenzoate

Citric Acid Monohydrate

Sodium Citrate

Green S E142

Xanthan Gum

Povidone 90

Polysorbate 20

Propylene Glycol

Simethicone Emulsion

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

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

7 MARKETING AUTHORISATION HOLDER

Univet Ltd.,
Tullyvin,
Cootehill,
Co. Cavan.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10990/038/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th January 2009

10 DATE OF REVISION OF THE TEXT

19th May 2010