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

Active Substance	**mg/ml**
Albendazole	100
Excipients	
Methyl Parahydroxybenzoate	2
Propyl Parahydroxybenzoate	0.2
Green S (142)	0.018
Other relevant constituents	
Sodium Selenite Pentahydrate	3.6
(equivalent to Selenium	1.08
Cobalt Sulphate Heptahydrate	12.052
(equivalent to Cobalt	2.52

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Suspension
A pale blue aqueous suspension

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep

4.2 Indications for use, specifying the target species

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 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 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*

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

This 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 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.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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 Tramazole 10% 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 Tramazole 10% 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 Tramazole 10% 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 Tramazole 10% per 20 kg bodyweight)

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

Do not exceed the stated dose.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelminthic

ATC vet code: QP52AC11

5.1 Pharmacodynamic properties

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 furmarate reductase system of helminths and impair energy production.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Green S E142
Sodium Selenite Pentahydrate
Cobalt sulphate Heptahydrate
Citric Acid Monohydrate
Sodium Citrate
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene Glycol
Simethicone Emulsion
Purified Water

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements**.**

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 11810/4011

9. DATE OF FIRST AUTHORISATION

18 February 2016

10. DATE OF REVISION OF THE TEXT

May 2024

Gavin Hall
Approved: 15 May 2024