SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramazole 2.5% w/v SC Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	**% w/v**
Albendazole	2.5
Excipients	
Chlorophyllin Copper Complex Sodium (E141)	0.3
Methyl Parahydroxybenzoate	0.2
Propyl Parahydroxybenzoate	0.02
Other relevant constituents	
Sodium Selenite	0.09
(equivalent to Selenium	0.027)
Cobalt Sulfate	0.301
(equivalent to Cobalt	0.063)

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension.
A pale green-coloured 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.

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*

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

4.3 Contraindications

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

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 effective 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 pharmalogical 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

i. 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.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Wash hands after use.
Avoid direct contact with the product.
Wear suitable protective clothing including impermeable rubber gloves.
In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical attention.
In the event of accidental skin exposure, wash the effected area with soap and water. If irritation persists, seek medical attention.

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 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.

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 Amount(s) 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. 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.

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

No effects at recommended usage. Treatment is symptomatic.

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: Anthelmintic

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 properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorophyllin Copper Complex Sodium (E141)
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Selenite
Cobalt Sulfate
Citric Acid
Sodium Citrate
Xanthan Gum
Povidone K90
Polysorbate 20
Propylene Glycol
Simethicone Emulsion
Water Purified

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and composition of immediate packaging

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

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

Not all pack sizes may be marketed.

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

Any unused product of waste material should be disposed of in accordance with national 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
Co. Down
BT23 8RE
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 11810/4007

9. DATE OF FIRST AUTHORISATION

23 August 1996

10. DATE OF REVISION OF THE TEXT

June 2016

Approved: 02 June 2016