

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramazole 2.5% w/v SC Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of suspension contains 25 mg albendazole

Other substances: Selenium (as sodium selenite), cobalt (as cobalt sulfate), chlorophyllin copper complex sodium (E141), methyl parahydroxybenzoate, propyl parahydroxybenzoate.

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

1, 2.5, 5 and 10 litres

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only. Read the package leaflet before use. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. Shake well before use.

<i>Sheep</i>			<i>Cattle</i>		
Bodyweight	Worm Dose (5 mg/kg)	Fluke & Worm (7.5 mg/kg)	Bodyweight	Worm Dose (7.5 mg/kg)	Fluke & 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.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

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

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. 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 product should only be used in areas where Cobalt and Selenium deficiencies are known to occur. If in doubt, consult a veterinary surgeon. Do not administer cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon.

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 affected area with soap and water. If irritation persists, seek medical attention.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product or empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with the product or used containers.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

POM- VPS

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11810/4007

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tramazole 2.5% w/v SC Oral Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active Substance	% w/v
Albendazole	2.5

Excipients

Chlorophyllin Copper Complex Sodium (E141)	0.3
Methyl Parahydroxybenzoate	0.2
Propyl Parahydroxybenzoate	0.02
Sodium Selenite	0.09
(equivalent to Selenium)	0.027)
Cobalt Sulfate	0.301
(equivalent to Cobalt)	0.063)

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. 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

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions. Do not use after the expiry date which is stated on the label.

Keep out of reach and sight of children.

12. SPECIAL WARNING(S)

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.

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.

Use during 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.

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 affected area with soap and water. If irritation persists, seek medical attention.

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product or empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with the product or used containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

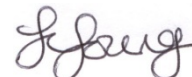
POM – VPS To be supplied only on veterinary prescription.

Vm 11810/4007

Selenium and cobalt are included on Tramazole 2.5% SC Oral Suspension as nutritional supplements and are not intended to be used therapeutically.

Pack sizes: 1, 2.5, 5 and 10 litres. Not all pack sizes may be marketed.

Approved: 04/01/2018

A handwritten signature in black ink, appearing to read 'J. J. J.', is positioned below the approval date.