MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Marketing Authorisation Holder:

Chanelle Pharmaceuticals Manufacturing Ltd.,

Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benzimole 25 mg/ml SC Oral Suspension

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

Oral suspension containing 25 mg/ml Albendazole, also contains Selenium and Cobalt

4. PHARMACEUTICAL FORM

Oral suspension

5. PACKAGE SIZE

1, 2.5, 5 and 10 litre

6. INDICATION(S)

FOR THE CONTROL OF ROUNDWORMS, LUNGWORMS, TAPEWORMS, ADULT LIVER FLUKE AND FLUKE AND ROUNDWORM EGGS.

Benzimole 25 mg/ml SC 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 sheep and cattle. The product is also ovicidal against fluke and roundworm eggs. The Selenium and cobalt in this product are trace elements of use as nutritional supplements.

In **sheep** it is active against benzimidazole- susceptible strains of the following species:

Roundworms: *Teladorsagisa (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*.

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*.

Benzimole 25 mg/ml SC is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

7. CONTRAINDICATIONS

Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cattle and sheep

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

SHAKE CONTAINER BEFORE USE. DO NOT MIX WITH OTHER PRODUCTS.

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. 1 ml of Benzimole 25 mg/ml SC contains 25_mg Albendazole. Each ml also contains 0.27 mg selenium (as sodium selenite]) and 0.63 mg cobalt (as cobalt sulphate).

Sheep: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs, 5 mg albendazole per kg bodyweight which is equivalent to 2.0 ml Benzimole 25 mg/ml SC per 10 kg bodyweight. For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep, 7.5 mg albendazole per kg bodyweight, which is equivalent to 3 ml Benzimole 25 mg/ml SC per 10 kg bodyweight.

Cattle: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs, 7.5 mg albendazole per kg bodyweight which is equivalent to 15 ml Benzimole 25 mg/ml SC per 50 kg bodyweight. For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle, 10 mg albendazole per kg bodyweight, which is equivalent to 20 ml Benzimole 25 mg/ml SC per 50 kg bodyweight.

11. ADVICE ON CORRECT ADMINISTRATION

DOSAGE GUIDE CATTLE

Bodyweight	Worm dose (7.5 mg/kg)	Fluke & worm (10 mg/kg)
50 kg	15 ml	20 ml
100 kg	30 ml	40 ml
150 kg	45 ml	60 ml
200 kg	60 ml	80 ml
250 kg	75 ml	100 ml
300 kg	90 ml	120 ml
350 kg	105 ml	140 ml
400 kg	120 ml	160 ml

Cattle over 400 kg - give a further 15 or 20 ml for each additional 50 kg bodyweight.

DOSAGE GUIDE SHEEP

Bodyweight	Worm dose (5 mg/kg)	Fluke & worm (7.5 mg/kg)
Up to 10 kg	2 ml	3 ml
11 - 20 kg	4 ml	6 ml
21 - 30 kg	6 ml	9 ml
31 - 40 kg	8 ml	12 ml
41 - 50 kg	10 ml	15 ml
51 - 60 kg	12 ml	18 ml
61 - 70 kg	14 ml	21 ml
71 - 80 kg	16 ml	24 ml

Sheep over 80 kg - give an additional 2 or 3 ml for each additional 10 kg bodyweight.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

12. WITHDRAWAL PERIOD

Cattle may be slaughtered for human consumption only after 14 days from the last treatment. Sheep may be slaughtered for human consumption only after 5 days from the last treatment.

Milk for human consumption may be taken from cows only after 60 hours from the last treatment. Do not use in sheep producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

14. SPECIAL WARNING(S)

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use. 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.

Do not dose ewes at the 'fluke and worm dose' (7.5 mg/kg) during tupping or for 1 month after removing the rams. Care must be taken not to damage the pharyngeal region, particularly in sheep, when dosing. Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon. Not to be diluted.

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 and extended period of time.

• Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any). To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon. Not to be diluted. 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, an 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 anthelminics.

15. EXPIRY DATE

DO NOT USE AFTER STATED EXPIRY DATE

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal products or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

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

POM-VPS

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

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4040

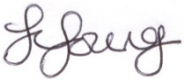
21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION

Selenium and cobalt are included in Benzimole 25 mg/ml SC as nutritional supplements and are not intended to be used therapeutically. Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of ionophores and Benzimole 25 mg/ml SC may therefore lead to an increased risk of selenium toxicity. The use of Benzimole 25 mg/ml SC in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance. Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment. The product should only be used in areas where deficiencies of selenium and cobalt are likely to occur. In cases of doubt, consult a veterinary surgeon.

1-BZ Albendazole belongs to the benzimidazole (1-BZ) class of anthelmintics.

Pack sizes 1 L, 2.5 L, 5 L and 10 L.

Not all pack sizes may be marketed.

Approved: 05/01/2018