

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

**Pack Label 1 L, 2.5 L, 5 L,
[There is no carton for the 1 L, 2.5 L, 5 L packs.
Package leaflet information will be printed on the immediate packaging]**

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Bimeda Animal Health Limited,
2, 3 & 4 Airtown Close,
Tallaght,
Dublin 24
Ireland

2. Name of the veterinary medicinal product

Ovidrench S & C 2.5% w/v Oral Suspension for Cattle and Sheep.

3. Statement of the active substance (s) and other ingredients

<u>Active substances:</u>	per ml
Albendazole	25 mg
<u>List of excipients:</u>	
Selenium (as sodium selenite)	0.27 mg
Cobalt (as cobalt sulfate)	0.624 mg
Copper Chlorophyll Complex Sodium (E141)	3 mg (colouring agent)
Methyl Parahydroxybenzoate (E218)	2 mg (preservative)
Propyl Parahydroxybenzoate (E216)	0.2 mg (preservative)

4. Pharmaceutical form

Oral Suspension.

5. Package size

1 L
2.5 L
5 L
10 L

6. Indication(s)

Ovidrench S & C 2.5% 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 roundworm eggs.

In **cattle** it is active against the following species:

Roundworms: *Teladorsagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Oesophagostomum*, *Bunostomum*, *Cooperia* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Teladorsagia*.

Lungworms: *Dictyocaulus viviparus*.

Tapeworms: *Moniezia* spp.

Adult liver fluke: *Fasciola hepatica*.

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

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

Roundworms: *Teladorsagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus* (including *N. battus*), *Chabertia* and *Oesophagostomum*. It is usually effective against inhibited larvae of *Teladorsagia*.

Lungworms: *Dictyocaulus filaria*.

Tapeworms: *Moniezia* spp.

Adult liver fluke: *Fasciola hepatica*

Ovidrench S & C 2.5% is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

7. Contraindications

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

8. Adverse reactions

None known.

9. Target species

Cattle and sheep.

10. 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 dosing device should be checked.
Shake the container before use.
Do not mix with other products.

CATTLE		
Bodyweight	Worm Dose (7.5 mg/kg)	Fluke & Worm Dose (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 400kg – give a further 15 ml (worm dose) or 20 ml (fluke and worm dose) for each additional 50 kg bodyweight.

SHEEP		
Bodyweight	Worm Dose (5.0 mg/kg)	Fluke & Worm Dose (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 a further 2 ml (worm dose) or 3 ml (fluke and worm dose) for each additional 10 kg bodyweight.

Cattle:

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

Dosage: 7.5 mg albendazole per kg bodyweight (0.3 ml/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 (0.4 ml/kg bodyweight).

Sheep:

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

Dosage: 5 mg albendazole per kg bodyweight (0.2 ml/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 (0.3 ml/kg bodyweight).

Administration with a suitable drenching gun is recommended.

11. Advice on correct administration

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

12. Withdrawal period(s)

Withdrawal period(s):

Cattle

Meat: 14 days.

Milk: 60 hours.

Sheep

Meat: 4 days.

Milk: Do not use in sheep producing milk for human consumption.

13. Special storage precautions

Do not store above 25°C

14. 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 dosing.

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 body weight, 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, 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. Resistance to albendazole has been reported in *Cooperia* and *Teladorsagia* species in cattle in 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. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.

Special precautions for use in animals:

Avoid the introduction of contamination during use.

The product should only be used in areas where deficiencies of cobalt and selenium are likely to occur. If in any doubt, seek the advice of a veterinary surgeon.

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

Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your veterinary surgeon. Not to be diluted.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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. Wash hands after use.

Pregnancy, lactation or lay:

The use of the product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

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.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Benzimidazoles have a wide safety margin.

Incompatibilities:

None known.

15. Special precautions for the disposal of unused product or waste materials, if any

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

16. Date on which the label was last approved

June 2023

17. Other information

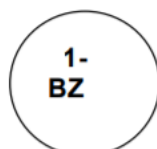
Available in 1 L, 2.5 L, 5 L and 10 L pack size.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Ireland

Bimeda Animal Health Limited,
2, 3 & 4 Airton Close,
Tallaght,
Dublin 24
Tel: + 353 (0) 1 4667900



18. The words “For animal treatment only” and conditions or restrictions regarding supply and use, if applicable

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. Expiry date

<EXP {month/year}>

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

21. Marketing authorisation number(s)

Vm 50146/4033

22. Manufacturer’s batch number

<Batch> <Lot>



Approved: 12 June 2023