

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

1L ,2.5L, 5 L and 10 L Label and Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovidrench S & C 10% w/v Oral Suspension for Cattle and Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Active substance: 100 mg albendazole

Other relevant constituents: 1.08 mg selenium (as sodium selenite)
2.5 mg cobalt (as cobalt sulfate)

Preservatives: 2 mg methyl parahydroxybenzoate (E218)
0.2 mg propyl parahydroxybenzoate (E216)

Colourant: 0.015 mg Acid Brilliant Green BS (E142)

3. PHARMACEUTICAL FORM

Oral suspension
Pale blue

4. PACKAGE SIZE

1L
2.5L
5 L
10L

Not all pack sizes may be marketed.

5. TARGET SPECIES

Broad spectrum wormer for Cattle and Sheep
[Picture of sheep and picture of cattle]

6. INDICATION(S)

Effective against: benzimidazole susceptible roundworms (including *Nematodirus*), lungworm, tapeworm, and adult liver fluke. Ovicidal against fluke and roundworm eggs. Also supplies trace elements selenium and cobalt of use as nutritional supplements.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION For oral administration only.

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

| Cattle | | |
|---|----------------------------------|---|
| Bodyweight | Worm Dose (7.5 mg/kg) | Fluke & Worm Dose (10 mg/kg) |
| 60kg | 4.5 | 6.0ml |
| 100 kg | 7.5 ml | 10.0 ml |
| 200 kg | 15.0 ml | 20.0 ml |
| 300 kg | 22.5 ml | 30.0 ml |
| 400kg | 30.0 ml | 40.0 ml |
| Cattle over 400 kg- give a further 3.75 ml (worm dose) or 5 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 10kg | 0.5 ml | 0.75 ml |
| 11-20 kg | 1.0 ml | 1.50 ml |
| 21-30 kg | 1.5 ml | 2.25 ml |
| 31-40 kg | 2.0ml | 3.00 ml |
| 41-50 kg | 2.5 ml | 3.75 ml |
| 51-60 kg | 3.0 ml | 4.50 ml |
| 61-70 kg | 3.5 ml | 5.25 ml |
| 71-80 kg | 4.0ml | 6.00ml |
| Sheep over 80 kg- give a further 0.5 ml (worm dose) or 0.75 ml (fluke and worm dose) for each additional 10 kg bodyweight. | | |

INSTRUCTIONS FOR USE WITH AUTOMATIC EQUIPMENT

Ovidrench S&C 10% w/v is readily administered through standard dosing equipment.

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

1. Shake the container.
2. Thread the strap through one of the holes at the base of the bottle and tie to the appropriate hole at the top of the bottle, to allow the bottle to be hung comfortably.

3. Remove the cap and replace with the nozzle provided.
4. The tube leading from the drench equipment should be attached firmly to the nozzle.
5. Hang the bottle upside down and gently prime the gun ready for use.
6. If the contents are not entirely used, the plain cap must be replaced to preserve the contents for further use.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

CATTLE:

meat: 14 days from the last treatment

milk: 60 hours from last treatment

SHEEP:

meat: 4 days from the last treatment

milk: Ovidrench S&C 10 % w/v must not be administered to lactating sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

General Precautions

Do not use in animals known to be hypersensitive to albendazole.

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. Ovidrench S&C 10 % w/v can be safely used during lactation.

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 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 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 anthelmintics.

To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

The product should only be used in areas where deficiencies of selenium and cobalt are likely to occur. If in doubt, consult your veterinary surgeon. Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your veterinary surgeon. Selenium and cobalt are included in Ovidrench S&C 10% w/v 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 Ovidrench S&C 10 % w/v may therefore lead to an increased risk of selenium toxicity.

The use of Ovidrench S&C 10 % w/v in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance. Do not dilute. Do not mix with other products. Avoid the introduction of contamination during use. Keep the container in the outer carton.

Operator Warnings

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 areas with soap and water. If irritation persists, seek medical attention. Wash hands after use.

Chemical group of anthelmintic: **1-BZ**

10. EXPIRY DATE

Use by end: <MM YYYY>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Shake the container before use.
Keep container in the outer carton.

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

Environmental warnings
DANGEROUS to fish and aquatic life.
Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

For animal treatment only.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4032

17. MANUFACTURER’S BATCH NUMBER

Batch

Lot

Approved: 24 July 2019

