

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovidown SC Oral Suspension for Sheep.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An aqueous oral suspension containing 5.0 % w/v oxfendazole, 0.369 % w/v cobalt (as cobalt sulphate heptahydrate), 0.11 % w/v selenium (as sodium selenate anhydrous) and 0.18 % w/v sodium methyl parahydroxy benzoate as preservative.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

500 ml, 1 litre, 2 litre, 2.5 litre, 4 litre and 5 litre

5. TARGET SPECIES

Sheep

6. INDICATION(S)

SHEEP WORM DRENCH

Controls mature and developing immature gastrointestinal roundworms and lungworms and also tapeworms in sheep.

Kills: Roundworms (Mature and Immature)

: Lungworms

: Tapeworms

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

The bodyweight of animals should be assessed as accurately as possible before calculating the dosage.

SHEEP: 5mg/kg bodyweight [1 ml per 10 kg (22 lb) bodyweight]

Bodyweight	Dose
Up to 10 kg (22 lb)	1.0 ml
11 to 20 kg (23 to 44 lb)	2.0 ml
21 to 30 kg (45 to 66 lb)	3.0 ml
31 to 40 kg (67 to 88 lb)	4.0 ml
41 to 50 kg (89 to 110 lb)	5.0 ml
51 to 60 kg (111 to 132 lb)	6.0 ml
61 to 70 kg (133 to 154 lb)	7.0 ml
71 to 80 kg (155 to 176 lb)	8.0 ml

Over 80 kg (over 176 lb) give a further 0.5 ml for each additional 5 kg (11 lb) bodyweight

Do not mix with other products.

8. WITHDRAWAL PERIOD

Animals should not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 21 days from the last treatment. Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not exceed the stated dose.

Shake well before use.

Chemical Group of Anthelmintics: 1-BZ

Operator Warnings: Avoid contact with the skin and eyes. Wash any splashes immediately with cold water. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

Further information: See carton text.

10. EXPIRY DATE

DOM: mm/yyyy

EXP: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

Protect from frost.

Keep container in outer carton.

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

Do not contaminate ponds, waterways or ditches with product or used containers. 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

POM-VPS

To be supplied only on veterinary prescription

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down,
BT35 6JP
Northern Ireland

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

On behalf of:

Downland Marketing Limited
15 Victoria Place
Carlisle
CA1 1EW

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm: 02000/4256

17. MANUFACTURER'S BATCH NUMBER

B.N.:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovidown SC Oral Suspension for Sheep.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An aqueous oral suspension containing 5.0 % w/v oxfendazole, 0.369 % w/v cobalt (as cobalt sulphate heptahydrate), 0.11 % w/v selenium (as sodium selenate anhydrous) and 0.18 % w/v sodium methyl parahydroxy benzoate as preservative.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

500 ml, 1 litre, 2 litre, 2.5 litre, 4 litre and 5 litre

5. TARGET SPECIES

Sheep

6. INDICATION(S)

A broad spectrum anthelmintic for the treatment and control of mature and developing immature gastro-intestinal roundworms, lungworms and also tapeworms in sheep. OVIDOWN SC is ovicidal for nematode eggs.

In sheep for the control of benzimidazole susceptible GASTROINTESTINAL ROUNDWORMS: *Ostertagia* spp, *Haemonchus* spp, *Trichostrongylus axei*, *Nematodirus* spp, including *N. battus*, *Cooperia* spp, intestinal *Trichostrongylus* spp, *Oesophagostomum* spp and *Chabertia* spp. Also provides useful control of *Trichuris* spp.

LUNGWORMS: *Dictyocaulus* spp

TAPEWORMS: *Moniezia* spp.

It is also effective against inhibited/arrested larvae of *Nematodirus* spp, *Haemonchus* spp and *Ostertagia* spp in sheep.

Selenium and cobalt act as nutritional supplements to aid in the prevention and control of selenium and cobalt deficiency and to improve performance of animals on selenium and cobalt deficient diets.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Sheep: 5.0 mg oxfendazole per kg bodyweight (1 ml OVIDOWN SC per 10 kg (22 lb) bodyweight).

Bodyweight	Dose No. of	Doses Per Pack
Up to 10 kg (22 lb)	1.0 ml	2000
11 to 20 kg (23 to 44 lb)	2.0 ml	1000
21 to 30 kg (45 to 66 lb)	3.0 ml	666
31 to 40 kg (67 to 88 lb)	4.0 ml	500
41 to 50 kg (89 to 110 lb)	5.0 ml	400
51 to 60 kg (111 to 132 lb)	6.0 ml	333
61 to 70 kg (133 to 154 lb)	7.0 ml	285
71 to 80 kg (155 to 176 lb)	8.0 ml	250

Sheep over 80 kg should be given a further 0.5 ml for each additional 5 kg (11 lb).

For oral administration only. Give the recommended dose by mouth using standard dosing equipment. Dosing may be repeated at required intervals.

Shake well before use.

Equipment should be thoroughly cleaned before and after dosing.

Do not mix with other products.

8. WITHDRAWAL PERIOD

Animals should not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 21 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

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.
- Under dosing, 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 oxfendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including the EU. 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

Do not use in sheep producing milk for human consumption.

Do not exceed the stated dose. For oral use only.

The bodyweight of animals should be assessed as accurately as possible before calculating the dose.

As with other anthelmintics veterinary advice should be sought: (a) on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing; (b) if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance may be present.

The product should only be used in areas where deficiencies of cobalt and selenium are likely to occur. If in doubt, veterinary advice should be sought. Do not administer other cobalt and selenium supplements unless specifically advised by your vet. Not to be diluted.

Operator Warnings: Avoid contact with the skin and eyes. Wash any splashes immediately with cold water. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

FURTHER INFORMATION

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

In case of lungworm infections coughing may persist for a considerable time following successful treatment. This is due to tissue damage caused by the parasites.

After treatment, animals should be moved to clean pasture in order to prevent re-infection. Where this is not done regular re-treatment may be necessary.

10. EXPIRY DATE

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11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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POM-VPS

To be supplied only on veterinary prescription

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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Approved: 04/08/2017

