

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovidown SC Oral Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s):	% w/v
Oxfendazole	5.0
Selenium	0.11
(as Sodium Selenate Anhydrous	0.264)
Cobalt	0.369
(as Cobalt Sulphate Heptahydrate	1.76)

Excipients:

Sodium Methyl Parahydroxy Benzoate	0.18
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For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Suspension
A pink suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for Use, specifying the target species

A broad spectrum anthelmintic for the treatment and control of mature and developing immature gastrointestinal roundworms, lungworms and also tapeworms in sheep. The product 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 effective against inhibited/arrested larvae of *Nematodirus* spp, *Haemonchus* spp and *Ostertagia* spp in sheep.

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

4.3 Contraindications

None

4.4 Special Warnings for each target species

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 *Trichostongylus* 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.

4.5 Special precautions for use

i. Special precautions for use in animals

For oral administration only

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

As with any husbandry procedure, care should be taken when handling the animals especially when inserting the dosing gun nozzle into the animal's mouth. Unnecessary force should not be used as this may cause damage to the mouth and pharyngeal region.

Shake container before use.

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

Do not exceed the recommended dosage.

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 effect, as other diseases, nutritional disturbances or anthelmintic resistance may be present.

- ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

4.6 Adverse reactions (frequency and seriousness)

None Known

4.7 Use during pregnancy, lactation and lay

Safe for use during pregnancy and lactation, when used at the recommended dose rate

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

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 per 10 kg (22 lb) bodyweight)

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

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. Do not mix with other products.

4.10 Overdose (symptoms, emergency procedures and antidotes), if necessary

Benzimidazoles have a wide margin of target species safety.

4.11 Withdrawal Period

Sheep (meat and offal): 21 days.

Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATCVet Code: QP52AC02

5.1 Pharmacodynamic properties

Oxfendazole, (methyl [5-phenylsulphinyl-1-H-benzimidazole-2 yl] carbamate), belongs to a class of compounds, the benzimidazoles.

Oxfendazole is believed to act by irreversibly inhibiting glucose uptake by the parasites resulting in depletion of the parasites energy sources, glycogen and ATP, and their consequent death and expulsion.

A relationship exists between plasma concentrations of active anthelmintic metabolites, the duration of high plasma metabolite concentrations and anthelmintic efficacy.

Oxfendazole is a sulfoxide identical to the sulfoxide metabolite of fenbendazole, both are known to be anthelmintically active and metabolically interconvertible.

Reduction of oxfendazole to fenbendazole occurs in the ruminal fluid while oxidation of fenbendazole to oxfendazole is carried out by hepatic microsomal enzymes in the liver. Much of fenbendazole's anthelmintic activity is attributed to oxfendazole, the latter being much more potent.

Cobalt has been recognised as a dietary essential for ruminants since the 1930's. It is peculiar as an essential trace element in ruminant nutrition in that it is stored in the body in limited amounts only and hence symptoms of deficiency can occur very rapidly. The effect of cobalt in the rumen is to participate in the production of vitamin B₁₂ (produced by ruminal micro-organisms) and compared to omnivores the requirement for vitamin B₁₂ is very much higher.

The biochemical role of selenium is as a component of the enzyme glutathione peroxidase (GSH-PX). The exact role of GSH-PX in mammalian cells is not fully understood but it is thought to act by protecting cells from oxidizing agents which are capable of irreversibly denaturing essential cellular proteins which leads to

degeneration and necrosis, resulting in muscular weakness and white muscle disease commonly associated with selenium deficiency. It is believed that a deficiency in selenium can cause a decrease in the humoral response of animals to vaccination and increase the susceptibility of animals to disease. The symptoms are most pronounced in young fast growing animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Parahydroxy Benzoate
Sodium Citrate Dihydrate
Citric Acid Anhydrous
Sodium Metabisulphite
Disodium Edetate Dihydrate
Polysorbate 80
Xanthan Gum
Antifoam M30
Water, Purified

6.2 Incompatibilities

None Known

6.3 Shelf Life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light. Protect from frost.

6.5 Nature and composition of immediate packaging

500 ml white high density polyethylene jerrican with green polypropylene cap (screw fit).

1, 2, 2.5, 4 and 5 litre white high density polyethylene flexi packs with white polypropylene cap (screw-fit).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4256

9. DATE OF FIRST AUTHORISATION

7th March 2000

10. DATE OF REVISION OF THE TEXT

August 2010