PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endoworm 2.265% w/v Oral Suspension

An Oral Worm Drench For Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An off-white aqueous suspension containing 2.265% w/v Oxfendazole.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

500 ml, 1 litre, 2.5 litre, 5 litre and 10 litre.

5. TARGET SPECIES

Sheep

6. INDICATION(S)

A broad spectrum anthelmintic for the control of mature and developing immature gastrointestinal roundworms and lungworms and also tapeworms in sheep. Endoworm is ovicidal for strongyle eggs.

For the treatment of sheep infested with benzimidazole susceptible strains of the following species:

GASTROINTESTINAL ROUNDWORMS:

Ostertagia spp, *Haemonchus* spp, *Nematodirus* spp, *Trichostrongylus* spp, *Cooperia* spp, *Oesophagostomum* spp and *Chabertia* spp. Also provides useful control of *Trichuris* spp.

LUNGWORMS: *Dictyocaulus* spp.

TAPEWORMS: *Moniezia* spp.

In sheep it is also effective against inhibited/arrested larvae of *Nematodirus* spp and benzimidazole susceptible *Haemonchus* spp and *Ostertagia* spp.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Sheep: 5.0 mg oxfendazole per kg bodyweight.

Bodyweight	Dose
Up to 9 kg (approx 20 lb)	2 ml
10 - 13.5 kg (22 - 30 lb)	3 ml
14 - 18 kg (31 - 40 lb)	4 ml
19 - 22.5 kg (42 - 50 lb)	5 ml
23 - 27 kg (51 - 59 lb)	6 ml
28 - 31.5 kg (62 - 69 lb)	7 ml
32 to 36 kg (71 - 79 lb)	8 ml
37 to 40.5 kg (80 - 89 lb)	9 ml
41 to 45 kg (90 - 99 lb)	10 ml

Sheep over 45 kg should be given a further 1 ml for each additional 4.5 kg bodyweight.

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

Shake container before use.

Equipment should be thoroughly cleaned before and after dosing.

Do not mix with other products.

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.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in the 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 the 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.

8. WITHDRAWAL PERIOD

Animals should not be slaughtered for human consumption during treatment.

Sheep may be slaughtered for human consumption only after 10 days from the last treatment.

Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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

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

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.

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.

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

10. EXPIRY DATE

D.O.M.:

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25oC.

Protect from frost.

Protect from light.

Keep container in outer carton.

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

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 a veterinary prescription

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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

Manufactured by:

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

Distributed by:

Countrywide Farmers

County Mills Worcester WRI 3NU

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm 02000/4190

17. MANUFACTURER'S BATCH NUMBER

Bn:

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.

B.N D.O.M EXP: dd/mm/yy

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endoworm 2.265% w/v Oral Suspension

An Oral Worm Drench For Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An aqueous suspension containing 2.265% w/v Oxfendazole

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

500 ml, 1 litre, 2.5 litre and 5 litre

5. TARGET SPECIES

Sheep

6. INDICATION(S)

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

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. Shake container before use.

Dosage Guide:

Sheep: 5 mg/kg bodyweight

Bodyweight	Dose
Up to 9 kg (approx 20 lb)	2 ml
10 to 13.5 kg (22 to 30 lb)	3 ml
14 to 18 kg (31 to 40 lb)	4 ml
19 to 22.5 kg (42 to 50 lb)	5 ml
23 to 27 kg (51 to 59 lb)	6 ml
28 to 31.5 kg (62 to 69 lb)	7 ml

32 to 36 kg (71 to 79 lb) 8 ml

37 to 40.5 kg (80 to 89 lb) 9 ml

41 to 45 kg (90 to 99 lb) 10 ml

Sheep over 45 kg should be given a further 3 ml for each additional 14 kg bodyweight (1ml/4.5kg).

Administer as an oral drench only.

Do not mix with other products.

8. WITHDRAWAL PERIOD

Animals should not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 10 days from the last treatment. Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Chemical group of anthelmintic: Benzimidazoles (1-BZ)

Do not exceed the stated dose.

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.

For Further Information: See Carton text.

10. EXPIRY DATE

D.O.M.:

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25oC.

Protect from frost.

Protect from light.

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

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UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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Distributed by:

Countrywide Farmers County Mills Worcester WRI 3NU

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm 02000/4190

17. MANUFACTURER'S BATCH NUMBER

B.N D.O.M EXP: dd/mm/yy

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {10L LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endoworm 2.265% w/v Oral Suspension

An Oral Worm Drench For Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An off-white aqueous suspension containing 2.265% w/v Oxfendazole.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

500 ml, 1 litre, 2.5 litre, 5 litre and 10 litre.

5. TARGET SPECIES

Sheep

6. INDICATION(S)

A broad spectrum anthelmintic for the control of mature and developing immature gastrointestinal roundworms and lungworms and also tapeworms in sheep. Endoworm is ovicidal for strongyle eggs.

For the treatment of sheep infested with benzimidazole susceptible strains of the following species:

GASTROINTESTINAL ROUNDWORMS:

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LUNGWORMS: Dictyocaulus spp.

TAPEWORMS: *Moniezia* spp.

In sheep it is also effective against inhibited/arrested larvae of *Nematodirus* spp and benzimidazole susceptible *Haemonchus* spp and *Ostertagia* spp.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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Sheep over 45 kg should be given a further 1 ml for each additional 4.5 kg bodyweight.

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

Shake container before use.

Equipment should be thoroughly cleaned before and after dosing.

Do not mix with other products.

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8. WITHDRAWAL PERIOD

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Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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Operator Warnings:

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Wear suitable protective clothing including impermeable rubber gloves.

Wash hands after use.

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

10. EXPIRY DATE

D.O.M.:

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25oC.

Protect from frost.

Protect from light.

Keep container in outer carton.

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

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

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 $\mathsf{B}.\mathsf{N}$

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EXP: dd/mm/yy

Approved: 25/07/2017 Fyburg