PARTICULARS TO APPEAR ON THE OUTER PACKAGE 500ML/1L/2.5L/5L CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parafend LV 9.06% w/v Oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An off-white aqueous suspension containing 9.06% w/v oxfendazole.

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

500ml

- 1 Litre
- 2.5 Litres
- 5 Litres

5. TARGET SPECIES

Cattle and Sheep.

6. INDICATION(S)

A broad spectrum anthelmintic for the control of mature and developing immature gastro-intestinal roundworms and lungworms and also tapeworms in cattle and sheep. Parafend LV is ovicidal for strongyle eggs.

For the treatment of cattle infested with the following species:

GASTRO-INTESTINAL ROUNDWORMS: Ostertagia spp., Haemonchus spp., Nematodirus spp., Trichostrongylus spp., Cooperia spp., Oesophagostomum spp., Chabertia spp., Capillaria spp. and Trichuris spp.

LUNGWORMS: Dictyocaulus spp.

TAPEWORMS: Moniezia spp.

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

GASTRO-INTESTINAL 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 cattle it is also effective against inhibited larvae of *Cooperia* spp., and usually effective against inhibited/arrested larvae of *Ostertagia* spp. In sheep it is effective against inhibited/arrested larvae of *Nematodirus* spp., and benzimidazole susceptible *Haemonchus* spp., and *Ostertagia* spp.

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.

Do not mix with other products.

Cattle: 4.5 mg oxfendazole per kg bodyweight.

Bodyweight	Dose	No.of Doses per pack			
		500ml	1 Litre	2.5 Litre	5 Litre
100 kg (2 cwt)	5 ml	100	200	500	1000
150 kg (3 cwt)	7.5 ml	66	133	333	666
200 kg (4 cwt)	10 ml	50	100	250	500
250 kg (5 cwt)	12.5 ml	40	80	200	400
300 kg (6 cwt)	15 ml	33	66	166	333

Above 300 kg give 2.5 ml per 50 kg

Sheep: 5.0 mg oxfendazole per kg bodyweight.

Bodyweight Dose		No. of Doses per pack			
		500ml	1 litre	2.5 litre	5 litre
Up to 17 kg (38 lb)	1.0 ml	500	1000	2500	5000
18 - 25 kg (39 - 55 lb)	1.5 ml	333	666	1666	3333
26 - 35 kg (56 - 79 lb)	2.0 ml	250	500	1250	2500
36 - 44 kg (80 - 97 lb)	2.5 ml	200	400	1000	2000
45 - 60 kg (98 - 132 lb)	3.5 ml	142	285	714	1428
61 - 80 kg (133 - 176 lb)	4.5 ml	111	222	555	1111

Above 80 kg give 0.5 ml per 9 kg

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.

8. WITHDRAWAL PERIOD

Cattle (meat) - 9 days

Sheep (meat) – 21 days.

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 has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia and Trichostongylus* species in small ruminants. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptability of nematode and recommendations on how to limit further selection for resistance to anthelmintics.

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

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

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.

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 reinfection. Where this is not done regular re-treatment may be necessary.

10. EXPIRY DATE

D.O.M.:

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

Protect from frost and light.

Keep the 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 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

Newry, Co. Down

Northern Ireland

DISTRIBUTED BY:

Norbrook Laboratories (GB) Limited

1 Saxon Way East

Oakley Hay Industrial Estate

Corby

Northamptonshire

NN18 9EX

United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm 02000/4121

17. MANUFACTURER'S BATCH NUMBER

Bn:

Your container of Drench is designed for use in a backpack with automatic dosing equipment

- 1. Shake well before use
- 2. Remove original cap
- 3. Replace with nozzle cap provided with pack
- 4. Automatic doser tube should be firmly attached to nozzle
- 5. If a harness is not supplies with automatic doser, cord or string may be used to hold backpack in inverted position for use.

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

500ML/1L/2.5L/5L LABEL

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufactured by:

Norbrook Laboratories Limited 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parafend LV 9.06% w/v Oral suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

A Low volume Cattle and Sheep Worm Drench containing oxfendazole 9.06% w/v

4. PHARMACEUTICAL FORM

An oral suspension containing 9.06% w/v oxfendazole.

5. PACKAGE SIZE

500 ml/1L/2.5L/5L

6. INDICATION(S)

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

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cattle and sheep

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administer as an oral drench only.

Shake well before use.

Do not mix with other products.

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

CATTLE: 4.5 mg/kg bodyweight

<u>Bodyweight</u>	<u>Dose</u>
100 kg (2 cwt)	5.0 ml
150 kg (3 cwt)	7.5 ml
200 kg (4 cwt)	10.0 ml
250 kg (5 cwt)	12.5 ml
300 kg (6 cwt)	15.0 ml
Soo kg (o cwi)	13.0 111

Above 300 kg give 2.5 ml per 50 kg

SHEEP: 5 mg/kg bodyweight

Bodyweight	<u>Dose</u>
Up to 17 kg (38lb)	1.0 ml
18 to 25 kg (39 to 55lb)	1.5 ml
26 to 35 kg (56 to 79lb)	2.0 ml
36 to 44 kg (80 to 97lb)	2.5 ml
45 to 60 kg (98 to 132lb)	3.5 ml
61 to 80 kg (133 to 176lb)	4.5 ml

Above 80 kg give 0.5ml per 9 kg

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Cattle (meat) – 9 days

Sheep (meat) – 21 days

Not for use in cattle or sheep producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from frost.

Protect from light.

Keep the container in outer carton.

14. SPECIAL WARNING(S)

Do not exceed the stated dose

Operator warnings:

Avoid contact with the skin or 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

15. EXPIRY DATE

DOM:

EXP: dd/mm/yy

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

June 2013

18. 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

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm: 02000/4121

21. MANUFACTURER'S BATCH NUMBER

B.N.:

<22. OTHER INFORMATION>

Approved: 17/08/2017