PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin Drench 0.8 mg/ml Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An oral solution containing 0.8 mg/ml ivermectin.

3. PHARMACEUTICAL FORM

An oral solution

4. PACKAGE SIZE

1.0, 2.5, 5.0 L
2 x 5 L

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

For the treatment and control of:

- Adult and immature gut roundworms including *Nematodirus* spp and adult *Chabertia ovina*.
- Adult and immature lungworms of sheep.
- Inhibited larval stages of *Haemonchus contortus* and *Ostertagia circumcincta* in sheep.
- Strains of *Haemonchus contortus* and *Ostertagia circumcincta* resistant to benzimidazole-based white drenches in sheep.
- All larval stages of nasal bots in sheep.

- Paramectin Drench treats and controls adult and immature gut roundworms including *Nematodirus* species and adult *Chabertia ovina* in sheep.
- Paramectin Drench treats and controls inhibited larval stages of *Haemonchus contortus* and *Ostertagia circumcincta* in sheep.
- Paramectin Drench treats and controls strains of *Haemonchus contortus* and *Ostertagia circumcincta* that are resistant to benzimidazole-based white drenches in sheep.
- Paramectin Drench treats and controls adult and immature lungworms in sheep.
- Paramectin Drench treats and controls all larval stages of nasal bots 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.

Do not mix with other products

Paramectin Drench should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight. Estimate bodyweight accurately prior to dosing.

The following table shows the actual dose to be given and the number of animals of differing bodyweights which can be dosed from this pack:

Weight range (kg)	Dose Volume (ml)	Doses per Pack
Up to 10	2.5	according to pack size
11 – 20	5.0	as presented on label
21 – 30	7.5	
31 – 40	10.0	
41 – 50	12.5	
51 – 60	15.0	

Over 60 kg bodyweight give 2.5 ml per 10 kg bodyweight. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing especially in young animals.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days
Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings

In case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.
Wash hands after use.
Do not smoke or eat while handling the product.
Avoid contact with skin and eyes.

Adverse reactions (frequency and seriousness)

Some animals may cough slightly immediately after treatment. This is a temporary occurrence and of no clinical consequence. Paramectin Drench has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
This product is not for intravenous or intramuscular use.

Use during pregnancy, lactation or lay

The product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.

Special Warnings for target species

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

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 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 ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU (and is common in *Haemonchus* in sheep outside 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.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep container in outer carton

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used container. Dispose of waste material in accordance with local requirements.

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 by veterinary prescription.

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

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

Manufactured by:
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

16. MARKETING AUTHORISATION NUMBER

ManA 2000
Vm 02000/4263

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

Chemical Group of Anthelmintic Endectocides [3-ML]

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin Drench 0.8 mg/ml Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An oral solution containing 0.8 mg/ml ivermectin.

3. PHARMACEUTICAL FORM

An oral solution

4. PACKAGE SIZE

1.0, 2.5, 5.0 L

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

For the treatment and control of: adult and immature gut roundworms including *Nematodirus* spp and adult and immature lungworms; inhibited larval stages of *Haemonchus contortus* and *Ostertagia circumcincta*; strains of *Haemonchus contortus* and *Ostertagia circumcincta* resistant to benzimidazole-based white drenches and all larval stages of nasal bots in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Paramectin Drench should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight. Estimate bodyweight accurately prior to dosing. The following table shows the actual dose to be given and the number of animals of differing bodyweights which can be dosed from this pack:

Weight range (kg)	**Dose Volume (ml)**	**Doses per Pack**
Up to 10	2.5	according to pack size
11 – 20	5.0	as presented on label
21 – 30	7.5	
31 – 40	10.0	
41 – 50	12.5	
51 – 60	15.0	

Over 60 kg give 2.5 ml per 10 kg bodyweight. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing especially in young animals.
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.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days
Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

This product is not for intravenous or intramuscular use.
Some animals may cough slightly immediately after treatment. This is a temporary occurrence and is of no clinical consequence. Paramectin Drench has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

USER WARNINGS

Avoid contact with skin and eyes. In case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists. Do not smoke, drink or eat while handling the product. Wash hands after use.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep container in outer carton

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used container. Dispose waste material in accordance with local requirements.

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 by veterinary prescription.

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

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

Manufactured by:
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

16. MARKETING AUTHORISATION NUMBER

ManA: 2000
Vm: 02000/4263

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

Chemical Group of Anthelmintic Endectocides [3-ML]
UK authorised veterinary medicinal product
* IMPORTANT: READ CARTON TEXT BEFORE USE.

PACKAGE LEAFLET FOR:

Paramectin Drench 0.8 mg/ml Oral Solution

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin Drench 0.8 mg/ml Oral Solution

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

A free-flowing aqueous pale yellow clear solution containing 0.8 mg/ml ivermectin for oral administration.

4. INDICATION(S)

For the treatment and control of gastrointestinal nematodes and lungworms and nasal bots of sheep.

Paramectin Drench at the recommended dosage level of 200 μg ivermectin per kg bodyweight effectively controls the following parasites of sheep:

Gastrointestinal worms (adult and immature):
Haemonchus contortus, Ostertagia circumcincta, Trichostrongylus spp, *Cooperia* spp, *Nematodirus* spp including *N. battus, Strongyloides papillosus*, *Oesophagostomum* spp, and adult *Chabertia ovina*

Inhibited larval stages and benzimidazole resistant strains of *H. contortus* and *Ostertagia circumcincta* also controlled.

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Paramectin Drench has been formulated specifically for use in sheep. It should not be used in other species, as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

Some animals may cough slightly immediately after treatment. This is a temporary occurrence and of no clinical consequence.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD 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

Dosage: 2.5 ml per 10 kg bodyweight (based on a recommended dosage level of 200 μg ivermectin per kg bodyweight).

Administration: Give as an oral drench. Estimate bodyweight accurately prior to dosing. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing especially in young animals.

Paramectin Drench can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.

9. ADVICE ON CORRECT ADMINISTRATION

This product is not for intravenous or intramuscular use.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days
Do not use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep out of the reach and sight of children.
Keep container in outer carton

12. SPECIAL WARNING(S)

For animal treatment only.

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.
- 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 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 ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU (and is common in *Haemonchus* in sheep outside 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with skin and eyes.
In case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.
Do not smoke, drink or eat while handling the product.
Wash hands after use.

Overdose (symptoms, emergency procedures, antidotes), if necessary
The product has demonstrated a wide safety margin at the recommended dose rate.
No antidote has been identified however symptomatic treatment may be beneficial.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused

veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2009

15. OTHER INFORMATION

Package quantities: 1.0L, 2.5L, 5.0L and 2 x 5.0L containers
Not all pack sizes may be marketed.

Marketing Authorisation Number

ManA: 2000
Vm 02000/4263

POM-VPS

To be supplied only on veterinary prescription

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

Approved: 27 July 2018