1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Drench 0.8 mg/ml Oral Solution for Sheep [IE, IT, PT, ES, IS]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin 0.8 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	30 mg
N,N-dimethylacetamide	
Polysorbate 80	
Disodium hydrogen (orthophosphate dihydrate)	
Sodium dihydrogen (orthophosphate dihydrate)	
Purified water	

A pale yellow clear liquid.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

This veterinary medicinal product is indicated for the treatment and control of gastrointestinal nematodes, lungworms, and nasal bots of sheep.

Gastro-intestinal worms
Haemonchus contortus [Adult, L4 and inhibited L4], *Ostertagia (Teladorsagia) circumcincta* [Adult, L4 and inhibited L4], *Trichostrongylus axei* [Adult and L4], *Trichostrongylus colubriformis* [Adult and L4], *Trichostrongylus vitrines* [Adult and L4], *Cooperia curticei* [Adult and L4], *Cooperia oncophora* [Adult and L4], *Nematodirus battus* [Adult and L4], *Nematodirus filicollis* [Adult and L4],

Nematodirus spathiger [Adult and L4], *Strongyloides papillosus* [Adult and L4], *Oesophagostomum columbianum* [Adult and L4], *Oesophagostomum venulosum* [Adult and L4] and adult *Chabertia ovina.*

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

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

3.3 Contraindications

Do not use in animals in which milk is intended for human consumption.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke or eat while handling the product.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the product into the eyes should be washed immediately.

Special precautions for the protection of the environment:
Not applicable.

Other precautions
The product has been formulated specifically for sheep. It should not be administered to other species as severe adverse reactions may occur. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

3.6 Adverse events

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cough[1]

[1] Immediately after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The medicinal product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.
Do not use in lactating sheep producing milk for human consumption.

Fertility:
The veterinary medicinal product will not affect the fertility of breeding ewes and rams and can be given to all ages of animals including young lambs.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use
Ivermectin should be administered at a dose rate of 200 micrograms per kg bodyweight. The medicinal product should be given orally at the recommended dose rate of 1 ml per 4 kg bodyweight. The treated animals should be monitored according to good husbandry practices.

To ensure correct dosage, body weight should be determined as accurately as possible. The accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal product was tolerated up to 3 times the recommended dose. Symptoms of overdose include trembling, convulsions and coma. In case of overdose, symptomatic treatment should be given.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 10 days.

Milk: Not permitted for use in lactating sheep producing milk for human consumption. Do not use in non-lactating dairy sheep within 60 days of lambing.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

Ivermectin in a 22,23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of 2 homologues: B1a and B1b. It is a parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligandgated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels. The macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

4.3 Pharmacokinetics

Peak levels of ivermectin are observed around 16 hours following oral administration of the medicinal product.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in 1.0 L, 2.5 L and 5.0 L and 2 x 5.0 L high density polyethylene Jerry can containers complete with polypropylene caps and 1.0 L, 2.5 L, 5.0 L and 2 x 5.0 L high density polyethylene Backpack containers complete with polypropylene plastic screw caps.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF THE FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1.0 L, 2.5 L, 5.0 L, 2 x 5 L CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Drench 0.8 mg/ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 0.8 mg

3. PACKAGE SIZE

1.0 L
2.5 L
5.0 L
2 x 5 L

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Ivermectin should be administered at a dose rate of 200 μg per kg bodyweight. The veterinary medicinal product for sheep should be given orally at the recommended dose rate of 1ml per 4 kg bodyweight.

The treated animals should be monitored according to good husbandry practices.

To ensure correct dosage, body weight should be determined as accurately as possible. The accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal:10 days.
Milk: Not permitted for use in lactating sheep producing milk for human consumption. Do not use in non-lactating dairy sheep within 60 days of lambing.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1.0 L, 2.5 L, 5.0 L, 2 x 5 L LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Drench 0.8 mg/ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 0.8 mg

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Oral use.
Ivermectin should be administered at a dose rate of 200 µg per kg bodyweight. The veterinary medicinal product for sheep should be given orally at the recommended dose rate of 1ml per 4 kg bodyweight. The treated animals should be monitored according to good husbandry practices.

To ensure correct dosage, body weight should be determined as accurately as possible. The accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal:10 days.
Milk: Not permitted for use in lactating sheep producing milk for human consumption. Do not use in non-lactating dairy sheep within 60 days of lambing.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Noromectin Drench 0.8 mg/ml Oral Solution for Sheep

2. Composition

Each ml contains:

Active substance:

Ivermectin 0.8 mg

Excipient:

Benzyl alcohol 30 mg

A pale yellow clear liquid.

3. Target species

Sheep.

4. Indications for use

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

Gastro-intestinal worms:
Haemonchus contortus [Adult, L4 and Inhibited L4], *Ostertagia (Teladorsagia) circumcincta* [Adult, L4 and Inhibited L4], *Trichostrongylus axei* [Adult and L4], *Trichostrongylus colubriformis* [Adult and L4], *Trichostrongylus vitrinus* [Adult and L4], *Cooperia curticei* [Adult and L4], *Cooperia oncophora* [Adult and L4], *Nematodirus battus* [Adult and nL4], *Nematodirus filicollis* [Adult and L4], *Nematodirus spathiger* [Adult and L4], *Strongyloides papillosus* [Adult and L4], *Oesophagostomum columbianum* [Adult and L4], *Oesophagostomum venulosum* [Adult and L4], and adult *Chabertia ovina*

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

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

5. Contraindications

Do not use in animals in which milk is intended for human consumption.

6. Special warnings

Special warnings:

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke or eat while handling the product.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the product into the eyes should be washed immediately.

Other Precautions
The product has been formulated specifically for sheep. It should not be administered to other species as severe adverse reactions may occur. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

Pregnancy and lactation:

The medicinal product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.
Do not use in lactating sheep producing milk for human consumption.

Fertility:
The veterinary medicinal product will not affect the fertility of breeding ewes and rams and can be given to all ages of animals including young lambs.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:

The veterinary medicinal product was tolerated up to 3 times the recommended dose. Symptoms of overdose include trembling, convulsions and coma. In case of overdose, symptomatic treatment should be given.

Major incompatibilities:
None known.

7. Adverse events

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cough[1]

[1] Immediately after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.
Ivermectin should be administered at a dose rate of 200 µg per kg bodyweight. The veterinary medicinal product for sheep should be given orally at the recommended dose rate of 1ml per 4 kg bodyweight.

9. Advice on correct administration

The treated animals should be monitored according to good husbandry practices.

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

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

10. Withdrawal periods

Meat and offal:10 days.

Milk: Not permitted for use in lactating sheep producing milk for human consumption. Do not use in non-lactating dairy sheep within 60 days of lambing.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

The veterinary medicinal product will be supplied in 1.0 L, 2.5 L and 5.0 L and 2 x 5.0 L high density polyethylene Jerry can containers complete with polypropylene caps and 1.0 L, 2.5 L, 5.0 L and 2 x 5.0 L high density polyethylene Backpack containers complete with polypropylene plastic screw caps.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release:
Norbrook Laboratories Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Newry, Co. Down,
Northern Ireland

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

For animal treatment only.