1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Macromectin 0.8 mg/ml oral solution for sheep [IE]
Noromectin vet 0.8 mg/ml oral solution for sheep [SE]

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	0.03 ml
Polysorbate 80	
N,N-Dimethylacetamide	
Disodium Hydrogen Phosphate Dihydrate	
Sodium Dihydrogen Phosphate Dihydrate	
Purified Water	

A pale yellow clear oral solution.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

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

Gastrointestinal 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*.

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

3.3 Contraindications

None.

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 veterinary medicinal 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 has been reported in *Haemonchus contortus* in sheep. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility and recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product has been formulated specifically for use in sheep.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not smoke or eat while handling the veterinary medicinal product. Use protective gloves.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the veterinary medicinal product into eyes should be washed immediately.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

The veterinary medicinal product should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

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:

Can be used during pregnancy or lactation provided that the milk is not used for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

Oral use.
The veterinary medicinal product should be administered orally at a dosage rate of 200 µg per kg bodyweight (1 ml per 4 kg bodyweight).

To ensure a correct dosage, body weight should be determined as accurately as possible; 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.

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

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.

Following administration of ivermectin at 20x the recommended dose level, only mild incoordination and depression were observed.

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: Do not use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP 54 AA 01

4.2 Pharmacodynamics

Ivermectin is 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.

Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

4.3 Pharmacokinetics

After oral administration of the veterinary medicinal product to sheep at the recommended dose of 200 µg/kg, the maximum plasma concentration of ivermectin was 5.99 µg/ml, 16 hours following administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

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 is supplied in 1.0 L, 2.5 L, 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 back-pack 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. Do not contaminate surface waters or ditches with veterinary medicinal product or used container.

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 FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{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

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Macromectin 0.8 mg/ml oral solution for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
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.
Administration: Give as an oral drench.
Estimate bodyweight accurately.
Use appropriate and properly calibrated equipment.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and Offal: 10 days.
Milk: Do not use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

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 AND REACH 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 NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Macromectin 0.8 mg/ml oral solution for sheep.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ivermectin 0.8 mg

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Oral use.
Administration: Give as an oral drench.
Estimate bodyweight accurately.
Use appropriate and properly calibrated equipment.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and Offal: 10 days.
Milk: Do not use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

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

Macromectin 0.8 mg/ml oral solution for sheep
Noromectin vet 0.8 mg/ml oral solution for sheep

2. Composition

Each ml contains:
Active Substance:
Ivermectin 0.8 mg

Excipients:
Benzyl alcohol 0.03 ml

A pale yellow clear oral solution.

3. Target species

Sheep.

4. Indications for use

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

Gastrointestinal 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*.

Benzimidazole resistant strains of *H contortus* and *Ostertagia circumcincta* are also controlled.

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

5. Contraindications

None.

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 veterinary medicinal 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 has been reported in *Haemonchus contortus* in sheep. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:
The veterinary medicinal product has been formulated specifically for use in sheep.

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

Other precautions:
The veterinary medicinal product should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Pregnancy and lactation:
Can be used during pregnancy or lactation provided that the milk is not used for human consumption.

Overdose:
The veterinary medicinal product was tolerated up to 3 times the recommended dose.
Following administration of ivermectin at 20x the recommended dose level, only mild incoordination and depression were observed.

7. Adverse events

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 on this label, 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 its local representative using the contact details on this label, or via your national reporting system: {national system details}

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

Oral use.
Administration: Give as an oral drench.
The veterinary medicinal product should be administered orally at a dosage rate of 200 µg per kg bodyweight (1 ml per 4 kg bodyweight).
The treated animals should be monitored according to good husbandry practices.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible; 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: Do not use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 6 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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. Do not contaminate surface waters or ditches with veterinary medicinal product or used container.

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.

Ask your veterinary surgeon or pharmacist 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

Pack sizes
The veterinary medicinal product is supplied in 1.0 L, 2.5 L, 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 back-pack 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 <and contact details to report suspected adverse events>:
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release:
Norbrook Laboratories Limited,
Station Works
Camlough Road,
Newry,
County Down,
Northern Ireland
BT35 6JP

Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

<Local representatives <and contact details to report suspected adverse events>:>

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