

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 10 mg/ml Solution for Injection for sheep.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin 10.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol Formal
Polyethylene Glycol 200

Clear, colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target Species

Sheep.

3.2 Indications for use for each target species

Indicated for the treatment of infections by the following species of gastrointestinal roundworms, lungworms, nasal bots and psoroptic mange (sheep scab).

Gastrointestinal roundworms (adults and fourth stage larvae):

Ostertagia circumcincta (including inhibited larvae), *Haemonchus contortus* (including inhibited larvae), *Trichostrongylus axei* (adults), *Trichostrongylus colubriformis* (adults), *Trichostrongylus vitrinus* (adults), *Cooperia curticei*, *Nematodirus filicollis*.

Lungworms:

Dictyocaulus filaria (adults and fourth stage larvae).

Nasal Bots:

Oestrus ovis (all larval stages).

MangeMites:

Psoroptes ovis.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer by the intravenous or intramuscular route.

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.

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 tests(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 *Ostertagia circumcincta* in lambs. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of this helminth species 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:

This veterinary medicinal product does not contain any antimicrobial preservative.

Avoid the introduction of contamination during use.

Should any apparent growth or discoloration occur the veterinary medicinal product should be discarded.

Treatment of psoroptic mange (sheep scab) with one injection is not recommended, because although clinical improvement may be seen elimination of all mites may not occur.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. Following treatment of infected sheep great care must be taken to avoid re-infestation, as mites may be viable for up to 15 days off the sheep. It is important to ensure all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and nontreated, non-infected flocks must be avoided until at least 7 days after the last treatment.

The shedding of nematode eggs can continue for some time after treatment.

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.

Direct contact of the veterinary medicinal product with the skin should be kept to a minimum.

Wash hands after use.

Take care to avoid self-administration: the veterinary medicinal product may cause irritation and/or pain at the site of injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal results are reported in dogs – especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

3.6 Adverse events

Target species: Sheep.

Common	Injection site swelling ¹
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(1 to 10 animals / 100 animals treated):	
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pain ²

¹ These soft tissue swellings and thickening of the skin disappear without treatment within one to four weeks.

² Immediately following subcutaneous injection. Sometimes intense, but usually transient.

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.

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

Fertility:

The fertility of males is not affected by administration of the veterinary medicinal product.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

3.9 Administration routes and dosage:

Subcutaneous use: 0.5 ml per 25 kg bodyweight (based on a recommended level of 200 µg ivermectin per kg bodyweight).

For the treatment of gastrointestinal roundworms, lungworms and nasal bots, inject once subcutaneously in the neck using aseptic precautions; a sterile 17 gauge ½ inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper. Swab the septum before removing each dose. Use a dry sterile needle and syringe.

For the treatment of *Psoroptes ovis* (sheep scab), two injections with a 7 day interval are required to treat clinical signs of scab and to eliminate living mites. It is recommended that the second injection should be administered at a different site (opposite side of the neck) to the first injection.

For young lambs weighing less than 20.0 kg give 0.1 ml per 5 kg. In these lambs the use of a syringe which can deliver as little as 0.1 ml is recommended.

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 over- dosing.

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

Clinical symptoms of ivermectin toxicity include ataxia and depression. No antidote has been identified. In case of overdose, symptomatic treatment should be given. No signs of systemic toxicity were observed in sheep treated at up to 2 times the recommended dose rate.

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: 42 days.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code: QP54AA01.

4.2 Pharmacodynamics

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 hyperpolarisation of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated 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

Following the subcutaneous administration of the veterinary medicinal product to sheep at a dose of 200 µg ivermectin/kg, the maximum concentration in plasma (C_{max}) (mean C_{max} = ~14 ng/ml) was reached within 1-4 days. The elimination half-life is ~109 hours. Only about 2% of the drug is excreted in urine, faecal excretion being the major route of elimination.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store below 30 °C.
Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in 50 ml, 100 ml, 250 ml, 500 ml and 1 litre volumes, presented in high density polyethylene vials with bromobutyl bungs and aluminium 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 may be 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)

VPA 22664/059/001

8. DATE OF FIRST AUTHORISATION

29/06/2001

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

22/11/2024

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).