1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Multi Injection Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin 10 mg

Excipients:

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

Clear, colourless to pale yellow solution.

3. CLINICAL PARTICULARS

3.1 Target species

Cattle (beef and non-lactating dairy cattle), sheep and pigs.

3.2 Indications for use for each target species

Cattle
The veterinary medicinal product is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, warbles, mites and lice in cattle.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Ostertagia lyrata, Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult)

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Warbles:
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

Mange Mites:
Psoroptes bovis, Sarcoptes scabiei var *bovis*

The veterinary medicinal product may also be used as an aid in the control of the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Sheep

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, nasal bots and psoroptic mange (sheep scab):

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia circumcincta (including inhibited larvae), *O. trifurcata, Haemonchus contortus* (including inhibited larvae), *Trichostrongylus axei* (adults), *Trichostrongylus colubriformis* (adults), *Trichostrongylus vitrinus* (adults), *Cooperia curticei, Oesophagostomum venulosum* (adults), *Oesophagostomum columbianum, Nematodirus filicollis, Chabertia ovina, Trichuris ovis* (adults)

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

Lungworms:
Dictyocaulus filaria (adults and fourth stage larvae)
Protostrongylus rufescens (adults)

Nasal Bots:
Oestrus ovis (all larval stages)

Mange Mites*:
Psoroptes ovis
*For the treatment and control of sheep scab, two injections with a seven day interval are required to treat clinical signs of scabs to eliminate the mites.

Pigs
The veterinary medicinal product is indicated for the treatment and control of parasitic diseases of pigs caused by the following parasites:

Gastrointestinal roundworms:
Ascaris suum (adults and fourth-stage larvae)
Hyostrongylus rubidus (adults and fourth-stage larvae)
Oesophagostomum spp. (adults and fourth-stage larvae)
Strongyloides ransomi (adults and somatic larval stages)

Lungworms:
Metastrongylus spp (adults)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var suis

The veterinary medicinal product may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

3.3 Contraindications

The veterinary medicinal product is not for intravenous or intramuscular use.

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

Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption. Do not use in pregnant heifers within 60 days prior to calving.

Not permitted for use in ewes producing milk for human consumption.
Do not use in ewes within 60 days of lambing where milk is intended for human consumption.

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

3.4 Special Warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In cattle, to avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

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

This product does not contain a preservative.
Avoid the introduction of contamination during use.
Should any apparent growth or discolouration occur, the product should be discarded.
Do not smoke or eat while handling the product.
Direct contact of the product with the skin should be kept to a minimum.
Take care to avoid self-administration; the product may cause irritation and /or pain at the site of injection.
Wash hands after use.

Other precautions:
Avermectins may not be well tolerated in all non-target species (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

Cattle (beef and non-lactating dairy cattle):

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

[1] These soft tissue swellings disappear without treatment.
[2] Following subcutaneous administration, transient in nature.

Sheep:

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

[1] These soft tissue swellings disappear without treatment.
[2] Immediately following subcutaneous injection. Sometimes intense, but usually transient.

Pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]

[1] These soft tissue swellings disappear without 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 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 veterinary medicinal product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Not permitted for use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Not permitted for use in ewes producing milk for human consumption.
Do not use in ewes within 60 days prior to lambing where milk is intended to be used for human consumption.

The veterinary medicinal product can be administered to sows at any stage of pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

A sterile 17-gauge, half-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.

Cattle
The veterinary medicinal product should be administered at a dose rate of 1ml per 50kg bodyweight (based on a recommended level of 200 μg per kg bodyweight). It should be injected subcutaneously in front of or behind the shoulder using aseptic technique.

Sheep
The veterinary medicinal product should be administered at a dose rate of 0.5ml per 25kg bodyweight (based on a recommended level of 200 μg per kg bodyweight). For the treatment of gastrointestinal roundworms, lungworms and nasal bots, inject once subcutaneously in the neck using aseptic precautions. For the treatment and control 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.

Pigs
The veterinary medicinal product should be administered at a dose rate of 1ml per 33kg bodyweight (based on a recommended level of 300 μg per kg bodyweight). It should be injected subcutaneously into the neck using aseptic technique.
Treat all animals in the herd. Since louse eggs are unaffected by ivermectin and may take up to 3 weeks to hatch, complete elimination may not occur following a single injection.

Ivermectin has sufficient persistence to control mite infections throughout the egg to adult life cycle. However since the effect is not immediate, care must be taken to prevent re-infestation from exposure to untreated animals or contaminated facilities. Generally pigs should be moved to clean quarters or exposed only to uninfested pigs for approximately one week after treatment.

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

In the case of overdose symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.

Ivermectin has a recognised wide safety margin in swine. Clinical signs of ivermectin toxicity in swine include tremors, bilateral mydriasis and recumbency with some biochemical abnormalities including a transient depression of serum iron. Such changes were only observed when ivermectin was administered subcutaneously at dose of 30 mg/kg (100 times the normal therapeutic dose).

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

Foodstuffs must not be taken for human consumption during the treatment period.

Cattle
Meat and offal: 49 days

Not authorised for use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Sheep
Meat and offal: 42 days

Not authorised for use in animals producing milk for human consumption.
Do not use in ewes within 60 days before lambing where milk is to be used for human consumption.

Pigs
Meat and offal: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code: QP54AA01

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 highly effective parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

Avermectins act to stimulate GABA mediated chloride ion conductance, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packing: 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. A 1.5 litre (1 x 1 litre and 1 x 500 ml) combination pack is also available.

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.

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.

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBERS

VPA 22664/068/001

8. DATE OF FIRST AUTHORISATION

22 February 2002

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

09 July 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*).