SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 1% w/v Multi Injection Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Ivermectin 1.0% w/v (10 mg in 1 ml)

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear colourless to pale yellow, slightly viscous, sterile non-aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Beef and non-lactating dairy cattle, sheep and pigs

4.2 Indications for Use, Specifying the Target Species

Cattle
For the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice in beef cattle and non-lactating dairy 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), *Nematodirus spathiger* (adult), and *Trichuris* spp (adults)

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp

Warbles (parasitic stages):
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

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

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

Sheep
For the treatment and control of psoroptic mange (sheep scab), gastrointestinal nematodes, lungworms and nasal bots of sheep.

At the recommended dosage level of 200 mcg ivermectin per kg bodyweight the product effectively controls the following parasites of sheep:

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

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

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

Mange Mites:
Psoroptes ovis

Nasal Bot:
Oestrus ovis (all larval stages)

Pigs
For the treatment and control of the harmful species of gastrointestinal roundworms, lungworms, lice and mange mites of pigs. At the recommended dose rate of 300 μg/kg the product provides effective control of the following parasites:

Gastrointestinal worms:
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 product may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

4.3 Contraindications

The product is for administration only by the subcutaneous route and must not be given via other routes. It should not be used in other species than those indicated as severe reactions, including fatalities in dogs, may occur.

4.4 Special Warnings for Each Target Species

Immediately following subcutaneous injection, activity suggesting pain, sometimes intense but usually transient, has been observed in some sheep.

4.5 Special Precautions for Use

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result 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 *Telodorsagia* in sheep and goats within the EU and it is common in *Haemonchus* in sheep outside the EU. It has been reported in *Cooperia oncophora* in cattle within the EU, in *Teladorsagia* in cattle in developed countries such as New Zealand and *Haemonchus* outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about the susceptibility of

nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

(i) Special precautions for use in animals
In pigs, especially those under 16 kg for which less than a volume of 0.5 ml is indicated, dosing accuracy is important. The use of a suitably calibrated syringe that can accurately deliver 0.1 ml is recommended.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not eat, drink or smoke while handling the product.
Direct contact of the product with the skin should be kept to a minimum.
Wash hands after use.

Take care to avoid accidental self-injection: this product may cause local irritation and/or pain at the injection site.

4.6 Adverse Reactions (Frequency and Seriousness)

Transitory discomfort has been observed in some cattle following subcutaneous administration. Tissue swellings at the injection site have been observed. These reactions resolve without treatment.
See also 4.10.

4.7 Use During Pregnancy, Lactation or Lay

The product can be administered to beef cows and ewes at any stage of pregnancy or lactation.

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

4.8 Interaction with Other Medicinal Products and Other Forms of Interaction

None identified.

4.9 Amounts to be Administered and Administration Route

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

Cattle
Ivermectin should be administered at a dosage rate of 200 µg per kg bodyweight (1 ml to 50 kg bodyweight). It should only be injected subcutaneously in front of or behind the shoulder using aseptic technique. A sterile 17 gauge x ½ inch needle is recommended.

Sheep

Administer only by subcutaneous injection in the neck at the recommended dosage level of 200 μg ivermectin per kg bodyweight using aseptic technique. Each ml contains 10 mg ivermectin to treat 50 kg of bodyweight. Swab the septum before removing each dose. Use a dry sterile needle and syringe.

Administer subcutaneously only. Inject once under the loose skin in the neck. For the treatment and control of sheep scab (*Psoroptes ovis*) two injections with a seven day interval are required to treat clinical signs of scab and eliminate living mites. Use of a 17 gauge x ½ inch (15-20 mm) needle is suggested. Replace with a fresh sterile needle after every 10-12 animals. Injection of wet or dirty animals is not recommended.

When treating sheep of less than 16 kg seek veterinary advice regarding the use of 1 ml disposable syringes graduated in increments of 0.1 ml.

For the treatment of individual sheep a syringe not exceeding 2.0 ml and calibrated in increments of 0.1 ml should be used.

Pigs

Administer at a dosage rate of 300 μg per kg bodyweight (1 ml per 33 kg). The product should be injected subcutaneously into the neck using aseptic technique. A sterile 17 gauge x ½ inch needle is recommended.

This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use a dry sterile needle and syringe. For 250 ml, 500 ml and 1 litre pack sizes, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper. Avoid introduction of contamination.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Cattle

Single doses of 4.0 mg/kg ivermectin (20 times the recommended dosage) administered subcutaneously, results in ataxia and depression. No antidote has been identified. Symptomatic treatment may be beneficial.

Sheep

Dose levels of up to 4mg/kg given subcutaneously can result in ataxia and depression. Symptomatic treatment may be beneficial.

Pigs

Ivermectin has a recognised wide safety margin and is known to be safe in all ages of swine. It has no adverse effects on fertility in sows or breeding performance of boars.

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 a dose of 30 mg/kg (100 times the normal therapeutic dose).

4.11 Withdrawal Period

Cattle must not be slaughtered for human consumption until 49 days after the last treatment.

This product should not be used in cattle producing milk for human consumption. The product should not be used in non-lactating dairy cows including pregnant heifers within 60 days of calving.

Sheep must not be slaughtered for human consumption until 42 days after the last treatment.

This product should not be used in lactating ewes producing milk for human consumption.

Pigs must not be slaughtered for human consumption until 28 days after the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATC Vet Code: QP 54 AA 01

5.1 Pharmacodynamic Properties

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.

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of this class bind 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 the hyper-polarisation of the nerve or muscle cell resulting in paralysis and death of the parasite.

Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABP).

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 lactone have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Glycerol Formal
Macrogol 200

6.2 Incompatibilities

None known.

6.3 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.

6.4 Special Precautions for Storage

Do not store above 25°C.
Protect from light.
Discard unused material.
Following withdrawal of the first dose, use the product within 28 days.
This product does not contain an antimicrobial preservative.
Swab the septum before removing each dose.
Use a dry sterile needle and syringe.
Avoid the introduction of contamination.
When using the 250 ml, 500 ml and 1 litre pack sizes, use only automatic syringe equipment. To refill the syringe use of a draw off needle is recommended to avoid excess broaching of the stopper.

6.5 Nature and Composition of Immediate Packaging

50 ml, 100 ml, 250 ml, 500 ml and 1 litre high-density polyethylene vials with bromobutyl bungs and aluminium overseals.
Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.
EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4174

9. DATE OF FIRST AUTHORISATION

20th October 1999

10. DATE OF REVISION OF THE TEXT

December 2009