Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Multi Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Ingredient
Ivermectin 10 mg

For full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the target species

Cattle
Noromectin Multi Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, warbles, mites and lice in cattle:

Gastro-intestinal 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, Oesophagostomumradiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult)

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparous

Warbles:
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

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

Noromectin Multi Injection may also be used as an aid in the control of the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Sheep
Noromectin Multi Injection 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, Haemonchuscontortus* (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 scab and to eliminate the mites.

Pigs
Noromectin Multi Injection 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

Noromectin Multi Injection may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

4.3 Contraindications

Noromectin Multi Injection 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 to be used for human consumption.

Do not use in animals known to be hypersensitive to the active substance.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
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).

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.

4.6 Adverse reactions (frequency and seriousness)

Transitory discomfort has been observed in some cattle following subcutaneous administration. Some soft tissue swelling at the injection site has been commonly observed. These reactions disappear without treatment.

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

4.7 Use during pregnancy, lactation or lay

Noromectin Multi Injection 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 of lambing where milk is intended to be used for human consumption.

Noromectin Multi Injection can be administered to sows at any stage of pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interactions

No data available.

4.9 Amounts to be administered and administration route

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
Noromectin Multi Injection should be administered at a dose rate of 1ml per 50kg bodyweight (based on a recommended level of 200µg ivermectin per kg bodyweight). It should be injected subcutaneously in front of or behind the shoulder using aseptic technique.

Sheep
Noromectin Multi Injection should be administered at a dose rate of 0.5ml per 25kg bodyweight (based on a recommended level of 200µg ivermectin 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
Noromectin Multi Injection should be administered at a dose rate of 1ml per 33kg bodyweight (based on a recommended level of 300µg ivermectin 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.

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

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

4.11 Withdrawal period(s)

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

Cattle
Edible tissues from slaughtered animal: 49 days

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.

Sheep
Edible tissues from slaughtered animal: 42 days

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

Pigs
Meat and offal: 28 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic classification; Ivermectin
ATC vet code; QP54AA01

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
Polyethylene Glycol 200

6.2 Major 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 packing: 28 days.

6.4 Special precautions for storage

Store below 30°C
Protect from direct sunlight

6.5 Nature and composition of immediate packaging

Noromectin Multi Injection 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 500ml) combination pack is also available.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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.

Ivermectin is extremely dangerous to fish and aquatic life. Do not contaminate surface water or ditches with the product or used containers.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/068/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 February 2002
Date of last renewal: 21 February 2007

10 DATE OF REVISION OF THE TEXT

January 2019