Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 1% w/v Solution for Injection for Cattle and Pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient(s)
Each ml:
Ivermectin 10 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and pigs.

4.2 Indications for use, specifying the target species

Cattle
In cattle: treatment of infections by the following parasites:

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, Oesophagostomum radiatum, Nematodirus helvetianus* (adult).

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Warbles (parasitic stages):
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus

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

The product may also be used to reduce infection of the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Pigs
In pigs: treatment of infections 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)

Lungworms:
Metastrongylus spp (adults)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var *suis*

4.3 Contraindications

Do not use in dogs or cats as severe adverse reactions may occur.

The product is not for intravenous or intramuscular use.

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each 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.

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 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 *Ostertagia ostertagi* in cattle. 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.

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 and crosses, and also in turtles/tortoises).

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not smoke or eat while handling the product.
Direct contact of the product with the skin should be avoided.
Wash hands after use.
Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at the injection site.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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

Mild and transient pain and/or swelling reactions may be seen in some pigs following subcutaneous injection. All these reactions disappear without treatment.

4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation in sows and in cattle provided that the milk is not intended for human consumption. See also Section 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

The effects of GABA agonists are increased by ivermectin.

4.9 Amounts to be administered and administration route

For single administration only.
To ensure administration of a correct dose, 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.

Cattle
Ivermectin should be administered at a dosage rate of 200 micrograms per kg bodyweight (1 ml/50 kg). It should be injected subcutaneously in front of or behind the shoulder using aseptic technique. A sterile 17 gauge, 12.7 mm needle (equivalent to half inch needle) is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper.

Pigs
The product should be administered at a dosage rate of 300 micrograms per kg bodyweight (1 ml/33 kg). It should be injected subcutaneously into the neck using aseptic technique. A sterile 17 gauge, 12.7 mm needle (equivalent to half inch needle) is recommended. Exact dosing is important especially in pigs with low bodyweight, therefore a syringe capable of dosing in 0.1 ml steps should be used.

The treatment schedule should be based on the local epidemiological situation.

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

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

In cattle, single dose of 4.0 mg ivermectin per kg (20 times the use level) given subcutaneously resulted in ataxia and depression. No systemic or local signs of toxic effects were reported at 3 times the recommended dose in both species - cattle and pigs.

Ivermectin has a recognised wide safety margin in swine. A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

4.11 Withdrawal period(s)

Cattle
Meat and offal: 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.

Pigs
Meat and Offal: 18 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide
ATC vet code: QP54AA01

5.1 Pharmacodynamic properties

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 hyperpolarization 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.

5.2 Pharmacokinetic particulars

After subcutaneous administration of the recommended dose of the product to cattle (200 µg/kg), the following parameters were observed: Cmax of 37 ng/ml and AUC of 7558 ng/ml.h. After subcutaneous administration of the recommended dose of the product to pigs (300 µg/kg), the following parameters were observed: Cmax of 14 ng/ml, and AUC of 1887 ng/ml.h. Ivermectin is only partially metabolised. In cattle, only about 1-2% is excreted in the urine the remainder is excreted in the faeces,

approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products. Biliary excretion, followed by elimination in faeces is probably the major route of ivermectin excretion in pigs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
Polyethylene Glycol 200

6.2 Major incompatibilities

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

6.3 Shelf-life

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

6.4 Special precautions for storage

Store below 25ºC.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

The product will be supplied in 50 ml, 100 ml, 250 ml, 500 ml and 1 L volumes, presented in high-density polyethylene vials with bromobutyl bungs and aluminium caps.

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

Ivermectin is extremely dangerous to fish and aquatic life. Do not contaminate surface water or ditches with the product or used containers. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 March 2000
Date of last renewal: 29 June 2010

10 DATE OF REVISION OF THE TEXT

February 2019