Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 1.0% w/v Solution for Injection for Pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Ivermectin	1.0 % w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A colourless to pale yellow, clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Noromectin Injection for Pigs is not for intravenous or intramuscular use. 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 and tortoises).

Special Precautions to be taken by the Person Administering the Product to Animals

Do not smoke or eat while handling the product.
Direct contact of the product with the skin should be kept to a minimum.Wash hands after use

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Noromectin Injection for Pigs should be administered at a dosage rate of 300 µg per kg bodyweight. It should be injected subcutaneously into the neck using aseptic technique. A sterile 17-gauge, half-inch needle is recommended.

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.

Swab the septum before removing each dose.
Use a dry sterile needle and syringe.

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

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.
Meat and Offal: 28 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Endectocides, Ivermectin.
ATCVet 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 parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

5.1 Pharmacodynamic properties

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 hyperpolarisation 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 (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 to pigs, the following parameters were observed: Cmax of 14.06 ng/ml and AUC of 1886 ng/ml/hr.

Ivermectin is highly lipophilic and has good ability to penetrate to the location of parasites. It is stored in and slowly released from fat after which it is converted by the liver to less lipid soluble metabolites by oxidative biotransformation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal Macrogol 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 packaging: 28 days.

6.4 Special precautions for storage

Do not store above 30ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

Noromectin Injection for Pigs is a colourless to pale yellow clear liquid supplied in 50 ml, 100 ml, 250 ml and 500 ml volumes, presented in high density polyethylene vials with bromobutyl bungs and aluminium caps.

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 product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 September 2002
Date of last renewal: 26 September 2007

10 DATE OF REVISION OF THE TEXT

February 2019