Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Premix 6 mg/g Premix for Medicated Feeding Stuff for Swine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Ivermectin 6 mg/g

Excipients
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feedingstuff. Free flowing yellow to light brown meal.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of the following gastrointestinal roundworms, lungworms, lice and mange in adult and growing pigs:

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)

Lungworms
Metastrongylus spp (adults)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var *suis*

The product given to pregnant sows before farrowing effectively controls transmission via the milk of *S. ransomi* to piglets.

4.3 Contraindications

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 turtle / tortoises).
Do not use in animals known to be hypersensitive to the active substance, or to any of the excipients.

4.4 Special warnings for each target species

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 antelmintics 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.

4.5 Special precautions for use

(i) Special precautions for use in animals:
Severely diseased animals with reduced appetite/anorexia should be treated parenterally.

Note 1
Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in reinfestation and retreatment may be necessary.

Note 2
Since the effect of ivermectin on mange mites is not immediate, avoid direct contact between treated and untreated pigs for at least one week after completion of treatment. Treated pigs can be transferred to clean pens or grouped with uninfected pigs only one week after completion of treatment.

Note 3
Louse eggs are unaffected by treatment.

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.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, drink or eat while handling the product.
Wash hands after use.
Mixing of the product with feed must take place in a well ventilated area.
Avoid contact with skin and eyes. In case of accidental contact, wash the affected area thoroughly with clean running water. If eye irritation persists, seek medical advice.

(iii) Other precautions:
Manure of treated animals should not be spread onto land where surface run-off may occur.

As ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

At the recommended dose rate, no adverse effects on fertility or gestation in breeding animals were observed.

The product can be administered during lactation.

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

In-feed use. For the production of medicated feedingstuff.

The product can be incorporated into meal feed or pelleted feed.

0.1 mg ivermectin per kg bodyweight per day (equivalent to 16.7 mg Noromectin Premix for Swine per kg bodyweight per day) administered for 7 consecutive days.

The dosage per tonne of feedingstuff (inclusion rate) should be adjusted to the current actual daily feed intake of the animals since this varies depending on age, general health, category of animals and animal husbandry (e.g. different environmental temperature, different feeding regime).

To ensure thorough dispersion, 0.333 kg or 1.67 kg of the product (depending on weight of pigs) should be first mixed with 5 kg feed ingredients before incorporation into the final mix.

The appropriate inclusion rate per kilogramme or tonne of feed can be calculated as follows:

$$\frac{\text{16.7 mg Noromectin Premix for Swine per kg bodyweight per day} \times \text{Heaviest pig bodyweight (kg)}}{\text{Average daily feed intake (kg per animal)}} = \text{mg Noromectin Premix for Swine per kg of feed} = \text{g Noromectin Premix for Swine per t of feed}$$

This product should be incorporated by licensed feed manufacturers only. The product can be incorporated in pelleted feed preconditioned with steam for up to 10 seconds at a temperature not exceeding 85ºC.

Growing Pigs: The recommended dose level of 0.1 mg/kg is obtained under most circumstances for pigs up to 40 kg bodyweight by including 333 g of the product in each tonne of final feed. The ivermectin should be thoroughly mixed in the finished feed and fed continuously as the only ration for seven consecutive days. In pigs weighing more than 40 kg, average daily feed consumption may fall below 5% of bodyweight, particularly if they are on a restricted feeding programme or where pigs are fed a high protein ration. Therefore for pigs weighing 40 kg to 100 kg, include 400 g of the product per tonne of feed.

Adult Pigs: The recommended dose level for adult pigs weighing over 100 kg liveweight is achieved in most circumstances by thoroughly mixing 1.67 kg the product in each tonne of finished feed. The resulting medicated feed should be fed at a rate of 1 kg per 100 kg bodyweight for seven days as part of the individual ration. Where medicated feed is fed as part of the ration, it is recommended that the ivermectin medicated feed is fed first. After this is consumed, any remaining daily feed allocation should be given. This should be repeated for seven consecutive days. Alternatively where dry feed intake can be accurately measured and all the animals to be treated have a similar bodyweight, the inclusion rate can be calculated using the previous formula. This assumes the total ration is to be medicated.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. When treating groups of pigs, ensure they are grouped by weight and dose to the heaviest pig in the group.

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

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

Ivermectin has a recognised wide safety margin in swine. No clinically significant signs of intolerance were observed when the product was administered orally to swine at up to 3 times the normal therapeutic dose.

No antidote has been identified. If suspected toxic reactions occur, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

4.11 Withdrawal period(s)

Meat and Offal: 12 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avermectins
ATC Vet Code: QP 54AA01.

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.

Avermectins interact selectively and with high affinity with glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membranes to chloride ions, causing irreversible neuromuscular blockade in nematodes, followed by 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 compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocylic 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

Ivermectin is highly lipid soluble and is well absorbed following administration by the oral route. Ivermectin and its metabolites are mainly excreted in faeces, less than 1% are excreted via the urine. Liver and fat contain the highest residue levels and muscles the lowest.

After oral administration of the product in feed at the recommended dose of 100 µg ivermectin/kg bodyweight once daily for 7 consecutive days, the following approximate parameters were observed
C_{max} = 6.8 ng/ml; AUC = 170 ng.h/ml and T_{max} = 6 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Propyl gallate
Citric Acid
Propylene Glycol
Ground Maize Meal

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 incorporation into meal feed or pelleted feed: 3 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

The product will be supplied in 1 kg and 5 kg 4-ply kraft paper bags, with high-density polyethylene liners sealed with a reinforced stitch.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. 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)

VPA22664/063/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 November 2001
Date of last renewal: 16 November 2006

10 DATE OF REVISION OF THE TEXT

February 2019