Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Drench 0.8 mg/ml Oral Solution for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Ivermectin 0.8 mg/ml

Excipient(s)
Benzyl alcohol 30 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Solution. A pale yellow clear liquid

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

The medicinal product is indicated for the treatment and control of gastrointestinal nematodes, lungworms, and nasal bots of sheep.

Gastro-intestinal worms
Haemonchus contortus [Adult, L4 and inhibited L4]*, Ostertagia (Teladorsagia) circumcincta* [Adult, L4 and inhibited L4]*, Trichostrongylus axei* [Adult and L4], *Trichostrongylus colubriformis* [Adult and L4], *Trichostrongylus vitrinus* [Adult and L4], *Cooperiacurticei* [Adult and L4], *Cooperia oncophora* [Adult and L4], *Nematodirus battus* [Adult and L4], *Nematodirus filicollis* [Adult and L4], *Nematodirusspathiger* [Adult and L4]*, Strongyloides papillosus* [Adult and L4]*, Oesophagostomumcolumbianum* [Adult and L4], *Oesophagostomum venulosum* [Adult and L4] and adult *Chabertia ovina*.

Inhibited larval stages and benzimidazole resistant strains of *H contortus* and *Ostertagia (Teladorsagia) circumcincta* are also controlled.

Lungworms (adult and immature):

Dictyocaulus filaria

Nasal bot (all larval stages):*Oestrus ovis*

4.3 Contraindications

Do not use in animals in which milk is intended for human consumption.

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 (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.

4.5 Special precautions for use

Special precautions for use in animals
The product has been formulated specifically for sheep. It should not be administered to other species as severe adverse reactions may occur. 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not smoke or eat while handling the product.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the product into the eyes should be washed immediately.

4.6 Adverse reactions (frequency and seriousness)

Some animals may cough slightly immediately after treatment.

4.7 Use during pregnancy, lactation or lay

The medicinal product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.Do not use in lactating sheep producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Ivermectin should be administered at a dose rate of 200 micrograms per kg bodyweight. The medicinal product should be given orally at the recommended dose rate of 1 ml per 4 kg bodyweight. The treated animals should be monitored according to good husbandry practices.

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 overdosing.

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

The veterinary medicinal product was tolerated up to 3 times the recommended dose. Symptoms of overdose include trembling, convulsions and coma. In case of overdose, symptomatic treatment should be given.

4.11 Withdrawal period(s)

Meat and offal: 10 days.

Milk: Not permitted for use in lactating sheep producing milk for human consumption. Do not use in non-lactating dairy sheep within 60 days of lambing.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide
ATC vet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin in 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 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

Peak levels of ivermectin are observed around 16 hours following oral administration of the medicinal product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N,N-dimethylacetamide
Polysorbate 80
Benzyl Alcohol
Disodium hydrogen (orthophosphate dihydrate)
Sodium dihydrogen (orthophosphate dihydrate)
Purified water

6.2 Major incompatibilities

None known

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:5 years
Shelf life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

The veterianry medicinal product will be supplied in 1.0 L, 2.5 L and 5.0 L and 2 x 5.0 L high density polyethylene Jerry can containers complete with polypropylene caps and 1.0 L, 2.5 L, 5.0 L and 2 x 5.0 L high density polyethylene Back-pack containers complete with polypropylene plastic screw 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

EXTREMELY DANGEROUS TO AQUATIC LIFE. Do not contaminate surface waters or ditches with 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)

VPA22664/053/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 June 2000
Date of last renewal: 20 September 2006

10 DATE OF REVISION OF THE TEXT

January 2019