Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 0.08% w/v Drench for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Ingredient
Ivermectin 0.8 mg

Excipient(s)
Benzyl alcohol (E1519) 0.03 ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
A clear yellow pale liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

For the treatment of the following gastrointestinal nematodes, lungworms and nasal bots of sheep.

Gastrointestinal roundworms (adult and fourth stage larvae):
Haemonchus contortus[adult, L4 and inhibited L4],
Ostertagia (Teladorsagia) circumcincta [adult, L4 and inhibited L4]
Trichostrongylus spp
Cooperia curticei (adults)
Cooperia oncophora [adult and L4]
Nematodirus spp including *N. battus*
Strongyloides papillosus
Oesophagostomum columbianum [adult and L4]
Oesophagostomum venulosum (adults)
Chabertia ovina (adults)

Lungworms(adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

4.3 Contraindications

Do not use in sheep known to be hypersensitive to ivermectin.
See section 4.7.

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 devise (if any).

Suspected clincal 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 *Haemonchus contortus* in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals
The product has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
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.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the product into 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

Do not treat sheep in lactation or pregnant sheep 28 days before parturition.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

The product should be given orally, on a single occasion, at the recommended dosage rate of 200 micrograms ivermectin per kg of bodyweight (1 ml per 4 kg bodyweight).
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 product has been administered to sheep at twice the recommended dose rate with no adverse effects.

4.11 Withdrawal period(s)

Meat and offal: 10 days

Milk: Not permitted for use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutical Group: Antiparasitic, avermectins
ATC Vet Code: QP54AA01

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 highly effective parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

Ivermectin has been demonstrated to be efficacious against benzimidazole resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta*.

Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

5.2 Pharmacokinetic particulars

After oral administration of the recommended dose of the product to sheep (200 µg per kg bodyweight), the following mean parameters were observed:

Cmax 5.99 ng/ml; AUC 227.1 ng/ml.h; Tmax 12 hours, T½ elimination 24 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Sodium Dihydrogen Orthophosphate Dihydrate
Disodium Hydrogen Orthophosphate Dihydrate
N,N-dimethylacetamide
Benzyl Alcohol (E1519)
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 product will be supplied in 1.0L, 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 fish and aquatic life. Do not contaminate surface waters or ditches with 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)

VPA22664/061/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 January 2001
Date of last renewal: 13 October 2010

10 DATE OF REVISION OF THE TEXT

February 2019