Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Macromectin 0.8 mg/ml oral solution for sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Ivermectin	0.8	mg/ml

Excipients:

Contains Benzyl alcohol (as preservative)	0.03	ml

Excipients to 1ml (For full list of excipients, see Section 6.1)

3 PHARMACEUTICAL FORM

A pale yellow clear oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

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

Gastrointestinal 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],*Cooperia curticei* [Adult and L4], *Cooperia oncophora* [Adult and L4], *Nematodirus battus* [Adult and L4], *Nematodirus filicollis* [Adult and L4], *Nematodirus spathiger* [Adult and L4], *Strongyloides papillosus* [Adult and L4], *Oesophagostomum columbianum* [Adult and L4], *Oesophagostomum venulosum* [Adult and L4], and adult *Chabertia ovina*.

Benzimidazole resistant strains of *H. contortus* and *Ostertagia (Teladorsagia) circumcincta* also controlled.

Lungworms(adult and immature)
Dictyocaulus filaria

Nasal bot (all larval stages)
Oestrus ovis

4.3 Contraindications

None.

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.

Resistance to ivermectinhas been reported in *Haemonchus contortus*in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibilityand recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals
Macromectin 0.8mg/ml Oral Solution 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not smoke or eat while handling the product. Use protective gloves.
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

The product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.

4.8 Interaction with other medicinal products and other forms of interactions

No data available.

4.9 Amounts to be administered and administration route

Ivermectin should be administered orally at a dosage rate of 200 µg per kg bodyweight (1ml per 4kg 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.

The treated animals should be monitored according to good husbandry practices.

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

The veterinary medicinal product was tolerated up to 3 times the recommended dose.

Following administration of ivermectin at 20x the recommended dose level, only mild incoordination and depression were observed.

4.11 Withdrawal period(s)

Meat and Offal: 10 days.
Milk: Do not 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

Pharmacotherapeutic group: Macrocyclic lactones - avermectins
ATC code: QP 54 AA 01

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 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 product to sheep at the recommended dose of 200 µg/kg, the maximum plasma concentration of ivermectin was 5.99 µg/ml, 16 hours following administration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
N,N-Dimethylacetamide
Benzyl Alcohol
Disodium Hydrogen Phosphate Dihydrate
Sodium Dihydrogen Phosphate Dihydrate
Purified Water

6.2 Major incompatibilities

Not applicable.

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 1.0 L, 2.5 L, 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 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)

VPA22664/075/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2 September 2005
Date of last renewal: 2 October 2010

10 DATE OF REVISION OF THE TEXT

February 2019