Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Primectin 1% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Ivermectin 1.0% w/v

Excipients

Polyethylene glycol to 100.0% v/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection for subcutaneous use.
Colourless to pale yellow, clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Beef and non-lactating dairy cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

Cattle

Treatment of infections by the following parasites:

Gastro-intestinal roundworms (adults and fourth stage larvae):
*Ostertagia ostertagi (*including inhibited *O. ostertagi*), *Ostertagia lyrata*, *Haemonchus placei*, *Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Oesophagostomum radiatum, Nematodirus helvetianus* (adult*).*

Lungworms (adult and fourth stage larvae)
Dictyocaulus viviparus

Warbles:
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus

Mange Mites:
Psoroptes communis var *bovis, Sarcoptes scabiei* var *bovis*

The product may be used to reduce infection of the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Pigs
In pigs: treatment of infections 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)

Lungworms:
Metastrongylus spp (adults)

Lice:
Haematopinus suis

Mange mites:

Sarcoptes scabiei var suis

Sheep

For the treatment of infections by the following species of gastrointestinal roundworms, lungworms, nasal bots and psoroptic mange (sheep scab).

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia circumcincta (including inhibited larvae), *Haemonchuscontortus*, (including inhibited larvae), *Trichostrongylus axei* (adults), *Trichylostrongylus colubriformis* (adults), *Trichostrongylus vitrinus* (adults), *Cooperia curticei, Nematodirus filicollis.*

Lungworms:
Dictyocaulus filaria (adults and fourth stage larvae)

Nasal Bots:
Oestrus ovis (all larval stages)

Mange Mites:
Psoroptes ovis

4.3 Contraindications

Do not use in dogs or cats as severe adverse reactions may occur.

The product is not for intravenous or intramuscular use.

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

In cattle: To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment**.**

Treatment of psoroptic mange (sheep scab) with one injection is not recommended, because although clinical improvement may be seen elimination of all mites may not occur.
Sheep scab (Psoroptes ovis) is an extremely contagious external parasite of sheep. Following treatment of infected sheep great care must be taken to avoid re-infestation, as mites may be viable for up to 15 days off the sheep. It is important to ensure all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and non-treated, non-infected flocks must be avoided until at least 7 days after the last treatment.

4.5 Special precautions for use

Special precautions for use in animals
Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid underdosing, animals should be grouped according to their bodyweight and dosed according to the heaviest animal in the group.

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.

Avoid the introduction of contamination during use.
Should any apparent growth or discolouration occur the product should be discarded

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Do not smoke or eat while handling the product.
Direct contact of the product with the skin should be avoided.
Wash hands after use.
Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at the injection site.

4.6 Adverse reactions (frequency and seriousness)

Transitory discomfort has been observed in some cattle following subcutaneous administration. Some soft tissue swelling at injection site has been commonly observed. These reactions disappear without treatment.

Mild and transient pain and/or swelling reactions may be seen in some pigs following subcutaneous injection. All these reactions disappear without treatment.

Immediately following subcutaneous injection, activity suggesting pain, sometimes intense but usually transient has been observed in some sheep. Soft tissue swelling and thickening of the skin at the injection site has been observed in treated animals. Typically, these reactions are transient and disappear within one to four weeks.

4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation in sows; and in cattle and sheep provided that the milk is not intended for human consumption. See also section 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

No data available.

4.9 Amounts to be administered and administration route

Bodyweight and dosage should be accurately determined prior to treatment to avoid underdosing
A sterile 17-gauge, half-inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper. Swab the septum before removing each dose. Use a dry sterile needle and syringe.

Cattle
Ivermectin should be administered at a dosage rate of 200 micrograms per kg bodyweight (1 ml/50 kg). It should be injected subcutaneously in front of or behind the shoulder using aseptic technique.

Pigs
The product should be administered at a dosage rate of 300 micrograms ivermectin per kg bodyweight (1ml/33 kg). It should be injected subcutaneously into the neck using aseptic technique. Exact dosing is important especially in pigs with low bodyweight, therefore a syringe capable of dosing in 0.1 ml steps should be used.

Sheep
0.5 ml per 25 kg bodyweight (based on a recommended level of 200 micrograms ivermectin per kg bodyweight).
For the treatment of gastrointestinal roundworms, lungworms and nasal bots, inject once subcutaneously in the neck using aseptic precautions.
For the treatment and control of *Psoroptes ovis* (sheep scab), two injections with a 7 days interval are required to treat clinical signs of scab and to eliminate living mites. It is recommended that the second injection should be administered at a different site (opposite side of the neck) to the first injection. For young lambs weighing less than 20.0kg give 0.1ml per 5kg. In these lambs the use of a syringe which can deliver as little as 0.1ml is recommended.

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

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

In the case of overdose a symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.

In cattle, a single dose of 4.0 mg ivermectin per kg (20 times the use level) given subcutaneously resulted in ataxia and depression. No systemic or local signs of toxic effects were reported at 3 times the recommended dose in both species - cattle and pigs.

Ivermectin has a recognised wide safety margin in swine. A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

In sheep, clinical symptoms of ivermectin toxicity include ataxia and depression. No signs of systemic toxicity were observed in sheep treated at up to two times the recommended dose rate.

No antidote has been identified. In case of overdose, symptomatic treatment should be given.

4.11 Withdrawal period(s)

Cattle
Meat and offal: 49 days
Not permitted for use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Pigs
Meat and offal: 35 days

Sheep
Meat and offal:42 days.
Milk: Do not use in lactating dairy sheep producing milk for human consumption. Do not use in non-lactating diary sheep within 60 days of lambing.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide
ATC vet code: QP54AA01

5.1 Pharmacodynamic properties

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

After subcutaneous administration of the recommended dose of Primectin Injection to cattle (200 micrograms/kg), the following parameters were observed: Cmax of 37 ng/ml and AUC of 7558 ng/ml.h. In cattle, only about 1-2% is excreted in the urine; the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products
After subcutaneous administration of the recommended dose of Primectin Injection to pigs (300 microgram/kg), the following parameters were observed: Cmax of 14 ng/ml, and AUC of 1887 ng/ml.h. Ivermectin is only partially metabolized. Biliary excretion, followed by elimination in faeces is probably the major route of ivermectin excretion in pigs.
Following the subcutaneous administration of the product to sheep at a dose of 200 micrograms ivermectin/kg, the maximum concentration in plasma (mean Cmax = ~14 ng/ml) was reached within 1-4 days. The elimination half-life is ~109 hours. Only about 2% of the drug is excreted in urine, faecal excretion being the major route of elimination.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal Polyethylene glycol 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

Store below 30^{o}C.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

Primectin Injection will be supplied in 50 ml, 100 ml, 250 ml and 500 ml volumes, presented in high density polyethylene vials with bromobutyl bungs and aluminium 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

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 safely in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/077/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 December 2000
Date of last renewal: 20 March 2009

10 DATE OF REVISION OF THE TEXT

February 2019