1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 10 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol Formal
Polyethylene Glycol 200

A clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle (beef and non-lactating dairy cattle) and pigs.

3.2 Indications for use for each target species

Cattle
Treatment of infections by the following parasites:

Gastrointestinal 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*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adult).

Lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus.*

Warbles (parasitic stages):
Hypoderma bovis, *Hypoderma lineatum.*

Sucking Lice:
Linognathus vituli, *Haematopinus eurysternus*, *Solenopotes capillatus*.

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

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

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.*

3.3 Contraindications

Do not use in dogs or cats as severe adverse reactions may occur.
The veterinary medicinal product is not for intravenous or intramuscular use.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the veterinary medicinal 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.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid under dosing animals should be grouped according to their body weight and dosed according to the heaviest animal in the group.
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:

Should any apparent growth or discolouration occur the veterinary medicinal product should be discarded.
Do not smoke or eat while handling the veterinary medicinal product.
Direct contact of the veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

The veterinary medicinal product has been formulated specifically for cattle and pigs. 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.

3.6 Adverse events

Target species: Cattle (beef and non-lactating dairy cattle).

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare	Discomfort

(<1 animal / 10,000 animals treated, including isolated reports):	

[1] These soft tissue swellings disappear without treatment.

Target species: Pigs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pain[1] Injection site swelling[1]

[1] Mild and transient. These reactions disappear without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used in beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Can be used in sows at any stage of pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use.

For single administration only.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Cattle
Ivermectin should be administered at a dosage rate of 200 microgram per kg bodyweight (1 ml/50 kg). It should be injected subcutaneously in front of or behind the shoulder using aseptic technique. A sterile 17-gauge, half-inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper. No untreated cattle should be added to the pasture. Treated animals should be monitored according to good husbandry practices always.

Pigs
The veterinary medicinal product should be administered at a dosage rate of 300 microgram per kg bodyweight (1 ml/33 kg). It should be injected subcutaneously into the neck using aseptic technique. A sterile 17-gauge, half-inch needle is recommended. Exact dosing is important especially in pigs with low bodyweight, therefore a syringe capable of dosing in 0.1 ml steps should be used.
The treatment schedule should be based on the local epidemiological situation.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle
Meat and offal: 49 days.

Not authorised 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: 18 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.1 Pharmacodynamics

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.

4.2 Pharmacokinetics

After subcutaneous administration of the recommended dose of the veterinary medicinal product to cattle (200 µg/kg), the following parameters were observed: Cmax of 37 ng/ml and AUC of 7558 ng/ml.hr. After subcutaneous administration of the recommended dose of the veterinary medicinal product to pigs (300 µg/kg), the following parameters were observed: Cmax of 14 ng/ml, and AUC of 1887 ng/ml.hr. Ivermectin is only partially metabolised. 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. Biliary excretion, followed by elimination in faeces is probably the major route of ivermectin excretion in pigs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in 50 ml, 100 ml, 250 ml, 500 ml and 1 litre volumes, presented in high density polyethylene vials with bromobutyl bungs and aluminium caps.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664-065-001

8. DATE OF FIRST AUTHORISATION

29/06/2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

11/12/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).