1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 5 mg/ml Pour-On Solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Ivermectin 5 mg

Excipients:

Qualitative composition of excipients and other constituents
Crodamol CAP
Triethanolamine
Patent Blue V Dye
Isopropyl Alcohol

A clear blue solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and non-lactating cattle).

3.2 Indications for use for each target species

This product is indicated for the treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*)
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Trichuris spp (adult).

Occasionally variable activity may be observed against *H. placei* (L4), *Cooperia* spp, *T. axei* and *T. colubriformis*.

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp

Warbles (parasitic stages):
Hypoderma bovis
Hypoderma lineatum

Sucking Lice:
Linognathus vituli
Haematopinus eurysternus,

Biting Lice:
Damalinia (bovicola) bovis

Mange mites:
Chorioptes bovis
Sarcoptes scabiei var *bovis*

3.3 Contraindications

Do not use in dairy cows, during lactation or the dry period, and in beef cows during the lactation period when milk is intended for human consumption.
Do not use in pregnant heifers within 60 days prior to calving**.**

3.4 Special warnings

Assess bodyweight as accurately as possible before calculating the dosage.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Do not treat cattle when their hair or hide is wet.
Do not treat cattle if rain is expected, as rain within 2 hours of treatment may reduce efficacy.
Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.

The veterinary medicinal product has been formulated for topical application specifically for cattle. 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.

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 body weight and dosed according to the heaviest animal in the group.

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

Highly flammable - keep away from heat, sparks, open flame or other sources of ignition.

The veterinary medicinal product may be irritating to human skin and eyes and the user should be careful not to apply it to themself or other persons.
Personal protective equipment consisting of rubber gloves and boots with a waterproof coat should be worn when handling the veterinary medicinal product. Protective clothing should be washed after use.
If accidental skin contact occurs, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush the eye immediately with water and seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke or eat while handling the product.
Wash hands after use.
Use only in well-ventilated areas or outdoors.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 its local representative 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:

The veterinary medicinal product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Do not use in dairy cows, during lactation or the dry period, and in beef cows during the lactation period, when milk is intended for human consumption.
Do not use in pregnant heifers within 60 days prior to calving.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Topical use.
The veterinary medicinal product should be administered topically at 500 µg ivermectin per kg bodyweight (1 ml per 10 kg bodyweight).

The formulation should be applied along the midline of the back in a narrow strip between the withers and the tailhead.

Squeeze-Measure-Pour System:
Important - Keep upright when filling and during storage.

It is recommended that calves which are set-stocked in their first season of grazing should be treated 3, 8 and 13 weeks after turnout, for optimal benefit from the persistent effect of ivermectin. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set-stocked. All calves should be included in the program, and no untreated cattle should be added to the pasture. Treated animals should be monitored according to good husbandry practices always.

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

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

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

Meat and offal: 28 days.

Milk: Not authorised for use in cows producing milk for human consumption. Do not use in dairy cows during the dry period.
Do not use in pregnant heifers which are intended to produce milk for human consumption or within 60 days of expected parturition.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

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 nematocial, 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 ligandgated 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 glumamate-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.

4.3 Pharmacokinetics

After administration of the product, the ivermectin is absorbed through the skin into the circulation of the treated animal. The maximum concentration in plasma occurs around 97 hours after application. Peak concentrations of about 11.3 ng/mL are obtained.
Elimination in the faeces (via biliary excretion).

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 of the immediate packaging: 12 months.

5.3 Special precautions for storage

Store below 30 °C.

Squeeze-Measure-Pour System:
Close container when not in use and store in an upright position.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in 250 ml and 1.0 L single-neck, twin-neck and squeeze- measure high density polyethylene dispensers, 1 L high density polyethylene backpacks and 2.5 L and 5 L low density polyethylene backpacks.

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)

VPA22664/066/001

8. DATE OF FIRST AUTHORISATION

29/06/2001

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

22/11/2024

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).