1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Macromectin 5 mg/ml Pour-On Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent Blue V (E131)	0.005 mg
Isopropyl alcohol	to 1.0 ml
Crodamol CAP	
Trolamine	

A clear blue solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of the following pathogenic species of parasites of cattle:

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi L4, adult (including inhibited stage)
Haemonchus placei L4, adult
Trichostrongylus axei L4, adult
T. colubriformis L4, adult
Cooperia spp. L4, adult
Oesophagostomum radiatum L4, adult
Strongyloides papillosus adults
Trichuris spp. adults

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp.

Warbles (parasitic stages):
Hypoderma bovis
H. lineatum

Mites:
Sarcoptes scabiei var bovis
Chorioptes bovis (reduction of infestation)

Lice:
Linognathus vituli,
Haematopinus eurysternus,
Damalinia bovis

The veterinary medicinal product given at the recommended dosage of 500 µg/kg bodyweight, has persistent activity against *Trichostrongylus axei* and *Cooperia* spp. acquired during the 14 days after treatment, only if the whole herd is treated simultaneously. It also has a persistent activity against *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment. It also has a persistent activity on horn flies (*Haematobia irritans*) for 28 days after treatment, partial efficacy may last for up to 35 days post application.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
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 including fatalities in dogs, may occur.

3.4 Special warnings

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in effective 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 veterinary medicinal 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 ivermectin has been reported in *Ostertagia ostertagi* in cattle. Therefore the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

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 veterinary medicinal product at the end of the period of warble fly activity and before the larvae reach their resting sites.

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. Under such conditions, efficacy of the veterinary medicinal product against infections of *Ostertagia ostertagi* or *Dictyocaulus viviparous* may be maintained.
Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.
Frequent and repeated use of ivermectin may lead to the development of resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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.
Use only in well-ventilated areas or outdoors.
As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Do not smoke or eat while handling the veterinary medicinal product.
Keep away from heat, spark, open flame or other sources of ignition.
HIGHLY FLAMMABLE.

Special precautions for the protection of the environment:
The influence of extreme climatic conditions on the persistent activity of the veterinary medicinal product is unknown. As ivermectin is extremely dangerous for fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

Other precautions:
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 breed or crosses, and also in turtles/tortoises.

3.6 Adverse events

Cattle:

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

[1] Slight. May occur occasionally and usually rapidly disappears 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 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. (For information on use in lactating animals, see section 3.12).

Fertility:

The veterinary medicinal product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pour-on use.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 µg/kg bodyweight). To ensure a correct dosage, body weight should be determined as accurately as possible.

Administration: The formulation should be applied along the mid-line of the back narrow strip between the withers and tailhead.

To obtain optimal benefit from the veterinary medicinal product, it is recommended that it be used as part of a treatment programme based on the epidemiology of the parasites in question.

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 over- dosing.

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

No sign of toxicity appeared up to 1000 µg/kg (2 times the recommended dose rate). No antidote has been identified.
The symptoms of overdose can be trembling, convulsions and coma.
In case of overdose, a symptomatic treatment should be given.

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.

Not authorised for use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of expected parturition.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind 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 parasite. 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.

4.3 Pharmacokinetics

After a single topical administration of 500 microgram per kilogram bodyweight, the mean maximum plasma concentration (C_{max}) of 11.26 ng/ml was reached after a mean (T_{max}) of 96.8 hours. The concentrations mentioned relate to the main compound of ivermectin, 22, 23-dihydroavermectin B_{1a}. The excretion occurs mainly through faeces and, in a lesser proportion, via urine.

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: 11 months.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.

Bottles should remain upright during storage.
If stored at temperatures less than 0 °C the veterinary medicinal product may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

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

5.4 Nature and composition of immediate packaging

250 ml and 1.0 L single-neck high density polyethylene dispensers.
250 ml and 1.0 L twin-neck high density polyethylene dispensers.
250 ml and 1.0 L squeeze-measure high density polyethylene dispensers.
1 L high density polyethylene backpacks.
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 is extremely 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)

VPA22664/076/001

8. DATE OF FIRST AUTHORISATION

25/11/2005

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

20/06/2025

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).