1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 5 mg/ml Pour-On Solution for cattle [IE]

Paramectin 5 mg/ml soluzione pour-on per bovini [IT]

Paramectin Pour On 5mg/ml Solução para unção contínua para Bovinos [PT]

PARAMECTIN POUR-ON 5 mg/ml solución para unción dorsal continua para bovino [ES]

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}>

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

{DD/MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

250 mL, 1 L, 2.5 L, 5 L CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 5 mg/ml Pour-On Solution for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 5 mg

3. PACKAGE SIZE

250 ml.
1.0 L.
2.5 L.
5 L.

4. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle).

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For topical administration.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 µg ivermectin /kg bodyweight)

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

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

Example:

Bodyweight kg	**Dose volume (ml)**	**Doses per pack 250 ml**	**Doses per pack 1 L**	**Doses per pack 2.5 L**	**Doses per pack 5 L**
100	10	25	100	250	500
150	15	16	66	166	333
200	20	12	50	125	250
250	25	10	40	100	200
300	30	8	33	83	166

Over 300 kg bodyweight, give 1 ml per 10 kg bodyweight.

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 under dosing animals should be grouped according to their body weight and dosed according to the heaviest animal in the group.

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 months.

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 ml, 1 L, 2.5 L, 5 L LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 5 mg/ml Pour-On Solution for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 5 mg

3. TARGET SPECIES

Cattle (beef and non-lactating cattle).

4. ROUTES OF ADMINISTRATION

For topical application.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 µg ivermectin per kg bodyweight).

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

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 months.

7. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Paramectin 5 mg/ml Pour-On Solution for Cattle

2. Composition

Each ml contains:

Active substance:

Ivermectin 5 mg

A clear blue solution.

3. Target species

Cattle (beef and non-lactating dairy cattle).

4. Indications for use

For the treatment and control of gastrointestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle.

The veterinary medicinal product applied at the recommended dose rate of 500 µg ivermectin per kg is indicated for the effective control of these parasites:

Gastrointestinal roundworms (adult 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 rhodesii

Warbles (parasitic stages):
Hypoderma bovis
H lineatum

Mange mites:
Sarcoptes scabiei var *bovis*

Chorioptes bovis

Sucking Lice:
Linognathus vituli
Haematopinus eurysternus,

Biting Lice:
Damalinia (bovicola) bovis

5. 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**.**

6. Special warnings

Special warnings:

Assess bodyweight as accurately as possible before calculating the dosage.

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 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.

Pregnancy and lactation:

This 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 which are intended to produce milk for human consumption within 60 days of expected parturition

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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

Major incompatibilities:

None known.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

For topical administration.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 microgram ivermectin per kg bodyweight).

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

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

9. Advice on correct administration

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

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.

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.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30 °C.

Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 12 months.

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

12. Special precautions for disposal

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

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

250 ml and 1.0 L single-neck dispensing bottles.

250 ml and 1.0 L twin-neck dispensing bottles.
250 ml and 1.0 L squeeze-measure dispensing bottles.
1 L, 2.5 L and 5 L backpacks.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release:
Norbrook Laboratories Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Newry, Co. Down,
Northern Ireland

<Local representatives <and contact details to report suspected adverse reactions>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

17. Other information

MODE OF ACTION

Ivermectin paralyses and ultimately kills parasitic nematodes, arachnids, and insects by its effect on the nervous systems of these parasites. At therapeutic doses, ivermectin has no adverse effect on cattle since it does not readily penetrate their central nervous systems. Ivermectin belongs to the avermectin class of anthelmintic endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents.