

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 0.5% w/v Pour-On Solution
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 0.5% w/v (5 mg/ml).

3. PHARMACEUTICAL FORM

pour-on solution

4. PACKAGE SIZE

250 ml / 1 litre / 2.5 litre / 5 litre

5. TARGET SPECIES

Beef and non-lactating dairy cattle

6. INDICATION(S)

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.

Paramectin Pour-On kills gastrointestinal nematodes (adult and fourth stage larvae): *Ostertagia ostertagi* including inhibited larvae, *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp, *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult) and *Trichuris* spp (adult).

Paramectin Pour-On kills lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus*.

Paramectin Pour-On kills eyeworms (adult): *Thelazia* spp.

Paramectin Pour-On kills warbles (parasitic stages): *Hypoderma bovis* and *Hypoderma lineatum*.

Paramectin Pour-On kills mange mites: *Sarcoptes scabiei* var *bovis* and *Chorioptes bovis*.

Paramectin Pour-On kills lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinea bovis* and *Solenopotes capillatus*.

Paramectin Pour-On given at the recommended dosage of 500 micrograms ivermectin/ kg bodyweight controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment; *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment. It also controls horn flies (*Haematobia irritans*) for up to 35 days after treatment.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Example:

Bodyweight (kg)	Dose volume (ml)	Doses per pack
100	10	100
150	15	66
200	20	50
250	25	40
300	30	33

Over 300 kg bodyweight, give an additional 1 ml for each additional 10 kg bodyweight.

To ensure administration of correct dose, bodyweight should be determined as accurately as possible, accuracy of dosing device should be checked.

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.

8. WITHDRAWAL PERIOD(S)

Cattle (meat): 28 days. Do not use in cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

FOR EXTERNAL USE ONLY

Do not treat cattle when their hide or hair 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 may have mange, scabs or other lesions or to areas contaminated with mud or manure.

Paramectin Pour-On has been formulated for topical application specifically in cattle. It should not be applied or administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

Operator Warnings:

Paramectin Pour-On may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves, rubber boots and a waterproof coat when applying the 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 eyes immediately with water and get medical attention.

Do not smoke or eat while handling the product.
Wash hands after use.
Use only in well ventilated areas or outdoors.

10. EXPIRY DATE

DOM:

EXP:

Once opened use by...

Shelf-life after opening the immediate packaging: 1 year

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Protect from light. Store in tightly closed original container. Use only in well ventilated areas or outdoors. The containers should be stored upright in their original boxes when not in use.

If stored at temperatures below 0°C, Paramectin Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE
[Distribution category]

For animal treatment only.

POM-VPS To be supplied only on veterinary prescription

Chemical Group of Anthelmintic Endectocides [3-AV]

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by: Norbrook Laboratories Limited
Newry
Co. Down
BT35 6JP
United Kingdom

Distributed by: Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

ManA 2000
Vm: 02000/4197

17. MANUFACTURER’S BATCH NUMBER

BN:

FLAME SYMBOL

Highly flammable
Keep container tightly closed
Keep away from sources of ignition
No smoking

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 0.5% w/v Pour-On Solution
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 0.5% w/v (5 mg/ml).

3. PHARMACEUTICAL FORM

pour-on solution

4. PACKAGE SIZE

250 ml / 1.0 L / 2.5 L / 5 L

5. TARGET SPECIES

Beef and non-lactating dairy cattle

6. INDICATION(S)

For the treatment and control of gastrointestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

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

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.

8. WITHDRAWAL PERIOD(S)

Cattle (meat): 28 days. Do not use in cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

Do not treat cattle when their hide or hair 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 may have mange, scabs or other lesions or to areas contaminated with mud or manure.

Paramectin Pour-On has been formulated for topical application specifically in cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

Do not smoke or eat while handling the product. Wash hands after use.

See package leaflet for full user warnings.

10. EXPIRY DATE

DOM:

EXP:

Once opened use by...

Shelf-life after opening the immediate packaging: 1 year

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

Protect from light.

Store in tightly closed original container. Use only in well ventilated areas or outdoors. The containers should be stored upright in their original boxes when not in use.

If stored at temperatures below 0°C, Paramectin Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate ponds, waterways or ditches with the product or used container.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE
[Distribution category]

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription.

Chemical Group of Anthelmintic Endectocides [3-AV]

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:

Norbrook Laboratories Limited
Newry
Co. Down, BT35 6JP
United Kingdom

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

ManA 2000
Vm: 02000/4197

17. MANUFACTURER’S BATCH NUMBER

B.N.:

**PACKAGE LEAFLET:
Paramectin 0.5% w/v Pour-On Solution**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Norbrook Laboratories Limited
Newry, Co. Down
BT35 6JP
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 0.5% w/v Pour-On Solution
Ivermectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Active Substance:

Ivermectin 0.5% w/v

Excipients:

Patent Blue V (E131) 0.0005% w/v

A clear blue liquid.

4. INDICATION(S)

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

This product offers users dosing flexibility in a pour-on, systemically active formulation. Paramectin Pour-On contains ivermectin a member of the avermectin class of anthelmintic endectocides. Its convenience, broad-spectrum efficacy and wide safety margin make it an ideal product for parasite control in cattle.

Ivermectin Pour-On applied at the recommended dose rate of 500 micrograms ivermectin per kg is indicated for the control of these parasites:

Gastrointestinal roundworms (adult and fourth stage larvae):

Ostertagia ostertagi (including inhibited larvae), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp, *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult), and *Trichuris* spp (adult).

Lungworms (adult and fourth stage larvae):

Dictyocaulus viviparus

Eyeworms (adult):

Thelazia spp

Warbles (parasitic stages):

Hypoderma bovis and *H. lineatum*

Mange mites:

Sarcoptes scabiei var. *bovis* and *Chorioptes bovis*

Lice:

Linognathus vituli, *Haematopinus eurysternus*, *Damalinia bovis* and *Solenopotes capillatus*

Paramectin Pour-On given at the recommended dosage of 500 micrograms/kg bodyweight controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment; *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment; *Dictyocaulus viviparus* acquired up to 28 days after treatment. It also controls horn fly (*Haematobia irritans*) for up to 35 days after treatment.

5. CONTRAINDICATIONS

Paramectin Pour-On has been formulated for topical application specifically in cattle. It should not be applied or administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

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 macrocyclic lactone endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents.

Studies have demonstrated a wide safety margin, and the recommended use level had no adverse effect on breeding performance.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Beef and non-lactating dairy cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

Squeeze-Measure-Pour System

250 ml bottle and 1 litre pack

(Squeeze dispensing bottle/twin-neck container/single neck container)

- Remove the cap (twin-neck container/single neck container) or attach the dispensing cup to the product bottle (squeeze-measure container) and hold the container in an upright position.
- Gently squeeze the container until the product is level with the desired dose volume increment.
- Dispense the product by tipping the container forward until inverted.

2.5 litre and 5 litre pack

(Collapsible Back Pack)

- Remove the shipping cap from the backpack container and replace with the vent cap provided.
- Attach the hose from the automatic dosing equipment to the outlet from the vent cap.
- Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Cattle should not be treated when hair or hide is wet. Rain falling on animals in less than two hours of dosing may result in reduced efficacy. However, the efficacy of Paramectin Pour-On against infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide or hair is wet or rain falls shortly after treatment. Do not apply to areas of skin which may have mange scabs or other lesions or to areas contaminated with mud or manure.

10. WITHDRAWAL PERIOD(S)

Cattle (meat): 28 days. Do not use in cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

11. SPECIAL STORAGE PRECAUTIONS

HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

Keep out of the sight and reach of children.
Do not store above 30°C.
Protect from light.

Store in tightly closed original container. Close container when not in use. Use only in well ventilated areas or outdoors. The containers should be stored upright in their original boxes when not in use.

If stored at temperatures below 0°C Paramectin Pour-On may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton/label after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 1 year
Important - Keep upright when filling and during storage.
Close container when not in use and store in an upright position.

12. SPECIAL WARNING(S)

This product has been formulated only for external application to cattle, do not use in other species. 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." Do not allow these species to come in contact with this product.

Operator Warnings:

Paramectin Pour-On may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the 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 eyes immediately with water and get medical attention.

Do not smoke or eat while handling the product.

Wash hands after use.

Use only in well ventilated areas or outdoors.

For animal treatment only.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective 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 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 (an avermectin) has been reported in *Cooperia oncophora* in cattle within the EU, in *Teladorsagia* in cattle in developed countries such as New Zealand and *Haemonchus* in cattle outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

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.

It is recommended to treat all animals within a herd or group.

The shedding of nematode eggs can continue for some time after treatment.

Do not combine ivermectin treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2022

15. OTHER INFORMATION

PACKAGE QUANTITIES

Paramectin Pour-On is available in 250 ml and 1 litre twin-neck packs, single-neck packs or a squeeze-measure-pour system or 2.5 litre and 5 litre collapsible backpacks.

Not all package sizes may be marketed.

Legal category

POM-VPS

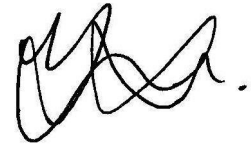
To be supplied only on veterinary prescription.

Ivermectin belongs to the avermectin [3-AV] class of anthelmintic in the endectocides. Chemical group of anthelmintic endectocides [3-AV].

FLAME SYMBOL

Highly flammable
Keep container tightly closed
Keep away from sources of ignition
No smoking

ManA 2000
Vm.: 02000/4197

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 28 October 2022