PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 0.5% w/v Pour-On Solution

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

A clear blue pour-on solution containing ivermectin 0.5% w/v (5 mg/ml).

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.

Noromectin 0.5% w/v Pour-On Solution 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).

Noromectin 0.5% w/v Pour-On Solution kills lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus.*

Noromectin 0.5% w/v Pour-On Solution kills eyeworms (adults): *Thelazia* spp.

Noromectin 0.5% w/v Pour-On Solution kills warbles (parasitic stages): *Hypoderma bovis* and *Hypoderma lineatum*.

Noromectin 0.5% w/v Pour-On Solution kills mange mites: *Sarcoptes scabiei* var *bovis* and *Chorioptes bovis*.

Noromectin 0.5% w/v Pour-On Solution kills lice: *Linognathus vituli, Haematopinus eurysternus, Damalinia bovis* and *Solenopotes capillatus.*

Noromectin 0.5% w/v Pour-On Solution 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.

Rainfall before or after treatment will not affect the efficacy of Noromectin Pour-On Solution.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

FOR EXTERNAL USE ONLY

1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 micrograms ivermectin / kg bodyweight). 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	250 ml 25 1L 100 2.5L 250 5L 500
150	15	250 ml 16 1L 66 2.5L 166 5L 333
200	20	250 ml 12 1L 50 2.5L 200 5L 250
250	25	250 ml 10 1L 40 2.5L 100 5L 200
300	30	250 ml 8 1L 33 2.5L 83 5L 166

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

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

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment. 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

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.

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

Do not apply to areas of skin which may have mange, scabs or other lesions or to areas contaminated with mud or manure.

Noromectin 0.5% w/v Pour-On Solution 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: Noromectin 0.5% w/v Pour-On Solution 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 eat, drink or smoke while handling the product.
Wash hands after use.
Use only in well ventilated areas or outdoors.

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.

10. EXPIRY DATE

EXP:

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, Noromectin 0.5% w/v Pour-On Solution may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
Following withdrawal of the first dose, use the product within 1 year.

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 containers.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription.

Chemical Group of Anthelmintic Endectocides [3-AV]

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

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

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

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

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm: 02000/4172

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 0.5% w/v Pour-On Solution

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

A clear blue pour-on solution containing Ivermectin 0.5% w/v (5 mg/ml)

4. PACKAGE SIZE

250 ml / 1 litre / 2.5 litre / 5 litre

5. TARGET SPECIES

Cattle

6. 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.

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.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption within 28 days after last treatment. Do not use in cows producing milk for human consumption or in such cattle within 60 days prior to calving.

9. SPECIAL WARNING(S), IF NECESSARY

IMPORTANT: **READ PACKAGE LEAFLET BEFORE USE.**
PRECAUTIONS:
HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

Rainfall before or after treatment will not affect the efficacy of Noromectin Pour-On.
Do not apply to areas of skin which may have mange, scabs or other lesions or to areas contaminated with mud or manure.
Noromectin 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.

Operator Warnings: Do not smoke, eat or drink while handling the product. See Package leaflet for full Operator Warnings.

10. EXPIRY DATE

EXP:

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 0ºC, Noromectin 0.5% w/v Pour-On Solution may appear cloudy. Allowing it to warm at room temperature will restore the normal appearance without affecting efficacy.
Following withdrawal of the first dose, use the product within 1 year.

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 used 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

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription.

Chemical Group of Anthelmintic Endectocides [3-AV].

FLAME SYMBOL

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

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4172
ManA 2000

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PACKAGE LEAFLET FOR:
Noromectin 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

Noromectin 0.5% w/v Pour-On Solution

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

A clear, blue pour-on solution containing Ivermectin 0.5% w/v (5 mg/ml)

4. INDICATION(S)

With this product, Norbrook offers users dosing flexibility in a pour-on, systemically active formulation. Noromectin 0.5% w/v Pour-On Solution 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.

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.

Noromectin 0.5% w/v Pour-On Solution 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*

Rainfall before or after treatment will not affect the efficacy of Noromectin 0.5% w/v Pour-On Solution.

5. CONTRAINDICATIONS

Noromectin 0.5% w/v Pour-On Solution 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.

HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.
Do not apply to areas of skin which may have mange scabs or other lesions or to areas contaminated with mud or manure.

Operator Warnings: Noromectin 0.5% w/v Pour-On Solution 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 eat, drink or smoke while handling the product.
Wash hands after use.
Use only in well ventilated areas or outdoors.
For animal treatment only.

6. ADVERSE REACTIONS

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

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.

This product has been formulated only for external application to cattle, do not use in other species.

9. ADVICE ON CORRECT ADMINISTRATION

Squeeze-Measure-Pour System
Important - Keep upright when filling and during storage.
Close container when not in use and store in an upright position.

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.

1 litre, 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, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

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

Keep out of the sight and reach of children.
Do not store above 30ºC.
Protect from light.
Store in a tightly closed container.
The containers should be stored upright in their original boxes when not in use.
If stored at temperatures below 0ºC, Noromectin 0.5% w/v Pour-On Solution may appear cloudy. Allowing it to warm at room temperature will restore the normal appearance without affecting efficacy.
Following withdrawal of the first dose, use the product within 1 year.

12. SPECIAL WARNING(S)

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

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.

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

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 containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2023

15. OTHER INFORMATION

Noromectin 0.5% w/v Pour-On Solution is available in 250 ml and 1 litre single-neck packs, twin-neck packs or a squeeze-measure-pour system or 1 litre, 2.5 litre and 5 litre collapsible backpacks

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.

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].

ManA 2000
Vm 02000/4172

Approved: 01 March 2023