

NOROMECTIN POUR-ON FOR CATTLE - ivermectin solution
Norbrook Laboratories Limited

Noromectin® Pour-On
(ivermectin topical solution)
for Cattle

Contains 5 mg ivermectin/mL

Parasiticide

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INTRODUCTION

Noromectin Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Noromectin Pour-On (ivermectin topical solution) contains ivermectin, a unique chemical entity.

MODE OF ACTION

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.

INDICATIONS

Noromectin Pour-On (ivermectin topical solution) applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L4)
<i>Haemonchus placei</i>	(adults and L4)
<i>Trichostrongylus axei</i>	(adults and L4)
<i>T. colubriformis</i>	(adults and L4)
<i>Cooperia oncophora</i>	(adults and L4)
<i>Cooperia punctata</i>	(adults and L4)
<i>Cooperia surnabada</i>	(adults and L4)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L4)
<i>Trichuris spp.</i>	(adults)

Lungworms

Dictyocaulus viviparus (adults and L4)

Cattle Grubs

Hypoderma bovis
H. lineatum (parasitic stages)

Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli
Haematopinus eurysternus
Damalinia bovis
Solenopotes capillatus

Horn Flies

Haematobia irritans

PERSISTENT ACTIVITY

Noromectin Pour-On (ivermectin topical solution) has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

TREATMENT OF CATTLE FOR HORN FLIES

Noromectin Pour-On (ivermectin topical solution) controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Noromectin Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

ADMINISTRATION

Metering Cup with Measure-Squeeze-Pour System (1 Liter (33.8 fl oz) Container with 25 mL Metering Cup)

This pack contains 1 Metering Cup and 1 dip tube

1. Insert the dip tube into base of the Metering Cup. Leave the “slotted end” of the dip tube exposed in

- the bottom of the container.
2. Unscrew shipping cap from container top.
 3. Screw the Metering Cup onto container top
 4. **Measure:** To select the correct dose rate, rotate the adjuster cap (top) in either direction to position the dose indicator to the weight of the animal you want to treat. When body weight is between markings, use the higher setting.
 5. **Squeeze** the container gently to fill the Metering Cup to the required dose. Release your grip and any excess will return to the container.
 6. **Pour:** Apply the full dose by tipping and pouring along the backline of the animal until the Metering Cup is empty.
 7. **Storage:** The Metering Cup should not remain attached to the container when not in use. Detach the Metering Cup after each use and replace the shipping cap to close the container top.

Collapsible Pack (84.5 fl oz/2.5 L Pack and 169 fl oz/5 L Pack)

Connect the applicator gun to the collapsible pack as follows:

- Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Simcro Tech gun, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage.)
- Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap. • Gently prime the applicator gun, checking for leaks.
- Follow the manufacturer's directions for adjusting the dose
- When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Simcro Tech gun, the gun and tubing must not be washed.

20 Liter Pack (676 fl oz/20 L Pack)

Use dosing equipment (applicator, draw-off tubing, cap with stem) compatible with Noromectin Pour-On (ivermectin topical solution). Other dosing equipment may be incompatible, resulting in locking, incorrect dosage and leakage. Follow the dosing equipment manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing equipment. Connect the dosing applicator and the draw-off tubing to the container as follows:

- Attach the open end of the draw-off tubing to an appropriate dosing applicator. Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap having the draw-off tubing. Gently prime the dosing applicator, checking for leaks.
- When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

Weight	Dose
220 lb (100 kg)	10 mL
330 lb (150 kg)	15 mL
440 lb (200 kg)	20 mL
550 lb (250 kg)	25 mL
660 lb (300 kg)	30 mL
770 lb (350 kg)	35 mL
880 lb (400 kg)	40 mL
990 lb (450 kg)	45 mL
1100 lb (500 kg)	50 mL

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING

NOT FOR USE IN HUMANS

Keep this and all drugs out of the reach of children.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Norbrook at 1-866-591-5777. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

- **Store at or below 25°C (77°F), excursions permitted up to 40°C (104°F). Protect from light.**
- Use only in well-ventilated areas or outdoors.
- Close container tightly when not in use.
- Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.
- Do not use when rain is expected to wet cattle within six hours after treatment.
- This product is for application to skin surface only. Do not give orally or parenterally.
- Cloudiness in the formulation may occur when Noromectin Pour-On is stored at temperatures below 32° F. Allowing it to warm at room temperature will restore the normal appearance without affecting efficacy.
- Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.
- Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Noromectin Pour-On (ivermectin topical solution) is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs

Noromectin Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with Noromectin Pour-On at the end of the fly season may be re-treated with Noromectin during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

OTHER WARNINGS

Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.

Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.

Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd/flock, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).

A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

Environmental Safety

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

HOW SUPPLIED

Noromectin Pour-On (ivermectin topical solution) is available in a 33.8 fl oz/1L bottle with a measure-squeeze-pour-system or in an 84.5 fl oz/2.5 L or 169 oz/5 L collapsible pack, or 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

Restricted Drug - California. Use Only as Directed.

Approved by FDA under ANADA # 200-272

Manufactured by:
Norbrook Laboratories Limited
Newry, BT35 6PU, Co. Down,
Northern Ireland

001670I04

Norbrook®

Principal Display Panel – 5 L Carton Label

Noromectin® Pour-On

(ivermectin topical solution)

for Cattle

Contains 5 mg ivermectin / mL

Parasiticide

Kills: Roundworms, (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains 200 - 550 lb doses.

Approved by FDA under ANADA # 200-272

169 fl oz (5L)

Norbrook®

Noromectin® Pour-On
(ivermectin topical solution)
for Cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS:
For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

DOSAGE:
The dose rate is 1 mL for each 22 lb of bodyweight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

ADMINISTRATION:
Connect the applicator gun to the collapsible pack as follows:
Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the applicator gun from Simco Tech, or equivalent, is recommended. Other applicators may exhibit compatibility problems, resulting in locking, incorrect dosage or leakage.)
Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.
Gently prime the applicator gun, checking for leaks.
Follow the manufacturer's direction for adjusting the dose.
When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Simco Tech gun, the gun and tubing must not be washed.

Manufactured by:
Norbrook Laboratories Limited
Newry, BT35 6PU, Co. Down,
Northern Ireland

Made in the UK.

Noromectin® Pour-On
(ivermectin topical solution)
for Cattle

ANIMAL SAFETY:
Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING
NOT FOR USE IN HUMANS
Keep this and all parts out of the reach of children.

This product should not be applied to wet or other animals because it may be irritating to human skin and eyes and absorbed through the skin. To prevent accidental skin contact, the user should wear a long sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

WARNING: FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS,
OPEN FLAME, AND OTHER SOURCES
OF IGNITION.

RESIDUE WARNING: Cattle must not be treated within 30 days of slaughter for human consumption. Because a withdrawal time is not established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

OTHER WARNINGS
Parasite resistance may develop to any dewormer, and has been reported for insect classes of dewormers.
Treatments with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animals to be treated may slow the development of parasite resistance.
Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd/flock, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored. The example with the use of a fecal egg count reduction test or another appropriate method.
A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

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Noromectin® Pour-On
(ivermectin topical solution)
for Cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

Contains 200 - 550 lb doses

Approved by FDA under ANADA # 200-272

169 fl oz (5 L)

Norbrook®

Noromectin® Pour-On
(ivermectin topical solution)
for Cattle

This topically applied formulation of Noromectin Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient, low-volume application.

PRECAUTIONS:
Store at or below 25°C (77°F). Excursions permitted up to 40°C (104°F). Protect from light.

Use only in well-ventilated areas or outdoors.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Close container tightly when not in use.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when Noromectin Pour-On is stored at temperatures below 32°F. Allowing it to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scales or lesions, or with dermatoses or salivary materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Noromectin Pour-On is not recommended for use in species other than cattle.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Norbrook at 1-800-351-5772. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/ispportanmaina.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Restricted Drug - California. Use Only as Directed.

Principal Display Panel – 5 L Container Label

Noromectin® Pour-On

**(ivermectin topical solution)
for Cattle**

Contains 5 mg ivermectin / mL

Parasiticide

Kills:

Roundworms, (including Brown Stomach Worm),
Lungworms, Grubs, Sucking Lice, Biting Lice,
Mange Mites, Horn Flies

Manufactured by:

Norbrook Laboratories Ltd.

Newry, Co. Down, BT35 6PU, Northern Ireland

Approved by FDA under ANADA # 200-272

169 fl oz (5L)

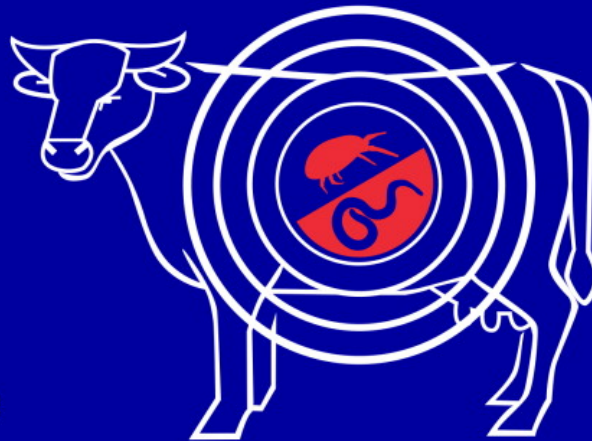
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Norbrook®

Noromectin[®] Pour-On

(ivermectin topical solution)
for Cattle

Contains 5 mg ivermectin / mL



Parasiticide

Kills:

Roundworms, (including Brown Stomach Worm),
Lungworms, Grubs, Sucking Lice, Biting Lice,
Mange Mites, Horn Flies

Manufactured by:

Norbrook Laboratories Ltd.
Newry, Co. Down, BT35 6PU, Northern Ireland

Approved by FDA under ANADA # 200-272

169 fl oz (5 L)

005670L04



NOROMECTIN POUR-ON FOR CATTLE

ivermectin solution

Product Information

Product Type

OTC ANIMAL DRUG

Item Code (Source)

NDC:55529-007

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
isopropyl myristate (UNII: 0RE8K4LNJS)	
trolamine (UNII: 9O3K93S3TK)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
isopropyl alcohol (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55529-007-06	1 in 1 CARTON		
1		1000 mL in 1 CONTAINER		
2	NDC:55529-007-07	1 in 1 CARTON		
2		2500 mL in 1 CONTAINER		
3	NDC:55529-007-08	1 in 1 CARTON		
3		5000 mL in 1 CONTAINER		
4	NDC:55529-007-09	1 in 1 CARTON		
4		20000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200272	12/01/2004	

Labeler - Norbrook Laboratories Limited (214580029)

Establishment

Name	Address	ID/FEI	Business Operations
Norbrook Laboratories Limited		232880554	MANUFACTURE, ANALYSIS

Establishment

Name	Address	ID/FEI	Business Operations
Norbrook Laboratories Limited		211218325	MANUFACTURE