

NOROMECTIN PLUS FOR CATTLE- ivermectin and clorsulon injection, solution

Norbrook Laboratories Limited

Noromectin®
(ivermectin and clorsulon) PLUS

Injection for Cattle

For the effective treatment and control of internal parasites, including adult liver flukes, and external parasites.

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

INTRODUCTION

The ability of ivermectin to deliver internal and external parasite control has been proven in cattle markets around the world. Now, Norbrook Laboratories Limited combines ivermectin with clorsulon, an effective adult flukicide.

A single injection of Noromectin® Plus (ivermectin and clorsulon) offers all the benefits of an ivermectin injection plus control of adult *Fasciola hepatica*.

The dosage level of clorsulon supplied by Noromectin Plus is effective only against adult liver flukes (*Fasciola hepatica*).

PRODUCT DESCRIPTION

Noromectin Plus is a ready-to-use sterile solution containing 1% w/v ivermectin, 10% clorsulon, 40% glycerol formal, and propylene glycol, q.s. ad 100%. It is formulated to deliver the recommended dose level of 200 mcg ivermectin/kg and 2 mg clorsulon/kg given subcutaneously behind the shoulder at the rate of 1 mL per 110 lb (50 kg) body weight.

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.

Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as

well as plasma are ingested by *Fasciola hepatica*. Adult *Fasciola hepatica* are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

INDICATIONS

Noromectin Plus Injection is indicated for the effective treatment and control of the following parasites in cattle:

Gastrointestinal Roundworms (adults and fourth-stage larvae):

Ostertagia ostertagi (including inhibited *O. ostertagi*)

O. lyrata

Haemonchus placei

Trichostrongylus axei

T. colubriformis

Cooperia oncophora

C. punctata

C. pectinata

Bunostomum phlebotomum

Nematodirus helvetianus (adults only)

N. spathiger (adults only)

Oesophagostomum radiatum

Lungworms (adults and fourth-stage larvae):

Dictyocaulus viviparus

Liver Flukes:

Fasciola hepatica (adults only)

Cattle Grubs (parasitic stages):

Hypoderma bovis

H. lineatum

Sucking Lice:

Linognathus vituli

Haematopinus eurysternus *Solenopotes capillatus*

Mange Mites (cattle scab*):

Psoroptes ovis (syn. *P. communis* var. *bovis*)

Sarcoptes scabiei var. *bovis*

Persistent Activity

Ivermectin and clorsulon injection has been proved to effectively control infections and to protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostrongylus axei* and *Cooperia punctata* for 21 days after treatment; *Haemonchus placei*, and *Cooperia oncophora* for 14 days after treatment.

* Ivermectin has been approved as a scabicide by USDA/APHIS. Federal regulations require that cattle infested with or exposed to scabies (i.e., infestations with *Psoroptes ovis*) be treated. Ivermectin when used according to label instructions meets this requirement. Treated cattle may be shipped interstate, but they must not be mixed with other cattle for 14 days following treatment. The federal regulations make no restriction on the movement of cattle not affected with or exposed to scabies. However, individual states have additional regulations to govern the interstate shipment of cattle and the regulatory veterinarian in the state of destination should be consulted for applicable regulations on the use of ivermectin in the control of scabies.

DOSAGE

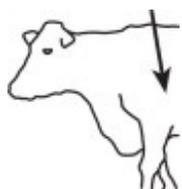
Noromectin Plus should be given only by subcutaneous injection at a dose volume of 1 mL per 110 lb (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon. For example:

| Body Weight (lb) | Dose (mL) |
|-------------------------|------------------|
| 220 | 2 |
| 330 | 3 |
| 440 | 4 |
| 550 | 5 |
| 660 | 6 |
| 770 | 7 |
| 880 | 8 |
| 990 | 9 |
| 1100 | 10 |

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

Noromectin Plus (ivermectin and clorsulon) Injection is to be given subcutaneously only. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, 1/2" to 3/4" sterile needle is recommended. Inject the solution subcutaneously (under the skin) behind the shoulder (see illustration).



Any single-dose syringe or standard automatic syringe equipment may be used with the 50 mL or 100 mL pack size. When using the 250 mL, 500 mL or 1000 mL pack size, use only automatic syringe equipment.

Use sterile equipment and sanitize the injection site by applying a suitable disinfectant. Clean, properly disinfected needles should be used to reduce the potential for injection site infections.

No special handling or protective clothing is necessary.

The viscosity of the product increases in cool temperatures.

Administering Noromectin Plus at temperatures of 41°F (5°C) or below may be difficult. Users can make dosing easier by warming both the product and injection equipment to about 59°F (15°C).

ANIMAL SAFETY

In breeding animals (bulls and cows), ivermectin and clorsulon used at the recommended level 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 Inc. at 1-866-5777. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

RESIDUE WARNINGS: Do not treat cattle within 21 days of slaughter. 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

Transitory discomfort has been observed in some cattle following subcutaneous administration. Soft-tissue swelling at the injection site has also been observed. These reactions have disappeared without treatment. Divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction. Different injection sites should be used for other parenteral products.

Noromectin Plus Injection has been developed specifically for use in cattle only. This

product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

For subcutaneous injection in cattle only.

This product is not for intravenous or intramuscular use.

When to Treat Cattle with Grubs

Noromectin Plus effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season.

Destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *Hypoderma lineatum* when it is in the tissue surrounding the esophagus (gullet) may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with Noromectin Plus, but can occur with any successful treatment of grubs. Cattle should be treated either before or after these stages of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Noromectin Plus after the end of the heel fly season may be retreated with ivermectin during the winter for internal parasites, mange mites, or sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

STORAGE

Protect product from light.

Store at 59° to 86°F (15° to 30°C). Use within 60 days of first puncture and puncture a maximum of 25 times. If more than 25 punctures are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle larger than 16 gauge, discard any remaining product immediately after use.

For 500 mL and 1000 mL sizes: For use with automatic syringe equipment only. Discard any remaining product immediately after use.

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 soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit water runoff from feedlots to enter lakes, streams, or ponds. Do not contaminate water by direct application or by 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 Plus Injection is available in five ready-to-use pack sizes:

The 50 mL pack is a multiple-dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 10 head of 550 lb (250 kg) cattle.

The 100 mL pack is a multiple-dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 20 head of 550 lb (250 kg) cattle.

The 250 mL pack is a multiple-dose, rubber-capped bottle designed for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 50 head of 550 lb (250 kg) cattle.

The 500 mL pack is a multiple-dose, rubber-capped bottle designed for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle.

The 1000 mL pack is a multiple-dose, rubber-capped bottle designed for use with automatic syringe equipment.

Each bottle contains sufficient solution to treat 200 head of 550 lb (250 kg) cattle.

Restricted Drug - California. Use Only as Directed.

Made in the UK.

Norbrook Laboratories Limited,
Newry, BT35 6QQ, Co. Down, Northern Ireland.

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Norbrook Laboratories
Limited

Approved by FDA under ANADA # 200-436

Rev. 11/2024

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Principal Display Panel - 1000 mL Carton Label

NDC 55529-011-06

Noromectin[®] PLUS
(ivermectin and clorsulon)
Injection for Cattle

Treats 200 - 550 lb Cattle

For the treatment and control of internal parasites,
including adult liver flukes, and external parasites.

1000 mL
(33.81 oz)

Approved by FDA under
ANADA # 200-436

Norbrook[®]



Principal Display Panel - 1000 mL Vial Label

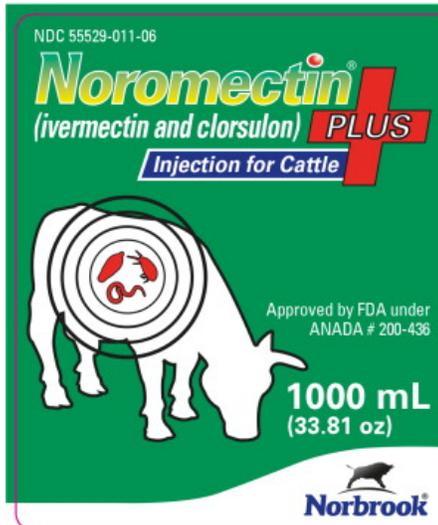
NDC 55529-011-06

Noromectin® PLUS **(ivermectin and clorsulon)** **Injection for Cattle**

Approved by FDA under
ANADA # 200-436

1000 mL
(33.81 oz)

Norbrook



For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

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

Do not contaminate water. Dispose of containers in an approved landfill or by incineration.

See package insert for complete indications, precautions, warnings, residue information, and use directions.

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



RESIDUE WARNINGS: Do not treat cattle within 21 days of slaughter. 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

For subcutaneous injection in cattle only.

Protect product from light. Store at 59° to 86°F (15° to 30°C). For use with automatic syringe equipment only. Discard any remaining product immediately after use.

Restricted Drug - California. Use Only as Directed.

Made in the UK.

Norbrook Laboratories Limited, Newry, BT35 6QQ, Co. Down, Northern Ireland.

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Rev. 11/2024

Lot No. & Exp. Date ▼



NOROMECTIN PLUS FOR CATTLE

ivermectin and clorsulon injection, solution

Product Information

| | | | |
|--------------------------------|-----------------|---------------------------|---------------|
| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:55529-011 |
| Route of Administration | SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D) | ivermectin | 10 mg in 1 mL |
| clorsulon (UNII: EG1ZDO6LRD) (clorsulon - UNII:EG1ZDO6LRD) | clorsulon | 100 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| propylene glycol (UNII: 6DC9Q167V3) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:55529-011-01 | 1 in 1 CARTON | | |
| 1 | | 50 mL in 1 VIAL, PLASTIC | | |
| 2 | NDC:55529-011-02 | 1 in 1 CARTON | | |
| 2 | | 100 mL in 1 VIAL, PLASTIC | | |
| 3 | NDC:55529-011-04 | 1 in 1 CARTON | | |
| 3 | | 250 mL in 1 VIAL, PLASTIC | | |
| 4 | NDC:55529-011-05 | 1 in 1 CARTON | | |
| 4 | | 500 mL in 1 VIAL, PLASTIC | | |
| 5 | NDC:55529-011-06 | 1 in 1 CARTON | | |
| 5 | | 1000 mL in 1 VIAL, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200436 | 04/01/2007 | |

Labeler - Norbrook Laboratories Limited (214580029)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|------------------------------------|
| Norbrook Laboratories Limited | | 211218325 | MANUFACTURE, PACK, LABEL, ANALYSIS |

Revised: 1/2025

Norbrook Laboratories Limited