

Approval Date: APR 20 2007

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION**

ANADA 200-437

**NOROMECTIN Injection for Cattle and Swine
ivermectin**

Indications for use: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking lice, and mange mites in cattle; for the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine; for the treatment and control of warbles (*Oedemagena tarandi*) in reindeer; and for the treatment and control of grubs (*Hypoderma bovis*) in American bison.

Sponsored by:

Norbrook Laboratories, Ltd.

2007.200.437

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-437
- b. Sponsor: Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP
Northern Ireland
- Drug Labeler Code: 055529
- US Agent: Norbrook, Inc.
Bill Zollers, Ph.D.
Directory of Regulatory Affairs – USA &
Canada
9733 Loiret Boulevard
Lenexa, KS 66219
- c. Established Name: Ivermectin
- d. Proprietary Name: NOROMECTIN Injection for Cattle and Swine
- e. Dosage Form: Sterile solution
- f. How Supplied: 50 mL rubber-capped bottle; 100 mL, 250 mL, and 500 mL rubber-capped bottles designed for use with automatic syringe equipment.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 10 mg/mL
- i. Route of Administration: Injection
- j. Species/Class: Cattle (exception: not approved for use in lactating dairy cattle and pre-ruminant calves); Swine; Reindeer; American Bison
- k. Recommended Dosage: Cattle: 1 mL per 110 lbs (50 kg) body weight, or 200 mcg/kg, given subcutaneously under the loose skin in front of or behind the shoulder, with a maximum of 10 mL per injection site.

Swine: 1 mL per 75 lbs body weight, or 300 mcg/kg, given subcutaneously under the skin immediately behind the ear.

Reindeer: 200 mcg/kg body weight, subcutaneously. Follow use directions for cattle as described under Administration.

American Bison: 200mcg/kg body weight, subcutaneously. Follow use directions for cattle as described under Administration.

l. Pharmacological Category:

Parasiticide

m. Indications:

Cattle: NOROMECTIN Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice, and mange mites 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

Oesophagostomum radiatum

Bunostomum phlebotomum

Nematodirus helvetianus (adults only)

N. spathiger (adults only)

Lungworms (adults and fourth-stage larvae):

Dictyocaulus viviparus

Cattle Grubs (parasitic stages):

Hypoderma bovis

H. lineatum

Sucking Lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

Mites (scabies):

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

Sarcoptes scabiei var. *bovis*

Persistent Activity

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

Swine: NOROMECTIN Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites in swine:

Gastrointestinal Roundworms:

Large roundworm, *Ascaris suum*
(adults and fourth-stage larvae)

Red stomach worm, *Hyostromgylus rubidus*
(adults and fourth-stage larvae)

Nodular worm, *Oesophagostomum* spp.
(adults and fourth-stage larvae)

Threadworm, *Strongyloides ransomi*
(adults)

Somatic Roundworm Larvae:

Threadworm, *Strongyloides ransomi* (somatic larvae). Sows must be treated at least seven days before farrowing to prevent infection in piglets.

Lungworms:

Metastrongylus spp.(adults)

Lice:

Haematopinus suis

Mange mites:

Sarcoptes scabiei var. *suis*

Special Minor Use:

NOROMECTIN Injection is indicated for the effective treatment and control of warbles (*Oedemagena tarandi*) in reindeer. Follow use directions for cattle as described under Administration

NOROMECTIN Injection is indicated for the effective treatment and control of grubs (*Hypoderma bovis*) in American bison. Follow use directions for cattle as described under Administration.

n. Pioneer Product:

IVOMEC Injection for Cattle and Swine; ivermectin; NADA 128-409; Merial, Ltd

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Norbrook Laboratories, Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic

product NOROMECTIN Injection for Cattle and Swine (ivermectin). The generic product is administered as a sterile solution, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, IVOMEK Injection for Cattle and Swine (ivermectin), the subject of Merial, Ltd., NADA 128-409, was approved on February 13, 1984.

3. **HUMAN SAFETY:**

- **Tolerances for Residues:**

The tolerance established for the pioneer product applies to the generic product. Tolerances of 100 parts per billion (ppb) and 10 ppb are established for 22, 23-dihydroavermectin B_{1a} (marker residue) residues in the liver (target tissue) and muscle, respectively, of cattle under 21 CFR 556.344. A tolerance of 20 parts per billion (ppb) is established for 22, 23-dihydroavermectin B_{1a} residues in the liver and muscle of swine under 21 CFR 556.344. Tolerances of 15 parts per billion (ppb) are established for 22, 23-dihydroavermectin B_{1a} residues in the liver of reindeer and American bison under 21 CFR 556.344. The Acceptable Daily Intake (ADI) for total residues of ivermectin is 1 microgram per kilogram of body weight per day.

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal time of 35 days has been established for ivermectin in cattle, 18 days withdrawal has been established in swine, 56 days in reindeer, and 56 days in American bison (21 CFR 522.1192). Withdrawal periods for milk and for pre-ruminating calves have not been established.

- **Regulatory Method for Residues:**

The analytical methods for detection of ivermectin in tissues are HPLC methods with fluorescence detection. The methods are found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. **AGENCY CONCLUSIONS:**

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that the injectable product NOROMECTIN Injection for Cattle and Swine, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-437:

NOROMECTIN Injection for Cattle and Swine (ivermectin) – container and carton label – 50 mL, 100 mL, 250 mL, 500 mL; insert

Pioneer Labeling for NADA 128-409:

IVOMEK Injection for Cattle and Swine (ivermectin) – container and carton label – 50 mL, 200 mL, 500 mL; insert

ANADA 200-437, Approved by the FDA

Noromectin®

(ivermectin) *Injection for Cattle and Swine*

1% Sterile Solution

A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine.

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

INTRODUCTION

Noromectin (ivermectin) Injection is an injectable parasiticide for cattle and swine. One low-volume dose effectively treats and controls the following internal and external parasites that may impair the health of cattle and swine: gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* in cattle), lungworms, grubs, sucking lice, and mange mites of cattle; and gastrointestinal roundworms, lungworms, lice, and mange mites of swine. Ivermectin's convenience, broad-spectrum efficacy and safety margin make Noromectin Injection a unique product for parasite control of cattle and swine.

PRODUCT DESCRIPTION

Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents isolated from fermentation of *Streptomyces avermitilis*.

Noromectin Injection is a clear, ready-to-use, sterile solution containing 1% ivermectin, 40% glycerol formal, and propylene glycol q.s. ad 100%. Noromectin Injection is formulated to deliver the recommended dose level of 200 mcg ivermectin/kilogram of body weight in cattle when given subcutaneously at the rate of 1 mL/110 lb (50 kg). In Swine, Noromectin Injection is formulated to deliver the recommended dose level of 300 mcg ivermectin/kilogram body weight when given subcutaneously in the neck at the rate of 1 mL per 75 lb (33 kg).

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

Cattle: Noromectin Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice, and mange mites 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
Oesophagostomum radiatum
Bunostomum phlebotomum
Nematodirus helvetianus (adults only)
N. spathiger (adults only)

Lungworms (adults and fourth-stage larvae):

Dictyocaulus viviparus

Cattle Grubs (parasitic stages):

Hypoderma bovis
H. lineatum

Sucking Lice:

Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Mites (scabies):

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

Persistent Activity

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

Swine: Noromectin Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites in swine:

Gastrointestinal Roundworms:

Large roundworm, *Ascaris suum* (adults and fourth-stage larvae)
 Red stomach worm, *Hydrostrongylus rubidus* (adults and fourth-stage larvae)
 Nodular worm, *Oesophagostomum* spp. (adults and fourth-stage larvae)
 Threadworm, *Strongyloides ransomi* (adults)

Somatic Roundworm Larvae:

Threadworm, *Strongyloides ransomi* (somatic larvae)
 Sows must be treated at least seven days before farrowing to prevent infection in piglets.

Lungworms:

Metastrongylus spp. (adults)

Lice:

Haematopinus suis

Mange Mites:

Sarcoptes scabiei var. *suis*

DOSAGE

Cattle: Noromectin Injection should be given only by subcutaneous injection under the loose skin in front of or behind the shoulder at the recommended dose level of 200 mcg of ivermectin per kilogram of body weight. Each mL of Noromectin Injection contains 10 mg of ivermectin, sufficient to treat 110 lb (50 kg) of body weight (maximum 10 mL per injection site).

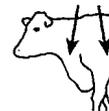
Body Weight (lb)	Dose Volume (mL)
220	2
330	3
440	4
550	5
660	6
770	7
880	8
990	9
1100	10

Swine: Noromectin Injection should be given only by subcutaneous injection in the neck of swine at the recommended dose level of 300 mcg of ivermectin per kilogram (2.2 lb) of body weight. Each mL of Noromectin Injection contains 10 mg of ivermectin, sufficient to treat 75 lb of body weight.

	Body Weight (lb)	Dose Volume (mL)
Growing Pigs	19	1/4
	38	1/2
	75	1
	150	2
Breeding Animals (Sows, Gilts, and Boars)	225	3
	300	4
	375	5
	450	6

ADMINISTRATION

Cattle: Noromectin Injection is to be given subcutaneously only, to reduce risk of potentially fatal clostridial infection of the injection site. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, 1/2 to 3/4 inch needle is suggested. Inject under the loose skin in front of or behind the shoulder (see illustration).



When using the 250 or 500 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.

Swine: Noromectin (ivermectin) Injection is to be given subcutaneously in the neck. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16- or 18-gauge needle is suggested for sows and boars, while an 18- or 20-gauge needle may be appropriate for young animals. Inject under the skin, immediately behind the ear (see illustration).



When using the 100, 250 or 500 mL pack size, use only automatic syringe equipment. As with any injection, sterile equipment should be used. The injection site should be cleaned and disinfected with alcohol before injection. The rubber stopper should also be disinfected with alcohol to prevent contamination of the contents. Mild and transient pain reactions may be seen in some swine following subcutaneous administration.

Recommended Treatment Program

Swine: At the time of initiating any parasite control program, it is important to treat all breeding animals in the herd. After the initial treatment, use Noromectin Injection regularly as follows:

BREEDING ANIMALS

Sows: Treat prior to farrowing, preferably 7-14 days before, to minimize infection of piglets.

Gilts: Treat 7-14 days prior to breeding.

Treat 7-14 days prior to farrowing.

Boars: Frequency and need for treatments are dependent upon exposure.

Treat at least two times a year.

FEEDER PIGS

(Weaners/Growers/Finishers)

All weaner/feeder pigs should be treated before placement in clean quarters. Pigs exposed to contaminated soil or pasture may need retreatment if reinfection occurs.

NOTE:

- (1) Noromectin Injection has a persistent drug level sufficient to control mite infestations throughout the egg to adult life cycle. However, since the ivermectin effect is not immediate, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities. Generally, pigs should not be moved to clean quarters or exposed to uninfested pigs for approximately one week after treatment. Sows should be treated at least one week before farrowing to minimize transfer of mites to newborn baby pigs.
- (2) Louse eggs are unaffected by Noromectin Injection and may require up to three weeks to hatch. Louse infestations developing from hatching eggs may require retreatment.
- (3) Consult a veterinarian for aid in the diagnosis and control of internal and external parasites of swine.

Special Misor Use

Reindeer: For the treatment and control of warbles (*Oedemagena tarandi*) in reindeer, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously. Follow use directions for cattle as described under ADMINISTRATION.

American Bison: For the treatment and control of grubs (*Hypoderma bovis*) in American bison, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously. Follow use directions for cattle as described under ADMINISTRATION.

RESIDUE INFORMATION: Do not treat reindeer or American bison within 8 weeks (56 days) of slaughter.

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

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Norbrook, Inc. at 1-913-599-5777.

RESIDUE INFORMATION: Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter.

PRECAUTIONS

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions have disappeared

without treatment. For cattle, divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction.

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.

Observe cattle for injection site reactions. Reactions may be due to clostridial infection and should be aggressively treated with appropriate antibiotics. If injection site infections are suspected, consult your veterinarian.

This product is not for intravenous or intramuscular use. Protect product from light.

Noromectin Injection for Cattle and Swine has been developed specifically for use in cattle, swine, reindeer, and American bison only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

When to Treat Cattle with Grubs

Noromectin Injection 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 salivation and 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 Injection, 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 Injection after the end of the heel fly season may be retreated with Noromectin Injection 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

Store at 15 - 30 °C (59 to 86 °F).

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 Injection for Cattle and Swine is available in four 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 or 100 head of 38 lb (17.3 kg) swine.

The 100 mL pack is a multiple-dose, rubber-capped bottle designed for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 20 head of 550 lb (250 kg) cattle or 200 head of 38 lb (17.3 kg) swine.

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 or 500 head of 38 lb (17.3 kg) swine.

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 or 1000 head of 38 lb (17.3 kg) swine.

Made in the UK.

Norbroad Laboratories Limited,
Newry, Co. Down, Northern Ireland.

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Norbroad

	<p>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.</p> <p>INDICATIONS For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites. See package insert for complete indications, precautions, warnings, residue information, and use directions.</p> <p>RECOMMENDED DOSE Cattle: 1 ml per 110 lb body weight Swine: 1 ml per 75 lb body weight</p>	<p>WARNING NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.</p> <p>RESIDUE INFORMATION: Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter.</p>	<p>PRECAUTIONS For subcutaneous injection in cattle and swine only. Protect product from light. Store at 15-30° C (59-86° F).</p> <p>Made in the UK Norbrook Laboratories Limited, Newry, Co. Down, Northern Ireland. Lot No & Exp Date ▼</p>
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<p>IVORONICUM</p> <p>100 mL</p>	<p>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.</p> <p>INDICATIONS For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites. See package insert for complete indications, precautions, warnings, residue information, and use directions.</p> <p>RECOMMENDED DOSE Cattle: 1 mL per 110 lb body weight Swine: 1 mL per 75 lb body weight</p>	<p>WARNING NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.</p> <p>RESIDUE INFORMATION: Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter.</p>	<p>PRECAUTIONS Use automatic syringe equipment in swine. For subcutaneous injection in cattle and swine only. Protect product from light.</p> <p>Store at 15-30° C (59-86° F).</p> <p>Made in the UK Norbrook Laboratories Limited, Newry, Co. Down, Northern Ireland. Lot No & Exp Date ▼</p>
<p>Norbrook</p>			



250 mL

Norbrook

STREPTOCYCLIN

Sterile Solution
for Cattle

INDICATIONS
For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites. See package insert for complete indications, precautions, warnings, residue information, and use directions.

RECOMMENDED DOSE
Cattle: 1 mL per 110 lb body weight
Swine: 1 mL per 75 lb body weight

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

RESIDUE INFORMATION:
Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter.

PRECAUTIONS
Use automatic syringe equipment only. For subcutaneous injection in cattle and swine only. Protect product from light.

Store at 15-30° C (59-86° F).

Made in the UK
Norbrook Laboratories Limited,
Newry, Co. Down,
Northern Ireland.

Lot No & Exp Date ▼

500 mL



MOVICHEL

1 mg/ml Moxidectin

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.

INDICATIONS
Cattle: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, gubs (note insert precautions), sucking lice, and mange mites in cattle.
Swine: For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine.
 See package insert for complete indications, precautions, warnings, residue information, and use directions.

RECOMMENDED DOSE
Cattle: 1 mL per 110 lb body weight
Swine: 1 mL per 75 lb body weight

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

RESIDUE INFORMATION:
 Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter.

PRECAUTIONS
 Use automatic syringe equipment only. For subcutaneous injection in cattle and swine only. Protect product from light.
 Store at 15-30° C (59-86° F).

Made in the UK
 Norbrook Laboratories Limited,
 Newry, Co. Down, Northern Ireland.

Lot No & Exp Date ▼

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100%

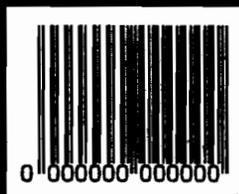
100%

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50 mL

 **Norbrook** 



Norbrook 

Ivoronecun



100 ml

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Norbrook 

100 ml



250000

500 ml

1% Sterile Solution

Lot No & Exp Date

Injection for Cattle and Swine

Noromectin
(ivermectin)

Noromectin
(ivermectin)
Injection for Cattle and Swine

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

INDICATIONS

Cattle: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs (larval insect precursors), sucking lice, and mange mites in cattle.
Swine: For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine.

RECOMMENDED DOSE

Cattle: 1 ml per 110 lb body weight
Swine: 1 ml per 75 lb body weight

See package insert for complete indications and use directions.

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

State of IL, 39°C (100°F to 86°F)

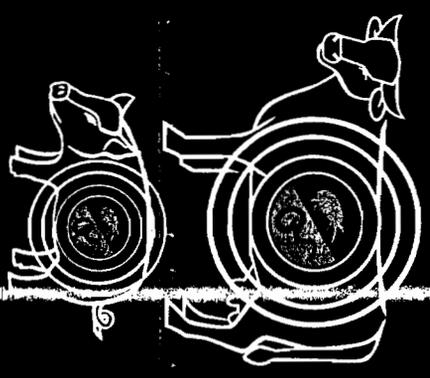


Noromectin
(ivermectin)
Injection for Cattle and Swine

ANADA 200-437
Approved by the FDA

Noromectin
(ivermectin)
Injection for Cattle and Swine

1% Sterile Solution



A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine

500 ml



Noromectin
(ivermectin)
Injection for Cattle and Swine



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

RESIDUE INFORMATION: Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter.

PRECAUTIONS
Use automatic syringe technique only. For subcutaneous injection in cattle and swine only.
Protect product from light.

Noromectin (ivermectin) Injection for Cattle and Swine has been developed specifically for use in cattle, swine, lambs, and American bison only. This product should not be used in other species. For more information, contact your local Norbrook representative.

Made in the UK

Norbrook Laboratories Limited



IVOMEC®
(ivermectin)
Injection
for Cattle and Swine
1% Sterile Solution

A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine
Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INTRODUCTION

IVOMEC® (ivermectin) is an injectable parasiticide for cattle and swine. One low-volume dose effectively treats and controls the following internal and external parasites that may impair the health of cattle and swine: gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* in cattle), lungworms, grubs, sucking lice, and mange mites of cattle; and gastrointestinal roundworms, lungworms, lice, and mange mites of swine. Discovered and developed by scientists from Merck Research Laboratories, Ivermectin is a novel chemical entity. Its convenience, broad-spectrum efficacy, and safety margin make IVOMEC Injection a unique product for parasite control of cattle and swine.

PRODUCT DESCRIPTION

Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents isolated from fermentation of *Streptomyces avermitilis*.

IVOMEC Injection is a clear, ready-to-use, sterile solution containing 1% ivermectin, 40% glycerol formal, and propylene glycol, q.s. ad 100%. IVOMEC Injection is formulated to deliver the recommended dose level of 200 mcg Ivermectin/kilogram of body weight in cattle when given subcutaneously at the rate of 1 mL/110 lb (50 kg). In Swine, IVOMEC Injection is formulated to deliver the recommended dose level of 300 mcg Ivermectin/kilogram body weight when given subcutaneously in the neck at the rate of 1 mL per 75 lb (33 kg).

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

Cattle: IVOMEC Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice, and mange mites 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

Oesophagostomum radiatum

Bunostomum phlebotomum

Nematodirus helvetianus (adults only)

N. spathiger (adults only)

Lungworms (adults and fourth-stage larvae):

Dictyocaulus viviparus

Cattle Grubs (parasitic stages):

Hypoderma bovis

H. lineatum

Sucking Lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

Mites (scabies):

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

Sarcoptes scabiei var. *bovis*

Persistent Activity

IVOMEC 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.

Swine: IVOMEC Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites in swine:

Gastrointestinal Roundworms:

Large roundworm, *Ascaris suum*

(adults and fourth-stage larvae)

Red stomach worm, *Hyostromylus rubidus*

(adults and fourth-stage larvae)

Nodular worm, *Oesophagostomum* spp.

(adults and fourth-stage larvae)

Threadworm, *Strongyloides ransomi* (adults)

Somatic Roundworm Larvae:

Threadworm, *Strongyloides ransomi* (somatic larvae)

Sows must be treated at least seven days before farrowing to prevent infection in piglets.

Lungworms:

Metastrongylus spp. (adults)

Lice:

Haematopinus suis

Mange Mites:

Sarcoptes scabiei var. *suis*

DOSAGE

Cattle: IVOMEC® Injection should be given only by subcutaneous injection under the loose skin in front of or behind the shoulder at the recommended dose level of 200 mcg of ivermectin per kilogram of body weight. Each mL of IVOMEC contains 10 mg of ivermectin, sufficient to treat 110 lb (50 kg) of body weight (maximum 10 mL per injection site).

Body Weight (lb) Dose Volume (mL)

220	2
330	3
440	4
550	5
660	6
770	7
880	8
990	9
1100	10

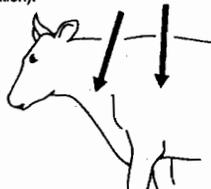
Swine: IVOMEC Injection should be given only by subcutaneous injection in the neck of swine at the recommended dose level of 300 mcg of ivermectin per kilogram (2.2 lb) of body weight. Each mL of IVOMEC contains 10 mg of ivermectin, sufficient to treat 75 lb of body weight.

Body Weight (lb) Dose Volume (mL)

Growing Pigs	19	1/4
	38	1/2
	75	1
	150	2
Breeding Animals	225	3
(Sows, Gilts, and Boars)	300	4
	375	5
	450	6

ADMINISTRATION

Cattle: IVOMEC Injection is to be given subcutaneously only, to reduce risk of potentially fatal clostridial infection of the injection site. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, 1/2 to 3/4" needle is suggested. Inject under the loose skin in front of or behind the shoulder (see illustration).



When using the 200, 500 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.

Swine: IVOMEC (ivermectin) Injection is to be given subcutaneously in the neck. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16- or 18-gauge needle is suggested for sows and boars, while an 18- or 20-gauge needle may be appropriate for young animals. Inject under the skin, immediately behind the ear (see illustration).



When using the 200 mL, 500 mL or 1000 mL pack size, use only automatic syringe equipment. As with any injection, sterile equipment should be used. The injection site should be cleaned and disinfected with alcohol before injection. The rubber stopper should also be disinfected with alcohol to prevent contamination of the contents. Mild and transient pain reactions may be seen in some swine following subcutaneous administration.

Recommended Treatment Program

Swine: At the time of initiating any parasite control program, it is important to treat all breeding animals in the herd. After the initial treatment, use IVOMEC® Injection regularly as follows:

BREEDING ANIMALS

- Sows:** Treat prior to farrowing, preferably 7–14 days before, to minimize infection of piglets.
- Gilts:** Treat 7–14 days prior to breeding.
Treat 7–14 days prior to farrowing.
- Boars:** Frequency and need for treatments are dependent upon exposure.
Treat at least two times a year.

FEEDER PIGS

(Weaners/Growers/Finishers)

All weaner/feeder pigs should be treated before placement in clean quarters.

Pigs exposed to contaminated soil or pasture may need retreatment if reinfection occurs.

NOTE:

- (1) IVOMEC Injection has a persistent drug level sufficient to control mite infestations throughout the egg to adult life cycle. However, since the ivermectin effect is not immediate, care must be taken to prevent reinfection from exposure to untreated animals or contaminated facilities. Generally, pigs should not be moved to clean quarters or exposed to uninfested pigs for approximately one week after treatment. Sows should be treated at least one week before farrowing to minimize transfer of mites to newborn baby pigs.
- (2) Louse eggs are unaffected by IVOMEC Injection and may require up to three weeks to hatch. Louse infestations developing from hatching eggs may require retreatment.
- (3) Consult a veterinarian for aid in the diagnosis and control of internal and external parasites of swine.

Special Minor Use

Reindeer: For the treatment and control of warbles (*Oedemagena tarandi*) in reindeer, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously. Follow use directions for cattle as described under **ADMINISTRATION**.

American Bison: For the treatment and control of grubs (*Hypoderma bovis*) in American bison, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously. Follow use directions for cattle as described under **ADMINISTRATION**.

◀ **RESIDUE INFORMATION:** Do not treat reindeer or American bison within 8 weeks (56 days) of slaughter. ▶

WARNING NOT FOR USE IN HUMANS.

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

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

▶ **RESIDUE INFORMATION:** Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter. ◀

PRECAUTIONS

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions have disappeared without treatment. For cattle, divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction.

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.

Observe cattle for injection site reactions. Reactions may be due to clostridial infection and should be aggressively treated with appropriate antibiotics. If injection site infections are suspected, consult your veterinarian.

This product is not for intravenous or intramuscular use.

Protect product from light.

IVOMEC Injection for Cattle and Swine has been developed specifically for use in cattle, swine, reindeer, and American bison only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

When to Treat Cattle with Grubs

IVOMEC 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 salivation and bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with IVOMEC, 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 IVOMEC after the end of the heel fly season may be retreated with IVOMEC during the winter for internal parasites, mange mites, or sucking lice without danger of grub-related reactions. A planned parasite control program is recommended.

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 feed lots 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

IVOMEC® Injection for Cattle and Swine is available in four 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 or 100 head of 38 lb (17.3 kg) swine.

The 200 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 40 head of 550 lb (250 kg) cattle or 400 head of 38 lb (17.3 kg) swine.

The 500 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle or 1000 head of 38 lb (17.3 kg) swine.

The 1000 mL is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 200 head of 550 lb (250 kg) cattle or 2000 head of 38 lb (17.3 kg) swine.

IVOMEC, Cattle Head Logo and Pig Head Logo are registered trademarks of Merial Limited.

Merial Limited, a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domesticated in Delaware, USA as Merial LLC.

U.S. Pat 4,199,569 & 4,853,372
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1050-1491-00
Rev. 09-2004

Merial Limited
Operational Headquarters
3239 Satellite Blvd.
Duluth, Georgia
30096-4640, U.S.A.

H23857(US)
H23861(US)
H23862(US)



69830/131004S

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.

INDICATIONS
For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites. 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 INFORMATION: Do not treat cattle within 35 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-ruminant calves. Do not use in calves to be processed for veal. Do not treat swine within 18 days of slaughter.

Ivomec
ivermectin
Injection
for Cattle and Swine

1% Sterile Solution
RECOMMENDED DOSE
Cattle: 1 mL per 110 lb body weight
Swine: 1 mL per 75 lb body weight

50 mL



1020-1492-00 Rev. 09-2004

Lot No:

Exp Date:

PRECAUTIONS
For subcutaneous injection in cattle and swine only.
Protect product from light.

IVOMEC is a registered trademark of Merial Limited.
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Merial Limited, Duluth, Georgia, U.S.A.
H23857(AS)



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H23857(US)
69832/081004E
300-720-021/050a

4138012

Ivomec

(ivermectin)

Injection

Ivomec

(ivermectin)

Injection

for Cattle and Swine

1% Sterile Solution



A Parasiticide for the Treatment and Control of
Internal and External Parasites of Cattle and Swine.

50 mL

MERIAL

Ivomec

(ivermectin)

Injection

for Cattle and Swine

SEAL CHECK
SERIAL

IF BROKEN
TEST ACCEPT



13826

Ivomec

(ivermectin)

Injection for Cattle and Swine

1% Sterile Solution

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.

INDICATIONS

For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites. See package insert for complete indications, precautions, warnings, residue information, and use directions.

RECOMMENDED DOSE

Cattle: 1 ml per 110 lb body weight

Swine: 1 ml per 75 lb body weight

WARNING

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

IVOMEK is a registered trademark of Merial Limited.
U.S. Pat. 4,189,569 & 4,853,372.
1020-1484-00 Rev. 09-2004

200 mL

RESIDUE INFORMATION:

Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in lactating dairy cattle or breeding sows. A withdrawal period has not been established for this product in pre-weaning calves. Do not use in calves to be processed for veal. Do not treat swine within 18 days of slaughter.

Lot No:

Exp Date:

PRECAUTIONS

Use automatic syringe equipment only. For subcutaneous injection in cattle and swine only. Protect product from light.

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H23861(US)

Merial Limited
3239 Satellite Blvd.
Duluth, Georgia
30096-4840, U.S.A.



H23861(US)
69834/300904E
300-720-001/093H

413826

Ivomec
(ivermectin)

Injection
for Cattle and Swine

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

RESIDUE INFORMATION

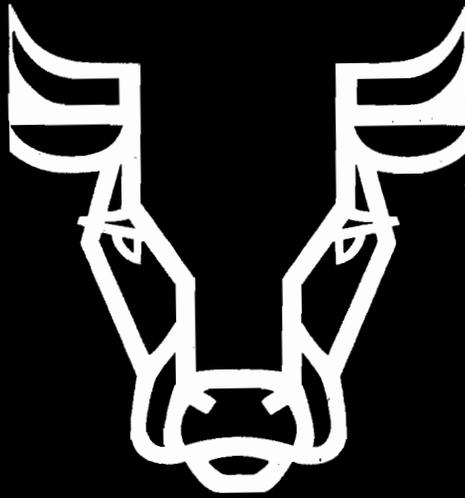
For information on residue withdrawal periods, consult the package insert for Ivomec Injection for Cattle and Swine.

PRECAUTION:

Keep this and all drugs out of the reach of children. Do not use if the stopper is broken or the solution is cloudy. Do not use if the solution is frozen. Do not use if the solution is discolored. Do not use if the solution is expired.

Ivomec
(ivermectin)

Injection
for Cattle and Swine
1% Sterile Solution



A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine.

200 mL

MERIAL

113836

Ivomec

(ivermectin)

Injection for Cattle and Swine

1% Sterile Solution

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.

INDICATIONS

Cattle: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs (note insert precautions), sucking lice, and mange mites in cattle.

Swine: For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine.

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

RECOMMENDED DOSE

Cattle: 1 mL per 110 lb body weight

Swine: 1 mL per 75 lb body weight

WARNING

NOT FOR USE IN HUMANS.

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

RESIDUE INFORMATION: Do not treat cattle within 35 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. Do not treat swine within 18 days of slaughter.

PRECAUTIONS

Use automatic syringe equipment only.

For subcutaneous injection in cattle and swine only.

Protect product from light.

Lot No:

Exp Date:

IVOMEC is a registered trademark of Merial Limited.

U.S. Pat. 4,199,569 & 4,853,372.

H23862(US)

500 mL

1020-1486-00
Rev. 09-2004

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69835/300604C

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H23862(US)
69836/300904E
300-720-002/093

NADA 128-409
Approved by the FDA

Product
413836

Ivomec

(ivermectin)

Injection

for Cattle and Swine

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

RESIDUE INFORMATION:
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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.
Do not treat swine within 18
days of slaughter.

PRECAUTIONS

Use automatic syringe equipment
only. For subcutaneous injection in
cattle and swine only.

Protect product from light.

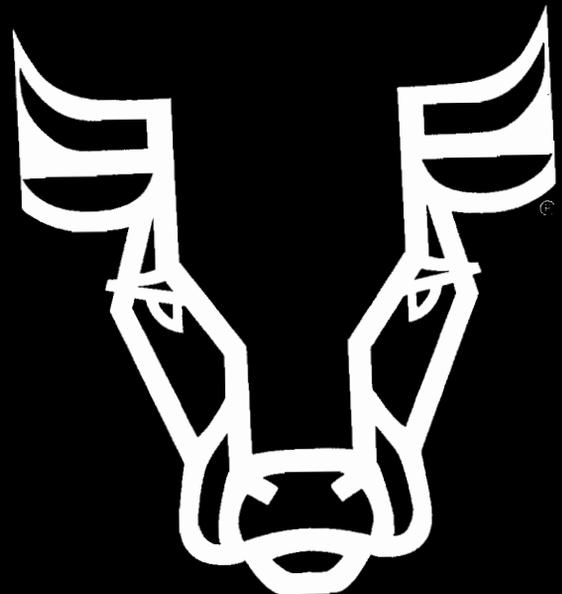
IVOMECC[®] (ivermectin) Injection for
Cattle and Swine has been
developed specifically for use in
cattle, swine, reindeer, and
American bison **only**. This product
should not be used in other animal
species as severe adverse
reactions, including fatalities in dogs,
may result.

Ivomec

(ivermectin)

Injection

for Cattle and Swine
1% Sterile Solution



**A Parasiticide for the Treatment and
Control of Internal and External
Parasites of Cattle and Swine.**

500 mL

MERIAL