

Date of Approval: SEP 13 2004

FREEDOM OF INFORMATION SUMMARY

AN ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-272

NOROMECTIN (ivermectin) Pour-On for Cattle

NOROMECTIN (ivermectin) Pour-On for Cattle when applied at the recommended dose of 500 mcg/kg is indicated for the effective control and treatment of gastrointestinal roundworms (including *Ostertagia ostertagi*) lungworms, grubs, hornflies, sucking and biting lice, and sarcoptic mange mites in cattle.

Sponsored by:

**Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP
Northern Ireland**

200-272

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-272
- b. Sponsor: Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP
Northern Ireland
- Drug Labeler Code: 055529
- c. Established Name: Ivermectin
- d. Proprietary Name: NOROMECTIN Pour-On for Cattle
- e. Dosage Form: Pour-On
- f. How Supplied: 33.8 fl oz / 1L, 84.5 fl oz / 2.5 L and 169 fl oz / 5L
collapsible pack with pour-on applicator gun or as a
replacement pack and 676 fl oz / 20 L container with
draw-off device and applicator gun.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each milliliter (mL) of solution contains
5 milligrams (mg) of ivermectin
- i. Route of Administration: Topical, on the dorsal midline, withers to tail head.
- j. Species/Class: Cattle
- k. Recommended Dosage: 500 mcg/kg (1 mL for each 22 lb of bodyweight)
- l. Pharmacological Category: Parasiticide
- m. Indications: NOROMECTIN Pour-On for Cattle applied at the
recommended dose level of 500 mcg/kg is indicated
for the effective control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (adults and L₄) (including
inhibited stage)

Haemonchus placei (adults and L₄)

Trichostrongylus axei (adults and L₄)

Trichostrongylus colubriformis (adults and L₄)

Cooperia spp. (adults and L₄)

Oesophagostomum radiatum (adults and L₄)

Strongyloides papillosus (adults)

Trichuris spp. (adults)

Lungworms

Dictyocaulus viviparus (adults and L₄)

Cattle Grubs (parasitic stages)

Hypoderma bovis

H. lineatum

Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli

Haematopinus eurysternus

Damalinia bovis

Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity:

NOROMECTIN Pour-On for Cattle has proven to effectively control infections and protect cattle from reinfection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment.

n. Pioneer Product:

IVOMEK Pour-on for Cattle; ivermectin;
NADA 140-841; 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 data, drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows 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 Guidance, revised October 9, 2003).

PRODUCT INFORMATION LEAFLET (100% SIZE - 210mm x 148mm)

Noromectin[®]

(ivermectin)

POUR-ON for Cattle

Contains 5 mg ivermectin/mL

ANADA 200-272, Approved by FDA

Parasiticide

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

Introduction

Noromectin (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application.

Indications

Noromectin Pour-On 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>	(adults and L ₄)
(including inhibited stage)	
<i>Haemonchus placei</i>	(adults and L ₄)
<i>Trichostrongylus axei</i>	(adults and L ₄)
<i>T. colubriformis</i>	(adults and L ₄)
<i>Cooperia</i> spp.	(adults and L ₄)
<i>Oesophagostomum radiatum</i>	(adults and L ₄)
<i>Strongyloides papillosus</i>	(adults)
<i>Trichuris</i> spp.	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L ₄)
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Cattle Grubs

<i>Hypoderma bovis</i>	(parasitic stages)
<i>H. lineatum</i>	

Mites

<i>Sarcoptes scabiei</i> var. <i>bovis</i>
--

Lice

<i>Linognathus vituli</i>
<i>Haematopinus eurysternus</i>
<i>Damalinea bovis</i>
<i>Solenopotes capillatus</i>

Horn Flies

<i>Haematobia irritans</i>

Persistent Activity

Noromectin Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies

Noromectin Pour-On 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.

Administration

Collapsible Packs (33.8 fl oz/1 liter pack; 84.5 fl oz/2.5 liter pack; 169 fl oz/5 liter pack with dosing gun/applicator)

Because of the solvents used in Noromectin Pour-On, the applicator gun from Simcro Tech*, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Remove the shipping cap from the backpack container and replace with the vent cap provided. Attach the hose from the automatic dosing equipment to the outlet from the vent cap. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

Container (676 fl oz/20 liter container with draw-off device and dosing gun/applicator)

Because of the solvents used in Noromectin Pour-On, the draw-off device and applicator gun from Simcro Tech*, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Screw Feedlot pack cap and dip tube onto the 20 liter drum ensuring a tight fit. Connect the long 3m feed tube at one end to the spigot on the Feedlot pack cap and the other end to the applicator gun. Then follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

When the interval between use of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw off tubing and dip tub and cap from the product container, empty the product from the gun and tubing back into the 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

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.

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.

RESIDUE INFORMATION: 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.

WARNING! NOT FOR USE IN HUMANS

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.

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

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

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS, or for assistance call Norbrook on (1) 913-424-4714.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and 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 (ivermectin) 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 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.

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.

Package Information

Noromectin Pour-On is available in a 33.8 fl oz/1 L collapsible pack, in an 84.5 fl oz/2.5 L collapsible pack, in a 169 fl oz/5 L collapsible pack and a 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland



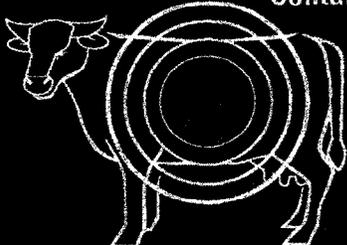
1 Liter Container Front Label (100% SIZE - 140mm x 97mm)

Noromectin [®]
(ivermectin)

AVADA 250 272, Approved by FDA

POUR-ON for Cattle

Contains 5 mg ivermectin / mL



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

WARNING!
NOT FOR USE IN HUMANS.

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

Lot No. & Exp. Date ▼


33.8 fl oz (1 L)



1 Liter Container Back Label (100% SIZE - 140mm x 97mm)

Noromectin[®]

(ivermectin)

POUR-ON for Cattle

Contains 5 mg ivermectin/ml

ANADA 200-272, Approved by FDA

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.

RECOMMENDED DOSE:

1 mL per 22 lb of body weight.

Administration

Because of the solvents used in Noromectin Pour-On, the applicator gun from Simcro Tech[®], or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in clogging, incorrect dosage or leakage. Remove the shipping cap from the backpack container and replace with the vent cap provided. Attach the hose from the automatic dosing equipment to the outlet from the vent cap. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

RESIDUE INFORMATION: 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.

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 call Norbrook on (1) 813-424-4714.

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.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and 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 (ivermectin) 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 is not recommended for use in species other than cattle.

Disposal:

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.

Made in the UK

33.8 fl oz (1 L)

Noromectin[®]

(ivermectin)

POUR-ON 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.

ADMINISTRATION:
Because of the solvents used in Noromectin Pour-On, the applicator gun from Simcro Tech, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Remove the shipping cap from the backpack container and replace with the vent cap provided. Attach the hose from the automatic dosing equipment to the outlet from the vent cap. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

Norbroad Laboratories Limited

Made in the UK.



Noromectin[®]
(ivermectin)

TS 5000000
Sole Agent: Simcro Tech, Ltd.
Norwich, Norfolk, England

TS 5000000
Sole Agent: Simcro Tech, Ltd.
Norwich, Norfolk, England

POUR-ON for Cattle

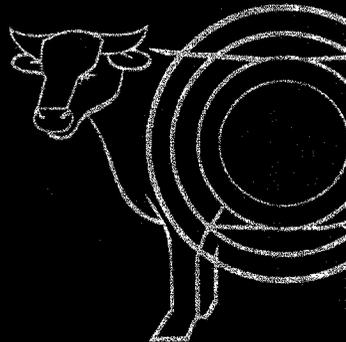
Noromectin[®]

Noromectin[®]

(ivermectin)

POUR-ON for Cattle

Contains 5 mg ivermectin / ml



PARASITICIDE

Kills Roundworms including Brown Stomach Worms, Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

Contains 40 x 550 lb doses

33.8 fl oz (1 L)

Norbroad



Noromectin[®]
(ivermectin)



POUR-ON for Cattle

TS 5000000
Sole Agent: Simcro Tech, Ltd.
Norwich, Norfolk, England

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TS 5000000
Sole Agent: Simcro Tech, Ltd.
Norwich, Norfolk, England

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

33.8 fl oz (1 L)

POUR-ON for Cattle

Noromectin
(ivermectin)

Noromectin
(ivermectin)

POUR-ON for Cattle

Noromectin
(ivermectin)

POUR-ON for Cattle

Contains 5 mg ivermectin / mL

Noromectin
(ivermectin)

POUR-ON for Cattle

Noromectin
(ivermectin)

POUR-ON for Cattle

...for assistance in the diagnosis, treatment
...ism

...and control of gastrointestinal roundworms
(*Ostertagia ostertagi*), lungworms, grubs, horn
...ing lice, and sarcoptic mange mites in cattle.

...for complete indications and use directions.

...L for each 22 lb of bodyweight. The formulation
...along the topline in a narrow strip extending
...the tailhead

...vents used in Noromectin Pour-On, the applicator
...Tech, or equivalent, is recommended. Other
...hibit compatibility problems resulting in locking,
...or leakage. Remove the shipping cap from the
...er and replace with the vent cap provided.
...in the automatic dosing equipment to the outlet
... Follow the applicator gun manufacturer's
...ing the gun, adjusting the dose, and care of the
...owing use.

...ries Limited



This typically aerosol formulation of ivermectin
...formulation. However, if the formulation is
...condition and appropriate handling should be used.

PRECAUTIONS
Store away from excessive heat (90°F/32°C) and
protect from light.

Use only in well ventilated areas.
Close container tightly when not in use.

Cattle should not be treated with ivermectin
...not have received other ivermectin products.

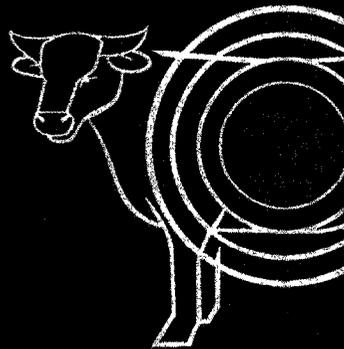
Do not use ivermectin in conjunction with
...or other anthelmintics.

This product is for application to the skin
...It is not for oral or parenteral use.

Cloudiness in the formulation may occur.
Ivermectin (ivermectin) Pour-On is stable at
...temperatures below 32°F. Allowing the
...room temperature will restore the original
...appearance without affecting efficacy.

Automatic delivery of the product is not
...if the formulation is applied to areas of the
...mange, sores or lesions, or wet, muddy or
...adhesive materials, e.g., dried mud.

Ivermectin has been associated with
...reactions in sensitive dogs. Do not use
...Pour-On in or around dogs, cats, horses,
...other farm animals.



PARASITICIDE

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

...Dosing: 40 x 550 lb doses.

33.8 fl oz (1 L)

Includes Applicator Gun



ANIMAL SAFETY

...of ivermectin in the formulation is
...the formulation is not for use in
...the formulation is not for use in
...the formulation is not for use in

RESIDUE INFORMATION

...of ivermectin in the formulation is
...the formulation is not for use in
...the formulation is not for use in
...the formulation is not for use in

WARNING

...NOT FOR USE IN HUMANS

...of ivermectin in the formulation is
...the formulation is not for use in
...the formulation is not for use in
...the formulation is not for use in

Disposal

...of ivermectin in the formulation is
...the formulation is not for use in
...the formulation is not for use in
...the formulation is not for use in

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

WARNING! FLAMMABLE
KEEP AWAY FROM HEAT, SPARKS, FLAMES
AND OTHER SOURCES OF IGNITION.

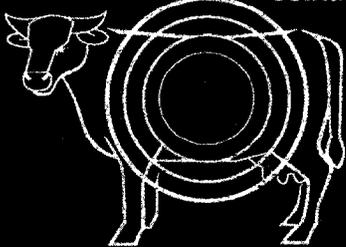
2.5 Liter Container Front Label (100% SIZE - 140mm x 97mm)

Noromectin[®]
(ivermectin)

ANADA 206-272, Approved by FDA

POUR-ON for Cattle

Contains 5 mg ivermectin / mL



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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

Lot No. & Exp. Date ▼

84.5 fl oz (2.5 L)

 **Norbrook**[®] 

Noromectin
(ivermectin)
POUR-ON 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.

ADMINISTRATION:
Because of the solvents used in Noromectin Pour-On, the applicator gun from Simcro Tech, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Remove the shipping cap from the backpack container and replace with the vent cap provided. Attach the hose from the automatic dosing equipment to the outlet from the vent cap. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

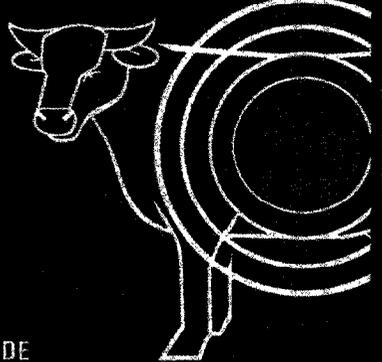
Norbroad Laboratories Limited

Made in the UK.



POUR-ON for Cattle
(ivermectin)
Noromectin

Noromectin
(ivermectin)
POUR-ON 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: 100 x 550 lb doses.
84.5 fl oz (2.5 L)



Noromectin
(ivermectin)

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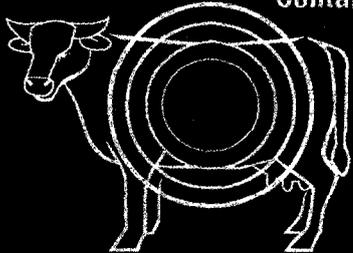
5 Liter Container Front Label (100% SIZE - 140mm x 97mm)

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

Lot No. & Exp. Date ▼

169 fl oz (5 L)

 **Norbrook**[®] 

5 Liter Container Back Label (100% SIZE - 140mm x 97mm)

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Administration

Because of the solvents used in Noromectin Pour-On, the applicator gun from Smcro Tech[®], or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Remove the shipping cap from the backpack container and replace with the vent cap provided. Attach the hose from the automatic dosing equipment to the outlet from the vent cap. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

RESIDUE INFORMATION: 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.

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 call Norbrook on (1) 913-424-4714.

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.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and 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 (ivermectin) 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 is not recommended for use in species other than cattle.

Disposal:

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.

Made in the UK.

169 fl oz (5 L)

163 fl oz (5 L)

POUR-ON for Cattle

(ivermectin)

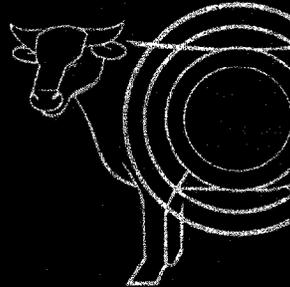
Noromectin

Noromectin

(ivermectin)

POUR-ON for Cattle

Contains 5 mg ivermectin / ml

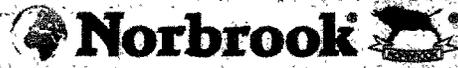


PARASITICIDE

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

Contains: 200 x 550 lb doses.

163 fl oz (5 L)



Noromectin

(ivermectin)

POUR-ON for Cattle



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

Noromectin

(ivermectin)

POUR-ON 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 sucking and biting lice, and sarcoptic mange mites in cattle

Package insert for complete indications and use directions.

DOSE:
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

ADMINISTRATION:
Use of the solvents used in Noromectin Pour-On, the applicator from Simcro Tech, or equivalent, is recommended. Other containers may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Remove the shipping cap from the pack container and replace with the vent cap provided. Attach hose from the automatic dosing equipment to the outlet from vent cap. Follow the applicator gun manufacturer's directions regarding the gun, adjusting the dose, and care of the applicator following use.

Norbroad Laboratories Limited

is in the UK.



Noromectin

(ivermectin)

POUR-ON for Cattle

PRECAUTIONS:
Store away from children, heat, fire, sparks, open flame, and other sources of ignition. Do not use in areas where smoking is prohibited. Do not use in areas where open flames, sparks, or other sources of ignition are present. Do not use in areas where food is prepared or stored. Do not use in areas where animals are housed. Do not use in areas where people are present. Do not use in areas where children are present. Do not use in areas where pregnant women are present. Do not use in areas where nursing infants are present. Do not use in areas where people with compromised immune systems are present. Do not use in areas where people with allergies are present. Do not use in areas where people with asthma are present. Do not use in areas where people with epilepsy are present. Do not use in areas where people with heart disease are present. Do not use in areas where people with high blood pressure are present. Do not use in areas where people with diabetes are present. Do not use in areas where people with kidney disease are present. Do not use in areas where people with liver disease are present. Do not use in areas where people with thyroid disease are present. Do not use in areas where people with diabetes are present. Do not use in areas where people with epilepsy are present. Do not use in areas where people with heart disease are present. Do not use in areas where people with high blood pressure are present. Do not use in areas where people with diabetes are present. Do not use in areas where people with kidney disease are present. Do not use in areas where people with liver disease are present. Do not use in areas where people with thyroid disease are present.

159 H 02 (51)



Contains 5 mg ivermectin / ml
POUR-ON for Cattle

Noromectin
(ivermectin)

Noromectin
(ivermectin)
POUR-ON for Cattle

Noromectin
(ivermectin)
POUR-ON for Cattle

Noromectin
(ivermectin)
POUR-ON for Cattle
Contains 5 mg ivermectin / ml

Noromectin
(ivermectin)
POUR-ON for Cattle

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

... control of gastrointestinal roundworms and *Ostertagia ostertagi*, lungworms, grubs, hornid biting lice, and sarcoptic mange mites in cattle.

... 1 ml for each 22 lb of bodyweight. The formulation is applied along the topline in a narrow strip extending to the tailhead

CAUTION: Always used in Noromectin Pour-On, the applicator to Tech, or equivalent, is recommended. Other exhibit compatibility problems resulting in locking, leakage or leakage. Remove the shipping cap from the vent and replace with the vent cap provided. Attach the automatic dosing equipment to the outlet from the applicator gun manufacturer's directions. Adjust the dose, and care of the applicator.

... Limited
UN 1279

PRECAUTIONS: Store away from children and livestock. Keep out of reach of children. Do not use if the seal is broken. Do not use if the seal is broken. Do not use if the seal is broken.

PARASITICIDE

Kills Roundworms including Brown Stomach Worms, Lungworms, Grubs, Tick-bug Lice, Biting Lice, Mange Mites, Horn Flies

Contains 200 & 500 lb doses
159 H 02 (51)

Includes Applicator Gun



FORM AND ACTION: This is a pour-on formulation. It is applied to the topline of the animal. It is effective against a wide range of parasites.

HOW TO USE: Apply to the topline of the animal. Do not use if the seal is broken. Do not use if the seal is broken.

CAUTION: This is a pour-on formulation. It is applied to the topline of the animal. It is effective against a wide range of parasites.

WARNING: IRRITANT. KEEP AWAY FROM PLAYS SPACES, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

20 Liter Drum Container Front Label (100% SIZE - 176mm x 200mm)

Noromectin[®]

(ivermectin)

POUR-ON for Cattle

ANADA 200-272, Approved by FDA

Contains 5 mg ivermectin / mL

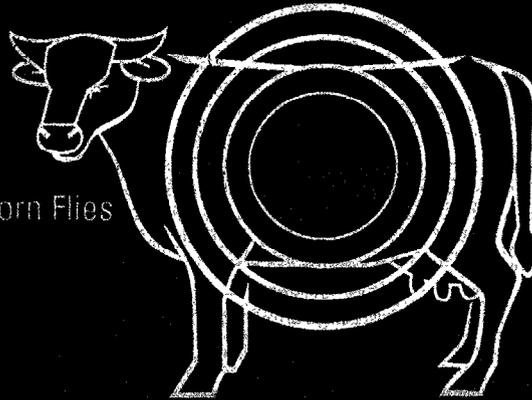
Parasiticide

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



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

WARNING!
NOT FOR USE IN HUMANS.

Lot No. & Exp. Date ▼

[Empty box for Lot No. & Exp. Date]

676 fl oz (20 L)

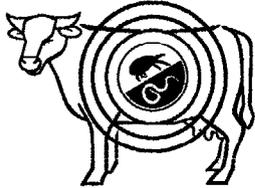
000001.01



Norbrook[®]



20 Liter Drum Container Back Label (100% SIZE - 176mm x 200mm)



Noromectin[®]
(ivermectin)

POUR-ON for Cattle

Contains 5 mg ivermectin / mL
ANADA 200-272, Approved by FDA

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 per 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION:

This container is designed to dispense Noromectin Pour-On into smaller containers or to be used with appropriate automatic dosing equipment. Because of the solvents used in Noromectin Pour-On, the draw-off device and applicator gun from Simcro Tech*, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Screw Feedlot pack cap and dip tube onto the 20 liter drum ensuring a tight fit. Connect the long 3m feed tube at one end to the spigot on the Feedlot pack cap and the other end to the applicator gun. Then follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use. See package insert for use of automatic dosing equipment. Use the following table to determine the proper dose. When body weight is between doses, use the higher dose.

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.

RESIDUE INFORMATION: 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.

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 call Norbrook on (1) 913-424-4714.

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.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and 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 (ivermectin) 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 is not recommended for use in species other than cattle.

Disposal:

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.

Made in the UK.

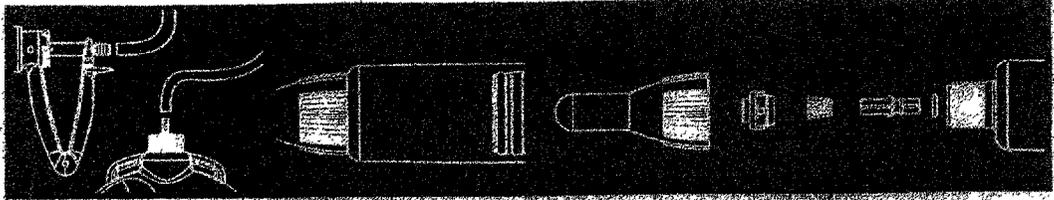
TAKE TIME



OBSERVE LABEL DIRECTIONS

676 fl.oz (20 L)

30ml	Simcro Applicator
	Pour-on/Drencher



To connect to backpack

- 1 Slide the two hose armour springs onto each end of the delivery tube.
- 2 Push one end of delivery tube full onto inlet barbs on applicator (see above). Slide armour spring back over the end of delivery tube to reduce the possibility of the tube kinking.
- 3 Push other end of delivery tube onto barb end of tube adaptor/spigot and slide armour spring over end.
- 4 Hold backpack upright and remove transit cap. Screw spigot cap onto backpack and tighten fully. Push end of delivery tubing firmly over barbs on spigot cap (see above).
- 5 Place backpack on back and adjust straps until comfortable.

Note:

This pack contains an adaptor for different sizes of tubing and/or spigot.

To set dose

Turn the dose adjuster band clockwise to move the plunger forward until the front face of the plunger lines up with the required dose, as marked on the barrel. (see above) Turning the dose adjuster band anti-clockwise increases the dose. The system is now ready to use.

To prime

Squeeze the handle of the applicator several times until the product is drawn through the tube filling the calibrated barrel. Gently squeeze the handle several times (into a clean, dry container to avoid wastage) until all air has been expelled from the tubing and applicator barrel.

To fit drench nozzle

Screw drench nozzle on to applicator, position at required angle and tighten the nut firmly.

Maintenance

- 1 Carefully remove the delivery tube from the backpack and pump warm soapy water through the applicator to flush out any excess product. Then flush with clean water.
- 2 Lubricate the piston O-ring and felt washer with olive oil or any food grade vegetable oil, by injecting oil into the hole in top of the barrel and into the felt washer.
- 3 Squeeze the applicator a few times to spread the oil through the barrel.
- 4 Store the applicator in a plastic bag to keep it dust free for re-use.

5 The only parts that can be removed are (see above):

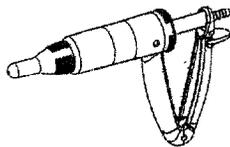
- 1 Nozzle
- 2 Front valve cage
- 3 Valve spring
- 4 Valve
- 5 Barrel

If reassembling, place the short fin end of the valve into the barrel, place the narrow end of the conical spring onto the long end of the valve, then replace the front valve cage. Finally replace the nozzle by threading clockwise onto the barrel.

Note:

Repeating this maintenance process after every use will extend the applicator's life.

002836



Simcro Applicator
Pour-on/Drencher
30ml

Ivomec[®]
(ivermectin)

pour-on 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 drugs out of the reach of children.

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.

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

RESIDUE INFORMATION:

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.

Product 41309A

Ivomec[®]
(ivermectin)

pour-on 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 10-550 lb Doses



NADA 140-841, Approved by the FDA

Rev. 04-2003

1150 1408-70

8 5 1 7 1251

MERIAL

Product 41309A

ivomec[®]
(ivermectin)
pour-on for cattle

Contains 5 mg
ivermectin/mL

Parasiticide

Kills:

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

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

WARNING
NOT FOR USE IN HUMANS.

Lot No & Exp Date ▼



8.5 fl oz (250 mL) NADA 140-041, Approved by the FDA

Rev. 04-2003
1020-1447-00

Merial Limited
3259 Satellite Blvd
Duluth, Georgia
30096-4030, U.S.A.



Rev. 4/03



1050144500

NADA 140-841, Approved by the FDA

IVOMEC®
(ivermectin)



pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

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

INTRODUCTION

IVOMEC (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On 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 this 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

IVOMEC Pour-On 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 L ₄)
<i>Haemonchus placei</i>	(adults and L ₄)
<i>Trichostrongylus axei</i>	(adults and L ₄)
<i>T. colubriformis</i>	(adults and L ₄)
<i>Cooperia</i> spp.	(adults and L ₄)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L ₄)
<i>Trichuris</i> spp.	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L ₄)
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Cattle Grubs

<i>Hypoderma bovis</i>	(parasitic stages)
<i>H. lineatum</i>	

Mites

<i>Sarcoptes scabiei</i> var. <i>bovis</i>
--

Lice

<i>Linognathus vituli</i>
<i>Haematopinus eurysternus</i>
<i>Damalinea bovis</i>
<i>Solenopotes capillatus</i>

Horn Flies

<i>Haematobia irritans</i>

Persistent Activity

IVOMEC Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOMEC 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.

ADMINISTRATION

Squeeze-Measure-Pour System
(8.5 fl oz/250 mL Bottle with 50 mL Metering Cup)
Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting. Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

Squeeze-Measure-Pour System
(33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)
Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting. Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Till the bottle to deliver the dose. When 220 lb (10 mL) or 330 lb (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.

Collapsible Pack
(64.5 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 Protector Drench Gun from Instrument Supplies Limited, 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 Protector Drench 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 IVOMEC® (ivermectin) Pour-On. 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.

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 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.

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 INFORMATION: 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 away from excessive heat (104°F/40°C) and 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 IVOMEC Pour-On is stored at temperatures below 32°F. Allowing 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 IVOMEC Pour-On is not recommended for use in

When to Treat Cattle with Grubs

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

Environmental Safety

Studies indicate that when ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive. Free ivermectin may adversely affect fish and certain aquatic organisms. 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 Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 fl oz/2.5 L or 169 fl oz/5 L collapsible pack, or 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

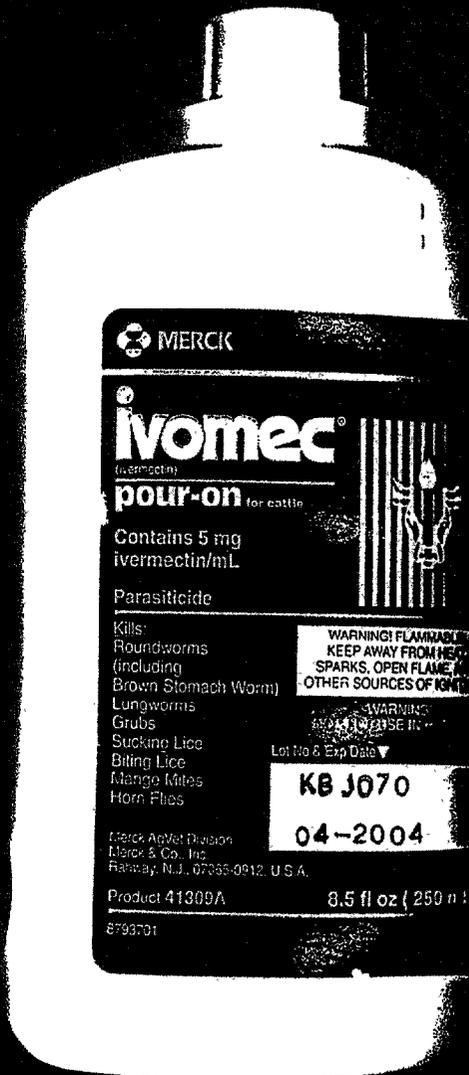
IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Merial Limited, a company limited by shares registered in England and Wales (registered number 3332761) 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.

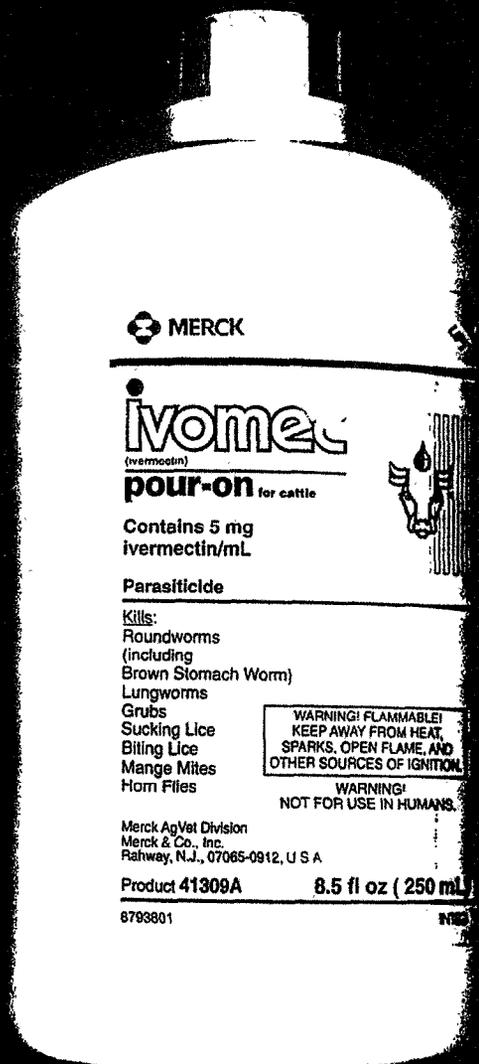
U.S. Pat 4,199,569
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Rev. 04-2003
1050-1445-00





250 mL Container
Front Label



MERCK

Ivomec
(ivermectin)
pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

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

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

WARNING!
NOT FOR USE IN HUMANS.

Merck Ag Vet Division
Merck & Co., Inc.
Rahway, N.J., 07065-0912, U S A

Product 41309A 8.5 fl oz (250 mL)

8793801

250 mL Container
Back Label



IVOMEC™ is protected by U.S. Patents U.S.A. 4680080, 4592, 4,757,422 Canada 422793 and 01.

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

Recommended Dose 1 mL per 22 lb of body weight

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

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.

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

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.



Use only in well-ventilated areas 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 IVOMEC (ivermectin) Pour-On is stored at temperatures below 32 F. Allowing 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, IVOMEC Pour-On is not recommended for use in species other than cattle.

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.

U.S. Pat. 4 199,569
IVOMEC and Cattle Head Logo are registered trademarks of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.
Made in U.S.A.

250mL BOTTLE OUTSERT (back)

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ivomec[®]
(ivermectin)

pour-on for cattle

TAKE TIME



OBSERVE LABEL
DIRECTIONS

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: 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.

WARNING!
NOT FOR USE IN HUMANS.
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.

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

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

84018



ivomec[®]

(ivermectin)

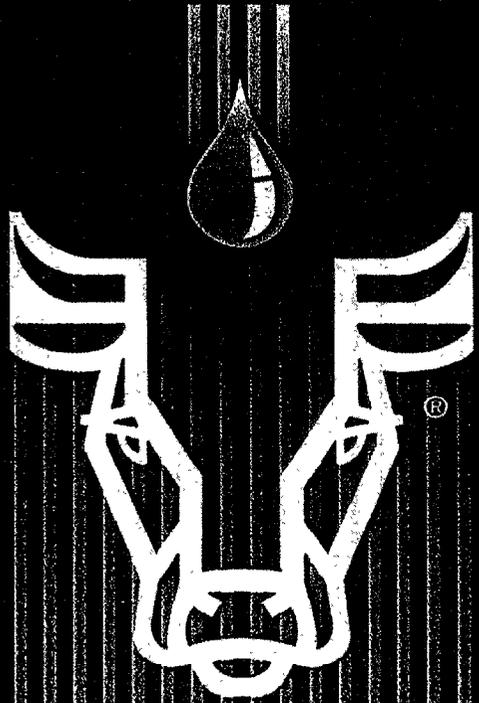
pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

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

Contains 10-550 lb Doses



8.5 fl oz (250 mL)

Product 41309A

Product
41309A

8.5 fl oz
(250 mL)

Contains 5 mg ivermectin/mL

IVOMEC
(ivermectin)
pour-on for cattle

IVOMEC

IVOMEC

MERCK

MERCK

ivomec[®]
(ivermectin)

pour-on for cattle

This topically applied formulation of IVOMEC[®] (ivermectin) delivers internal and external parasite control in one convenient low-volume application.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect contents 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 IVOMEC Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMEC Pour-On is not recommended for use in species other than cattle.

IVOMEC[®]

(ivermectin)

pour-on 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 body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION:

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off (STOP) position will close the system between dosing.

MERCK

AgVet Division

Merck & Co., Inc.
Rahway, New Jersey, 07065-0912, U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

U.S. Pat 4,199,569

Made in U.S.A.



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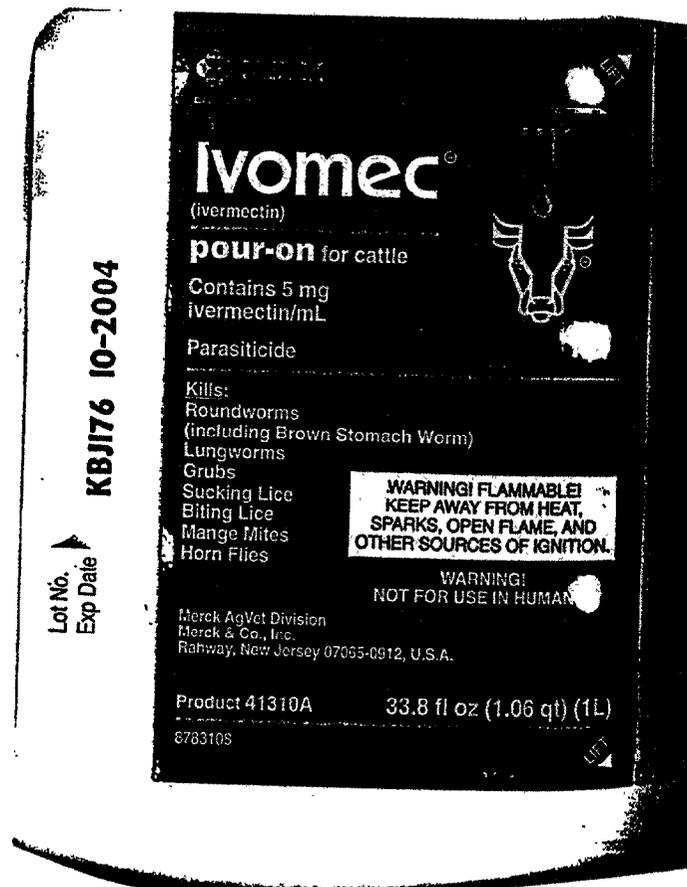


00084018

Lot No & Exp Date ▼

KE J170

04



Ivomec[®]

(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL

Parasiticide

Kills:

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

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

WARNING!
NOT FOR USE IN HUMAN

Merck AgVet Division
Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

Product 41310A 33.8 fl oz (1.06 qt) (1L)

878310S

KBJ176 10-2004

Lot No.
Exp Date

1 Liter container front label
(no back container label)

IVOMEC[®]
(ivermectin)

pour-on for cattle

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

Introduction

IVOMEC[®] (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On contains ivermectin, a unique chemical entity.

Indications

IVOMEC Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (adults and L₄)
(including inhibited stage)

Haemonchus placei (adults and L₄)

Trichostrongylus axei (adults and L₄)

T. colubriformis (adults and L₄)

Cooperia spp (adults and L₄)

Strongyloides papillosus (adults)

Oesophagostomum radiatum (adults and L₄)

Trichuris spp (adults)

Lungworms

Dictyocaulus viviparus (adults and L₄)

Cattle Grubs (parasitic stages)

Hypoderma bovis

H. lineatum

Mites

Sarcoptes scabiei var. *bovis*

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Lice

Linognathus vituli

Haematopinus eurysternus

Damalinia bovis

Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity

IVOMEC (ivermectin) Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOMEC 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.

Administration

Squeeze-Measure-Pour System (8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off (STOP) position will close the system between dosing.

Squeeze-Measure-Pour System (33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. When 220 lb (10 mL) or 330 lb (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.

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 Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems, resulting in locking, incorrect dosage or leakage.)

Replace the shipping cap with 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 Protector Drench Gun, the gun and tubing must not be washed.

Mode of Action

Ivermectin as a member of the avermectin family kills certain parasitic roundworms and ectoparasites, such as mites, lice, horn flies and other insects. Its action is unique to the avermectin class of antiparasitic agents. This action involves a chemical that serves as a signal from one nerve cell to another, or from a nerve cell to a muscle cell. This chemical, a neurotransmitter, is called gamma-aminobutyric acid or GABA.

In roundworms, ivermectin stimulates the release of GABA from nerve endings and enhances binding of GABA to special receptors at nerve junctions, thus interrupting nerve impulses — thereby paralyzing and killing the parasite.

The enhancement of the GABA effect in arthropods such as mites, lice, and horn flies resembles that in roundworms except that nerve impulses are interrupted between the nerve ending and the muscle cell. Again, this leads to paralysis and death.

Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter.

The principal peripheral neurotransmitter in mammals, acetylcholine, is unaffected by ivermectin. Ivermectin does not readily penetrate the central nervous system of mammals where GABA functions as a neurotransmitter.

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.

1 Liter bottle outsert
(front side)

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.

WARNING! NOT FOR USE IN HUMANS.

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.

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

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

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and 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 IVOMEK® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMEK Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs

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

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 water-borne organisms on which they feed. 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.

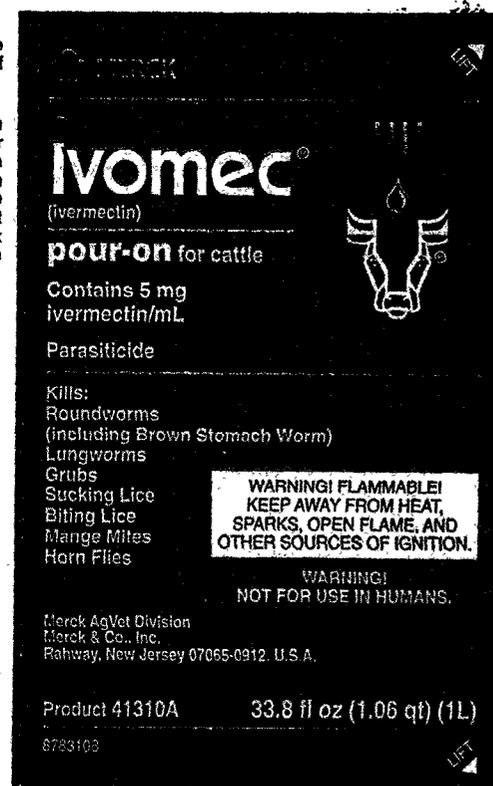
Package Information

IVOMEK (ivermectin) Pour-On is available in an 8.5 fl oz/250 mL bottle with a squeeze-measure-pour system (Product 41309A), a 33.8 fl oz/1 L bottle with a squeeze-measure-pour system (Product 41310A), or in an 84.5 fl oz/2.5 L collapsible pack intended for use with appropriate automatic dosing equipment (Product 41311A), and a 169 oz/5 L collapsible pack (Product 41350A) intended for use with appropriate automatic dosing equipment.



Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

U.S. Pat 4,199,589
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All Rights Reserved. November 1998
Extended Text™ INSEAL™ has the following Patent: U.S.A. 4933043



1 Liter bottle outsert (back side)

1 Liter Carton
Top Label
(no bottom label)

Ivomec[®]

(Ivermectin)

pour-on

for cattle

Contains 5 mg ivermectin/mL

33.8 fl oz (1.06 qt) (1 L)

Product 41310A

Ivomec

Ivomec[®]

(ivermectin)

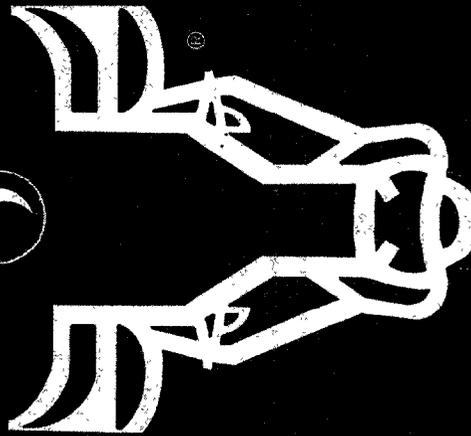
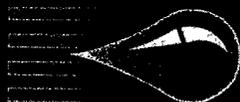
Pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

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

Contains 40-550 lb Doses



3.8 fl oz (1.06 qt) (1 L)

Product 41310A

1 Liter carton (front panel)

Ivomec[®]

(ivermectin)

pour-on 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 body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION:

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. When 220 lb (10 mL) or 330 lb (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.



AgVet Division

Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

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U.S. Pat. 4,199,569
Made in U.S.A.



Lot No & Exp Date ▼

KBJ176
10-2004

1 Liter carton (back panel)

Ivomec
(ivermectin)
Pour-On for cattle

This topically applied formulation of IVOMEC® (ivermectin) delivers internal and external parasite control in one convenient low-volume application.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect contents 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 IVOMEC Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMEC Pour-On is not recommended for use in species other than cattle.



Ivomec
(ivermectin)
Pour-On for cattle

TAKE TIME



OBSERVE LABEL

DIRECTIONS

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: Cattle must not be treated within 43 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.

WARNING!

NOT FOR USE IN HUMANS.

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.

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

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

84019

1 Liter Side Panels
Carton

Ivomec[®]

(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL

Parasiticide

Kills:

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

Product 41311A

8778101



 **MERCK**
AgVet Division

Merck & Co., Inc.
Rahway, New Jersey, 07065-0912, U.S.A.

84.5 fl oz (2.64 qt) (2.5 L)

2.5 Liter container (front panel)

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.

Recommended Dose: 1 mL per 22 lb of body weight.

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.

WARNING! NOT FOR USE IN HUMANS.

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.

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

WARNING! FLAMMABLE!

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

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and 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 IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMEC Pour-On is not recommended for use in species other than cattle.

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.

U.S. Pat. 4,199,569

Made in U.S.A.

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8778201

Lot No & Exp Date ▼

KBJ152

09-2004

84.5 fl oz (2.64 qt)(2.5L)

2.5 Liter container (back panel)

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.

Recommended Dose: 1 mL per 22 lb of body weight.

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.

WARNING! NOT FOR USE IN HUMANS.

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.

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

WARNING! FLAMMABLE!

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

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and 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 IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMEC Pour-On is not recommended for use in species other than cattle.

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.

U.S. Pat. 4,199,569

Made in U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

8778201

Lot No & Exp Date ▼

KBJ152

09-2004

84.5 fl oz (2.64 qt)(2.5L)

2.5 Liter container (back panel)

vomec[®]

ivermectin

pour-on for cattle

Contains 5 mg ivermectin/mL

34.5 fl oz (2.64 qt) (2.5 L)

Product 41311A



2.5L carton top label

ivomec[®]

ivermectin

pour-on for cattle

Contains 5 mg ivermectin/mL

34.5 fl oz (2.64 qt) (2.5 L)

Product 41311A



2.5L carton top label

ivomec[®]

(ivermectin)

pour-on for cattle

contains 5 mg ivermectin/mL

Parasiticide

Controls: Roundworms (including Brown Stomach Worm),
Pinworms, Grubs, Sucking Lice, Biting Lice,
Large Mites, Horn Flies

contains 100-550 lb Doses



2.5L carton (front label)

41311 07 (2/64) (2.5 L)

Product 41311A

Ivomec®

(ivermectin)

Pour-on 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.

DOSE:

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.

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 Protector Drench Gun from Instrument Supplies Limited, 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.

Recently 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 24 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 Protector Drench Gun, the gun and tubing must not be washed.



Merck & Co., Inc.
Kenilworth, New Jersey, 07033-0312, U.S.A.

OMITC and Cattle Head Logo are registered trademarks of Merck & Co., Inc.
Phelioscapes Station, N.J., U.S.A.

U.S. Pat. 4,194,563

Made in U.S.A.

Let's & Exp. Date ▼



00084065

KBJ152

09 2004

2.5L carton (back label)

Ivomec[®]

(ivermectin)

pour-on for cattle

TAKE TIME



OBSERVE LABEL
DIRECTIONS

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: Cattle must not be treated within 45 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.

WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to humans 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.

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

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

Ivomec[®]

(ivermectin)

pour-on for cattle

This topically applied formulation of IVOMECS[®] (ivermectin) delivers internal and external parasite control in one convenient low-volume application.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect contents 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.

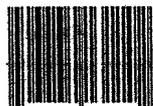
This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMECS Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMECS Pour-On is not recommended for use in species other than cattle.

2.5L carton (side panels)



3 0373-413110 2



0919202

915292

MERCK

IVOMEC®

(ivermectin)



Pour-On for cattle

Contains 5 mg ivermectin/mL

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

Indications
IVOMEC® (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On contains ivermectin, a unique chemical entity.

Indications
IVOMEC Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms (adults and L ₁)	
<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L ₁)
<i>Haemonchus placei</i>	(adults and L ₁)
<i>Trichostrongylus axei</i>	(adults and L ₁)
<i>T. colubriformis</i>	(adults)
<i>Cooperia</i> spp.	(adults and L ₁)
<i>Strongylus edentatus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults)
<i>Trichouris</i> spp.	(adults and L ₁)
Lungworms <i>Dictyocaulus viviparus</i>	(adults and L ₁)
Cattle Grubs <i>Hypoderma bovis</i> <i>H. lineatum</i>	(parasitic stages)
Mites <i>Sarcoptes scabiei</i> var. <i>bovis</i>	
Lice <i>Limnephilus vitellus</i> <i>Haematopinus eurysternus</i> <i>Dermanis bovis</i> <i>Solenopotes capillatus</i>	
Horn Flies <i>Haematobia irritans</i>	

Parasiticide Activity
IVOMEC Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Neserochus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies
IVOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOMEC 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.

Administration
Squeeze-Measure-Pour System (0.5 l oz/250 mL Bottle with 25 mL Measuring Cup)

Attach the measuring cup to the bottle.
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the inverted cap. When body weight is between markings, use the higher setting.
Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Turn the bottle to deliver the dose. The dot (STOP) position will close the system between dosing.
Squeeze-Measure-Pour System (33.8 l oz/1 Liter Bottle with 60 mL Measuring Cup)

Attach the measuring cup to the bottle.
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the inverted cap. When body weight is between markings, use the higher setting.
Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Turn the bottle to deliver the dose. When pointer to "STOP" before delivering the dose. The dot (STOP) position will close the system between dosing.
Collapsible Pack (0.5 l oz/2.5 L Pack and 189 mL Collapsible 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 solvent used in the formulation, only the Protector Drench Gun used in the formulators' Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in leakage, incorrect dosage or leakage.)
Replace the shipping cap with the draw-off cap and tighten gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose expected to ensure 12 hours, disconnect the applicator gun is draw-off tubing from the product container and empty the container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

*IVOMEC and Cattle Head Logo are registered trademarks of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

Mode of Action
Ivermectin as a member of the avermectin family kills certain parasitic roundworms and ectoparasites, such as mites, lice, horn flies and other insects. Its action is unique to the avermectin class of antiparasitic agents. This action involves a chemical that conveys a signal from one nerve cell to another, or from a nerve cell to a muscle cell. This chemical, a neurotransmitter, is called gamma-aminobutyric acid or GABA.

In roundworms, ivermectin stimulates the release of GABA from nerve endings and enhances binding of GABA to special receptors at nerve junctions, thus interrupting nerve impulses — thereby paralyzing and killing the parasite. The enhancement of the GABA effect in arthropods such as mites, lice, and horn flies resembles that in roundworms except that nerve impulses are interrupted between the nerve ending and the muscle cell. Again, this leads to paralysis and death.

Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter.

The peripheral nervous system of mammals, including acetylcholine, is unaffected by ivermectin. Ivermectin does not readily penetrate the central nervous system of mammals where GABA functions as a neurotransmitter.

Safety
Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on 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: 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.

WARNING! NOT FOR USE IN HUMANS.
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.

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

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

PRECAUTIONS
Store away from excessive heat (104°F/40°C) and 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 IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing 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., caudal mud or manure.

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

When to Treat Cattle with Grubs
IVOMEC 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 (stable fly) season. While this is not possible to determine, destruction of *Hypoderma* larvae (*cutis grub*) 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 throat 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 IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety
Studies indicate that when ivermectin comes in contact with the soil it readily and lightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain water-borne organisms on which they feed. 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.

Package Information
IVOMEC Pour-On is available in a 0.5 l oz/250 mL bottle with a squeeze-measure-pour system (Product 41303A), a 33.8 l oz/1 L bottle with a squeeze-measure-pour system (Product 41310A), or in an 0.5 l oz/2.5 L collapsible pack (Product 41311A), and a 189 oz/5 L collapsible pack (Product 41301A) intended for use with appropriate automatic dosing equipment.

MERCK
Arling Division

Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

U.S. Pat 4,198,569
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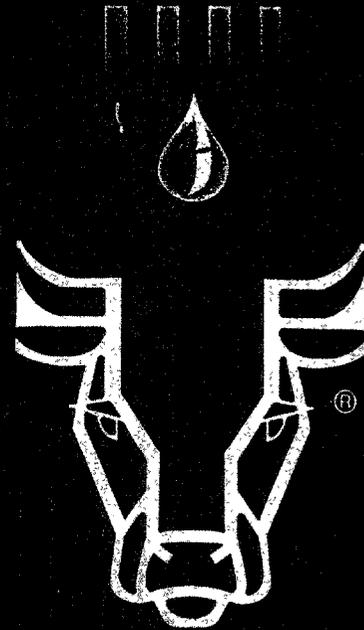
Package Insert from 2.5 Liter carton

Ivomec[®]

(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL



Parasiticide

Kills:

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



MERCK

AgVet Division

Merck & Co., Inc.
Rahway, New Jersey 07065-0912. U.S.A.

Product **41350A**

169 fl oz (5L)

5L Container (front Label)

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.

Recommended Dose: 1 mL per 22 lb of body weight.

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.

WARNING! NOT FOR USE IN HUMANS.

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.

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

WARNING! FLAMMABLE!

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

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and 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 IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMEC Pour-On is not recommended for use in species other than cattle.

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.

U.S. Pat. 4,199,569

Made in U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

Lot No & Exp Date ▼

8866000

LBJ0060

01-2004

169 fl oz (5 L)

5L container (back label)

Ivomec[®]

(ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

169 fl oz (5 L)



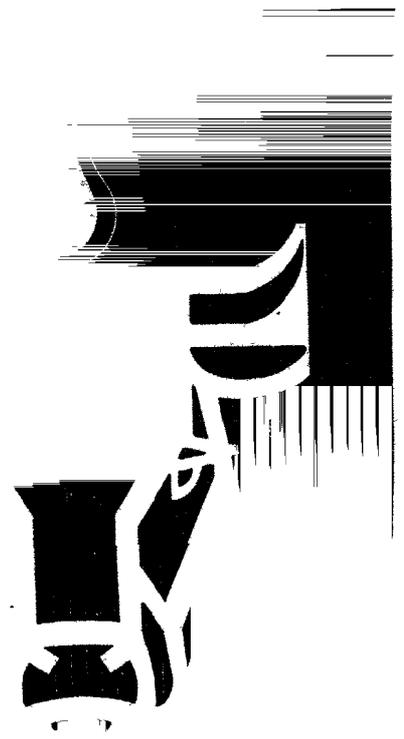
Product 41350A

5L carton (top label)

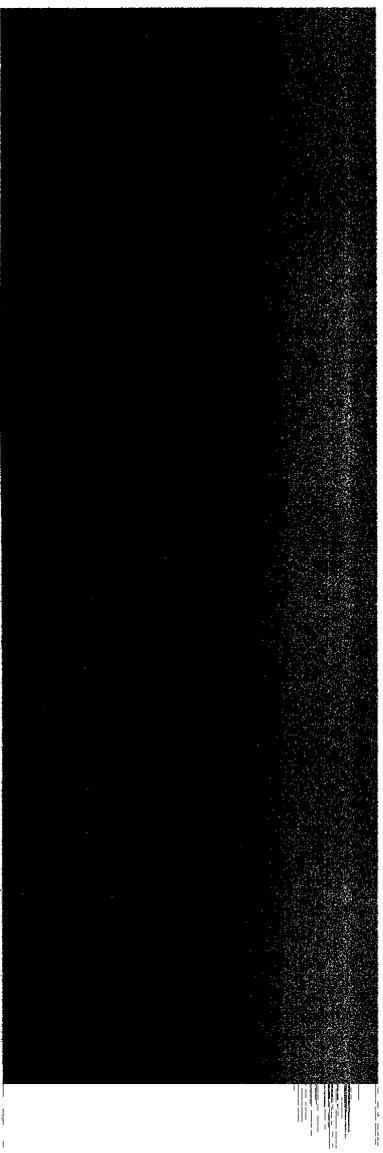
med

on for cattle

the Brown Stomach Worm),
the Lice, Biting Lice,



5L carton (front label)



Ivomec®

(ivermectin)

pour-on 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 body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

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 Protector Drench Gun from Instrument Supplies Limited, 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 Protector Drench Gun, the gun and tubing must not be washed.

5L carton (back label)



MERCK

AgVet Division

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Rahway, New Jersey 07065-0912, U.S.A.

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U.S. Pat 4,199,569

Made in U.S.A.



Lot No & Exp Date

LB J006 0
01-2004

Ivomec®

(ivermectin)

pour-on for cattle

TAKE TIME



**OBSERVE LABEL
DIRECTIONS**

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: 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.

WARNING!

NOT FOR USE IN HUMANS.

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.

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

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

B4065

Ivomec®

(ivermectin)

pour-on for cattle

This topically applied formulation of IVOMEC® (ivermectin) delivers internal and external parasite control in one convenient low-volume application.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect contents 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 IVOMEC Pour-On is stored at temperatures below 32°F. Allowing 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, IVOMEC Pour-On is not recommended for use in species other than cattle.



5L carton (side panels)

Mode of Action
Ivermectin is a member of the avermectin family kills certain parasitic roundworms and ectoparasites, such as mites, lice, horn flies and other insects. Its action is unique to the avermectin class of antiparasitic agents. This action involves a chemical that serves as a signal from one nerve cell to another, or from a nerve cell to a muscle cell. This chemical, a neurotransmitter, is called gamma-aminobutyric acid or GABA.

In roundworms, ivermectin stimulates the release of GABA from nerve endings and enhances binding of GABA to special receptors at nerve junctions, thus interrupting nerve impulses — thereby paralyzing and killing the parasite. The enhancement of the GABA effect in arthropods such as mites, lice, and horn flies resembles that in roundworms except that nerve impulses are interrupted between the nerve ending and the muscle cell. Again, this leads to paralysis and death.

Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter.

The principal peripheral neurotransmitter in mammals, acetylcholine, is unaffected by ivermectin. Ivermectin does not affect the peripheral (central nervous system) of arthropods since GABA functions as a neurotransmitter there.

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Even on plasma levels, the typically 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: 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.

WARNING! NOT FOR USE IN HUMANS.
This product should not be applied to soil 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.
Keep this and all drugs out of the reach of children.

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

PRECAUTIONS
Store away from excessive heat (104°F/40°C) and 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 surfaces only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVMOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing 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, IVMOMEC Pour-On is not recommended for use in species other than cattle.

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

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 water-bottom organisms on which they feed. 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.

Package Information
IVMOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle with a squeeze-measure-pour system (Product 41309A), a 33.8 fl oz/1 L bottle with a squeeze-measure-pour system (Product 41310A), or in an 84.5 fl oz/2.5 L collapsible pack (Product 41311A), and a 169 oz/5 L collapsible pack (Product 41350A) intended for use with appropriate automatic dosing equipment.



091822Z

MERCK

918222

Ivomec®
(ivermectin)



pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

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

Introduction

IVMOMEC (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVMOMEC Pour-On contains ivermectin, a unique chemical entity.

Indications

IVMOMEC Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia circumcincta</i> (including inhibited stage)	(adults and L ₁)
<i>Haemonchus placei</i>	(adults and L ₁)
<i>Trichostrongylus axei</i>	(adults and L ₁)
<i>T. colubriformis</i>	(adults and L ₁)
<i>Cooperia</i> spp.	(adults)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L ₁)
<i>Trichuris</i> spp.	(adults)
Lungworms	
<i>Dicrocoelium imprints</i>	(adults and L ₁)
Cattle Grubs	(parasitic stages)
<i>Hypoderma bovis</i>	
<i>H. lineatum</i>	
Mites	
<i>Sarcoptes scabiei</i> var. <i>bovis</i>	
Lice	
<i>Limnephilus vituli</i>	
<i>Haematoporus eurysternus</i>	
<i>Damalinia bovis</i>	
<i>Solenopotes capillatus</i>	
Horn Flies	
<i>Haematobia irritans</i>	

Parasiticide Activity

IVMOMEC Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia circumcincta*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies

IVMOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVMOMEC 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.

Administration
Squeeze-Measure-Pour System (8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tip the bottle to deliver the dose. The off (STOP) position will close the system between dosing.

Squeeze-Measure-Pour System (33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tip the bottle to deliver the dose. When 220 lb (10 mL) or 550 lb (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.

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

Contact 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 Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in foaming, incorrect dosage or leakage.)

Replace the dosing 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 Protector Drench Gun, the gun and tubing must not be washed.

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SL package insert



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