

HFA 305

SEP 21 2001

Date of Approval _____

FREEDOM OF INFORMATION SUMMARY

ANADA 200-318

Indication for use: Virbamec™ Pour-On
applied at the recommended dose level of 500 mcg/kg
is indicated for the effective control and treatment of parasites in cattle.

Sponsored by:

Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

FOISL

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA: 200-318

Sponsor: Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

Generic Name: Ivermectin Topical Liquid

Trade Name: Virbamec™ Pour-On for Cattle

Dosage Form: Topical Solution

How Supplied: 8.5 fl oz/250 mL, 16 fl oz/500mL, 33.8 fl oz/1 L,
84 fl oz/2.5 L, 169 fl oz/5 L collapsible pack

How Dispensed: OTC

Amount of Active Ingredients: 5 mg of ivermectin/mL

Route of Administration: Topical, on the dorsal midline, withers to tailhead

Species: Cattle

Labeled Dosage: 500 mcg/kg (1 mL/22 lbs) body weight

Indications for Use: Verbamec™ Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control and treatment of these parasites in cattle.

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)

C-imperia spp. adults and L₄)

Strongyloides papillosus (adults)

Oesophagostomum radiatum (adults and L₄)

O. venulosum (adults only)

Trichuris spp. (adults)

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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 spp.</i>	adults and L ₄)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L ₄)
<i>O. venulosum</i>	(adults only)
<i>Trichuris spp.</i>	(adults)

Lungworms

Dictyocaulus viviparous (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

It is also used to control infections of gastrointestinal roundworms: *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.

Pioneer Product/
“Listed Product:

Ivomec[®] 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, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October, 2000).

Based upon the formulation characteristics of the generic product, Virbac AH, Inc. was granted a waiver on February 21, 2000, from conducting an *in vivo* bioequivalence study for Virbamec™ Pour-On for Cattle. The generic and pioneer products contain the same active and inactive ingredients and are topical solutions.

3. HUMAN FOOD SAFETY:

TOLERANCES:

The tolerances established for the pioneer product apply to the generic product. The acceptable daily intake for total residues of ivermectin is 1 microgram per kilogram of body weight per day. The marker residue used to monitor the total residues of ivermectin and its metabolites is 22,23-dihydroavermectin B_{1a}. The target tissue is liver. A tolerance is established for 22,23-dihydroavermectin B_{1a} in liver (target tissue) as follows:

- (i) Cattle: 100 parts per billion [21 CFR 556.344(b)]

A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in muscle as follows:

- (ii) Cattle: 10 parts per billion [21 CFR 556.344(b)]

WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for ivermectin pour-on is established under 21 CFR 524.1193(e)(3) - 48 days in cattle.

REGULATORY METHODS FOR RESIDUES

The official analytical method for residues is an HPLC method with fluorescence detection. [The validated regulatory analytical methods for detection of residues of ivermectin are on file at the Center for Veterinary Medicine, FDA 7500 Standish Place, Rockville, MD 20855]

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the Act and demonstrates that Virbamec™ Pour-On for Cattle is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

Bottle Labels:

8.5 fl oz/250 mL, 33.8 fl oz/1 L

Generic Labeling:

Package Insert

Bottle Labels:

8.5 fl oz/250 mL, 16 fl oz/500mL, 33.8 fl oz/1 L,

84 fl oz/2.5 L, 169 fl oz/5 L collapsible pack

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

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.

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 mud 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® (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, IVOMECS Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs
IVOMECS 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 IVOMECS Pour-On at the end of the fly season may be re-treated with IVOMECS 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
IVOMECS (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 4,199,569
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Made in U.S.A.
May 1995

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

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

8783102

Ivomec®
(ivermectin)

pour-on for cattle

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

Introduction

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

Indications

IVOMECS 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) |
| <i>Strongylides 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) |
| Cattle Grubs | (parasitic stages) |
| <i>Hypoderma bovis</i> | |
| <i>H. lineatum</i> | |
| Mites | |
| <i>Sarcoptes scabiei</i> var. <i>bovis</i> | |

Lice

- Linognathus vituli*
- Haematopinus eurysternus*
- Damalima bovis*
- Solenopotes capillatus*

Horn Flies

Haematobia irritans

Treatment of Cattle for Horn Flies

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

* IVOMECS and Cattle Head Logo are registered trademarks of



Ivomec[®]

(ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

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

Contains 10-550 lb Doses



8.5 fl oz (250 mL)

Product 41309A

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.

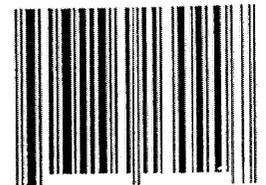
Do not use when rain is expected to wet cattle within six hours after treatment.

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.



3 0373-413090 7

Product

8.5 fl oz

Contains 5 mg ivermectin/mL



Ivomec
(ivermectin)
pour-on for cattle



Ivomec[®]

(ivermectin)
pour-on for cattle

Ivomec[®]

(ivermectin)
pour-on for cattle

TAKETIME



OBSERVE LABEL DIRECTIONS

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

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.

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.

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.

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.

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.

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

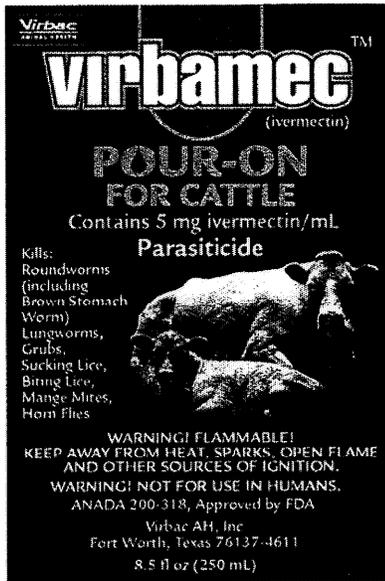
Lot No & Exp Date ▼

BBJ031
FEB97

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



8399Z



Front Label

5" for Lot Number and Exp

	<p>Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.</p> <p>Indications: For the treatment and control of gastrointestinal roundworms (including inhibited <i>Ostertagia oosterbeeki</i>), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.</p> <p>See package insert for the complete indications and use directions.</p> <p>Recommended Dose: 1 mL per 22 lb of body weight.</p> <p>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.</p> <p>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.</p> <p>Keep this and all drugs out of the reach of children.</p>	<p>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.</p> <p>Cloudiness in the formulation may occur when VIRBAMEC™ (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.</p> <p>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.</p> <p>Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, VIRBAMEC™ Pour-On is not recommended for use in species other than cattle.</p> <p>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.</p>
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Fold Out Back Label

Virbamec 8.5 oz (250ml) Bottle Label

.5" for
Lot Number
and Exp ▶

Virbac
ANIMAL HEALTH

virbamec™
(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.**

ANADA 200-318, Approved by FDA

Virbac AH, Inc
Fort Worth, Texas 76137-4611

16 fl oz (500 mL)

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 the 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:

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Close container tightly when not in use.

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

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Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, VIRBAMEC™ 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.

Back Label

5" for
t Number
and Exp

Virbac
ANIMAL HEALTH

virbamec™

(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.**

ANADA 200-318, Approved by FDA

Virbac AH, Inc
Fort Worth, Texas 76137-4611

33.8 fl oz (1 Liter)

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.

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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 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 VIRBAMEC™ (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, VIRBAMEC™ 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.

.5" for Lot Number and Exp

Virbac
ANIMAL HEALTH

virbamec™
(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.**

ANADA 200-318, Approved by FDA

Virbac AH, Inc
Fort Worth, Texas 76137-4611

84.5 fl oz (2.5 Liter)

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 the 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 VIRBAMEC™ (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, VIRBAMEC™ 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.

Back Label

.5" for Lot Number and Exp

Virbac
ANIMAL HEALTH

VIRBAMEC™

(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.**

ANADA 200-318, Approved by FDA

Virbac AH, Inc
Fort Worth, Texas 76137-4611

169 fl oz (5 Liter)

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 osterlagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for the 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 VIRBAMEC™ (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, VIRBAMEC™ 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.

Back Label

Virbamec™ (ivermectin) **POUR-ON** **FOR CATTLE**

ANADA 200-318, Approved by FDA

Contains 5 mg Ivermectin/mL

Parasiticide

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

Introduction

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

Indications

VIRBAMEC 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 L4)
(including inhibited stage)	
<i>Haemonchus placei</i>	(adults and L4)
<i>Trichostrongylus axei</i>	(adults and L4)
<i>T. colubriformis</i>	(adults and L4)
<i>Cooperia</i> spp.	(adults and L4)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L4)
<i>Trichostrongylus axei</i>	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L4)
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Cattle Grubs

Hypoderma bovis

H. lineatum

Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli
Haematopinus eurysternus
Damalinia bovis
Solenopotes capillatus

Horn Flies

Haematobia irritans

Treatment of Cattle for Horn Flies

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

Parasitist Activity

VIRBAMEC 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.

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 (250 mL, 500 mL, or 1 Liter Bottle with 25 mL Measuring Cap)

Attach metering cap to the bottle

Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose.

Gently squeeze the bottle to fill to level (any excess will return to the bottle) and then tip and apply to animal along topline.

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

Connect the applicator gun to the backpack 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.

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.

WARNING: Cattle must not be treated with in 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 VIRBAMEC (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., soaked mud or manure.

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

When to Treat Cattle with Grubs

VIRBAMEC 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 oesophageal 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 VIRBAMEC Pour-On at the end of the fly season may be re-treated with ivermectin 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

VIRBAMEC Pour-On is available in an 8.5 fl oz/250 mL, 16.9 fl oz/500 mL, and 33.8 fl oz/1 liter bottle with a measure-pour system, an 84.5 fl oz/2.5 L, or a 169 fl oz/5 L backpack intended for use with appropriate automatic dosing equipment.



VIRBAMEC is a trademark of Virbac S A

Virbac AH, Inc
Fort Worth, Texas 76137-4611, U.S.A.

301438-01

May 2001

Contains 5 mg ivermectin/mL

POUR-ON
(ivermectin)

VirbamecTM

virbamecTM

(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 metering cap onto container.

Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose.

Gently squeeze the bottle to fill to level (any excess will return to the bottle) and then tip and apply to animal along topline.

Virbac AH, Inc.
Fort Worth, Texas 76137-4611

Barcode

Lot No & Exp Date ▼

virbamec

(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.

Virbac
ANIMAL HEALTH

virbamecTM

(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)



virbamec

(ivermectin)

POUR-ON
FOR CATTLE

This topically applied formulation of VIRBAMECTM (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 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.

Coldness in the formulation may occur when VIRBAMECTM 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., soaked mud or manure.

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

ANADA 200-315, Approved by FDA
Virbac AH, Inc. - Fort Worth, TX 76137-4611

Contains 5 mg ivermectin/mL

POUR-ON
(ivermectin)
FOR CATTLE

VirbamecTM

virbamecTM
(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 metering cap onto container.

Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose.

Gently squeeze the bottle to fill to level (any excess will return to the bottle) and then tip and apply to animal along topline.

Virbac AH, Inc.
Fort Worth, Texas 76137-4611

Barcode

Lot No & Exp Date ▼

virbamecTM

(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.

Virbac
ANIMAL HEALTH

Virbamec

**POUR-ON
FOR CATTLE**

**Kills: Roundworms
Lungworms
Mange Mites**



Virbac Animal Health

Virbamec Pour-On (500 mL) Inner Carton (5.375" x 2.3125" x 9.375")

virbamec™

(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.

Virbac
ANIMAL HEALTH

virbamec™

(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 20-550 lb Doses

16.9 fl oz (500 mL)



ANADA 200-318, Approved by FDA
Virbac AH, Inc. • Fort Worth, TX 76137-4611

virbamec™

(ivermectin)

**POUR-ON
FOR CATTLE**

This topically applied formulation of VIRBAMEC™ (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 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 VIRBAMEC™ 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, VIRBAMEC™ Pour-On is not recommended for the use in species other than cattle.

(.3125" x 9.375")



amec™

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ABEL DIRECTIONS

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USE IN HUMANS

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! FLAMMABLE!
Y FROM HEAT,
OPEN FLAME,
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IGNITION.

virbamec™

(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 40-550 lb Doses

33.8 fl oz (1 Liter)



ANADA 200-318, Approved by FDA
Virbac AH, Inc. · Fort Worth, TX 76137-4611

virbamec™

(ivermectin)

POUR-ON FOR CATTLE

This topically applied formulation of VIRBAMEC™ (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 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 VIRBAMEC™ 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, VIRBAMEC™ Pour-On is not recommended for the use in species other than cattle.

x 11.75")

Contains 5 mg ivermectin/mL

FOR CATTLE
POUR-ON
(ivermectin)

Virbamec™

Virbamec™

(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 back 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.

Virbac AH, Inc.
Fort Worth, Texas 76137-4611

Barcode

Lot No & Exp Date ▼

Virban

(ivermectin)

POUR-ON
FOR CATTLE

Virban



Virban

SAFETY:

Studies conducted in cattle have demonstrated a wide margin for ivermectin plasma levels; the pour-on formulation is especially safe, at least as well tolerated by animals as is the oral formulation which has been shown to affect breeding performance.

WARNING:

Cattle must not be used within 48 days of milking for human consumption. Because a withdrawal in milk has not been established, do not use in female dairy cattle in breeding age.

WARNING!

NOT FOR USE IN HUMANS

This product should not be used on humans because it is irritating to human skin 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 water. If accidental eye contact occurs, flush eyes immediately with water and seek medical attention.

Keep this and all other containers of this product out of the reach of children.

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

Virbac
ANIMAL HEALTH

virbamecTM
(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 100-550 lb Doses

84.5 fl oz (2.5 Liter)



virbamecTM

(ivermectin)

**POUR-ON
FOR CATTLE**

This topically applied formulation of VIRBAMECTM (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 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 VIRBAMECTM 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, VIRBAMECTM Pour-On is not recommended for the use in species other than cattle.

ANADA 200-318, Approved by FDA
Virbac AH, Inc. · Fort Worth, TX 76137-4611

virbamec™

(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.**

Virbac
ANIMAL HEALTH

virbamec

(ivermectin)

**POUR-ON
FOR CATTLE**

Contains 5 mg ivermectin/ml

Parasiticide

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

Contains 200-550 lb Doses

169 fl oz (5 Liter)



ANADA 200-318, Approved by FDA
Virbac-AH, Inc. Fort Worth, TX 76137-4611

4 25" x 13 125" 1

Contains 5 mg ivermectin/mL

POUR-ON
(ivermectin)
FOR CATTLE

VirbamecTM

VirbamecTM

(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 back 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.)

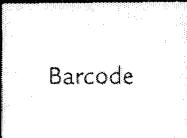
Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

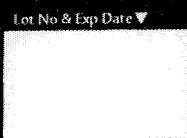
Follow the manufacturer's directions for adjusting the dose.

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.

Virbac AH, Inc.
Fort Worth, Texas 76137-4611



Barcode



Lot No & Exp Date ▼

Virbamec
(ivermectin)
POUR-ON
FOR CATTLE

SAFETY:
Studies have shown a wide margin for safety. The formulation is at least as well tolerated by animals as other formulations. Safe for breeding purposes.

WARNING:
Cattle withers for use in breeding.

WARNING: NOT FOR
This product is for use only in cattle. Do not use in horses and avoid contact with the user's skin and clothing. Accidental contact with water. If contact occurs, flush with water and soap.

WARNING:
KEEP AWAY FROM SPARKS AND OPEN FLAMES.