

HFA-305

Date of Approval Letter: DEC - 4

## **FREEDOM OF INFORMATION SUMMARY**

### **ANADA 200-340**

Indication for use: Ivermectin Pour-On  
applied at the recommended dose level of 500 mcg/kg  
is indicated for the effective control and treatment of internal and external parasites.

Sponsored by:

First Priority, Inc.  
1585 Todd Farm Drive  
Elgin, IL 60123

**ANADA 200-340**

**FOLS-1**

**FREEDOM OF INFORMATION SUMMARY**

## 1. GENERAL INFORMATION:

ANADA: 200-340

Sponsor: First Priority, Inc.  
1585 Todd Farm Drive  
Elgin, IL 60123

Generic Name: Ivermectin Topical Liquid

Trade Name: Privermectin™ Pour-On for Cattle

Dosage Form: Topical Solution

How Supplied: 250 ml, 1 L, 2.5 L, 5 L and 18.9 L (5 gallon) containers

How Dispensed: OTC

Amount of Active Ingredients: 5 mg/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: Ivermectin Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control and treatment of these parasites.

**Gastrointestinal Roundworms**

<i>Ostertagia ostertagi</i>	(adults and L <sub>4</sub> )
(including inhibited stage)	
<i>Haemonchus placei</i>	(adults and L <sub>4</sub> )
<i>Trichostrongylus axei</i>	(adults and L <sub>4</sub> )
<i>T. colubriformis</i>	(adults and L <sub>4</sub> )
<i>Cooperia spp.</i>	adults and L <sub>4</sub> )
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L <sub>4</sub> )
<i>O. venulosum</i>	(adults only)
<i>Trichuris spp.</i>	(adults)

**Lungworms**

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

(parasitic stages)

<i>Hypoderma bovis</i>
<i>H. lineatum</i>

**Mites**

<i>Sarcoptes scabiei var. bovis</i>
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**Lice**

<i>Linognathus vituli</i>
<i>Haematopinus euryesternus</i>
<i>Damalinia bovis</i>
<i>Solenopotes capillatus</i>

**Horn Flies**

<i>Haematobia irritans</i>
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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<sup>®</sup> 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. 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 Guideline, October 2000).

Based upon the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver on April 7, 2000, from conducting an *in vivo* bioequivalence study for Privermectin™ Pour-On for Cattle. The generic and pioneer products contain the same active and inactive ingredients and are topical solutions.

## 3. HUMAN SAFETY:

### TOLERANCES:

The tolerances established for the pioneer product apply to the generic product. The marker residue used to monitor the total residues of ivermectin and its metabolites is 22,23-dihydroavermectin B<sub>1a</sub>. The target tissue is liver. A tolerance is established for 22,23-dihydroavermectin B<sub>1a</sub> 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<sub>1a</sub> (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 METHOD 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 filed in the Food Additives analytical Manual on display in FDA's Freedom of Information Public Room (Room 12A-30, 5600 Fisher's Lane, Rockville, MD 20857) and 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 is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Privermectin <sup>TM</sup> Pour-On for Cattle were established by demonstration of chemical equivalence to the pioneer product, Merial Limited's Ivomec<sup>®</sup> Pour-On for Cattle (NADA 140-841).

This generic product and the pioneer product have identical labeling indications for use in cattle. The route and method of administration of the two drugs are identical. Both drugs are administered topically. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy promulgated to implement section 512(b)(2) of FFD&C Act, no *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Privermectin™ Pour-On for Cattle is safe and effective for its labeled indications when used under its proposed conditions of use.

Attachments:

1. Generic Labeling:

Package Insert

Bottle Labels- 250 mL, 1 L, 2.5 L, 5 L, 18.9 L (5 gal)

2. Pioneer Labeling

Package Insert

Bottle Label- 250 mL, 1 L, 2.5 L, 5 L

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.

**PRECAUTIONS:**  
Store at controlled room temperature 15°-30°C (59°-86°F). Store away from excessive heat (104°F / 40°C) and protect from light.

Iss: 04-02

NDC# 58829-302-02

Priority  
Care 

**Privermectin™  
Pour-On for Cattle**

(ivermectin)

**PARASITICIDE**

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

**5 mg ivermectin per mL**

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 Privermectin™ Pour-On for Cattle 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 dermatosis or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Privermectin™ Pour-On for Cattle 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.

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

**WARNING! NOT FOR USE IN HUMANS.**

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

Lot No.

Exp. Date



**For Animal Use Only • Keep Out of Reach of Children**  
Net Contents: 250 mL (8.5 fl. oz.)

ANADA 200-340, Approved by FDA

Reorder No. TP330PCARE



NDC# 58829-302-34

Priority Care   
**Privermectin™  
Pour-On for Cattle**  
(ivermectin)

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.

**PRECAUTIONS:**  
Store at controlled room temperature 15°-30°C (59°-86°F).  
Store away from excessive heat (104°F / 40°C) and protect from light.



Iss: 04-02



For Animal Use Only • Keep Out of Reach of Children  
Net Contents: 1 Liter (33.8 fl. oz.)

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 Privermectin™ Pour-On for Cattle 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 dermatosis or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Privermectin™ Pour-On for Cattle 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.

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

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

Lot No. Exp. Date

ANADA 200-340, Approved by FDA

Reorder No. TP331PCARE

NDC# 58829-302-25

Priority  
Care 

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.

**PRECAUTIONS:**  
Store at controlled room temperature 15°-30°C (59°-86°F).  
Store away from excessive heat (104°F / 40°C) and protect from light.



Iss: 04-02



**Privermectin™  
Pour-On for Cattle**

(ivermectin)

**PARASITICIDE**

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

**5 mg ivermectin per mL**

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 Privermectin™ Pour-On for Cattle 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 dermatosis or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Privermectin™ Pour-On for Cattle 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.

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

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

Lot No. Exp. Date

**For Animal Use Only • Keep Out of Reach of Children**

**Net Contents: 2.5 Liter (84.5 fl. oz.)**

Reorder No. TP332PCARE

ANADA 200-340, Approved by FDA

NDC# 58829-302-05

Priority  
Care 

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.

**PRECAUTIONS:**  
Store at controlled room temperature 15°-30°C (59°-86°F).  
Store away from excessive heat (104°F / 40°C) and protect from light.

TAKE TIME  OBSERVE LABEL DIRECTIONS

Iss: 04-02

  
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**Privermectin™  
Pour-On for Cattle**

(ivermectin)

**PARASITICIDE**

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

**5 mg ivermectin per mL**

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 Privermectin™ Pour-On for Cattle 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 dermatosis or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Privermectin™ Pour-On for Cattle 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.

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

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

Lot No. Exp. Date

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 5 Liter (169 fl. oz.)

Reorder No. TP333PCARE

ANADA 200-340, Approved by FDA



FIRST PRIORITY, INC.

NDC# 58829-902-31

Priority Care 

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.

**PRECAUTIONS:**  
Store at controlled room temperature 15°-30°C (59°-86°F). Store away from excessive heat (104°F / 40°C) and protect from light.



Iss: 04-02



**Privermectin™  
Pour-On for Cattle**

(ivermectin)

**PARASITICIDE**

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

**5 mg ivermectin per mL**

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 Privermectin™ Pour-On for Cattle 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 dermatosis or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Privermectin™ Pour-On for Cattle 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.

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

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

Lot No.                      Exp. Date

**For Animal Use Only • Keep Out of Reach of Children**

**Net Contents: Five Gallon (18.9 L)**

Reorder No. TP334PCARE

ANADA 200-340, Approved by FDA

**Privermectin™  
Pour-On for Cattle**

(ivermectin)  
Contains 5 mg Ivermectin/mL

**Parasiticide**

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

**Introduction**

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

**Indications**

Privermectin™ Pour-On for Cattle (ivermectin) 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 L<sub>4</sub>)  
(Including inhibited stage)  
*Haemonchus placei* (adults and L<sub>4</sub>)  
*Trichostrongylus axei* (adults and L<sub>4</sub>)  
*T. Colubriformis* (adults and L<sub>4</sub>)  
*Cooperia* spp (adults and L<sub>4</sub>)  
*Strongylodes papillosus* (adults)  
*Oesophagostomum radiatum* (adults and L<sub>4</sub>)  
*Trichuris* spp (adults)

**Lungworms**

*Dictyocaulus viviparus* (adults and L<sub>4</sub>)

**Cattle Grubs**

*Hypoderma bovis* (parasitic stages)

*H. Lineatum*

**Mites**

*Sarcoptes scabiei* var. *Bovis*

**Lice**

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

**Horn Flies**

*Haematobia irritans*

**Persistent Activity**

Privermectin™ Pour-On for Cattle (ivermectin) 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 for Cattle for Horn Flies**

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

Because of the solvents used in Privermectin™ Pour-On for Cattle (ivermectin), the applicator gun from Genesis Instruments (EZ Doser™) or equivalent is recommended. Other applicators may exhibit compatibility problems, resulting in locking, incorrect dosage or leakage.

Operation: Set the recommended dosage by turning the adjustment nut. To prime the system, squeeze the handles repeatedly. This draws the fluid out of the container and into the EZ Doser™ barrel. To expel air out of the system, hold the EZ Doser™ in a vertical position and gently squeeze the handles until the air is purged. EZ Doser™ is activated by squeezing handles. The pre-set dose will be given each time. The EZ Doser™ will automatically refill after each use.

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

**Cleaning** After use, disconnect the draw off cap and pump the medicant in the system back into the container then rinse the system with clean soapy water by inserting the draw hose into the water and operate the EZ Doser™ until the system is thoroughly rinsed. Lubrication. Recommended lubricant is Vaseline®. The plunger o-ring needs periodic lubrication, evidence of this will be if the return action of the plunger becomes sluggish. Lubricate by unscrewing the barrel to expose the plunger and o-ring then apply Vaseline® around the o-ring surface.

**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 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 Privermectin™ Pour-On for Cattle (ivermectin) 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 dermatosis or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs, therefore, Privermectin™ Pour-On for Cattle (ivermectin) is not recommended for use in species other than cattle.

**When to Treat Cattle with Grubs**

Privermectin™ Pour-On for Cattle (ivermectin) 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 bloating, 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 Privermectin™ Pour-On for Cattle (ivermectin) at the end of the fly season may be re-treated with Privermectin™ Pour-On for Cattle (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**

Privermectin™ Pour-On for Cattle (ivermectin) is available in an 8.5 fl oz/ 250 mL bottle, an 33.8 fl oz/ 1 L pack, an 84.5 fl oz/ 2.5 L pack, an 169 fl oz/ 5 L pack intended for use with appropriate automatic dosing equipment, and a 5 gallon bulk pack.

Priority  
Care

...would you settle for less?

FIRST PRIORITY, INC.  
Elgin, IL 60123-1146, U.S.A.I

**MERCK**

**Ivomec**  
 (ivermectin)  
**pour-on** for cattle

Contains 5 mg ivermectin/mL

**Parasiticide**

**Kills:**  
 Roundworms (including Brown Stomach Worm)  
 Lungworms  
 Grubs  
 Biting Lice  
 Ring 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 ▼

**EBJ277**  
**10-2001**

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

Product 41309A **8.5 fl oz (250 mL)**  
 8793701

17

ivomec

**Ivomec**<sup>®</sup>  
(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)

6783102

Lot No. EB1248 08-2001

Exp. Date

LOT

LOT



# ivomec<sup>®</sup>

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

Product 41311A

84.5 fl oz (2.64 qt) (2.5 L)

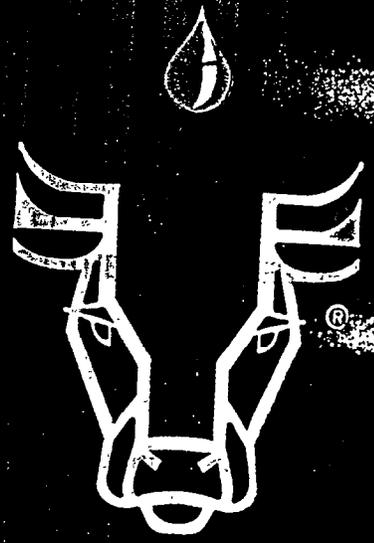
8778101

# Ivomec<sup>®</sup>

(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

8865900

169 fl.oz (5L)

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

**INDICATIONS:**  
Treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, 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:**

- Keep away from excessive heat (104°F/40°C) and protect from light.
- Use only in well-ventilated areas or outdoors.
- Seal 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 the product to warm at room temperature will restore the normal appearance without affecting efficacy.
- The parasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or crusts 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.

Pat. 4,199,569  
U.S.A.  
IVOMEC and Cattle Head Logo are registered trademarks of  
Merial, Inc., Whitehouse Station, N.J., U.S.A.

Lot No & Exp Date ▼

E3J271  
OCT00

6.9 fl oz (5 L)



09158201

9158201

**IVOMEC**<sup>®</sup>  
(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<sup>®</sup> (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**

<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L <sub>4</sub> )
<i>Haemonchus placei</i>	(adults and L <sub>4</sub> )
<i>Trichostrongylus axei</i>	(adults and L <sub>4</sub> )
<i>T. colubriformis</i>	(adults and L <sub>4</sub> )
<i>Cooperia</i> spp.	(adults and L <sub>4</sub> )
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L <sub>4</sub> )
<i>Trichuris</i> spp.	(adults)

**Lungworms**

<i>Dictyocaulus viviparus</i>	(adults and L <sub>4</sub> )
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**

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 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 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.

\*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 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 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 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 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**

IVOMECS 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.



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

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September 1998