

MAY 16 2001

Approval letter \_\_\_\_\_

HFA-305  
Docket Management  
Branch

**Supplemental ANADA 200-219**

**FREEDOM OF INFORMATION SUMMARY**

The supplement provides for the addition of the persistent activity claims.

Phoenix Scientific, Inc.  
3915 South 48<sup>th</sup> Street Terrace  
P.O. Box 8039  
St. Joseph, MO 64503

200-219-FOIS 2

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

ANADA: 200-219

Sponsor: Phoenix Scientific, Inc.  
3915 South 48<sup>th</sup> Street Terrace  
P.O. Box 6457  
St. Joseph, MO 64506-0457

Generic Name: Ivermectin Topical Liquid

Trade Name: Phoenectin™ Pour-On for Cattle

Dosage Form: Topical Solution

How Supplied: 250 mL, 500 mL, 1 L, 3.785 L (1 gallon) Bottles  
5 L & 25 L

How Dispensed: OTC

Amount of Active Ingredients: 5 mg/mL ivermectin

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 500mcg/kg is indicated for the effective control and treatment 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>)

*Strongyloides papillosus* (adults)  
*Oesophagostomum radiatum* (adults and L<sub>4</sub>)  
*Trichuris spp.* (adults)  
**Lungworms**  
*Dictyocaulus viviparus* (adults and L<sub>4</sub>)

**Cattle Grubs** (parasitic stages)  
*Hypoderma bovis*  
*H. lineatum*

**Mites**  
*Sarcoptes scabiei var. bovis*

**Lice**  
*Linognathus vituli*  
*Haematopinus eurysterhus*  
*Damalinia bovis*  
*Solenopotes capillatus*

**Horn Flies**  
*Haematobia irritans*

Phoenectin™ Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia 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). Phoenix Scientific, Inc. is supplementing their ANADA for the addition of the persistent activity claims. Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on from conducting an *in vivo* bioequivalence study with Ivermectin® Pour-On for Cattle. The generic product was approved on July 6, 1998. The three-year exclusivity period for the additional claims granted to the pioneer product ended on June 4, 2000. No new data was required for the additional new claims.

3. HUMAN FOOD SAFETY:

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(d)(3) - 48 days in cattle. Therefore, no human food safety information is required for the approval of the supplement.

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.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change providing for the addition of new claims to the previous approved label. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Attachments:

1. Generic Labeling:

Package Insert

Bottle Label

2. Pioneer Labeling

Package Insert

Bottle Label

Diagnosis, treatment and control of parasitism.  
**INDICATIONS:**  
 For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, scabs, head flies, ear mites and other head and surface mites in cattle.  
 See package insert for complete indications and use.

**Recommended Dose:** 1 mL per 22 lb of body weight.  
**USE WARNING:** Cattle must not be treated within 48 days of slaughter for human consumption. Because 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 at controlled room temperature 15°-30°C (59°-86°F). Store away from excessive heat (104°F/40°C) and protect from light.

Lot No. \_\_\_\_\_  
 Exp. Date \_\_\_\_\_



W. 139-881-02

**PHOENECTIN**  
 (ivermectin)  
**POUR-ON for Cattle**  
 5 mg ivermectin per mL  
 Parasiticide  
 Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

ANADA 200-219, Approved by FDA

**NET CONTENTS: 250 mL (8.5 fl oz)**



Use only in well-ventilated areas or outdoors.  
 Close container tightly when not in use.  
 Cattle should not be treated until hair is hidden since reduced efficacy may result.

Do not use when rain is expected for 6 hours within six hours after treatment.

Do not give orally or parenterally.  
 Cloudiness in the formulation may occur when PHOENECTIN™ (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 material, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, PHOENECTIN™ (ivermectin) 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.

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

**WARNING! NOT FOR USE IN HUMANS**

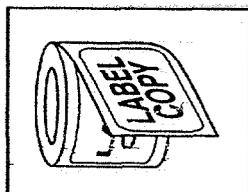
Manufactured By:  
 Phoenix Scientific, Inc.  
 St. Joseph, MO 64503  
 500018

Rev. 11-00

**CUSTOMER PROOF • CHECK CAREFULLY!**

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE  
 CYREL #: 29283 (TS) Date Sent: 11/22/00

LABEL: PHOENICTIN UNWIND #: 4  
 SIZE: 3 X 6.75  
 VARNISH:  YES  PATTERN  FLOOD  
 NO  
 COLORS: 1797 RED BLACK



Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

**INDICATIONS:**  
 For the treatment and control of external and internal parasites including Oestriasis, Fasciolosis, Trichostrongylidosis, and other internal and external parasites of cattle.

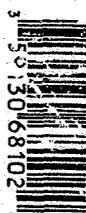
**RESIDUE WARNINGS:** Cattle should not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

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 at controlled room temperature 15°-30°C (59°-85°F). Store away from excessive heat (104°F/40°C) and protect from light.

Lot No. \_\_\_\_\_  
 Exp. Date \_\_\_\_\_



**PHOENECTIN™**  
**(ivermectin)**  
**POUR-ON for Cattle**  
**5 mg ivermectin per mL**  
**Parasiticide**  
**Kills: Roundworms (Including Brown Stomach Worm), Lungworms, Cattle Sucking Lice, Biting Lice, Mange Mites, Horn Flies**

ANADA 200-219, Approved by FDA

**NET CONTENTS: 250 mL (8.5 fl oz)**



Use only in well-ventilated areas outdoors.  
 Close container tightly when not in use.  
 Cloudiness in the formulation may occur when stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.  
 Do not use within 72 hours of treatment.

Do not give orally or parenterally.  
 Cloudiness in the formulation may occur when PHOENECTIN™ (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 may be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dry scabs or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, PHOENECTIN™ (ivermectin) 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.

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

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

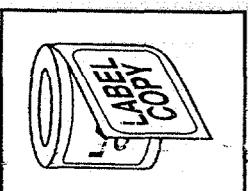
Manufactured By:  
 Phoenix Scientific, Inc.  
 St. Joseph, MO 64503  
 500018

Rev. 11-00

**CUSTOMER PROOF • CHECK CAREFULLY!**

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE  
 CYREL #: 29283 (TS) Date Sent: 11/22/00

LABEL: PHOENECTIN UNWIND #: 4  
 SIZE: 3 X 6.75  
 VARNISH:  YES  PATTERN  FLOOD  
 NO  
 COLORS: 1797 RED BLACK



Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

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

NDC 59130-681-04

**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.

**RESIDUE 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.



Lot No.

Exp. Date

# PHOENECTIN™ (ivermectin) POUR-ON for Cattle 5 mg ivermectin per mL

**Parasiticide**

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

ANADA 200-219, Approved by FDA

NET CONTENTS: 1 L (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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503  
500018

Iss. 11-00

## CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE

CYREL #: 29290 (ts) Date Sent: 11/22/00

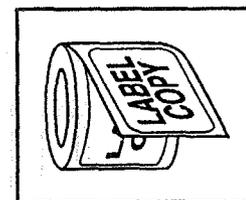
LABEL: phoenectin™

UNWIND #: 4

SIZE: 4 x 8.875

VARNISH:  YES  PATTERN  FLOOD  
 NO

COLORS: black 1797 red



Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

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

NDC 59130-681-03

**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.

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

Lot No. \_\_\_\_\_  
Exp. Date \_\_\_\_\_



# PHOENECTIN™ (ivermectin) POUR-ON for Cattle 5 mg ivermectin per mL Parasiticide

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

ANADA 200-219, Approved by FDA

**NET CONTENTS: 500 mL (16.9 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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

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

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

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503  
500018

Rev. 11-00

## CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE

CYREL #: 29284 (TS) Date Sent: 11/22/00

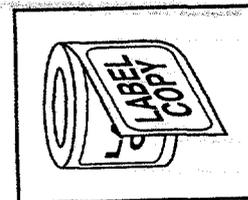
LABEL: PHOENICTIN

UNWIND #: 4

SIZE: 3 X 6.75

VARNISH:  YES  PATTERN  FLOOD  
 NO

COLORS: 1797 RED BLACK



Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

NDC 59130-681-37



# PHOENECTIN™ (ivermectin)

## POUR-ON for Cattle 5 mg ivermectin per mL

Parasiticide

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

ANADA 200-219, Approved by FDA

**NET CONTENTS: 5 L (169 fl oz)**



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.

**RESIDUE 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.

**IMPORTANT:** This package is intended for use only with the Applicator Gun provided. Additional Applicator Guns are available through your local retail dealer or through Phoenix Scientific, Inc. (816) 364-3777.

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

500018

Rev. 11-00

Lot No.

Exp. Date



### CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE  
CYREL #: 29285 (TS) Date Sent: 11/22/00 12/18/00

LABEL:	<u>AM TECH</u>	UNWIND #:	<u>4</u>
SIZE:	<u>7.5 X 5.25</u>		
VARNISH:	<input type="checkbox"/> YES <input type="checkbox"/> PATTERN <input type="checkbox"/> FLOOD <input type="checkbox"/> NO		
COLORS:	<u>1797 RED</u> <u>BLACK</u>		

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

# 29283 and 29284 booklet

<p>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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> <p><b>WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION.</b></p> </div> <p style="text-align: center;"><b>WARNING!</b> <b>NOT FOR USE IN HUMANS</b></p> <p>Manufactured By: Phoenix Scientific, Inc. St. Joseph, MO 64503 500018</p>	<p>ANADA 200-219, Approved by FDA <b>PHOENECTIN™</b> (ivermectin) <b>POUR-ON for Cattle</b> Contains 5 mg ivermectin/mL</p> <p><b>Parasiticide</b> Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.</p> <p><b>Introduction</b> PHOENECTIN™ (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents.</p> <p><b>Indications</b> PHOENECTIN™ Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.</p> <p><b>Gastrointestinal Roundworms</b></p> <table style="width:100%; border: none;"> <tr> <td style="border: none;"><i>Ostertagia ostertagi</i> (including inhibited stage)</td> <td style="border: none;">(adults and L4)</td> </tr> <tr> <td style="border: none;"><i>Haemonchus placei</i></td> <td style="border: none;">(adults and L4)</td> </tr> <tr> <td style="border: none;"><i>Trichostrongylus axei</i></td> <td style="border: none;">(adults and L4)</td> </tr> <tr> <td style="border: none;"><i>T. colubriformis</i></td> <td style="border: none;">(adults and L4)</td> </tr> <tr> <td style="border: none;"><i>Cooperia spp</i></td> <td style="border: none;">(adults)</td> </tr> <tr> <td style="border: none;"><i>Strongyloides papillosus</i></td> <td style="border: none;">(adults)</td> </tr> <tr> <td style="border: none;"><i>Oesophagostomum radiatum</i></td> <td style="border: none;">(adults and L4)</td> </tr> <tr> <td style="border: none;"><i>Trichuris spp</i></td> <td style="border: none;">(adults)</td> </tr> </table> <p><b>Lungworms</b> <i>Dictyocaulus viviparus</i> (adults and L4)</p> <p><b>Cattle Grubs</b> <i>Hypoderma bovis</i> (parasitic stages) <i>H. lineatum</i></p> <p><b>Mites</b> <i>Sarcoptes scabiei var. bovis</i></p>	<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L4)	<i>Haemonchus placei</i>	(adults and L4)	<i>Trichostrongylus axei</i>	(adults and L4)	<i>T. colubriformis</i>	(adults and L4)	<i>Cooperia spp</i>	(adults)	<i>Strongyloides papillosus</i>	(adults)	<i>Oesophagostomum radiatum</i>	(adults and L4)	<i>Trichuris spp</i>	(adults)	<p><b>Lice</b> <i>Linognathus vituli</i> <i>Haematopinus eurysternus</i> <i>Damalinea bovis</i> <i>Solenopotes capillatus</i></p> <p><b>Horn Flies</b> <i>Haematobia irritans</i></p> <p><b>Persistent Activity</b> PHOENECTIN™ Pour-On has been proved to effectively control infections and to protect cattle from re-infection with <i>Ostertagia ostertagi</i>, <i>Oesophagostomum radiatum</i>, <i>Haemonchus placei</i>, <i>Trichostrongylus axei</i>, <i>Cooperia punctata</i> and <i>Cooperia oncophora</i> for 14 days after treatment.</p> <p><b>Treatment for Cattle for Horn Flies</b> PHOENECTIN™ Pour-On controls horn flies (<i>Haematobia irritans</i>) for up to 28 days after dosing. For best results PHOENECTIN™ 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.</p> <p><b>Dosage</b> 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.</p> <p><b>Administration</b> Dispensing Cap (250 mL, 500 mL and 1 L bottles). The enclosed dispensing cap is graduated in 5 mL increments. Each 5 mL will treat 110 lbs body weight. When body weight is between markings, use the next higher increment.</p> <p>Attach the dispensing cap to the bottle. Select the correct dose rate by rotating the adjuster top in either direction to position the dose indicator to the appropriate level.</p>
<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L4)																	
<i>Haemonchus placei</i>	(adults and L4)																	
<i>Trichostrongylus axei</i>	(adults and L4)																	
<i>T. colubriformis</i>	(adults and L4)																	
<i>Cooperia spp</i>	(adults)																	
<i>Strongyloides papillosus</i>	(adults)																	
<i>Oesophagostomum radiatum</i>	(adults and L4)																	
<i>Trichuris spp</i>	(adults)																	

29283/29284 amtech phoenectin 133-2400 onsert booklet inside black

<p>Hold the bottle upright and gently squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.</p> <p>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.</p> <table style="width:100%; border: none;"> <thead> <tr> <th style="border: none;">Weight</th> <th style="border: none;">Dose</th> </tr> </thead> <tbody> <tr> <td style="border: none;">220 lb (100 kg)</td> <td style="border: none;">10 mL</td> </tr> <tr> <td style="border: none;">330 lb (150 kg)</td> <td style="border: none;">15 mL</td> </tr> <tr> <td style="border: none;">440 lb (200 kg)</td> <td style="border: none;">20 mL</td> </tr> <tr> <td style="border: none;">550 lb (250 kg)</td> <td style="border: none;">25 mL</td> </tr> <tr> <td style="border: none;">660 lb (300 kg)</td> <td style="border: none;">30 mL</td> </tr> <tr> <td style="border: none;">770 lb (350 kg)</td> <td style="border: none;">35 mL</td> </tr> <tr> <td style="border: none;">880 lb (400 kg)</td> <td style="border: none;">40 mL</td> </tr> <tr> <td style="border: none;">990 lb (450 kg)</td> <td style="border: none;">45 mL</td> </tr> <tr> <td style="border: none;">1100 lb (500 kg)</td> <td style="border: none;">50 mL</td> </tr> </tbody> </table> <p><b>Mode of Action</b> 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 ivermectin 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.</p> <p>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.</p> <p>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.</p>	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	<p>Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter.</p> <p>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.</p> <p><b>Safety</b> 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.</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> <p><b>RESIDUE WARNING:</b> 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> </div> <p style="text-align: center;"><b>WARNING! NOT FOR USE IN HUMANS.</b></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 style="text-align: center;">Keep this and all drugs out of the reach of children.</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> <p><b>WARNING! FLAMMABLE!</b> <b>KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.</b></p> </div>	<p><b>PRECAUTIONS</b></p> <p>Store at controlled room temperature 15°-30°C (59°-86°F).</p> <p>Store away from excessive heat (104°F/40°C) and protect from light.</p> <p>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 PHOENECTIN™ (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, PHOENECTIN™ Pour-On is not recommended for use in species other than cattle.</p> <p><b>When to Treat Cattle with Grubs</b> PHOENECTIN™ 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 <i>Hypoderma larvae</i> (cattle</p>	<p>grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing <i>Hypoderma lineatum</i> when it is in the esophageal tissues may cause blood killing <i>H. bovis</i> 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.</p> <p>Cattle treated with PHOENECTIN™ Pour-On at the end of the fly season may be re-treated with PHOENECTIN™ during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.</p> <p><b>Environmental Safety</b> 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.</p> <p><b>Package Information</b> PHOENECTIN™ Pour-On is available in a 250 mL (8.5 fl oz) bottle, a 500 mL (16.9 fl oz) bottle, a 1 L (33.8 fl oz) bottle for use with the dispensing cap provided, or in 3.785 L (1 Gall) bottle, a 5 L (16.9 oz) backpack, or a 25 L carboy for use with the appropriate automatic dosing applicator.</p>
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																						

29283/29284 amtech phoenectin 133-2400 onsert booklet inside black

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.

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

Lot No.

Exp. Date



NDC 59130-681-03

# PHOENECTIN™ (ivermectin) POUR-ON for Cattle 5 mg ivermectin per mL Parasiticide

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

ANADA 200-219, Approved by FDA

**NET CONTENTS: 500 mL (16.9 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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

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

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

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503  
500018

Rev. 11-00



## CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE

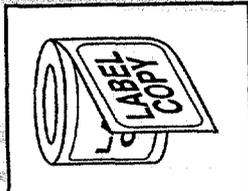
CYREL #: 29284 (TS) Date Sent: 11/22/00

LABEL: PHOENECTIN UNWIND #: 4

SIZE: 3 X 6.75

VARNISH:  YES  PATTERN  FLOOD  
 NO

COLORS: 1797 RED BLACK



Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

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.

**RESIDUE 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.



Lot No.

Exp. Date

NDC 59130-681-04

# PHOENECTIN™ (ivermectin) POUR-ON for Cattle 5 mg ivermectin per mL

**Parasiticide**

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

ANADA 200-219, Approved by FDA

NET CONTENTS: 1 L (33.8 fl oz)

**AmTech**®  
Group, Inc.

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503  
500018

Iss. 11-00

## CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE

CYREL #: 29290 (ts) Date Sent: 11/22/00

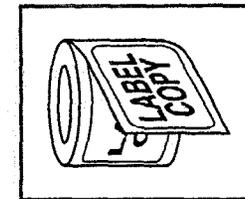
LABEL: phoenectin™

UNWIND #: 4

SIZE: 4 x 8.875

VARNISH:  YES  PATTERN  FLOOD  
 NO

COLORS: black 1797 red



Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

NDC 59130-681-37



# PHOENECTIN™ (ivermectin)

## POUR-ON for Cattle 5 mg ivermectin per mL

Parasiticide

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

ANADA 200-219, Approved by FDA

**NET CONTENTS: 5 L (169 fl oz)**



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.

**RESIDUE 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.

**IMPORTANT:** This package is intended for use only with the Applicator Gun provided. Additional Applicator Guns are available through your local retail dealer or through Phoenix Scientific, Inc. (816) 364-3777.

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

500018

Rev. 11-00

Lot No.

Exp. Date



### CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE  
CYREL #: 29285 (TS) Date Sent: 11/22/00 12/18/00

LABEL: <u>AM TECH</u>	UNWIND #: <u>4</u>
SIZE: <u>7.5 X 5.25</u>	
VARNISH: <input type="checkbox"/> YES <input type="checkbox"/> PATTERN <input type="checkbox"/> FLOOD <input type="checkbox"/> NO	
COLORS: <u>1797 RED</u> <u>BLACK</u>	

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

ANADA 200-219, Approved by FDA

**PHOENECTIN™**  
(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**

PHOENECTIN™ (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents.

**Indications**

PHOENECTIN™ 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 L4)
<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>Trichuris</i> spp	(adults)

**Lungworms**

<i>Dictyocaulus viviparus</i>	(adults and L4)
-------------------------------	-----------------

**Cattle Grubs**

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

**Mites**

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

**Lice**

<i>Linognathus vituli</i> <i>Haematopinus eurysternus</i> <i>Damalinia bovis</i> <i>Solenopotes capillatus</i>
---

**Horn Flies**

<i>Haematobia irritans</i>
----------------------------

**Persistent Activity**

PHOENECTIN™ 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 for Cattle for Horn Flies**

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

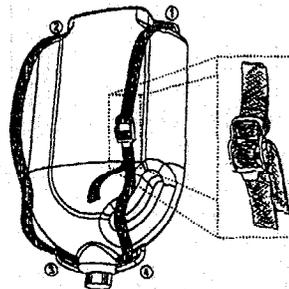
The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

**Administration**

**Applicator Gun\* (5 L backpack)**

Because of the solvents used in PHOENECTIN™ Pour-On, only the PHOENECTIN™ applicator gun from Simcro Tech Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems, resulting in locking, incorrect dosage or leakage.

Remove the draw-off cap and the backpack strap from the indentation in the back of the bottle and refer to the diagram to fit the strap to the bottle.



Thread the strap through the bottle eyelet number 1, then 2, 3, and 4, taking care to follow the diagram when connecting the strap to the buckle. The strap is adjustable by lifting the tab on the buckle.

Slide one of the coil springs over one end of the draw-off tubing. Attach that end of the draw-off tubing to the stem on the applicator gun and slide the spring up to the connection. Slide the second coil spring over the other end of the draw-off tubing and connect that end to the cap that has the stem. Slide the spring to the connection. Replace the shipping cap with the cap having the draw-off tubing attached. Tighten this draw-off cap to the bottle. Invert the bottle and use as a backpack.

Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following 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

\*Additional Applicator Guns may be purchased from your local retail dealer or through Phoenix Scientific, Inc. • St. Joseph, MO • (816)364-3777

**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

PHOENECTIN™ 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**

PHOENECTIN™ Pour-On is available in a 250 mL (8.5 fl oz) bottle, a 500 mL (16.9 fl oz) bottle, a 1 L (33.8 fl oz) bottle for use with the dispensing cap provided, or in a 3.785 L (1 Gal) bottle, a 5 L (16.9 fl oz) backpack, or a 25 L carboy for use with the appropriate automatic dosing applicator.

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503  
500018

Rev. 11-00

ANADA 200-219, Approved by FDA

**PHOENECTIN™**  
(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**

PHOENECTIN™ (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents.

**Indications**

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

**Gastrointestinal Roundworms**

- Ostertagia ostertagi* (adults and L4) (including inhibited stage)
- Haemonchus placei* (adults and L4)
- Trichostrongylus axei* (adults and L4)
- T. colubriformis* (adults and L4)
- Cooperia spp* (adults and L4)
- Strongyloides papillosus* (adults)
- Oesophagostomum radiatum* (adults and L4)
- Trichuris spp* (adults)

**Lungworms**

- Dictyocaulus viviparus* (adults and L4)
- Cattle Grubs** (parasitic stages)

- Hypoderma bovis*
- H. lineatum*

**Mites**

- Sarcoptes scabiei*

**Lice**

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

**Horn Flies**

- Haematobia irritans*

**Persistent Activity**

PHOENECTIN™ 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 34 days after treatment.

**Treatment for Cattle for Horn Flies**

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

**Dispensing Cap** (250 mL, 500 mL and 1 L bottles)  
The enclosed dispensing cap is graduated in 5 mL increments. Each mL will treat 110 lbs body weight. When body weight is between

markings, use the next higher increment.

Attach the dispensing cap to the bottle.

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

Hold the bottle upright and gently 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.

Weight	Dose
220 lb (100 kg)	10 mL
330 lb (150 kg)	15 mL
440 lb (200 kg)	20 mL
550 lb (250 kg)	25 mL
660 lb (300 kg)	30 mL
770 lb (350 kg)	35 mL
880 lb (400 kg)	40 mL
990 lb (450 kg)	45 mL
1100 lb (500 kg)	50 mL

**Mode of Action**

Ivermectin 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.

**RESIDUE 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 at controlled room temperature 15°-30°C (59°-86°F).

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 PHOENECTIN™ (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, PHOENECTIN™ Pour-On is not recommended for use in species other than cattle.

**When to Treat Cattle with Grubs**

PHOENECTIN™ 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 PHOENECTIN™ Pour-On at the end of the fly season may be re-treated with

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.

**RESIDUE 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.

**IMPORTANT:** This package is intended for use only with the Applicator Gun and Draw Tube provided with the Applicator Gun. Additional Applicator Guns and Draw Tubes are available through your local retail dealer or through Phoenix Scientific, Inc. (816) 364-3777.

Lot No.

Exp. Date

NDC 59130-681-05

**PHOENECTIN™  
(ivermectin)  
POUR-ON for Cattle  
5 mg ivermectin per mL**

**Parasiticide**

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

ANADA 200-219, Approved by FDA

NET CONTENTS: 3.785 L (1 Gal)

**AmTech**®  
Group, Inc.

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

500018

Rev. 11-00

**CUSTOMER PROOF • CHECK CAREFULLY!**

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE

CYREL #: 29289 (TS) Date Sent: 11/22/00 12/11/00

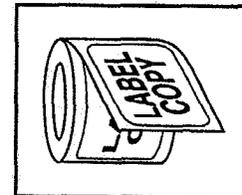
LABEL: PHOENECTIN

UNWIND #: 4

SIZE: 4 X 8.875

VARNISH:  YES  PATTERN  FLOOD  
 NO

COLORS: BLACK 1797 RED



Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503  
500018

Rev. 11-00

ANADA 200-219, Approved by FDA

**PHOENECTIN™**  
(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**

PHOENECTIN™ (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents.

**Indications**

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

**Gastrointestinal Roundworms**

*Ostertagia ostertagi* (adults and L4)  
(including inhibited stage)  
*Haemonchus placei* (adults and L4)  
*Trichostrongylus axei* (adults and L4)  
*T. colubriformis* (adults and L4)  
*Cooperia* spp (adults)  
*Strongyloides papillosus* (adults)  
*Oesophagostomum radiatum* (adults and L4)  
*Trichuris* spp (adults)

**Lungworms**

*Dictyocaulus viviparus* (adults and L4)

**Cattle Grubs**

*Hypoderma bovis* (parasitic stages)  
*H. lineatum*

**Mites**

*Sarcoptes scabiei* var. *bovis*

**Lice**

*Linognathus vituli*

1

*Haematopinus eury.*  
*Damalinea bovis*  
*Solenopotes capillatus*

**Horn Flies**

*Haematobia irritans*

**Persistent Activity**

PHOENECTIN™ Pour-On has been proved 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**

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

**Applicator Gun\***

Because of the solvents used in PHOENECTIN™ Pour-On, only the PHOENECTIN™ applicator gun from Simcro Tech Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems, resulting in locking, incorrect dosage or leakage.

Insert the brass end of the draw tube into the larger hole on the back side of the cap with the stem.

Slide one of the coil springs over one end of the draw-off tubing. Attach that end of the draw-off tubing to the stem on the applicator gun and slide

2

the spring up to the connection. Slide the other coil spring over the other end of the draw-off tubing and connect that end to the cap that has the stem. Slide the spring to the connection. Replace the shipping cap with the cap having the draw-off tubing and draw tube attached. Tighten this draw-off cap to the bottle. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following 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

\*Additional Applicator Guns and Draw Tubes may be purchased from your local retail dealer or through Phoenix Scientific, Inc. • St. Joseph, MO • (816)364-3777

**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.

**RESIDUE 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.**

4

**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.

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 PHOENECTIN™ (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, PHOENECTIN™ Pour-On is not recommended for use in species other than cattle.

**When to Treat Cattle with Grubs**

PHOENECTIN™ 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

5

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 PHOENECTIN™ Pour-On at the end of the fly season may be re-treated with PHOENECTIN™ 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**

PHOENECTIN™ Pour-On is available in a 250 mL (8.5 fl oz) bottle, a 500 mL (16.9 fl oz) bottle, a 1 L (33.8 fl oz) bottle for use with the dispensing cap provided, or in a 3.785 L (1 Gal) bottle, a 5 L (169 fl oz) backpack or a 25 L carboy for use with the appropriate automatic dosing applicator.

6

NDC 59130-681-37



# PHOENECTIN™ (ivermectin)

## POUR-ON for Cattle 5 mg ivermectin per mL

Parasiticide

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

ANADA 200-219, Approved by FDA

**NET CONTENTS: 5 L (169 fl oz)**



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.

➡ **RESIDUE 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.

**IMPORTANT:** This package is intended for use only with the Applicator Gun provided. Additional Applicator Guns are available through your local retail dealer or through Phoenix Scientific, Inc. (816) 364-3777.

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

500018

Rev. 11-00



Lot No.

Exp. Date

### CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE  
CYREL #: 29285 (TS) Date Sent: 11/22/00 12/18/00

LABEL:	<u>AM TECH</u>	UNWIND #:	<u>4</u>
SIZE:	<u>7.5 X 5.25</u>		
VARNISH:	<input type="checkbox"/> YES <input type="checkbox"/> PATTERN <input type="checkbox"/> FLOOD <input checked="" type="checkbox"/> NO		
COLORS:	<u>1797 RED</u> <u>BLACK</u>		

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

ANADA 200-219, Approved by FDA

**PHOENECTIN™**  
(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**

PHOENECTIN™ (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents.

**Indications**

PHOENECTIN™ 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 L4)
<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>Trichuris</i> spp	(adults)

**Lungworms**

<i>Dictyocaulus viviparus</i>	(adults and L4)
-------------------------------	-----------------

**Cattle Grubs**

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

**Mites**

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

**Lice**

<i>Linognathus vituli</i> <i>Haematopinus eurysternus</i> <i>Damalinia bovis</i> <i>Solenopotes capillatus</i>
---

**Horn Flies**

<i>Haematobia irritans</i>
----------------------------

**Persistent Activity**

PHOENECTIN™ 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 for Cattle for Horn Flies**

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

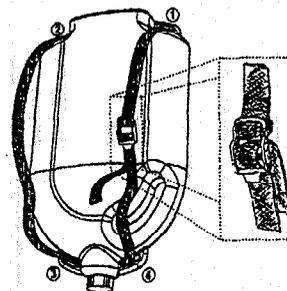
The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

**Administration**

**Applicator Gun\* (5 L backpack)**

Because of the solvents used in PHOENECTIN™ Pour-On, only the PHOENECTIN™ applicator gun from Simcro Tech Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems, resulting in locking, incorrect dosage or leakage.

Remove the draw-off cap and the backpack strap from the indentation in the bottom of the bottle and refer to the diagram to fit the strap to the bottle.



Thread the strap through the bottle eyelet number 1, then 2, 3, and 4, taking care to follow the diagram when connecting the strap to the buckle. The strap is adjustable by lifting the tab on the buckle.

Slide one of the coil springs over one end of the draw-off tubing. Attach that end of the draw-off tubing to the stem on the applicator gun and slide the spring up to the connection. Slide the second coil spring over the other end of the draw-off tubing and connect that end to the cap that has the stem. Slide the spring to the connection. Replace the shipping cap with the cap having the draw-off tubing attached. Tighten this draw-off cap to the bottle. Invert the bottle and use as a backpack.

Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following 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

\*Additional Applicator Guns may be purchased from your local retail dealer or through Phoenix Scientific, Inc. • St. Joseph, MO • (816)364-3777

**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.

➔ **RESIDUE 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 at controlled room temperature 15°-30°C (59°-86°F).

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 PHOENECTIN™ (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, PHOENECTIN™ Pour-On is not recommended for use in species other than cattle.

**When to Treat Cattle with Grubs**

PHOENECTIN™ 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 PHOENECTIN™ Pour-On at the end of the fly season may be re-treated with PHOENECTIN™ 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**

PHOENECTIN™ Pour-On is available in a 250 mL (8.5 fl oz) bottle, a 500 mL (16.9 fl oz) bottle, a 1 L (33.8 fl oz) bottle for use with the dispensing cap provided, or in a 3.785 L (1 Gal) bottle, 5 L (169 fl oz), backpack or a 25 L carboy for use with the appropriate automatic dosing applicator.

NDC 59130-681-37

# PHOENECTIN™ (ivermectin)

## POUR-ON for Cattle 5 mg ivermectin per mL

Parasiticide

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

ANADA 200-219, Approved by FDA

**NET CONTENTS: 5 L (169 fl oz)**

**Amtech**®  
Group, Inc.

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.

➔ **RESIDUE 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.

**IMPORTANT:** This package is intended for use only with the Applicator Gun provided. Additional Applicator Guns are available through your local retail dealer or through Phoenix Scientific, Inc. (816) 364-3777.

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 PHOENECTIN™ (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, PHOENECTIN™ (ivermectin) 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.

**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.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

500018

Rev. 11-00

NDC 59130-681-48

# PHOENECTIN™ (ivermectin)

## POUR-ON for Cattle 5 mg ivermectin per mL Parasiticide

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



ANADA 200-219, Approved by FDA  
NET CONTENTS: 25 L (6.6 Gallons)

Weight	Dose	Weight	Dose
220 lb (100 kg)	10 mL	660 lb (300 kg)	30 mL
330 lb (150 kg)	15 mL	770 lb (350 kg)	35 mL
440 lb (200 kg)	20 mL	880 lb (400 kg)	40 mL
550 lb (250 kg)	25 mL	990 lb (450 kg)	45 mL
		1100 lb (500 kg)	50 mL

### 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.

**IMPORTANT:** This package is intended for use only with Applicator Guns and Draw Tubes from Simcro Tech Limited.

### Parasiticide

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

### Introduction

PHOENECTIN™ (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents.

### Indications

PHOENECTIN™ 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>Trichuris</i> spp.	(adults)
<b>Lungworms</b>	
<i>Dictyocaulus viviparus</i>	(adults and L4)
<b>Cattle Grubs</b>	(parasitic stages)
<i>Hypoderma bovis</i>	
<i>H. lineatum</i>	
<b>Mites</b>	
<i>Sarcoptes scabiei</i> var. <i>bovis</i>	
<b>Horn Flies</b>	
<i>Haematobia irritans</i>	

### Lice

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

1

**RESIDUE 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 at controlled room temperature 15°-30°C (59°-86°F).

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 PHOENECTIN™ (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 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, PHOENECTIN™ Pour-On is not recommended for use in species other than cattle.

### Persistent Activity

PHOENECTIN™ Pour-On has been proved to effectively control infectious and 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

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

### Applicator Gun

Because of the solvents used in PHOENECTIN™ Pour-On, only the PHOENECTIN™ applicator gun from Simcro Tech Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems, resulting in locking, incorrect dosage or leakage.

Attach one end of the draw-off tubing, with spring, to the stem on the applicator gun and slide the spring up to the connection. Remove the small snap cap from one of the two draw tubes attached to the draw-off cap. Attach the other end of the draw-off tubing, with spring, to the stem on the draw-off cap and slide the spring up to the connection. If the second applicator gun is to be used, repeat these operations. Remove the shipping cap from the container and replace it with the draw-off cap with the draw-off tubing and tubes attached. Tighten this draw-off cap to the bottle.

Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

2

### When to Treat Cattle with Grubs

PHOENECTIN™ 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 PHOENECTIN™ Pour-On at the end of the fly season may be re-treated with PHOENECTIN™ 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

PHOENECTIN™ Pour-On is available in a 250 mL (8.5 fl oz) bottle, a 500 mL (16.9 fl oz) bottle, a 1 L (33.8 fl oz) bottle for use with the measuring cup provided, or in a 3.785 L (1 Gal) bottle, a 5.0 L (169 fl oz.) backpack and a 25 L (6.6 Gal) carboy for use with the appropriate automatic dosing applicator.

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503  
Lot No.:

500018

Rev. 11-00

Exp. Date:



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

### Mites

*Sarcoptes scabiei* var. *bovis*

### Lice

*Linognathus vituli*  
*Haematophorus 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 IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

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

**When to Treat Cattle with Grubs**

IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

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

**Environmental Safety**

Studies indicate that when ivermectin comes in contact with 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**

IVOMEC 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.



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

U.S. Pat 4,199,569  
Copyright © 1990, 1992, 1998 Merck & Co., Inc.  
Whitehouse Station, New Jersey, U.S.A.  
All Rights Reserved.

September 1998

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, lice, sucking and biting flies, and sarcoptic mange mites in cattle.  
See package insert for complete indications and use directions.  
Recommended Dose: 1 mL per 22 lb of body weight.

**WARNING:** Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

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

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

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

**WARNING! FLAMMABLE!**

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

**PRECAUTIONS:**

- Store away from excessive heat (104°F/40°C) and protect from light.
- Use only in well-ventilated areas or outdoors.
- 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.
- A change in the formulation may occur when IVOMEC (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
- Parasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or crusts of 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  
In USA

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

Lot No & Exp Date ▼

EBJ271

OCT00

6.9 fl oz (5 L)

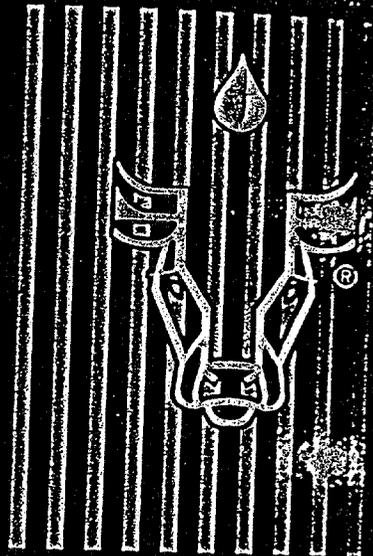


# IVOMEC<sup>®</sup>

(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

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, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

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

**WARNING:** Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

## WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to self or others because it may be irritating to human skin and be 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 ocular 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.

## CAUTIONS:

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.

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

Crystals in the formulation may occur when IVOMEC® (Ivermectin) Pour-On is stored at temperatures below 32°F.

Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Parasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Reaction 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 fl oz (2.64 qt)(2.5L)

Lot No & Exp Date ▼

U.S.A.

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

EBJ239

08-2001

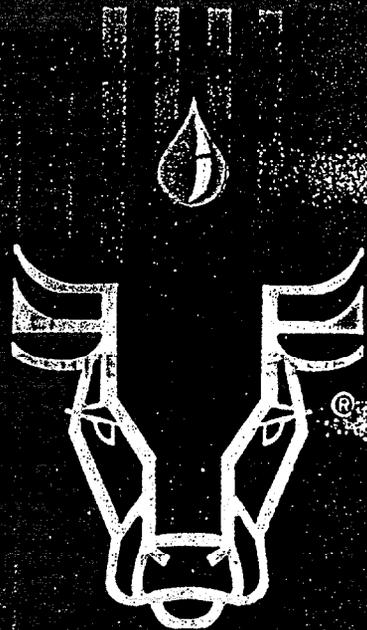
MERCK

# 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

169 fl.oz (5L)

8865900



# Ivomec

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

Contains 5 mg  
ivermectin/mL



### Parasiticide

- Kills:**
- Roundworms  
(including Brown Stomach Worm)
  - Lungworms
  - Grubs
  - Sticking 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

1007-98 8 EB248 06-7001

Lot No. Exp. Date

