

**IVERMAX POUR-ON FOR CATTLE- ivermectin cattle pour-on solution
ASPEN VETERINARY RESOURCES, LTD.**

**Ivermax® Pour-On for Cattle
(ivermectin topical solution)**



5 mg ivermectin/mL

PARASITICIDE

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

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

Restricted Drug (California) - Use Only as Directed.

**FOR ANIMAL USE ONLY
Keep Out of Reach of Children**

Approved by FDA under ANADA # 200-340

See attached booklet for complete indications and use directions.

Parasiticide

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

Introduction

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

Mode of Action

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.

This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

Indications

Ivermax® Pour-On for Cattle applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and 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 oncophora</i>	(adults and L4)
<i>Cooperia punctata</i>	(adults and L4)
<i>Cooperia surnabada</i>	(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)
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Cattle Grubs

(parasitic stages)

Hypoderma bovis
H. lineatum

Mites

Sarcoptes scabiei var. *Bovis*

Lice

Linognathus vituli
Haematopinus eurysternus
Damalinia bovis
Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity

Ivermax® Pour-On for Cattle has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

TREATMENT OF CATTLE FOR HORN FLIES

Ivermax[®] Pour-On for Cattle controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Ivermax[®] Pour-On for Cattle 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

For the 250 mL and 1 Liter containers, see the diagram on the last page of this insert. Each 5 mL will treat 110 lbs body weight. When body weight requires a drug product volume that is between the measuring markings, use the next higher increment.

Applicator Gun

(2.5 L, 5 L and 5 gallon bottles)

Because of the solvents used in Ivermax[®] Pour-On for Cattle, an applicator gun is recommended.

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

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment and encourage the development of parasite resistance.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING! NOT FOR USE IN

HUMANS

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

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects, obtain an SDS or for assistance, contact First Priority, Inc. at 1-800-650-4899.

WARNING! FLAMMABLE! KEEP

AWAY FROM

HEAT, SPARKS, OPEN FLAME, AND

OTHER

SOURCES OF IGNITION.

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

RESIDUE 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. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

OTHER WARNINGS

- Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.
- Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.
- Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd/flock, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatments should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).
- A decrease in a drug's effectiveness over time as calculated by fecal egg count reductions tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

PRECAUTIONS:

- **Store at or below 25°C (77°F) and protect from light. Excursions permitted to 104°F (40°C).**

- 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 Ivermax[®] Pour-On for Cattle is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
- Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatosis or adherent materials, e.g., caked mud or manure.
- Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Ivermax[®] Pour-On for Cattle is not recommended for use in species other than cattle.
- Restricted Drug (California) - Use only as directed.

When to Treat Cattle with Grubs

Ivermax[®] Pour-On for Cattle 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 Ivermax[®] Pour-On for Cattle at the end of the fly season may be re-treated with Ivermax[®] Pour-On for Cattle 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 and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

HOW SUPPLIED:

Ivermax[®] Pour-On for Cattle is available in 250 mL (8.5 fl oz) and 1 L (33.8 fl oz) tip and measure bottles, and 2.5 L (84.5 fl oz), 5 L (169.0 fl oz), and 5 Gallon (639.0 fl oz)

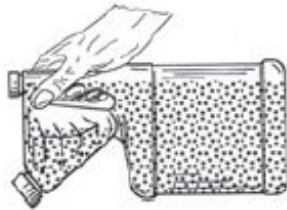
containers for use with an appropriate automatic dosing applicator.



Manufactured for:

Aspen Veterinary Resources,® Ltd.
Liberty, MO 64068, USA A190FP 12/20
www.aspenveterinaryresources.com

tip "N" measure[®]
the exact amount



① MEASURE



② CHECK



③ ADJUST



④ POUR

The graduated measuring chamber of the container has 10 mL, 15 mL, 20 mL and 25 mL graduations.

250 mL (8.5 fl oz)

Base Onsert Label

Onsert

8	9	10	11	12	FACE
<p>PRECAUTIONS:</p> <ul style="list-style-type: none"> Store at or below 25°C (77°F) and protect from light. Excursions permitted to 14°F (4°C). Use only in well-ventilated areas or outdoors. Close container tightly when not in use. Cattle should not be treated when heat 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 Ivermax Pour-On for Cattle is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy. Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatitis or adhesive materials, e.g., calmed mud or manure. Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Ivermax Pour-On for Cattle is not recommended for use in species other than cattle. Restricted Drug (California) - Use only as directed. <p>When to Treat Cattle with Grubs Ivermax Pour-On for Cattle effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be</p>	<p>treated as soon as possible after the end of the hot fly (warble fly) season. While this is not peculiar to ivermectin, destruction of <i>Hypoderma larvae</i> (cattle grubs) at the period when those 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 bloat; 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 those stages of grub development.</p> <p>Cattle treated with Ivermax Pour-On for Cattle at the end of the fly season may be re-treated with Ivermax Pour-On for Cattle 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>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 and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration. As with other avermectins, ivermectin is acralcine in</p>	<p>the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.</p> <p>HOW SUPPLIED: Ivermax Pour-On for Cattle is available in 250 mL (8.5 fl oz) and 1 L (33.8 fl oz) tip and measure bottles, and 2.5 L (84.5 fl oz), 5 L (169.0 fl oz), and 5 Gallon (200.0 fl oz) containers for use with an appropriate automatic dosing applicator.</p>	<p>tip N' measure® the exact amount</p> <p>The graduated measuring chamber of the container has 10 mL, 15 mL, 20 mL, and 25 mL graduations.</p>	<p>Manufactured by: Aspen Veterinary Products, LLC 10070 MC 4040, USA</p> <p>AT311P 11/200</p> <p>www.aspenivm.com</p>	<p>NDC 46066-302-02</p> <p>aspen VETERINARY PRODUCTS</p> <p>IVERMAX®</p> <p>POUR-ON for Cattle (ivermectin topical solution) 5 mg ivermectin per mL</p> <p>PARASITICIDE Kills: Roundworms (Including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies</p> <p>WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION. Restricted Drug (California) - Use Only as Directed.</p> <p>FOR ANIMAL USE ONLY Keep Out of Reach of Children Approved by FDA under ANADA # 200-340</p> <p>NET CONTENTS: 250 mL (8.5 fl oz)</p>

2	3	4	5	6	7																								
<p>Ivermax® Pour-On for Cattle (ivermectin topical solution) Approved by FDA under ANADA # 200-340 Contains 5 mg ivermectin/mL</p> <p>Parasiticide Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.</p> <p>INTRODUCTION Ivermax Pour-On for Cattle (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Ivermax Pour-On for Cattle contains ivermectin, a unique chemical entity.</p> <p>MODE OF ACTION Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of this class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.</p> <p>This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).</p>	<p>The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactone class has a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.</p> <p>INDICATIONS Ivermax Pour-On for Cattle applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and control of those parasites.</p> <p>Gastrointestinal Roundworms <i>Ostertagia circumcincta</i> (including inhibited stages) (adults and L4) <i>Trichostrongylus axei</i> (adults and L4) <i>Haemonchus placei</i> (adults and L4) <i>Trichostrongylus axei</i> (adults and L4) <i>Cooperia oncophora</i> (adults and L4) <i>Cooperia punctata</i> (adults and L4) <i>Cooperia sunabada</i> (adults and L4) <i>Strongylidae papillae</i> <i>Oesophagostomum radiatum</i> (adults and L4) <i>Trichostrongylus</i> spp. (adults) Lungworms <i>Dictyocaulus viviparus</i> (adults and L4) Cattle Grubs <i>Hypoderma bovis</i> (parasitic stages) <i>H. lineatum</i></p>	<p>Mites <i>Sarcoptes scabiei</i> var. <i>bovis</i> Lice <i>Linognathus seti</i> <i>Haemaphysalis eurysternus</i> <i>Dematobia dimorpha</i> <i>Solenopotes capillatus</i> Horn Flies <i>Hemesebia irritans</i></p> <p>PERSISTENT ACTIVITY Ivermax Pour-On for Cattle has been proved to effectively control infestations and to protect cattle from re-infestation with: <i>Oesophagostomum radiatum</i> and <i>Dictyocaulus viviparus</i> for 28 days after treatment; <i>Cooperia punctata</i> and <i>Trichostrongylus axei</i> for 21 days after treatment; <i>Ostertagia circumcincta</i>, <i>Haemonchus placei</i>, <i>Cooperia oncophora</i> and <i>Cooperia sunabada</i> for 14 days after treatment; <i>Dematobia dimorpha</i> for 14 days after treatment.</p> <p>TREATMENT OF CATTLE FOR HORN FLIES Ivermax Pour-On for Cattle controls horn flies (<i>Hemesebia irritans</i>) for up to 28 days after dosing. For best results Ivermax Pour-On for Cattle 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</p>	<p>effective timing of applications.</p> <p>DOSEAGE The dose rate is 1 mL for each 20 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>ADMINISTRATION For the 250 mL and 1 Liter containers, see the diagram on the last page of this insert. Each 5 mL will treat 110 lb body weight. When body weight requires a drug product volume that is between the measuring markings, use the next higher increment.</p> <p>Applicator Gun (2.5 L, 5 L, and 5 gallon bottles) (because of the solvents used in Ivermax Pour-On for Cattle, an applicator gun is recommended.) Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and use of the applicator gun following use.</p> <table border="1"> <thead> <tr> <th>Weight</th> <th>Dose</th> <th>Weight</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>220 lb (100 kg)</td> <td>10 mL</td> <td>770 lb (350 kg)</td> <td>35 mL</td> </tr> <tr> <td>330 lb (150 kg)</td> <td>15 mL</td> <td>880 lb (400 kg)</td> <td>40 mL</td> </tr> <tr> <td>440 lb (200 kg)</td> <td>20 mL</td> <td>990 lb (450 kg)</td> <td>45 mL</td> </tr> <tr> <td>550 lb (250 kg)</td> <td>25 mL</td> <td>1100 lb (500 kg)</td> <td>50 mL</td> </tr> <tr> <td>660 lb (300 kg)</td> <td>30 mL</td> <td></td> <td></td> </tr> </tbody> </table> <p>Do not underdose. Ensure each animal receives a complete dose based on a current body weight.</p>	Weight	Dose	Weight	Dose	220 lb (100 kg)	10 mL	770 lb (350 kg)	35 mL	330 lb (150 kg)	15 mL	880 lb (400 kg)	40 mL	440 lb (200 kg)	20 mL	990 lb (450 kg)	45 mL	550 lb (250 kg)	25 mL	1100 lb (500 kg)	50 mL	660 lb (300 kg)	30 mL			<p>Underdosing may result in ineffective treatment and encourage the development of parasite resistance.</p> <p>ANIMAL SAFETY Studies conducted in the U.S.A. have demonstrated the safety margin for Ivermectin. Based on plasma levels, the typically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.</p> <p>WARNING! NOT FOR USE IN HUMANS Keep this and all drugs out of the reach of children.</p> <p>The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects, obtain an SDS or for assistance, contact First Priority, Inc. at 1-800-850-4800.</p> <p>WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION. This product should not be applied to soil or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.</p>	<p>RESIDUE WARNING: Cattle must not be treated within 45 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminant calves. Do not use in calves to be processed for veal.</p> <p>OTHER WARNINGS</p> <ul style="list-style-type: none"> Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers. Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance. Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd/flock, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatments should be monitored for example, with the use of a fecal egg count reduction test or another appropriate method. A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. 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Case Label

NDC 46066-302-02

See enclosed labeling for complete indications and use directions.

aspen
VETERINARY PHARMACEUTICALS, LTD.

IVERMAX[®]

POUR-ON for Cattle
(ivermectin topical solution)
5 mg ivermectin per mL

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

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Approved by FDA under ANADA # 200-340

NET CONTENTS:
250 mL (8.5 fl oz)

0 99355 00451 1

A190FP 12/20

1 Liter (33.8 fl oz)

NDC 46066-302-34

See attached booklet for complete indications and use directions.

aspen
VETERINARY PHARMACEUTICALS, LTD.

IVERMAX[®]

POUR-ON for Cattle
(ivermectin topical solution)
5 mg ivermectin per mL

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

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.

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FOR ANIMAL USE ONLY
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Approved by FDA under ANADA # 200-340

NET CONTENTS:
1 Liter (33.8 fl oz)

0 99355 00450 4

A190FP 12/20

Ivermax® Pour-On for Cattle
(ivermectin topical solution)
Approved by FDA under ANADA # 200-340
Contains 5 mg ivermectin/mL

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

INTRODUCTION
Ivermax® Pour-On for Cattle (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Ivermax® Pour-On for Cattle contains ivermectin, a unique chemical entity.

MODE OF ACTION
Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of this class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.

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The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

INDICATIONS
Ivermax® Pour-On for Cattle applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and control of these parasites.

Gastrointestinal Roundworms
(adults and L4)
Ostertagia ostertagi (including inhibited stage)
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
Cooperia punctata
Cooperia curatata

Strongyloides papillosus
Oesophagostomum radiatum
Trichostrongylus axei
Lungworms
Dictyocaulus viviparus
Cattle Grubs
Hypoderma bovis
H. lineatum
Mites
Sarcoptes scabiei var. *Bovis*
Lice
Linognathus setosus
Haematopinus eurysternus
Dermania bovis
Solenopotes capillatus
Horn Flies
Haematobia irritans

PERSISTENT ACTION
Ivermax® Pour-On for Cattle has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia curatata* for 14 days after treatment; *Dermania bovis* for 56 days after treatment.

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DOSEAGE
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
For the 250 mL and 1 Liter containers, see the diagram on the last page of this insert. Each 5 mL will treat 110 lbs body weight. When body weight requires a

drug product volume that is between the measuring markings, use the next higher increment.

Applicator Gun
(2.5 L, 5 L and 5 gallon bottles)
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Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

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660 lb (300 kg)	30 mL		

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment and encourage the development of parasite resistance.

ANIMAL SAFETY
Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

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

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

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects, obtain an SDS or for assistance, contact First Priority, Inc. at 1-800-650-4899.

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

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. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

OTHER WARNINGS
Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.

- Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.
- Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd/flock, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatments should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).
- A decrease in a drug's effectiveness over time as calculated by fecal egg count reductions tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

PRECAUTIONS:

- Store at or below 25°C (77°F) and protect from light. Excursions permitted to 104°F (40°C).
- Use only in well-ventilated areas or outdoors.
- Close containers 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 Ivermax® Pour-On for Cattle is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

- Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatitis or adherent materials, e.g., caked mud or manure.
- Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Ivermax® Pour-On for Cattle is not recommended for use in species other than cattle.
- Restricted Drug (California) - Use only as directed.

When to Treat Cattle with Grubs
Ivermax® Pour-On for Cattle 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 lineatum* (cattle grub) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause blood-letting; 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 Ivermax® Pour-On for Cattle at the end of the fly season may be re-treated with Ivermax® Pour-On for Cattle 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 and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact First Priority, Inc. at 1-800-650-4899.

HOW SUPPLIED:
Ivermax® Pour-On for Cattle is available in 250 mL (8.5 fl oz) and 1 L (33.8 fl oz) tip and measure bottles, and 2.5 L (84.5 fl oz), 5 L (169.0 fl oz), and 5 Gallon (839.0 fl oz) containers for use with an appropriate automatic dosing applicator.

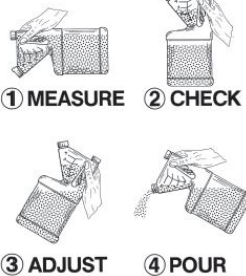




Manufactured for:
Aspen Veterinary Resources®, Ltd.
Liberty, MO 64068, USA
www.aspenveterinaryresources.com

A190FP 12/20

tipN® measure®
the exact amount




1 MEASURE 2 CHECK

3 ADJUST 4 POUR

The graduated measuring chamber of the container has 10 mL, 15 mL, 20 mL and 25 mL graduations.

NDX 4606-302-34



IVERMAX®

POUR-ON for Cattle
(ivermectin topical solution)
5 mg ivermectin per mL

PARASITICIDE

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

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.
Restricted Drug (California) - Use Only as Directed.

FOR ANIMAL USE ONLY
Keep Out of Reach of Children
Approved by FDA under ANADA # 200-340

NET CONTENTS:
1 Liter (33.8 fl oz)

NDC 46066-302-34



IVERMAX[®]



POUR-ON for Cattle
(ivermectin topical solution)

5 mg ivermectin per mL

PARASITICIDE

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

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.

Restricted Drug (California) – Use Only as Directed.

FOR ANIMAL USE ONLY

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Approved by FDA under ANADA # 200-340

NET CONTENTS:
1 Liter (33.8 fl oz)

See enclosed labeling for complete indications and use directions.



A190FP 12/20

2.5 Liter (rev. 12/20)



IVERMAX®

POUR-ON for Cattle (ivermectin topical solution) 5 mg ivermectin per mL PARASITICIDE

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

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.
Restricted Drug (California) – Use Only as Directed.

FOR ANIMAL USE ONLY
Keep Out of Reach of Children

Approved by FDA under ANADA # 200-340

NET CONTENTS:
2.5 Liter (84.5 fl oz)

See attached booklet for complete indications and use directions.



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Ivermax® Pour-On for Cattle (ivermectin topical solution) Approved by FDA under ANADA # 200-340 Contains 5 mg ivermectin/mL

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

INTRODUCTION
Ivermax® Pour-On for Cattle (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Ivermax® Pour-On for Cattle contains ivermectin, a unique chemical entity.

MODE OF ACTION

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.

This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactone have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood brain barrier.

INDICATIONS

Ivermax® Pour-On for Cattle applied at the recommended dose level of 500 mg/kg is indicated for the effective treatment and 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 oncophora</i>	(adults and L4)
<i>Cooperia punctata</i>	(adults and L4)
<i>Cooperia burnabadi</i>	(adults and L4)
<i>Strongylidae papillosum</i>	(adults)

Ceophogostomum radicum
Trichostrongylus axei
Lungworms
Dicrocoelium viviparum
Cattle Grubs
Hypoderma bovis
H. irritans
Mites
Sarcoptes oedematis var. *Bovis*
Lice
Linognathus vituli
Haematopinus eurysternus
Dermanyssus bovis
Solenopotes capillatus
Horn Flies
Haematobia irritans

PERSISTENT ACTIVITY

Ivermax® Pour-On for Cattle has been proved to effectively control infections and to protect cattle from re-infection with *Ceophogostomum radicum* and *Dicrocoelium viviparum* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia burnabadi* for 14 days after treatment; *Dermanyssus bovis* for 56 days after treatment.

TREATMENT OF CATTLE FOR HORN FLIES
Ivermax® Pour-On for Cattle controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Ivermax® Pour-On for Cattle 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.

DOSE

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

ADMINISTRATION

For the 200 mL and 1 Liter containers, see the diagram on the last page of this insert. Each 5 mL vial will treat 110 lbs body weight. When body weight requires a drug product volume that is between the measuring markings, use

(adults and L4) (adults)
(adults and L4) (parasitic stages)

the next higher increment.

Applicator Gun (2.5 L, 5 L and 5 gallon bottles)
Because of the solvents used in Ivermax® Pour-On for Cattle, an applicator gun is recommended.

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

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

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment and encourage the development of parasite resistance.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the typically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING! NOT FOR USE IN HUMANS

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

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects, obtain an SDS or for assistance, contact First Priority, Inc. at 1-800-850-4692.

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

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

RESIDUE 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. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

OTHER WARNINGS

- Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.
- Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.
- Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the use of any dewormer, effectiveness of treatments should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).
- A decrease in a drug's effectiveness over time as calculated by fecal egg count reductions tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

PRECAUTIONS:

- Store at or below 25°C (77°F) and protect from light. Excursions permitted to 104°F (40°C).
- 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 Ivermax® Pour-On for Cattle is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting

page 5

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face

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, Ivermax® Pour-On for Cattle is not recommended for use in species other than cattle.
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When to Treat Cattle with Grubs

Ivermax® Pour-On for Cattle 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 blood-tinging *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 Ivermax® Pour-On for Cattle at the end of the fly season may be re-treated with Ivermax® Pour-On for Cattle 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 and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration. As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

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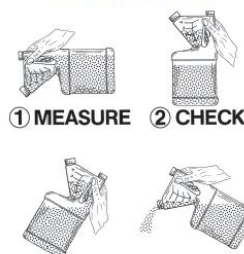
HOW SUPPLIED:

Ivermax® Pour-On for Cattle is available in 200 mL (6.8 fl oz) and 1 L (33.8 fl oz) tip and measure bottles, and 2.5 L (84.5 fl oz), 5 L (169 fl oz), and 5 Gallon (189.3 fl oz) containers for use with an appropriate automatic dosing applicator.



Manufactured by:
Aspen Veterinary Resources®, Ltd.
Liberty, MO 64066, USA
www.aspenveterinaryresources.com A188FP 12/20

tipNmeasure® the exact amount



The graduated measuring chamber of the container has 10 mL, 15 mL, 20 mL and 25 mL graduations.



IVERMAX®

POUR-ON for Cattle (ivermectin topical solution) 5 mg ivermectin per mL PARASITICIDE

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

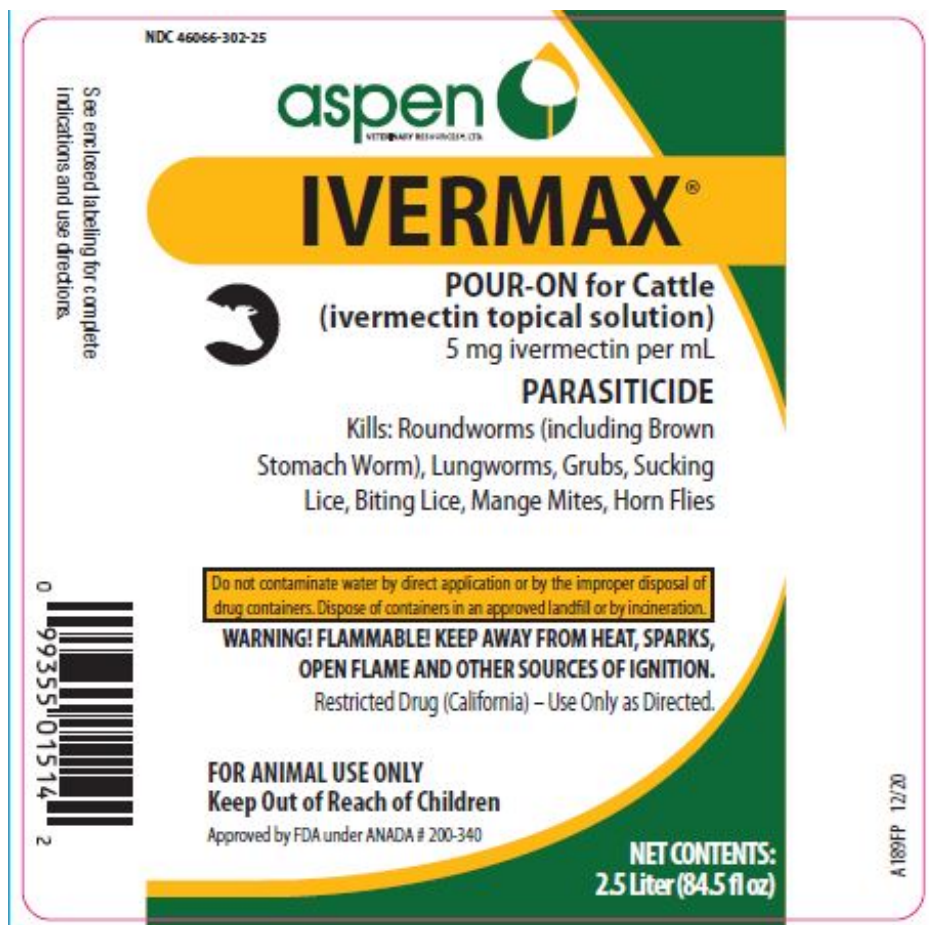
Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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Restricted Drug (California) – Use Only as Directed.

FOR ANIMAL USE ONLY
Keep Out of Reach of Children

Approved by FDA under ANADA # 200-340

NET CONTENTS:
2.5 Liter (84.5 fl oz)



IVERMAX POUR-ON FOR CATTLE

ivermectin cattle pour-on solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:46066-302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	5 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-302-02	12 in 1 CASE		
1		250 mL in 1 BOTTLE, PLASTIC		
2	NDC:46066-302-34	12 in 1 CASE		
2		1000 mL in 1 BOTTLE, PLASTIC		
3	NDC:46066-302-25	4 in 1 CASE		
3		2500 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200340	01/30/2017	

Labeler - ASPEN VETERINARY RESOURCES, LTD. (627265361)

Establishment

Name	Address	ID/FEI	Business Operations
First Priority Incorporated		179925722	manufacture, label

Revised: 1/2022

ASPEN VETERINARY RESOURCES, LTD.