

HFA-305

Date of Approval MAY 15 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-327

Privermectin™ (ivermectin) Drench for Sheep

Sponsored by:
First Priority, Inc.
Elgin, IL 60123

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number	200-327
Sponsor:	First Priority, Inc. 1585 Todd Drive Elgin, IL 60123
	21 CFR 510.600: Labeler Code 058829
Established Name:	Ivermectin liquid
Trade/Proprietary Name:	Privermectin™ Drench for Sheep
Dosage Form:	Drench
How Supplied:	32.46 fl. oz (1 quart) 960 mL size bottle
How Dispensed:	OTC
Amount of Active Ingredients:	200 mcg/kg of body weight as a single dose oral drench
Route of Administration:	Oral
Species:	Sheep
Labeled Dosage	3 mL per 26 lbs. b.w.
Indications for Use:	Treatment and control of gastrointestinal roundworms, lungworms, and nasal bots.
Pharmacological Category:	Antiparasitic

Pioneer Product:

Ivomec® Drench for Sheep manufactured by
Merial Limited (NADA 131-392)

2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 10, 2000).

Based upon the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver on January 28, 2000, from conducting an *in vivo* bioequivalence study for Privermectin Drench for Sheep. The generic and pioneer products contain the same active in the same concentration as the pioneer, and nearly the same inactive ingredients and are oral solutions.

3. HUMAN FOOD SAFETY:

WITHDRAWAL TIME:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Ivermectin liquid is established under 21 CFR 520.1194- 11 days in sheep.

TOLERANCE:

Under section §556.344, **Ivermectin**, the tolerances for ivermectin (1) Liver: A tolerance is established for 22,23-dihydroaivermectin B¹a (marker residue) in liver of sheep at 30 parts per billion. The ADI for total residues of ivermectin is 1 microgram per kilogram of body weight per day.

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND
ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal, Food, Drug and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Privermectin™ Drench for Sheep is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

32.46 fl. oz (1 quart) 960 mL pack

Generic Labeling:

Package Insert

32.46 fl. oz (1 quart) 960 mL pack

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

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

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

PRODUCT DATA

IVOMEC® (ivermectin)

Sheep Drench

Packaging:

IVOMEC® (ivermectin) Sheep Drench is available in two convenient pack sizes:

The 32.46 fl. oz (960 mL) pack (Product 41264) contains sufficient solution to treat 53 sheep averaging 100 lbs.

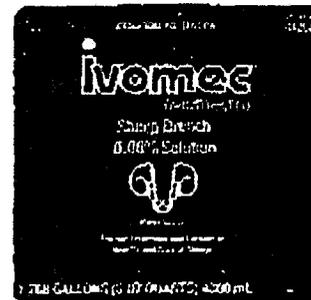
The 1.268 gallon (4800 mL) pack (Product 41268) contains sufficient solution to treat 415 sheep averaging 100 lbs.

Both packs are high-density polyethylene containers, colored opaque white, with screw caps and tamper-evident seals.

They are shipped in cardboard cartons as follows:

2 x 4800 mL containers per case.

4 x 960 mL containers per case.



PRODUCT DESCRIPTION

IVOMEC Sheep Drench is a liquid, administered orally to sheep, consisting of an 0.08% solution of ivermectin. Discovered and developed by scientists from Merck Sharp and Dohme Research Laboratories, ivermectin is a unique chemical entity. As such, the chances of cross-resistance in parasites that have developed resistance to other wormers is highly unlikely. Additionally, its convenience, broad spectrum efficacy, and wide therapeutic index make IVOMEC Sheep Drench an exceptionally valuable product for parasite control in sheep.

DOSING

IVOMEC Sheep Drench is formulated only for administration to sheep; do not use in other species. The recommended dose level is 3 mL of IVOMEC Sheep Drench, containing 2400 mcg ivermectin, which is sufficient to treat 26 pounds of body weight.

ADVANTAGES

Unique chemistry—unrelated to existing formulations.

Because IVOMEC Sheep Drench is chemically different, cross-resistance is unlikely in parasite strains which may have developed resistance to other wormers.

Broad spectrum effectiveness.

One low-volume dose effectively treats and controls many gastrointestinal roundworms (including *Haemonchus contortus*), lungworms, and nasal bots.

Easy administration.

IVOMEC Sheep Drench can be administered with any standard drenching equipment or any equipment that provides a consistent dose volume.

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From: MERIAL LTD

800-727-5557

T-668 P.003/006 F-538

FORMULATION

IVOMEC Sheep Drench is an 0.08% w/v pale amber colored solution of ivermectin.

Ivermectin is derived from the avermectins, a family of highly active, broad spectrum, antiparasitic agents which are produced from fermentation products of *Streptomyces avermitilis*.

PRODUCT INDICATIONS

IVOMEC Sheep Drench is indicated for the effective treatment of gastrointestinal roundworms (including *Haemonchus contortus*), lungworms and nasal bots in sheep.

When used as recommended, it provides effective control of the parasites shown in the table.

IVOMEC SHEEP DRENCH KILLS THESE PARASITES		
	Adults	Larvae (4th stage)
Gastrointestinal roundworms:		
<i>Haemonchus contortus</i>	X	X
<i>Haemonchus placei</i>	X	
<i>Ostertagia circumcincta</i>	X	X
<i>Trichostrongylus axei</i>	X	X
<i>Trichostrongylus colubriformis</i>	X	X
<i>Cooperia curticei</i>	X	X
<i>Cooperia oncophora</i>	X	
<i>Oesophagostomum columbianum</i>	X	X
<i>Oesophagostomum venulosum</i>	X	
<i>Nematodirus battus</i>	X	X
<i>Nematodirus spathiger</i>	X	X
<i>Strongyloides papillosus</i>	X	
<i>Trichostrongylus axei</i>	X	
<i>Trichostrongylus colubriformis</i>	X	
Lungworms:		
<i>Dictyocaulus filaria</i>	X	X
Nasal bots:		
<i>Oestrus ovis</i>		(all larval stages)

DOSAGE

IVOMEC Sheep Drench should only be administered orally at the recommended dose level of 200 mcg ivermectin per kilogram of body weight. Three mL of IVOMEC Sheep Drench contains sufficient ivermectin to treat 26 pounds of body weight.

Volume	Sheep Body Weight Dosed
3 mL	26 lbs
6 mL	52 lbs
8 mL	78 lbs
12 mL	104 lbs
15 mL	130 lbs
18 mL	156 lbs
21 mL	182 lbs
24 mL	208 lbs
27 mL	234 lbs
30 mL	260 lbs

In sheep weighing 250 lbs or more, it is recommended to use the dose according to the weight of the animal (based on 2.2 grams (0.08 oz) ivermectin per 100 lbs body weight). Amounts of less than 2.2 grams should be weighed, judgment by the user is necessary.

ADMINISTRATION

Standard drenching equipment, or any equipment which provides a consistent dose volume, can be used. Dose rates and equipment should be checked before drenching commences. Be sure the head is properly positioned for each sheep to receive the full dose. IVOMEC Sheep

Drench is readily accepted by sheep, but inconsequential coughing may be observed in some animals during and for several minutes after drenching. If slobbering occurs, the dose may be lost, and that sheep should be redosed.

FREQUENCY OF DOSING

Resistant parasites are a particular problem in sheep.

Please consult your veterinarian, county extension office or animal health supplier for the control program recommended in your area.

MODE OF ACTION

The avermectin family of compounds, of which ivermectin is a member, kills certain parasitic nematodes (roundworms)

and arthropods. The action is unique and not shared by other antiparasitic agents and 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 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 in most species.

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

Recommended doses of ivermectin have a wide safety margin in livestock. 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.

STABILITY

IVOMEC Sheep Drench is stable for 24 months when stored under normal conditions. Protect from light.

SAFETY

IVOMEC Sheep Drench has been demonstrated to have a wide safety margin at the recommended dose level and margin

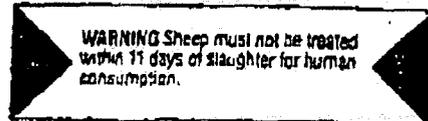
used in sheep of all ages. Ewes may be treated at any stage of pregnancy.

ACCEPTABILITY

Coughing may be observed in some animals during and for several minutes following drenching.

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 water-born organisms on which they feed. Do not permit water runoff from feedlots to enter lakes, streams, or ground water. Do not contaminate water by direct application or by the improper disposal of drug containers. Spills of IVOMEC Sheep Drench should be contained and soaked up with absorbent towels or into loose soil. Gloves should be worn to prevent skin exposure. All the collected materials (contaminated towels and soil), as well as all used drug containers, should be placed in an impervious film bag (plastic) and disposed of by incineration or in an approved landfill.



CAUTION

IVOMEC Sheep Drench has been formulated for use in sheep ONLY. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

PRECAUTIONS

This product is not to be used parenterally. Protect from light.

Keep this and all drugs out of reach of children.

HUMAN SAFETY

When used as recommended in sheep, IVOMEC Sheep Drench does not pose a hazard to human health. As a routine precaution, it is advisable to wash hands after use. As with all drugs, the product should be kept out of reach of children. Contact with skin and eyes should be avoided, but protective clothing is not required.

For customer service, contact Technical Services Department, U.S. Operations, MSD AGVET, Division of Merck & Co., Inc., Box 2000, Rahway, New Jersey 07065.



Division of MERCK & CO., INC.

Merial

**IVOMEC® 0.08% Solution Sheep Drench
(ivermectin)**

Formulation: IVOMEC Sheep Drench is an 0.08% w/v pale amber colored solution of ivermectin.

Ivermectin is derived from the avermectins, a family of highly active, broad-spectrum, antiparasitic agents which are produced from fermentation products of *Streptomyces avermitilis*.

Product Indications: IVOMEC Sheep Drench is indicated for the effective treatment of gastrointestinal roundworms (including *Haemonchus contortus*), lungworms and nasal bots in sheep.

When used as recommended, it provides effective control of the parasites shown in the following table:

Gastrointestinal roundworms:	Adults	Larvae (4th stage)
<i>Haemonchus contortus</i>	X	X
<i>Haemonchus placei</i>	X	
<i>Ostertagia circumcincta</i>	X	X
<i>Trichostrongylus axei</i>	X	X
<i>Trichostrongylus colubriformis</i>	X	X
<i>Cooperia curticei</i>	X	X
<i>Cooperia oncophora</i>	X	
<i>Oesophagostomum columbianum</i>	X	X
<i>Oesophagostomum venulosum</i>	X	
<i>Nematodirus battus</i>	X	X
<i>Nematodirus spathiger</i>	X	X
<i>Strongyloides papillosus</i>	X	
<i>Chabertia ovina</i>	X	
<i>Trichuris ovis</i>	X	
Lungworms:		
<i>Dictyocaulus filaria</i>	X	X
Nasal bots:		
<i>Oestrus ovis</i>		(all larval stages)

Dosage: IVOMEC Sheep Drench should only be administered orally at the recommended dose level of 200 mcg ivermectin per kilogram of body weight. Three mL of IVOMEC Sheep Drench contains sufficient ivermectin to treat 26 pounds of body weight.

Volume	Sheep Body Weight Dosed
3 mL	26 lbs
6 mL	52 lbs

(chart continued)

Volume	Sheep Body Weight Dosed
9 mL	78 lbs
12 mL	104 lbs
16 mL	130 lbs
18 mL	156 lbs
21 mL	182 lbs
24 mL	208 lbs
27 mL	234 lbs
30 mL	260 lbs

To avoid underdosing, it is important to set the dose according to the weight of the heaviest sheep in a group (ewes, lambs, or rams), not the average weight. Several of the largest sheep should be weighed, judgment by eye can be deceiving.

Administration: Any standard drenching equipment, or any equipment which provides a consistent dose volume, can be used. Dose rates and equipment should be checked before drenching commences. Be sure the head is properly positioned for each sheep to receive the full dose. IVOMEC Sheep Drench is readily accepted by sheep, but inconsequential coughing may be observed in some animals during and for several minutes after drenching. If slobbering occurs, the dose may be lost, and that sheep should be redosed.

Frequency of Dosing: Resistant parasites are a particular problem in sheep.

Please consult your veterinarian, county extension office or animal health supplier for the control program recommended in your area.

Mode of Action: The avermectin family of compounds, of which ivermectin, is a member, kills certain parasitic nematodes (roundworms) and arthropods. The action is unique and not shared by other antiparasitic agents and 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

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

Recommended doses of ivermectin have a wide safety margin in

FROM: FIRST PRIORITY

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From-MERIAL LTD

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800-727-5667

T-669

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livesrock. 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.

Stability: IVOMEC Sheep Drench is stable for 24 months when stored under normal conditions. Protect from light.

Safety: IVOMEC Sheep Drench has been demonstrated to have a wide safety margin at the recommended dose level and may be used in sheep of all ages. Ewes may be treated at any stage of pregnancy.

Acceptability: Coughing may be observed in some animals during and for several minutes following drenching.

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 waterborn organisms on which they feed. Do not permit water runoff from feedlot to enter lakes, streams, or ground water. Do not contaminate water by direct application or by the improper disposal of drug containers. Spills of IVOMEC Sheep Drench should be contained and soaked up with absorbent towels or into loose soil. Gloves should be worn to prevent skin exposure. All the collected materials (contaminated towels and soil), as well as all used drug containers should be placed in an impervious film bag (plastic) and disposed of by incineration or in an approved landfill.

Warning: Sheep must not be treated within 11¹ days of slaughter for human consumption.

Caution: IVOMEC Sheep Drench has been formulated for use in sheep ONLY. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Precautions: This product is not to be used parenterally. Protect from light.

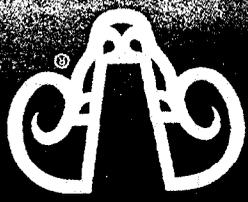
Keep this and an drugs out of reach of children.

Human Safety: When used as recommended in sheep, IVOMEC Sheep Drench does not pose a hazard to human health. As a routine precaution, it is advisable to wash hands after use. As with all drugs, the product should be kept out of reach of children. Contact with skin and eyes should be avoided, but protective clothing is not required.



8678904

32.46 fl oz (1 qt 0.46 fl oz) 960 mL



Parasiticide
For the Treatment and Control of
Worms and Bots of Sheep
83-100 lb Doses

Drench for Sheep
0.08% Solution

IVOMEC
(ivermectin)

Product 41264



ivomec
(ivermectin)

Drench for Sheep
0.08% Solution

Product
41264

FOR ORAL USE IN SHEEP ONLY

DESCRIPTION: IVOMEC Drench for Sheep is a ready-to-use, free-flowing solution of ivermectin. It is formulated to deliver the recommended dose rate of 0.2 mg ivermectin per 1 kg body weight given orally at a volume of 3.0 mL per 26 lbs body weight.

INDICATIONS: IVOMEC Drench for Sheep provides treatment and control of adult and fourth-stage larvae of the following parasites: Gastrointestinal Roundworms - *Haemonchus contortus*, *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia curtipicei*, *Nematodirus spathiger*, *N. battus*, and *Oesophagostomum columbianum*; Lungworms - *Dictyocaulus filaria*; and all the larval stages of Nasal Bot - *Oestrus ovis*. It also provides treatment and control of adult forms only of the following Gastrointestinal Roundworms - *Haemonchus placei*, *Cooperia oncophora*, *Strongyloides papillosus*, *Oesophagostomum venulosum*, *Trichuris ovis*, and *Chabertia ovis*.

DOSAGE AND ADMINISTRATION: IVOMEC Drench for Sheep may be used in any standard drenching equipment or in any equipment which provides a consistent dose volume. IVOMEC Drench for Sheep is administered orally at a dose of 3.0 mL (2.4 mg ivermectin) per 26 lbs body weight or 200 mcg ivermectin per kilogram of body weight.

Coughing may be observed in some animals during and for several minutes following drenching. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

WARNING: Do not treat sheep within 11 days of slaughter.

CAUTION: IVOMEC Drench for Sheep has been formulated specifically for use in sheep only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Keep this and all drugs out of reach of children.

Refrain from smoking and eating when handling. Avoid contact with eyes. Immediately wash hands and any spills on the skin with plenty of soap and water following use.

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 water-borne organisms on which they feed. Do not permit water runoff from feedlots to enter lakes, streams or ground water. Do not contaminate water by direct application or by the improper disposal of drug containers. Spills should be contained and soaked up with absorbent towels or into loose soil. Gloves should be worn to prevent skin exposure. All the collected materials (contaminated towels and soil), as well as all empty drug containers should be placed in an impervious film (plastic) bag and disposed of by incineration or in an approved landfill.

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

8679004
U.S. Pat. 4,199,569
Made in U.S.A.



Lot No & Exp Date



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

3 03734 12640 5

PRODUCT DATA

Privermectin™ Drench for Sheep (Ivermectin)

Packaging:

Privermectin™ (ivermectin) Drench for Sheep is available in a convenient pack size:

The 32.46 fl. oz (960 mL) pack contains sufficient solution to treat 83 sheep averaging 100 lbs.

The packs are high-density polyethylene containers, colored opaque white, with screw caps and tamper-evident seals.

They are shipped in cardboard cartons as follows:

4 x 960 mL containers per case.

Label graphic
goes here

PRODUCT DESCRIPTION

Privermectin™ (ivermectin) Drench for Sheep is a liquid, administered orally to sheep, consisting of an 0.08% solution of ivermectin. Discovered and developed by scientists from Merck Sharp and Dohme Research Laboratories, ivermectin is a unique chemical entity. As such, the chances of cross-resistance in parasites that have developed resistance to other wormers is highly unlikely. Additionally, its convenience, broad spectrum efficacy, and wide therapeutic index make Privermectin™ (ivermectin) Drench for Sheep an exceptionally valuable product for parasite control in sheep.

DOSING

Privermectin™ (ivermectin) Drench for Sheep is formulated only for administration to sheep; do not use in other species. The recommended dose level is 3 mL of Privermectin™ (ivermectin) Drench for Sheep, containing 2400 mcg ivermectin, which is sufficient to treat 26 pounds of body weight.

ADVANTAGES

Unique chemistry - unrelated to existing formulations.

Because Privermectin™ (ivermectin) Drench for Sheep is chemically different, cross-resistance is unlikely in parasite strains which may have developed resistance to other wormers.

Broad spectrum effectiveness.

One low-volume dose effectively treats and controls many gastrointestinal roundworms (including *Haemonchus contortus*), lungworms, and nasal bots.

Easy administration.

Privermectin™ (ivermectin) Drench for Sheep can be administered with any standard drenching equipment or any equipment that provides a consistent dose volume.

FORMULATION

Privermectin™ (ivermectin) Drench for Sheep is an 0.08% w/v pale amber colored solution of ivermectin.

Ivermectin is derived from the avermectins, a family of highly active, broad spectrum, antiparasitic agents which are produced from fermentation products of *Streptomyces avermitilis*.

PRODUCT INDICATIONS

Privermectin™ (ivermectin) Drench for Sheep is indicated for the effective treatment of gastrointestinal roundworms (including *Haemonchus contortus*), lungworms and nasal bots in sheep. When used as recommended, it provides effective control of the parasites shown in the table.

PRIVERMECTIN™ DRENCH FOR SHEEP KILLS THESE PARASITES		
	Adults	Larvae (4th stage)
Gastrointestinal roundworms		
<i>Haemonchus contortus</i>	X	X
<i>Haemonchus placei</i>	X	
<i>Ostertagia circumcincta</i>	X	X
<i>Trichostrongylus axei</i>	X	X
<i>Trichostrongylus colubriformis</i>	X	X
<i>Cooperia curticei</i>	X	X
<i>Cooperia oncophora</i>	X	
<i>Oesophagostomum columbianum</i>	X	X
<i>Oesophagostomum venulosum</i>	X	
<i>Nematodirus battus</i>	X	X
<i>Nematodirus spathiger</i>	X	X
<i>Strongyloides papillosus</i>	X	
<i>Chabertia ovina</i>	X	
<i>uris ovis</i>	X	
Lungworms:		
<i>Dictyocaulus filaria</i>	X	X
Nasal bots:		
<i>Oestrus ovis</i>	(all larval stages)	

DOSAGE

Privermectin™ (ivermectin) Drench for Sheep should only be administered orally at the recommended dose level of 200 mcg ivermectin per kilogram of body weight. Three mL of Privermectin™ (ivermectin) Drench for Sheep contains sufficient ivermectin to treat 26 pounds of body weight.

Volume	Sheep Body Weight Dosed
3 mL	26 lbs
6 mL	52 lbs
9 mL	78 lbs
12 mL	104 lbs
15 mL	130 lbs
18 mL	156 lbs
21 mL	182 lbs
24 mL	208 lbs
27 mL	234 lbs
30 mL	260 lbs

To avoid underdosing, it is important to get the dose according to the weight of the heaviest sheep in a group (ewes, lambs or rams), not the average weight. Several of the largest sheep should be weighed, judgment by the eye can be deceiving.

ADMINISTRATION

Any standard drenching equipment, or any equipment which provides a consistent dose volume, can be used. Dose rates and equipment should be checked before drenching commences. Be sure the head is properly positioned for each sheep to receive the full dose.

Privermectin™ (ivermectin) Drench for Sheep is readily accepted by sheep, but inconsequential coughing may be observed in some animals during and for several minutes after drenching. If slobbering occurs, the dose may be lost, and that sheep should be redosed.

FREQUENCY OF DOSING

Resistant parasites are a particular problem in sheep. Please consult your veterinarian, county extension office or animal health supplier for the control program recommended in your area.

MODE OF ACTION

The avermectin family of compounds, of which ivermectin is a member, kills certain parasitic nematodes (roundworms) and arthropods. The action is unique and not shared by other antiparasitic agents and 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 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 in most species. Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter. Recommended doses of ivermectin have a wide safety margin in livestock. 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.

STABILITY

Privermectin™ (ivermectin) Drench for Sheep is stable for 24 months when stored under normal conditions. Protect from light.

SAFETY

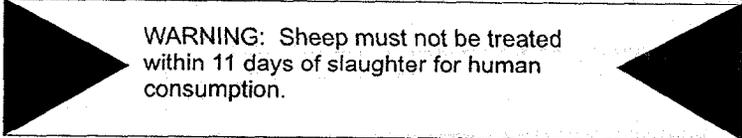
Privermectin™ (ivermectin) Drench for Sheep has been demonstrated to have a wide safety margin at the recommended dose level and may be used in sheep of all ages. Ewes may be treated at any stage of pregnancy.

ACCEPTABILITY

Coughing may be observed in some animals during and for several minutes following drenching.

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 water-born organisms on which they feed. Do not permit water runoff from feedlots to enter lakes, streams, or ground water. Do not contaminate water by direct application or by the improper disposal of drug containers. Spills of Privermectin™ (ivermectin) Drench for Sheep should be contained and soaked up with absorbent towels or into loose soil. Gloves should be worn to prevent skin exposure. All the collected materials (contaminated towels and soil), as well as all used drug containers, should be placed in an impervious film bag (plastic) and disposed of by incineration or in an approved landfill.



WARNING: Sheep must not be treated within 11 days of slaughter for human consumption.

CAUTION

Privermectin™ (ivermectin) Drench for Sheep has been formulated for use in sheep ONLY. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

PRECAUTIONS

This product is not to be used parenterally. Protect from light. Store at controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use. Keep this and all drugs out of reach of children.

HUMAN SAFETY

When used as recommended in sheep, Privermectin™ (ivermectin) Drench for Sheep does not pose a hazard to human health. As a routine precaution, it is advisable to wash hands after use. As with all drugs, the product should be kept out of reach of children. Contact with skin and eyes should be avoided, but protective clothing is not required.

For customer service, contact First Priority, Inc., 1585 Todd Farm Drive, Elgin, IL 60123

**Priority
Care** 

...would you settle for less?

FOR ORAL USE IN SHEEP ONLY

DESCRIPTION: Ivermectin™ Drench for Sheep is a ready-to-use, free-flowing solution of ivermectin. It is formulated to deliver the recommended dose rate of 0.2 mg ivermectin per 1 kg body weight given orally at a volume of 3.0 mL per 26 lbs body weight.

INDICATIONS: Ivermectin™ Drench for Sheep provides treatment and control of adult and fourth-stage larvae of the following parasites: Gastrointestinal Roundworms - *Haemonchus contortus*, *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *N. battus*, and *Oesophagostomum columbianum*; Lungworms - *Dictyocaulus filaria*; and all the larval stages of Nasal Bot - *Oestrus ovis*. It also provides treatment and control of adult forms only of the following Gastrointestinal Roundworms - *Haemonchus placei*, *Cooperia oncophora*, *Strongyloides papillosus*, *Oesophagostomum venulosum*, *Trichuris ovis*, and *Chabertia ovis*.

DIRECTIONS FOR USE: Ivermectin™ Drench for Sheep may be used in any standard drenching equipment or in any equipment which provides a consistent dose volume. Ivermectin™ Drench for Sheep is administered orally at a dose of 3.0 mL (2.4 mg ivermectin) per 26 lbs body weight or 200 mcg ivermectin per kilogram of body weight.

Coughing may be observed in some animals during and for several minutes following drenching. Consult your veterinarian for assistance in diagnosis, treatment, and control of parasitism.

CAUTION: Ivermectin™ Drench for Sheep has been formulated specifically for use in sheep only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Refrain from smoking and eating when handling. Avoid contact with eyes. Immediately wash hands and any spills on the skin with plenty of soap and water following use.

STORAGE: Store at controlled room temperature between 15° and 30°C (59°-86°F). Keep tightly closed, protected from light.

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 water-borne organisms on which they feed. Do not permit water runoff from feedlots to enter lakes, streams or ground water. Do not contaminate water by direct application or by the improper disposal of drug containers. Spills should be contained and soaked up with absorbent towels or into loose soil. Gloves should be worn to prevent skin exposure. All the collected materials (contaminated towels and soil), as well as all empty drug containers should be placed in an impervious film (plastic) bag and disposed of by incineration or in an approved landfill.

Iss. D9-01

WARNING: Do not treat sheep within 11 days of slaughter.

Lot No. Exp. Date

TAKE TIME



OBSERVE LABEL DIRECTIONS

Reorder No. OM040PCARE

NO VARNISH

